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APPENDIX 3

Endeavor II CA 24 Month Report

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APPENDIX 4

Endeavor III 24 Month Report

(Listing 1 Detailed Patient Listing was Provided Electronically to FDA)

A Randomized Controlled Trial of the Medtronic ENDEAVOR Drug (ABT-578) Eluting Coronary Stent System[§] versus the CYPHER* Sirolimus-Eluting Coronary Stent System in *De Novo* Native Coronary Artery Lesions

The ENDEAVOR III Trial
Clinical Study Report (Index Procedure through 720 Days)

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Date:	September 07, 2007
Version:	1.1 FINAL

This report has undergone a quality control process at HCRI.

[§]Endeavor Zotarolimus-Eluting Coronary Stent System
*CYPHER is a trademark of the Cordis Corporation.

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Section I: Structured Abstract

Title: A Randomized Controlled Trial of the Medtronic ENDEAVOR Drug (ABT-578) Eluting Coronary Stent System versus the CYPHER Sirolimus-Eluting Coronary Stent System in *De Novo* Native Coronary Artery Lesions.

Design: This was a prospective, multi-center, single-blind, parallel, two-arm, randomized, controlled study that enrolled 436 patients with symptomatic ischemic heart disease attributable to stenotic lesions of the native coronary arteries that are amenable to treatment by percutaneous stenting.

Clinical follow-up was performed during an office visit for all patients at 30 days and 8 months. A telephone assessment, consisting of the collection of angina status (according to the Canadian Cardiovascular Society Classification of angina), all adverse events, all concomitant medications, and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization) for all patients, was performed at 6, 9, 12 and 24 months and will be performed annually thereafter out to 5 years post-procedure. All study patients enrolled were scheduled to have angiographic and intravascular ultrasound (IVUS) follow-up at 8 months post-index procedure.

Purpose: To demonstrate the equivalency in in-segment late lumen loss at 8 months between the Endeavor Zotarolimus-Eluting Coronary Stent System coated with ABT-578 (10 μg/mm) and the CYPHER Sirolimus-Eluting Coronary Stent System for the treatment of single *de novo* lesions in native coronary arteries 2.5-3.5 mm in diameter.

Clinical Sites: Twenty-nine (29) study sites enrolled 436 patients in this trial. Patients were randomized in a 3:1 ratio (Endeavor : CYPHER™). The study population consisted of patients with symptomatic ischemic heart disease due to *de novo* stenotic lesions in native coronary arteries with reference vessel diameters between 2.5 mm and 3.5 mm and a lesion length ≥14 mm and ≤27 mm that were amenable to percutaneous treatment with stenting.

Methods: Baseline clinical and angiographic data were collected on standardized case report forms by study personnel at the study sites. Angiographic films were qualified at follow-up based on the qualification scheme in Appendix A.

On March 5, 2007, with the inclusion of an additional baseline angiogram for patient 105-204, the database was unlocked and updated. The following tables and figures have been affected as a result of this database change: Tables 1a, 1b, 4, 6a, 6b, 7, 8, 9 and Figures 1 and 2.

The primary endpoint for this trial was in-segment late lumen loss at 8 months post-procedure.

The secondary endpoints for this trial included: in-stent late lumen loss at 8 months; device success; lesion success; procedure success; Major Adverse Cardiac Event (MACE) rate at 30 days, 6, 9, and 12 months post-procedure; Clinically-Driven Target Lesion Revascularization (TLR) rate at 9 months post-procedure; Clinically-Driven Target Vessel Revascularization (TVR) rate at 9 months post-procedure; Target Vessel Failure (TVF) rate at 9 months post-

procedure; Angiographic binary restenosis (≥50% diameter stenosis) rate at 8 months post-procedure; in-stent and in-segment minimum lumen diameter (MLD) at 8 months post-procedure; and neointimal hyperplastic volume at 8 months as measured by IVUS.

Demographics: Of the 436 enrolled patients, baseline demographics and clinical characteristics showed a mean age of 61.4 years in the Endeavor arm and 61.7 years in the CYPHER arm. The Endeavor group had 65.3% (211/323) male enrollment and the CYPHER group had 81.4% (92/113) male enrollment (p-value of the difference =0.001). In the Endeavor arm, 22.6% (73/323) had prior percutaneous coronary revascularization compared to 16.8% (19/113) in the CYPHER arm. In the Endeavor group, 29.7% (96/323) of patients had a history of diabetes mellitus compared to 28.3% (32/113) of patients in the CYPHER group.

Results: The effectiveness and safety results for Endeavor and CYPHER are presented in Table 1a. Baseline angiographic results were obtained for all of the 436 enrolled patients on whom treatment was attempted. Follow-up angiographic results were obtained for 371 patients with qualified angiographic films at the eight month follow-up period. Safety measure values were obtained for patients with follow-up information before the lower window of the follow-up period or with an incidence of the corresponding safety measure prior to the time of interest.

The primary endpoint of In-Segment Late Lumen Loss at 8 months for the Endeavor arm was 0.36±0.46 (mm) and for the CYPHER arm it was 0.13±0.33 (mm), ($p<0.001$). The secondary endpoint of In-Stent Late Lumen Loss at 8 months for the Endeavor group was 0.62±0.49 (mm) and for the CYPHER group it was 0.15±0.34 (mm), ($p<0.001$). The rate of In-Stent Binary Restenosis at 8 months for the Endeavor group was 9.7% (27/277); for the CYPHER group it was 2.1% (2/94), ($p=0.014$).

Effectiveness measures were reported for 436 patients with available baseline angiographic data. The lesion success rate was 100.0% (323/323) for patients in the Endeavor arm and 99.1% (112/113) for patients in the CYPHER arm. The device success rate was 98.8% (319/323) for patients in the Endeavor group and 94.7% (107/113) for patients in the CYPHER group (p-value=0.022 from Fisher's Exact Test). The procedure success rate was 99.4% (321/323) for patients in the Endeavor arm and 95.6% (108/113) for patients in the CYPHER arm (p-value=0.014 from Fisher's Exact Test). The Device-Specific Procedure Success, defined as device success and no in-hospital MACE, rate for Endeavor patients was 98.1% (317/323) and 91.2% (103/113) for CYPHER patients (p-value=0.002 from Fisher's Exact Test).

Additionally, in-hospital incidence of MACE was 0.6% (2/323) for patients in the Endeavor arm and 3.5% (4/113) for patients in the CYPHER arm. Incidence of MACE at 720 days was 9.3% (29/313) for patients in the Endeavor group and 11.6% (13/112) for patients in the CYPHER group ($p=0.465$).

The cumulative incidence of TLR at 720 days post-index procedure for Endeavor was 7.0% (22/313); for CYPHER it was 4.5% (5/112). The cumulative incidence of TVR at 720 days post-index procedure for Endeavor was 13.7% (43/313); for CYPHER it was 9.8% (11/112). The cumulative incidence of TVF at 720 days post-index procedure for Endeavor was 14.4% (45/313); for CYPHER it was 13.4% (15/112). There is no significant difference between the two treatment arms for the clinical event rates at 720 days post-procedure.

The Kaplan-Meier estimate of freedom from MACE at 720 days for Endeavor was 90.9%; for CYPHER it was 88.5%. The treatment comparison p-value=0.464 (Log-rank test).

Hypothesis Test

The primary endpoint evaluated in this study was in-segment late lumen loss at 8 months as measured by quantitative coronary angiography (QCA).

This randomized study assessed non-inferiority of Endeavor to CYPHER with respect to 8-month in-segment late lumen loss, using a non-inferiority definition (delta) of late lumen loss of 0.2 mm. Specifically, the null hypothesis for this study was that the Endeavor Zotarolimus-Eluting Coronary Stent System had a primary endpoint (in-segment late lumen loss) mean exceeding that of the control CYPHER stent by 0.2 mm or more. The alternative hypothesis was that the Endeavor Zotarolimus-Eluting Coronary Stent System had a mean in-segment late lumen loss less than the control CYPHER stent mean plus 0.2 mm. Specifically, the null and alternative hypotheses are:

$$H_o: \mu_A \geq \mu_C + 0.20$$
$$H_1: \mu_A < \mu_C + 0.20$$

where μ_A is the mean late lumen loss for Endeavor and μ_C is the mean late lumen loss for the control arm. The mean late lumen loss was 0.36 mm ±0.46 mm (n=277) in the Endeavor arm and was 0.13 mm ±0.33 mm (n=94) for the CYPHER arm, yielding a difference (Endeavor minus CYPHER) of 0.24 mm. The upper bound of the one-sided 95% confidence interval is 0.32 mm, which is greater than 0.20 mm, therefore signifying at a one-sided 0.05 significance level that the criterion for non-inferiority of Endeavor to CYPHER has not been met for the Endeavor Zotarolimus-Eluting Coronary Stent System with regard to 8-month in-segment late lumen loss.

A two-way analysis of variance adjusting for study site was used to assess the consistency of treatment effect across study sites; specifically, a treatment-by-study site interaction effect was assessed at the 0.10 level of significance. A non-significant interaction with a p-value of 0.2193 supported the acceptability of pooling sites for the primary analysis.

Analysis of Homogeneity Between Single-Blind and Single-Blind Plus Groups

The ENDEAVOR III study was a prospective, multi-center, randomized, two-arm, single-blind trial. In an effort to minimize bias (selection, observation, etc.) in the trial, Medtronic introduced additional blinding procedures. To ensure that introducing additional blinding measures during the course of the study had no effect on outcomes, the patient population was divided into two cohorts: (1) a cohort of patients accrued prior to introducing the additional measures; and (2) a cohort of patients accrued post-introduction of the additional measures. Two logistic regression models were applied, with qualified angiographic follow-up available (Y/N) as the dependent variable. The first logistic regression model simply assessed the relationship between cohort and follow-up, and yielded a p-value of 0.4298 indicating no relationship between cohort and patient availability for follow-up. The second model included two main effect variables, treatment and patient cohort, and the interaction between treatment and patient cohort. A non-significant interaction term (p-value of 0.3380) provided evidence that the rate of follow-up between treatments did not differ between the two cohorts of patients.

Homogeneity between the two cohorts of patients on baseline characteristics was also assessed. For each baseline characteristic, simple comparisons were performed to compare baseline demographics between cohorts for both treatments combined (see Homogeneity Table below). As is seen in the table, the only significant difference between cohorts is for the prevalence of IIb/IIIa Inhibitor use. This is not expected to have markedly affected treatment comparisons on primary and secondary endpoints, since, as will be discussed below, the distribution of the prevalence of IIb/IIIa use between treatments did not differ between cohorts.

Homogeneity Table - Baseline Demographics and Clinical Characteristics by Blinding Status - ITT Population

Patient Characteristic	Single-Blind (N= 242 Patients)	Single-Blind Plus* (N= 194 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Age (yrs)					
Mean±SD (n)	61.60±10.75 (242)	61.39±10.97 (194)	61.50±10.84 (436)	0.21 [-1.85,2.26]	0.842
Range (min,max)	(34.00,85.00)	(37.00,86.00)	(34.00,86.00)		
Number of Men	66.9% (162/242)	72.7% (141/194)	69.5% (303/436)	-5.7% [-14.4%,2.9%]	0.210
History of Smoking	69.7% (168/241)	67.5% (129/191)	68.8% (297/432)	2.2% [-6.6%,11.0%]	0.676
Diabetes Mellitus	29.3% (71/242)	29.4% (57/194)	29.4% (128/436)	-0.0% [-8.6%,8.6%]	1.000
Revascularization for Angina or MI	84.3% (204/242)	86.1% (167/194)	85.1% (371/436)	-1.8% [-8.5%,4.9%]	0.685
Angina Status					0.173
Stable	46.1% (94/204)	37.7% (63/167)	42.3% (157/371)		
Unstable	48.0% (98/204)	57.5% (96/167)	52.3% (194/371)		
MI	5.9% (12/204)	4.8% (8/167)	5.4% (20/371)		
Race					0.538
White	92.1% (223/242)	91.2% (177/194)	91.7% (400/436)		
Black	2.9% (7/242)	4.6% (9/194)	3.7% (16/436)		
Asian	1.2% (3/242)	0.5% (1/194)	0.9% (4/436)		
Native Hawaiian or Other Pacific Islander	0.4% (1/242)	0.0% (0/194)	0.2% (1/436)		
American Indian or Alaska Native	2.1% (5/242)	1.0% (2/194)	1.6% (7/436)		
Other	1.2% (3/242)	2.6% (5/194)	1.8% (8/436)		
In-Segment Post-Procedure MLD					
Mean±SD (n)	2.28±0.44 (242)	2.25±0.48 (194)	2.27±0.46 (436)	0.04 [-0.05,0.12]	0.410
Range (min,max)	(1.25,3.41)	(0.11,3.64)	(0.11,3.64)		
Stent/Lesion Length					
Mean±SD (n)	1.69±0.62 (240)	1.65±0.63 (193)	1.67±0.62 (433)	0.03 [-0.08,0.15]	0.568
Range (min,max)	(0.82,4.09)	(0.79,4.37)	(0.79,4.37)		
IIb/IIIa Use	38.2% (92/241)	51.5% (100/194)	44.1% (192/435)	-13.4% [-22.7%,-4.0%]	0.006

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N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.
* Medtronic is committed to maximizing the quality and integrity of data from ENDEAVOR III and has worked to implement additional blinding procedures to minimize bias (selection, observation, etc.) in this trial.

In addition, a logistic regression model and analysis of variance were applied for binary and continuous baseline characteristics, respectively. In each model, the baseline characteristic was the dependent variable. The independent variables included two main effects, treatment and patient cohort, and an interaction term between treatment and patient cohort. No interaction term was significant at the 0.10 level of significance, implying that the distribution of the baseline characteristic between treatments did not differ between the two cohorts of patients.

The following baseline characteristics were assessed:

Characteristic	P-value for Interaction
Age	0.7748
Gender	0.2529
Race: White vs Non-White	0.1479
In-Segment Post Procedure MLD	0.7077
Stent/Lesion Length	0.2874
Diabetes	0.3032
Revascularization for Angina or MI	0.7332
Smoking status	0.1880
IIb/IIIa Use	0.5231

Outcome poolability between cohorts was assessed on the primary endpoint of in-segment late lumen loss at 8 months and on the secondary endpoints of 30-day MACE and 9-month TVF. Analysis of variance was applied for in-segment late lumen loss at 8 months. In addition to using baseline characteristics and treatment indicators as independent variables, an indicator variable for cohort, and the interaction between treatment and cohort were added as independent variables into the model. A non-significant treatment-by-cohort interaction term (p-value= 0.5410) indicated that the treatment effect was consistent between the two cohorts of ENDEAVOR III patients with respect to the primary endpoint.

A logistic regression model was applied for 30-day MACE using the same independent variables as were used for in-segment late loss above. (Note, due to the small number of events, the model may not be valid.) The lack of significant treatment-by-cohort interaction term (p-value=0.9494) indicated treatment effect was consistent between the two cohorts of ENDEAVOR III patients with respect to the secondary endpoint of 30-day MACE. Finally, a logistic regression model was applied for 9-month TVF. A non-significant treatment-by-cohort interaction term (p-value= 0.5164) indicated treatment effect was consistent between the two cohorts of ENDEAVOR III patients with respect to the secondary endpoint of 9-month TVF.

The above analysis supports pooling the data between the two cohorts prior to carrying out analysis on the primary and secondary endpoints.

Table 1a. Principal Effectiveness and Safety Result (ITT)

Effectiveness Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Lesion Success	100.0% (323/323)	99.1% (112/113)	99.8% (435/436)	0.9% [-0.8%,2.6%]	0.259
Device Success	98.8% (319/323)	94.7% (107/113)	97.7% (426/436)	4.1% [-0.2%,8.4%]	0.022
Procedure Success	99.4% (321/323)	95.6% (108/113)	98.4% (429/436)	3.8% [-0.1%,7.7%]	0.014
Device-Specific Procedure Success	98.1% (317/323)	91.2% (103/113)	96.3% (420/436)	7.0% [1.6%,12.4%]	0.002
Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.67±0.42 (323)	2.67±0.40 (112)	2.67±0.42 (435)	0.00 [-0.09,0.09]	0.993
Range (min,max)	(1.62,3.87)	(1.92,3.83)	(1.62,3.87)		
Post-Procedure In-Stent Percent Diameter Stenosis (% DS)					
Mean±SD (n)	4.33±9.77 (323)	5.92±9.07 (112)	4.74±9.61 (435)	-1.59 [-3.66,0.48]	0.132
Range (min,max)	(-30.96,34.60)	(-27.55,28.28)	(-30.96,34.60)		
Post-Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.27±0.45 (323)	2.28±0.47 (113)	2.27±0.46 (436)	-0.01 [-0.11,0.09]	0.836
Range (min,max)	(1.26,3.64)	(0.11,3.56)	(0.11,3.64)		
Post-Procedure In-Segment Percent Diameter Stenosis (% DS)					
Mean±SD (n)	19.38±9.25 (323)	20.17±11.74 (113)	19.59±9.95 (436)	-0.78 [-2.92,1.36]	0.522
Range (min,max)	(1.87,47.61)	(3.53,94.55)	(1.87,94.55)		
Eight-Month Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.06±0.57 (277)	2.52±0.56 (94)	2.17±0.60 (371)	-0.46 [-0.60,-0.33]	<0.001
Range (min,max)	(0.27,3.39)	(0.10,3.75)	(0.10,3.75)		
Eight-Month Follow-up In-Stent Percent Diameter Stenosis (% DS)					
Mean±SD (n)	24.90±17.45 (277)	11.01±15.91 (94)	21.38±18.09 (371)	13.89 [9.88,17.90]	<0.001
Range (min,max)	(-9.34,88.41)	(-12.20,95.07)	(-12.20,95.07)		
Eight-Month Follow-up In-Segment Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	1.91±0.53 (277)	2.16±0.50 (94)	1.97±0.53 (371)	-0.25 [-0.37,-0.13]	<0.001
Range (min,max)	(0.27,3.39)	(0.10,3.45)	(0.10,3.45)		
Eight-Month Follow-up In-Segment Percent Diameter Stenosis (% DS)					
Mean±SD (n)	30.42±15.57 (277)	23.86±13.87 (94)	28.76±15.41 (371)	6.56 [3.01,10.12]	<0.001
Range (min,max)	(6.33,88.41)	(3.53,95.07)	(3.53,95.07)		
Eight-Month Late Loss In-Stent (mm)					
Mean±SD (n)	0.62±0.49 (277)	0.15±0.34 (94)	0.50±0.50 (371)	0.47 [0.36,0.58]	<0.001
Range (min,max)	(-0.26,2.51)	(-0.50,1.82)	(-0.50,2.51)		
Eight-Month Late Loss In-Segment (mm)					
Mean±SD (n)	0.36±0.46 (277)	0.13±0.33 (94)	0.30±0.44 (371)	0.24 [0.13,0.34]	<0.001
Range (min,max)	(-0.46,2.20)	(-0.58,1.15)	(-0.58,2.20)		
Eight-Month In-Stent Binary Restenosis	9.7% (27/277)	2.1% (2/94)	7.8% (29/371)	7.6% [3.1%,12.2%]	0.014
Eight-Month In-Segment Binary Restenosis	12.3% (34/277)	4.3% (4/94)	10.2% (38/371)	8.0% [2.4%,13.6%]	0.029

Table 1a. Principal Effectiveness and Safety Result (ITT) (Continued)

Safety Measures (30 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
In-Hospital MACE	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Out-of-Hospital MACE to 30 Days	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
MACE to 30 Days	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Death	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Vascular Complications	1.9% (6/323)	4.4% (5/113)	2.5% (11/436)	-2.6% [-6.6%,1.5%]	0.162
Early Stent Thrombosis	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Perforation	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Vessel Revascularization	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)	-0.9% [-2.6%,0.8%]	0.259
Target Lesion Revascularization	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Vessel Failure	0.6% (2/323)	4.4% (5/113)	1.6% (7/436)	-3.8% [-7.7%,0.1%]	0.014

Safety Measures (180 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Out-of-Hospital MACE to 180 Days	2.2% (7/321)	1.8% (2/113)	2.1% (9/434)	0.4% [-2.5%,3.3%]	1.000
MACE to 180 Days	2.8% (9/321)	5.3% (6/113)	3.5% (15/434)	-2.5% [-7.0%,2.0%]	0.233
Death	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Vascular Complications	1.9% (6/321)	4.4% (5/113)	2.5% (11/434)	-2.6% [-6.6%,1.5%]	0.164
Early Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Perforation	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Target Vessel Revascularization	2.8% (9/321)	2.7% (3/113)	2.8% (12/434)	0.1% [-3.3%,3.6%]	1.000
Target Lesion Revascularization	2.2% (7/321)	1.8% (2/113)	2.1% (9/434)	0.4% [-2.5%,3.3%]	1.000
Target Vessel Failure	3.4% (11/321)	6.2% (7/113)	4.1% (18/434)	-2.8% [-7.6%,2.1%]	0.270

Safety Measures (270 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Out-of-Hospital MACE to 270 Days	6.9% (22/321)	3.5% (4/113)	6.0% (26/434)	3.3% [-1.1%,7.7%]	0.253
MACE to 270 Days	7.5% (24/321)	7.1% (8/113)	7.4% (32/434)	0.4% [-5.1%,5.9%]	1.000
Death	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
Vascular Complications	1.9% (6/321)	5.3% (6/113)	2.8% (12/434)	-3.4% [-7.8%,1.0%]	0.088
Early Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
Perforation	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Target Vessel Revascularization	11.2% (36/321)	8.0% (9/113)	10.4% (45/434)	3.3% [-2.8%,9.3%]	0.375
Target Lesion Revascularization	6.2% (20/321)	3.5% (4/113)	5.5% (24/434)	2.7% [-1.6%,7.0%]	0.346
Target Vessel Failure	11.8% (38/321)	11.5% (13/113)	11.8% (51/434)	0.3% [-6.5%,7.2%]	1.000

Table 1a. Principal Effectiveness and Safety Result (ITT) (Continued)

Safety Measures (360 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Out-of-Hospital MACE to 360 Days	7.2% (23/320)	4.5% (5/112)	6.5% (28/432)	2.7% [-2.0%,7.5%]	0.379
MACE to 360 Days	7.8% (25/320)	8.0% (9/112)	7.9% (34/432)	-0.2% [-6.1%,5.6%]	1.000
Death	0.6% (2/320)	0.9% (1/112)	0.7% (3/432)	-0.3% [-2.2%,1.7%]	1.000
Vascular Complications	1.9% (6/320)	5.4% (6/112)	2.8% (12/432)	-3.5% [-7.9%,0.9%]	0.087
Early Stent Thrombosis	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.6% (2/320)	0.0% (0/112)	0.5% (2/432)	0.6% [-0.2%,1.5%]	1.000
Perforation	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Target Vessel Revascularization	12.2% (39/320)	8.0% (9/112)	11.1% (48/432)	4.2% [-2.0%,10.3%]	0.295
Target Lesion Revascularization	6.6% (21/320)	3.6% (4/112)	5.8% (25/432)	3.0% [-1.4%,7.4%]	0.347
Target Vessel Failure	12.8% (41/320)	11.6% (13/112)	12.5% (54/432)	1.2% [-5.8%,8.2%]	0.868

Safety Measures (720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Out-of-Hospital MACE to 720 Days	8.6% (27/313)	8.9% (10/112)	8.7% (37/425)	-0.3% [-6.4%,5.8%]	1.000
MACE to 720 Days	9.3% (29/313)	11.6% (13/112)	9.9% (42/425)	-2.3% [-9.1%,4.4%]	0.465
Death	1.6% (5/313)	4.5% (5/112)	2.4% (10/425)	-2.9% [-6.9%,1.2%]	0.138
Vascular Complications	1.9% (6/313)	5.4% (6/112)	2.8% (12/425)	-3.4% [-7.9%,1.0%]	0.090
Early Stent Thrombosis	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.6% (2/313)	0.9% (1/112)	0.7% (3/425)	-0.3% [-2.2%,1.7%]	1.000
Perforation	0.0% (0/313)	0.9% (1/112)	0.2% (1/425)	-0.9% [-2.6%,0.8%]	0.264
Target Vessel Revascularization	13.7% (43/313)	9.8% (11/112)	12.7% (54/425)	3.9% [-2.8%,10.6%]	0.325
Target Lesion Revascularization	7.0% (22/313)	4.5% (5/112)	6.4% (27/425)	2.6% [-2.2%,7.3%]	0.498
Target Vessel Failure	14.4% (45/313)	13.4% (15/112)	14.1% (60/425)	1.0% [-6.4%,8.4%]	0.875

Kaplan-Meier Estimate	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	P-value
MACE-Free at 720 days	90.9%	88.5%	90.3%	0.464
TLR-Free at 720 days	93.0%	95.5%	93.7%	0.336
TVR-Free at 720 days	86.4%	90.2%	87.4%	0.304
TVF-Free at 720 days	85.8%	86.7%	86.0%	0.867

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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Table 1b. Principal Effectiveness and Safety Result (PP)

Effectiveness Measures	Endeavor (N= 309 Patients)	CYPHER™ (N= 109 Patients)	All Patients (N= 418 Patients)	Difference [95% CI]	P-value
Lesion Success	100.0% (309/309)	100.0% (109/109)	100.0% (418/418)	0.0% [--,--]	--
Device Success	99.7% (308/309)	98.2% (107/109)	99.3% (415/418)	1.5% [-1.1%,4.1%]	0.168
Procedure Success	99.4% (307/309)	96.3% (105/109)	98.6% (412/418)	3.0% [-0.6%,6.7%]	0.042
Device-Specific Procedure Success	99.0% (306/309)	94.5% (103/109)	97.8% (409/418)	4.5% [0.1%,9.0%]	0.012
Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.67±0.42 (309)	2.67±0.41 (109)	2.67±0.41 (418)	0.00 [-0.09,0.09]	0.952
Range (min,max)	(1.62,3.87)	(1.92,3.83)	(1.62,3.87)		
Post-Procedure In-Stent Percent Diameter Stenosis (% DS)					
Mean±SD (n)	4.44±9.72 (309)	6.24±8.57 (109)	4.91±9.46 (418)	-1.81 [-3.87,0.26]	0.086
Range (min,max)	(-30.96,34.60)	(-15.63,28.28)	(-30.96,34.60)		
Post-Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.27±0.46 (309)	2.30±0.42 (109)	2.28±0.45 (418)	-0.03 [-0.12,0.07]	0.595
Range (min,max)	(1.26,3.64)	(1.25,3.56)	(1.25,3.64)		
Post-Procedure In-Segment Percent Diameter Stenosis (% DS)					
Mean±SD (n)	19.33±9.19 (309)	19.55±9.54 (109)	19.39±9.27 (418)	-0.22 [-2.26,1.81]	0.828
Range (min,max)	(1.87,47.11)	(3.53,42.33)	(1.87,47.11)		
Eight-Month Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.05±0.57 (268)	2.53±0.56 (93)	2.17±0.61 (361)	-0.48 [-0.62,-0.35]	<0.001
Range (min,max)	(0.27,3.39)	(0.10,3.75)	(0.10,3.75)		
Eight-Month Follow-up In-Stent Percent Diameter Stenosis (% DS)					
Mean±SD (n)	25.12±17.63 (268)	11.03±15.99 (93)	21.49±18.28 (361)	14.08 [10.01,18.16]	<0.001
Range (min,max)	(-9.34,88.41)	(-12.20,95.07)	(-12.20,95.07)		
Eight-Month Follow-up In-Segment Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	1.90±0.53 (268)	2.16±0.50 (93)	1.97±0.53 (361)	-0.26 [-0.39,-0.14]	<0.001
Range (min,max)	(0.27,3.39)	(0.10,3.45)	(0.10,3.45)		
Eight-Month Follow-up In-Segment Percent Diameter Stenosis (% DS)					
Mean±SD (n)	30.59±15.72 (268)	24.02±13.86 (93)	28.89±15.51 (361)	6.57 [2.96,10.18]	<0.001
Range (min,max)	(6.33,88.41)	(3.53,95.07)	(3.53,95.07)		
Eight-Month Late Loss In-Stent (mm)					
Mean±SD (n)	0.63±0.49 (268)	0.15±0.34 (93)	0.50±0.50 (361)	0.48 [0.37,0.58]	<0.001
Range (min,max)	(-0.19,2.51)	(-0.50,1.82)	(-0.50,2.51)		
Eight-Month Late Loss In-Segment (mm)					
Mean±SD (n)	0.37±0.46 (268)	0.13±0.32 (93)	0.31±0.44 (361)	0.24 [0.14,0.34]	<0.001
Range (min,max)	(-0.46,2.20)	(-0.58,1.15)	(-0.58,2.20)		
Eight-Month In-Stent Binary Restenosis	10.1% (27/268)	2.2% (2/93)	8.0% (29/361)	7.9% [3.3%,12.6%]	0.014
Eight-Month In-Segment Binary Restenosis	12.7% (34/268)	4.3% (4/93)	10.5% (38/361)	8.4% [2.7%,14.1%]	0.029

Table 1b. Principal Effectiveness and Safety Result (PP) (Continued)

Safety Measures (30 Days)	Endeavor (N= 309 Patients)	CYPHER™ (N= 109 Patients)	All Patients (N= 418 Patients)	Difference [95% CI]	P-value
In-Hospital MACE	0.6% (2/309)	3.7% (4/109)	1.4% (6/418)	-3.0% [-6.7%,0.6%]	0.042
Out-of-Hospital MACE to 30 Days	0.0% (0/309)	0.0% (0/109)	0.0% (0/418)	0.0% [--,--]	--
MACE to 30 Days	0.6% (2/309)	3.7% (4/109)	1.4% (6/418)	-3.0% [-6.7%,0.6%]	0.042
Death	0.0% (0/309)	0.0% (0/109)	0.0% (0/418)	0.0% [--,--]	--
Vascular Complications	1.6% (5/309)	4.6% (5/109)	2.4% (10/418)	-3.0% [-7.1%,1.2%]	0.136
Early Stent Thrombosis	0.0% (0/309)	0.0% (0/109)	0.0% (0/418)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.0% (0/309)	0.0% (0/109)	0.0% (0/418)	0.0% [--,--]	--
Perforation	0.0% (0/309)	0.0% (0/109)	0.0% (0/418)	0.0% [--,--]	--
Target Vessel Revascularization	0.0% (0/309)	0.0% (0/109)	0.0% (0/418)	0.0% [--,--]	--
Target Lesion Revascularization	0.0% (0/309)	0.0% (0/109)	0.0% (0/418)	0.0% [--,--]	--
Target Vessel Failure	0.6% (2/309)	3.7% (4/109)	1.4% (6/418)	-3.0% [-6.7%,0.6%]	0.042

Safety Measures (180 Days)	Endeavor (N= 309 Patients)	CYPHER™ (N= 109 Patients)	All Patients (N= 418 Patients)	Difference [95% CI]	P-value
Out-of-Hospital MACE to 180 Days	2.3% (7/307)	1.8% (2/109)	2.2% (9/416)	0.4% [-2.6%,3.5%]	1.000
MACE to 180 Days	2.9% (9/307)	5.5% (6/109)	3.6% (15/416)	-2.6% [-7.3%,2.1%]	0.235
Death	0.0% (0/307)	0.0% (0/109)	0.0% (0/416)	0.0% [--,--]	--
Vascular Complications	1.6% (5/307)	4.6% (5/109)	2.4% (10/416)	-3.0% [-7.1%,1.2%]	0.136
Early Stent Thrombosis	0.0% (0/307)	0.0% (0/109)	0.0% (0/416)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/307)	0.0% (0/109)	0.0% (0/416)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.0% (0/307)	0.0% (0/109)	0.0% (0/416)	0.0% [--,--]	--
Perforation	0.0% (0/307)	0.0% (0/109)	0.0% (0/416)	0.0% [--,--]	--
Target Vessel Revascularization	2.6% (8/307)	1.8% (2/109)	2.4% (10/416)	0.8% [-2.3%,3.9%]	1.000
Target Lesion Revascularization	2.3% (7/307)	1.8% (2/109)	2.2% (9/416)	0.4% [-2.6%,3.5%]	1.000
Target Vessel Failure	3.3% (10/307)	5.5% (6/109)	3.8% (16/416)	-2.2% [-7.0%,2.5%]	0.382

Safety Measures (270 Days)	Endeavor (N= 309 Patients)	CYPHER™ (N= 109 Patients)	All Patients (N= 418 Patients)	Difference [95% CI]	P-value
Out-of-Hospital MACE to 270 Days	6.8% (21/307)	3.7% (4/109)	6.0% (25/416)	3.2% [-1.3%,7.7%]	0.347
MACE to 270 Days	7.5% (23/307)	7.3% (8/109)	7.5% (31/416)	0.2% [-5.6%,5.9%]	1.000
Death	0.3% (1/307)	0.0% (0/109)	0.2% (1/416)	0.3% [-0.3%,1.0%]	1.000
Vascular Complications	1.6% (5/307)	5.5% (6/109)	2.6% (11/416)	-3.9% [-8.4%,0.6%]	0.041
Early Stent Thrombosis	0.0% (0/307)	0.0% (0/109)	0.0% (0/416)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/307)	0.0% (0/109)	0.0% (0/416)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.3% (1/307)	0.0% (0/109)	0.2% (1/416)	0.3% [-0.3%,1.0%]	1.000
Perforation	0.0% (0/307)	0.0% (0/109)	0.0% (0/416)	0.0% [--,--]	--
Target Vessel Revascularization	11.1% (34/307)	7.3% (8/109)	10.1% (42/416)	3.7% [-2.3%,9.8%]	0.355
Target Lesion Revascularization	6.5% (20/307)	3.7% (4/109)	5.8% (24/416)	2.8% [-1.6%,7.3%]	0.345
Target Vessel Failure	11.7% (36/307)	11.0% (12/109)	11.5% (48/416)	0.7% [-6.2%,7.6%]	1.000

Table 1b. Principal Effectiveness and Safety Result (PP) (Continued)

Safety Measures (360 Days)	Endeavor (N= 309 Patients)	CYPHER™ (N= 109 Patients)	All Patients (N= 418 Patients)	Difference [95% CI]	P-value
Out-of-Hospital MACE to 360 Days	7.2% (22/306)	4.6% (5/108)	6.5% (27/414)	2.6% [-2.3%,7.5%]	0.497
MACE to 360 Days	7.8% (24/306)	8.3% (9/108)	8.0% (33/414)	-0.5% [-6.5%,5.5%]	0.839
Death	0.3% (1/306)	0.9% (1/108)	0.5% (2/414)	-0.6% [-2.5%,1.3%]	0.454
Vascular Complications	1.6% (5/306)	5.6% (6/108)	2.7% (11/414)	-3.9% [-8.5%,0.6%]	0.040
Early Stent Thrombosis	0.0% (0/306)	0.0% (0/108)	0.0% (0/414)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/306)	0.0% (0/108)	0.0% (0/414)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.3% (1/306)	0.0% (0/108)	0.2% (1/414)	0.3% [-0.3%,1.0%]	1.000
Perforation	0.0% (0/306)	0.0% (0/108)	0.0% (0/414)	0.0% [--,--]	--
Target Vessel Revascularization	12.1% (37/306)	7.4% (8/108)	10.9% (45/414)	4.7% [-1.5%,10.8%]	0.211
Target Lesion Revascularization	6.9% (21/306)	3.7% (4/108)	6.0% (25/414)	3.2% [-1.4%,7.7%]	0.347
Target Vessel Failure	12.7% (39/306)	11.1% (12/108)	12.3% (51/414)	1.6% [-5.4%,8.6%]	0.735

Safety Measures (720 Days)	Endeavor (N= 309 Patients)	CYPHER™ (N= 109 Patients)	All Patients (N= 418 Patients)	Difference [95% CI]	P-value
Out-of-Hospital MACE to 720 Days	8.7% (26/300)	9.3% (10/108)	8.8% (36/408)	-0.6% [-6.9%,5.7%]	0.845
MACE to 720 Days	9.3% (28/300)	12.0% (13/108)	10.0% (41/408)	-2.7% [-9.7%,4.3%]	0.456
Death	1.3% (4/300)	4.6% (5/108)	2.2% (9/408)	-3.3% [-7.5%,0.9%]	0.059
Vascular Complications	1.7% (5/300)	5.6% (6/108)	2.7% (11/408)	-3.9% [-8.4%,0.7%]	0.075
Early Stent Thrombosis	0.0% (0/300)	0.0% (0/108)	0.0% (0/408)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/300)	0.0% (0/108)	0.0% (0/408)	0.0% [--,--]	--
Cerebrovascular Accident (CVA)	0.3% (1/300)	0.9% (1/108)	0.5% (2/408)	-0.6% [-2.5%,1.3%]	0.460
Perforation	0.0% (0/300)	0.9% (1/108)	0.2% (1/408)	-0.9% [-2.7%,0.9%]	0.265
Target Vessel Revascularization	13.7% (41/300)	9.3% (10/108)	12.5% (51/408)	4.4% [-2.3%,11.1%]	0.308
Target Lesion Revascularization	7.3% (22/300)	4.6% (5/108)	6.6% (27/408)	2.7% [-2.2%,7.6%]	0.498
Target Vessel Failure	14.3% (43/300)	13.0% (14/108)	14.0% (57/408)	1.4% [-6.1%,8.8%]	0.872

Kaplan-Meier Estimate	Endeavor (N= 309 Patients)	CYPHER™ (N= 109 Patients)	All Patients (N= 418 Patients)	P-value
MACE-Free at 720 days	90.8%	88.0%	90.1%	0.413
TLR-Free at 720 days	92.7%	95.4%	93.4%	0.327
TVR-Free at 720 days	86.5%	90.8%	87.6%	0.246
TVF-Free at 720 days	85.9%	87.1%	86.2%	0.781

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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Section II: Detailed Summary

A. Definitions

ABRUPT CLOSURE

Abrupt Closure. Defined as the occurrence of new (during the index procedure) severely reduced flow (TIMI grade 0-1) within the target vessel that persisted and required rescue by stenting or other treatment, or resulted in myocardial infarction or death. Abrupt closure requires proven association with a mechanical dissection of the treatment site or instrumented vessel, coronary thrombus, or severe spasm. Abrupt closure does not connote "no reflow" (due to microvascular flow limitation), in which the epicardial artery is patent but had reduced flow. Abrupt closure also does not connote transient closure with reduced flow in which the index treatment application does reverse the closure.

Subabrupt Closure. Defined as abrupt closure that occurred after the index procedure is completed (and the patient left the catheterization laboratory) and before the 30-day follow-up evaluation.

Threatened Abrupt Closure. Defined as a grade B dissection and ≥50% diameter stenosis or any dissection of grade C or higher.

ACUTE GAIN

Defined as the immediate dimensional change in minimal luminal diameter (in mm) that occurred after the final post dilatation as compared to the minimal luminal diameter at baseline and measured by quantitative coronary angiography from the average of 2 orthogonal views.

ACUTE SUCCESS[1]

Device Success: Attainment of < 50 % residual stenosis of the target lesion using only the assigned device.

Lesion Success: Attainment of < 50 % residual stenosis of the target lesion using any percutaneous method.

Procedure Success: Attainment of < 50 % residual stenosis of the target lesion and no in-hospital MACE.

Device-Specific Procedure Success[2]: Device success and no in-hospital MACE.

ADVERSE EFFECT

An adverse event which was or may have been caused by a device.

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[1] All analyses to determine acute success measures were conducted utilizing *in-stent* residual stenosis values. When in-stent % residual stenosis was not available, in-lesion % residual stenosis was used to complete the analysis.
[2] Device-Specific Procedure Success is utilized to account for procedural successes/failures that are related to the implanted device.

ADVERSE EVENT

An adverse event is any undesirable medical occurrence in a clinical study patient, whether it is considered to be related to the device or not, that includes a clinical sign, symptom, or condition and/or an observation of a near incident.

ANGIOGRAPHIC BINARY RESTENOSIS RATE (ABR)

Percent of patients with a follow-up percent diameter stenosis of ≥50%.

ANTICIPATED ADVERSE EVENT

Any undesirable experience (sign, symptom, illness, abnormal laboratory value, or other medical event) occurring to a patient, whether or not considered related to the investigational product(s) or drug regimen prescribed as part of the protocol, predefined in the protocol and/or Instructions For Use (IFU), that is identified or worsens during a clinical study.

BLEEDING COMPLICATION

Defined as a procedure related hemorrhagic event that requires a transfusion or surgical repair. These may include a hematoma requiring treatment, retroperitoneal bleed.

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION (CCS) OF ANGINA

Class I Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation.

Class II Slight limitation of ordinary activity. Angina upon walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the first hours after awakening. Angina if walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.

Class III Marked limitations of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace.

Class IV Inability to carry on any physical activity without discomfort. Angina syndrome may be present at rest.

CLINICALLY-DRIVEN TARGET SITE REVASCULARIZATION (TSR)

Revascularization at the target site associated with positive functional ischemia study or ischemic symptoms AND an angiographic minimal lumen diameter stenosis ≥50% by quantitative coronary angiography (QCA), or revascularization of a target site with diameter stenosis ≥70% by QCA without either angina or a positive functional study.

CLINICALLY-DRIVEN TARGET VESSEL REVASCULARIZATION (TVR)

Revascularization in the target vessel associated with positive functional ischemia study or ischemic symptoms AND an angiographic minimal lumen diameter stenosis ≥50% by quantitative coronary angiography (QCA), or revascularization of a target vessel with diameter stenosis ≥70% by QCA without either angina or a positive functional study.

CBC (COMPLETE BLOOD COUNT)

Includes:

- Hematocrit (HCT)
- Hemoglobin (HGB)
- Platelet count
- Red blood cell (RBC) count
- White Blood Cell (WBC)
- White Blood Cell (WBC) Differential
- Eosinophil Counts

CEREBROVASCULAR ACCIDENT (CVA) (See Stroke)

The occurrence of cerebral infarction (ischemic stroke) and intracerebral hemorrhage and subarachnoid hemorrhage (hemorrhagic stroke).

CHEMISTRY PANEL

Includes:

- Alanine aminotransferase*
- Alkaline phosphatase
- Aspartate aminotransferase**
- Calcium
- Cholesterol (total)
- Creatinine
- Gamma glutamyl transferase
- Glucose
- Chloride
- HDL
- LDL
- Potassium
- Sodium
- Triglycerides
- Urea nitrogen (BUN)

* Also called serum glutamic pyruvic transaminase (SGPT)
** Also called serum glutamic oxaloacetic transaminase (SGOT)

DE NOVO LESION

Defined as a native coronary artery lesion not previously treated.

DEATH

Divided into 2 categories:

Cardiac death is defined as death due to any of the following:

1. Acute myocardial infarction.
2. Cardiac perforation/pericardial tamponade.
3. Arrhythmia or conduction abnormality.
4. Stroke within 30 days of the procedure or stroke suspected of being related to the procedure.
5. Death due to complication of the procedure, including bleeding, vascular repair, transfusion reaction, or bypass surgery.
6. Any death in which a cardiac cause cannot be excluded.

Non-cardiac death is defined as a death not due to cardiac causes (as defined above).

DEVICE RELATED ADVERSE EVENT

A device related adverse event is defined as any adverse event for which a causal relationship between the device and the event is at least a reasonable possibility, i.e., the relationship cannot be excluded.

Device Failure: A device has failed if it is used in accordance with the Instructions for Use, but does not perform according to Instructions for Use and negatively impacts the treatment.

Device Malfunction: A device malfunction is an unexpected change to the device that is contradictory to the Instructions for Use and may or may not affect device performance.

Near Incident: Malfunction or deterioration in the characteristics and/or performance of the device which might have led to death or serious deterioration in health; incident occurred and is such that if it occurred again, it might lead to death or serious deterioration in health.

Device Misuse: A misused device (one that is used by the Investigator in a manner that is contradictory to the Instructions for Use) will not be considered a malfunction.

DEVICE SUCCESS

Attainment of <50 % residual stenosis of the target lesion using only the assigned device.

DEVICE SPECIFIC PROCEDURE SUCCESS*:* Device success and no in-hospital MACE.

DISSECTION, NHLBI (National Heart, Lung, and Blood Institute) classification

Grade A Small radiolucent area within the lumen of the vessel disappearing with the passage of the contrast material.

Grade B Appearance of contrast medium parallel to the lumen of the vessel disappearing within a few cardiac cycles.

Grade C Dissection protruding outside the lumen of the vessel persisting after passage of the contrast material.

Grade D Spiral shaped filling defect with or without delayed run-off of the contrast material in the antegrade flow.

Grade E Persistent luminal filling defect with delayed run-off of the contrast material in the distal lumen.

Grade F Filling defect accompanied by total coronary occlusion.

DISTAL EMBOLIZATION

Defined as a new abrupt cut off or filling defect distal to the treated lesion.

EMERGENT BYPASS SURGERY

Defined as coronary bypass surgery performed on an urgent or emergent basis for severe vessel dissection or closure, or treatment failure resulting in new ischemia.

INCOMPLETE APPOSITION

Failure of the stent to completely appose to the vessel wall after placement is defined as one or more stent struts separated from the vessel wall with evidence of blood speckles behind the strut in the ultrasound image.

IN-SEGMENT MEASUREMENT

Defined as the measurements either within the stented segment or within 5 mm proximal and distal to the stent edges.

IN-STENT MEASUREMENT
Defined as the measurements within the boundaries of the stent.

LATE INCOMPLETE APPOSITION
Incomplete apposition of the stent at follow-up which was not present post-procedure. See also Incomplete Apposition.

LATE LUMEN LOSS
Defined as the difference between the post-procedure minimal lumen diameter (MLD) and the follow-up angiography MLD.

LESION CLASS (American College of Cardiology/American Heart Association Class)
Type A Lesions: Minimally complex, discrete (length < 10 mm), concentric, readily accessible, non angulated segment (< 45°), smooth contour, little or no calcification, less than totally occlusive, not ostial in location, no major side branch involvement, and an absence of thrombus.

Type B Lesions: Moderately complex, tubular (length 10 to 20 mm), eccentric, moderate tortuosity of proximal segment, moderately angulated segment (> 45°, < 90°), irregular contour, moderate or heavy calcification, total occlusions < 3 months old, ostial in location, bifurcation lesions requiring double guidewires, and some thrombus present.

Type C Lesions: Severely complex, diffuse (length > 20 mm), excessive tortuosity of proximal segment, extremely angulated segments > 90°, total occlusions > 3 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions.

LESION SUCCESS
Attainment of <50% residual stenosis of the target lesion using any percutaneous method.

MAJOR ADVERSE CARDIAC EVENTS (MACE)
Defined as death, MI[3] (Q wave and non-Q wave), emergent cardiac bypass surgery, or target site revascularization (repeat PTCA or CABG).

MINIMAL LUMINAL DIAMETER (MLD)
The average of two orthogonal views (when possible) of the narrowest point within the area of assessment - in lesion, in stent or in segment. MLD is visually estimated during angiography by the Investigator; it is measured during QCA by the Angiographic Core Lab.

[3] Myocardial infarction that has been adjudicated by the Clinical Events Committee as being clearly related to a non-target vessel will not be considered a MACE.

MYOCARDIAL INFARCTION

A positive diagnosis of myocardial infarction is made when one of the following criteria is met:

Q wave MI (QMI): will require one of the following criteria:

1.1 Chest pain or other acute symptoms consistent with myocardial ischemia and new pathological Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC, in the absence of timely cardiac enzyme data.

1.2 New pathologic Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC and elevation of cardiac enzymes. In the absence of ECG data the CEC may adjudicate Q wave MI based on the clinical scenario and appropriate cardiac enzyme data.

Non-Q Wave MI (NQWMI): for this study NQWMI will be defined as elevated CK >2X the upper laboratory normal with the presence of elevated CK-MB (any amount above the institution's upper limit of normal) in the absence of new pathological Q waves.

NO REFLOW

Defined as a sustained or transient reduction in antegrade flow that is not associated with an obstructive lesion at the treatment site.

PERCENT DIAMETER STENOSIS

The value calculated as 100 x (RVD – MLD)/RVD using the mean values from two orthogonal views (when possible) by QCA.

PERCENT VOLUME OBSTRUCTION

Defined as stent intimal hyperplasia and calculated as 100 x (Stent Volume - Lumen Volume)/Stent Volume

PERFORATION

Perforations will be classified as follows:

Angiographic perforation: perforation detected by the clinical site or the core laboratory at any point during the procedure.

Clinical perforation: perforation requiring additional treatment (including efforts to seal the perforation or pericardial drainage), or resulting in significant pericardial effusion, abrupt closure, myocardial infarction, or death.

Pericardial hemorrhage/tamponade: perforation resulting in cardiac tamponade.

PERCUTANEOUS CORONARY INTERVENTION (PCI)

Refers to all interventional cardiology methods for treatment of coronary artery disease.

PERSISTING DISSECTION

Dissection at follow-up that was present post-procedure.

PERSISTING INCOMPLETE APPOSITION

Incomplete apposition at follow-up that was present post-procedure. See also "Incomplete Apposition."

PROCEDURE SUCCESS

Attainment of <50 % residual stenosis of the target lesion and no in-hospital MACE.

RESTENOTIC LESION

Defined as a lesion in a vessel segment that has undergone prior percutaneous treatment with or without a stent placement.

REFERENCE VESSEL DIAMETER (RVD)

Defined as the average of normal segments within 10 mm proximal and distal to the target lesion from 2 orthogonal views using QCA.

SERIOUS ADVERSE EVENT

A study-related event that is fatal, life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, requires intervention to prevent permanent impairment/damage, results in persistent or significant disability, results in a congenital anomaly, or is cancer.

STENT THROMBOSIS

Defined as angiographic thrombus or subacute closure within the stented vessel at the time of the clinically driven angiographic restudy for documented ischemia (chest pain and ECG changes). Any death not attributed to a non-cardiac cause within the first 30 days is considered a surrogate for stent thrombosis in the absence of documented angiographic stent patency. Late Stent Thrombosis is reported according to the following criteria[4]:

Definite Late Stent Thrombosis. Myocardial Infarction >30 days after index and attributable to the target vessel, angiographic documentation (site reported or by QCA) of thrombus or total occlusion at the target site, and freedom from interim revascularization of the target vessel.

Possible Late Stent Thrombosis. Myocardial Infarction >30 days after index and attributable to the target vessel, no identifiable culprit lesion elsewhere, freedom from interim revascularization of the target lesion, and freedom from interim bypass grafting of the target vessel.

STROKE

Defined as sudden onset of vertigo, numbness, dysphasia, weakness, visual field defects, dysarthria or other focal neurological deficits due to vascular lesions of the brain such as hemorrhage, embolism, thrombosis, or rupturing aneurysm, that persists >24 hours.

[4] Medtronic utilizes stent thrombosis definitions that are consistent with the Harvard Clinical Research Institute Clinical Events Committee's standard definitions.

STUDY DEVIATION

An incident where the Investigator or site personnel did not conduct the study according to the investigational plan, protocol or the Investigator agreement.

Major deviation: Any deviation from patient inclusion and exclusion criteria or patient informed consent procedures.

Minor deviation: Deviation from a protocol requirement such as incomplete/inadequate patient testing procedures, non-compliance with medication regimens, follow-ups performed outside specified time windows, etc.

TARGET LESION

The lesion intended to be treated with a randomized treatment device.

TARGET SITE REVASCULARIZATION (TSR)

Repeat PCI or CABG to the target lesion. Synonymous with target lesion revascularization (TLR).

TARGET VESSEL FAILURE (TVF)

The composite endpoint comprised of cardiac death, myocardial infarction, or clinically-driven target vessel revascularization.

Target vessel failure includes any target vessel revascularization and MI.

Target vessel failure will be reported when:

- MI occurs in territory not clearly attributed to a vessel other than the target vessel.
- Target vessel revascularization is performed.

TARGET VESSEL REVASCULARIZATION (TVR)

Repeat PCI or CABG of the target vessel. See also Clinically-Driven Target Vessel Revascularization.

TIMI CLASSIFICATION

TIMI 0 No perfusion.

TIMI 1 Penetration with minimal perfusion. Contrast fails to opacify the entire bed distal to the stenosis for the duration of the cine run.

TIMI 2 Partial perfusion. Contrast opacifies the entire coronary bed distal to the stenosis. However, the rate of entry and/or clearance is slower in the coronary bed distal to the obstruction than in comparable areas not perfused by the dilated vessel.

TIMI 3 Complete perfusion. Filling and clearance of contrast equally rapid in the coronary bed distal to stenosis as in other coronary beds.

UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

An Unanticipated Adverse Device Effect (UADE) is defined as any adverse effect on health or safety or any life-threatening problem or death that is caused by or associated with an investigational device. The effect must have not been previously identified in nature, severity or degree of incidence in the Investigational Plan, Investigator's Brochure or

Instructions for Use. Other serious problems associated with the device that affects the rights or welfare of study patients may also be considered UADEs.

VASCULAR COMPLICATIONS

Vascular complications may include the following:

1. Pseudoaneurysm
2. Arteriovenous fistula
3. Peripheral ischemia/nerve injury
4. Vascular event requiring transfusion or surgical repair

B. Study Design

This was a prospective, multi-center, single-blind, parallel, two-arm, randomized, controlled study that enrolled 436 patients with symptomatic ischemic heart disease attributable to stenotic lesions of the native coronary arteries that are amenable to treatment by percutaneous stenting.

Clinical follow-up was performed during an office visit for all patients at 30 days and 8 months. An assessment, consisting of the collection of angina status (according to the Canadian Cardiovascular Society Classification of angina), all adverse events, all concomitant medications, and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization) for all patients, was performed at 6, 9, 12 and 24 months and then annually thereafter out to 5 years post-procedure.

All study patients enrolled were scheduled to have angiographic and intravascular ultrasound (IVUS) follow-up at 8 months post-index procedure.

Subject Selection Criteria

This trial includes 436 subjects with *de novo* native coronary artery lesions who agreed to participate in the study. Thirty-four (34) patients didn't meet the eligibility criteria.

General Inclusion Criteria

1. The patient was ≥18 years of age.
2. The patient had clinical evidence of ischemic heart disease, stable or unstable angina, silent ischemia, <u>or</u> a positive functional study.
3. The patient was an acceptable candidate for percutaneous transluminal coronary angioplasty (PTCA), stenting, and emergent coronary artery bypass graft (CABG) surgery.
4. Female patients of childbearing potential had a negative pregnancy test within seven (7) days before the procedure.
5. The patient was informed of the nature of the study and agreed to its provisions and has provided written informed consent as approved by the Institutional Review Board of the respective clinical site.
6. The patient and the treating physician agreed that the patient will return to the treating research center, or an affiliated institution under the same IRB jurisdiction, for all required post-procedure follow-up visits. A research staff member who has been properly trained to the ENDEAVOR III protocol must have conducted all follow-up evaluations.

Angiographic Inclusion Criteria

The target lesion / vessel met the following criteria:

1. The target lesion was a single *de novo* lesion that had not been previously treated with any interventional procedure.

2. The target vessel was a native coronary artery with a stenosis of ≥50% and <100%.
3. The target vessel had a TIMI flow 2 or greater.
4. The target lesion was ≥14 mm and ≤27 mm in length.
5. The target vessel reference diameter was ≥2.5 mm and ≤3.5 mm.

   Note: Measurements were made by careful visual estimate, on-line QCA, or intravascular ultrasound (IVUS).

General Exclusion Criteria

1. A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine, clopidogrel, cobalt, nickel, chromium, molybdenum, or a sensitivity to contrast media, which could not be adequately pre-medicated.
2. History of an allergic reaction or significant sensitivity to drugs similar to ABT-578 (rapamycin or rapamycin analog).
3. A platelet count <100,000 cells/mm³ or > 700,000 cells/mm³, or a WBC < 3,000 cells/mm³.
4. A creatinine level >2.0 mg/dL.
5. Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave myocardial infarction having creatine kinase (CK) enzymes ≥2X the upper laboratory normal with the presence of a creatine kinase myocardial-band isoenzyme (CK-MB) elevated above the Institution's upper limit of normal).
6. Any previous or planned treatment of <u>any vessel</u> with a drug eluting stent.
7. Previous or planned percutaneous coronary intervention of <u>any vessel</u> within 30 days pre or post procedure.
8. Previous stenting anywhere in the target vessel.
9. During the index procedure, the target lesion required treatment with a device other than PTCA prior to stent placement (such as, but not limited to, cutting balloon, directional coronary atherectomy, excimer laser, rotational atherectomy, thrombectomy, etc.).
10. History of a stroke or transient ischemic attack within the prior 6 months.
11. Active peptic ulcer or upper gastrointestinal (GI) bleeding within the prior 6 months.
12. History of bleeding diathesis or coagulopathy or refused blood transfusions.
13. Concurrent medical condition with a life expectancy of less than 12 months.
14. Any previous or planned treatment of the target vessel with anti-restenotic therapies including, but not limited to brachytherapy.
15. Currently participating in an investigational drug or another device study that had not completed the primary endpoint or that clinically interfered with the current study endpoints; or required coronary angiography, intravascular ultrasound (IVUS) or other coronary artery imaging procedures.

    Note: Trials that required extended follow-up for products that were investigational, but have since become commercially available, were not considered investigational trials.

Angiographic Exclusion Criteria

1. A documented left ventricular ejection fraction <30% at any time prior to index procedure.
2. Target lesion was located in a native vessel distal to anastomosis with a saphenous vein graft or LIMA/RIMA bypass.
3. Target vessel had other lesions with greater than 40% diameter stenosis based on visual estimate or on-line QCA.
4. The target vessel had evidence of thrombus.
5. The target vessel was excessively tortuous.
6. The target lesion had any of the following characteristics:
   a) Lesion location was aorto-ostial, an unprotected left main lesion, or within 5 mm of the origin of the LAD, LCX, or RCA,
   b) Involved a side branch >2.0 mm in diameter,
   c) Was at or distal to a >45º bend in the vessel,
   d) Was severely calcified.
7. Unprotected left main coronary artery disease (an obstruction greater than 50% in the left main coronary artery).
8. The target lesion involved a bifurcation.

Baseline and Screening

Patient Screening

All patients admitted for potential percutaneous revascularization of the native coronary arteries were screened for study eligibility. A qualified member of the Institution's research team assigned to the ENDEAVOR III trial reviewed the patient's medical and cardiac history to screen for study eligibility. A screening log was provided to study sites to maintain a log of all the patients screened by the sites. Clinical research sites were instructed to complete the screening logs and to fax the logs to Medtronic on a weekly basis.

Clinical Laboratory Procedures and Tests

Within seven days before the procedure, a complete blood count (CBC) with differential (including eosinophil counts), a chemistry panel including urea (BUN), creatinine, electrolytes, liver function test, and in addition, a pregnancy test (ßHCG subunit) for women of childbearing potential, was obtained.

Within seven days before the procedure, a 12-lead electrocardiogram was performed.

Within 72 hours prior to the procedure, creatine kinase (CK) and creatine kinase myocardial-band (CK-MB) isoenzyme tests was obtained.

Schedule of Treatments and Assessments

INDEX HOSPITALIZATION				FOLLOW-UP				
Event	Screen	Procedure	Post Procedure	30 Day	6 Month	8 Month	9 Month	1-5 Years Annually
				Clinic Visit	Patient Contact[9]	Clinic Visit Angio & IVUS	Patient Contact[7, 9]	Patient Contact[9]
Informed Consent Signed	X							
Inclusion/Exclusion Criteria	X							
Medical and Cardiac History	X							
Angina Status	X		X	X	X	X	X	X
Pregnancy test	X [1,2]							
Liver Function test	X [2]							
CBC with differential, chemistry panel (including serum urea, creatinine, electrolytes)	X [2]			X[8]				
CK & CK-MB	X [4]		X [5]					
12-Lead Electrocardiogram	X [2]		X [3]					
ACT Measurements		X						
Medication Regimen [6]	X	X	X	X	X	X	X	X
Adverse Event Monitoring		X	X	X	X	X	X	X
Angiography (QCA)	X	X				X		
IVUS		X				X		

1. For women of childbearing potential only.
2. Within 7 days prior to procedure.
3. Within 24 hours post-procedure or at discharge, which ever came first.
4. Within 72 hours prior to procedure.
5. Within 6-8, 12-16 hours, and 20-24 hours post-procedure or prior to hospital discharge, whichever came first.
6. It was expected that clopidogrel would be used, unless the patient was sensitive to this medication. For patients who were unable to take clopidogrel, or at the discretion of the physician, ticlopidine was used.
7. If during the follow-up assessment the patient stated that he/she had undergone any repeat intervention, diagnostic testing/imaging, or had any ischemic symptoms, the patient should have returned to the clinic for a full follow-up office visit.
8. CBC with differential (including eosinophils) only.
9. Patient contact included phone calls, email, and/or office visit.

C. Statistical Methods

General Overview

A clinical summary report containing results from the analysis described below was completed based on data collected through 24 months of follow-up (including analysis on primary endpoint of 8-month in-segment late lumen loss).

Data collected in this study were documented using summary tables. Demographic and background characteristics, safety and efficacy data were summarized.

Descriptive statistics were provided. The statistics for continuous variables included mean, standard deviation, minimum, maximum, and sample sizes for each treatment group. Categorical variables were described with counts and percentages for each treatment group. Comparisons between groups were presented using two sample t-test for continuous variables and Fisher's exact test for binary variables. In addition, differences (with 95% Confidence Intervals) were provided. Percentages were rounded to one decimal place.

Computations for all results were performed using SAS Version 8.2 or higher computer software package.

Analysis Populations

Intent to Treat (ITT): For this study, all patients who met the study entry criteria and signed the written informed consent, were randomized to a treatment arm and were counted in the primary analysis. Missing data for the primary endpoint were imputed via the multiple imputation technique if applicable.

Per-Protocol (PP):
Following table highlights the conditions that need to be met for PP:

Condition	ENDEAVOR III Criteria			
	Endeavor	Patients	CYPHER	Patients
De-registered	During index procedure: 1. Did not receive any device 2. Received assigned study device, and another type of DES	---------- ---------- ---------- ---------- ----------	During index procedure: 1. Did not receive any device 2. Received assigned study device, and another type of DES	---------- ----------
Cross Over Implantation	Assigned Endeavor, but received Cypher	---------- ---------- ----------	Assigned Cypher, but received Endeavor	---------- ----------

Condition	ENDEAVOR III Criteria			
	Endeavor	Patients	CYPHER	Patients
The target lesion is a single de novo lesion that has not been previously treated with any interventional procedure. Only one lesion may be treated per subject.	Angiographic Inclusion 1	None	Angiographic Inclusion 1	None
Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave infarction having CK enzymes 2X the upper laboratory normal with the presence of a CK – MB elevated above the Institution's upper limit of normal).	General Exclusion 5	---------- ---------- ----------	General Exclusion 5	None
The target lesion requires treatment with a device other than PTCA prior to stent placement (such as, but not limited to, directional coronary atherectomy, excimer laser, rotational atherectomy, etc).	General Exclusion 9	----------	General Exclusion 9	None
Previous stenting anywhere in the target vessel.	General Exclusion 8	----------	General Exclusion 8	None
Currently participating in an investigational drug or another device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints.[Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational trials.]	General Exclusion 15	None	General Exclusion 15	None

Principal safety and effectiveness analysis were performed on the ITT population (Table 1a) and repeated for PP population (Table 1b). For the analysis on the primary endpoint, missing data was imputed in the following manners: 1) by multiple imputation in SAS (Markov Chain Monte Carlo method); 2) worst case imputation, and the non-inferiority test was performed based on these imputation results as well as on the available data (Table 7).

For the clinical outcomes, incidence rates were based on ITT patients with follow-up information before the lower window of the follow-up period or with an incidence of the corresponding safety measure prior to the time of interest. Kaplan-Meier estimates were presented for all ITT patients by treatment group, where patients without an event and without available follow-up information were censored at the last follow-up time point.

Quantitative Angiographic Analysis

The analyses described on angiographic parameters was based upon the ITT population with available data. Angiographic films were qualified at follow-up based on the qualification scheme in Appendix A.

Descriptive statistics (sample size, mean, standard deviation, minimum, maximum for each treatment group) of the angiographic parameters included minimal lumen diameter (MLD) and

percent stenosis at each visit at which they were measured, acute gain (change in MLD from pre-procedure to post-implantation), in-segment and in-stent late lumen loss (change in MLD from post-implantation to 8-month follow-up), change in MLD from pre-procedure to 8-month follow-up, and late loss index were presented by treatment group. Ninety-five percent confidence intervals and p-values for the treatment difference were presented (Tables 6a and 6b).

As mentioned above, in-segment late lumen loss differences was tested using a non-inferiority test (Table 7).

In addition, the cumulative frequency distribution of percent diameter stenosis and minimum lumen diameter were presented in graphical and tabular forms for Pre-Procedure, Post-Procedure (in-stent) and Follow-Up (in-stent at 8 months) for the ITT population (Figures 1 and 2). Differences between groups and 95% confidence intervals of the difference were presented.

Safety Endpoint Analyses

Analysis described below was performed on the ITT population.

Primary Safety Evaluation

The incidence of Major Adverse Cardiac Events (MACE), in-hospital and at 30 days, 6 months, 9 months, 12 months, 24 months, as well as each component of MACE, was reported.

A Kaplan-Meier estimate of time to MACE and its corresponding standard error was presented, with a corresponding Kaplan-Meier (K-M) curve. Log rank test statistics was provided for the treatment group comparison (Figures 3-6).

The incidence of TVF, TLR and TVR was handled the same as the incidence of MACE. Analysis on time to each of TVF, TLR and TVR was handled as discussed above for MACE (Tables 11-14).

Stent Summaries

Study subjects may have had multiple vessel disease but only a single lesion per subject was treated in this trial. The actual number of stents used was summarized in a table. The table included the number of stents implanted and total length of stents implanted for each treatment group (Table 15).

IVUS Evaluations

The analysis described on IVUS parameters was made on the ITT population with available IVUS data.

Descriptive statistics (sample size, mean, standard deviation, minimum, maximum for each group) of IVUS parameters (external elastic membrane area, external elastic membrane volume, stent area, stent volume, lumen area, lumen volume, plaque and media area, plaque and media volume, volume obstruction) at stent implantation, at 8-month follow-up, and change in IVUS

parameters from stent implantation to 8-month follow-up will be presented along with differences between groups (with 95% Confidence Intervals). Incomplete stent appositions were also presented at baseline and at 8-month follow-up (Tables16-19).

Safety Analyses

Descriptive statistics and appropriate tests were used to summarize and to analyze the safety parameters. All safety analyses were performed on the ITT population in whom treatment was attempted.

Adverse Events

Adverse events were mapped to the Medical Dictionary for Regulatory Activities (MedDRA™) dictionary, version 4.0. Events were defined as all events beginning at or after enrollment. Adverse events were summarized through 24 months for this report, by tabulating, for each treatment group, the number and percentage of subjects with an event by MedDRA™ System Organ Class and Preferred Term. Adverse events were also presented by site (Tables 22a and 22b). The same will be done for the 2, 3, 4, and 5 years report updates.

Serious adverse events (SAEs) were summarized by tabulating the number and percentage of subjects for each treatment group with an event by System Organ Class (e.g., cardiovascular, GI system) and preferred term using the MedDRA™ dictionary. System Organ Classes were presented in descending order of incidence; within each system organ class, preferred terms were sorted in descending order of incidence. Serious adverse events were also presented by site (Tables 23a and 23b).

All MACE and UADE narratives were compiled on an ongoing basis and appended to the final study report.

Section III: Tables and Figures

Table 2a. Number of Patients Treated by Investigator - All Enrolled Subjects

Site	Clinical Site	Location	Principal Investigator	Enrollment
4	Washington Hospital Center	Washington, DC	Lowell Satler	18
6	William Beaumont Hospital	Royal Oak, MI	William O'Neill	9
8	Lenox Hill Hospital	New York, NY	Sriram Iyer	9
9	Abbott Northwestern Hospital	Minneapolis, MN	Michael Mooney	10
10	St Vincents Hospital	Indianapolis, IN	Michael Ball	46
31	Washington Adventist Hospital	Takoma Park, MD	Mark Turco	26
39	St Mary's Duluth Clinic	Duluth, MN	Michael Lucca	14
42	St Joseph Medical Center	Towson, MD	Mark Midei	19
43	Duke University Medical Center	Durham, NC	Michael Sketch	19
44	The Christ Hospital	Cincinnati, OH	Dean Kereiakes	9
48	Piedmont Hospital	Atlanta, GA	Charles Brown	8
63	Elyria Memorial Hospital	Elyria, OH	Charles O'Shaughnessy	63
65	Scripps Memorial Hospital	La Jolla, CA	Richard Fortuna	5
81	Forsyth Medical Center	Winston-Salem, NC	Greg Braden	1
82	Florida Hospital	Orlando, FL	Andrew Taussig	11
86	Baptist Medical Center	Winston-Salem, NC	Robert Applegate	22
90	St. Joseph Hospital Health Center	Syracuse, NY	Ronald Caputo	22
91	St Luke's Hospital	Kansas City, MO	Barry Rutherford	17
95	Brigham and Women's Hospital	Boston, MA	Campbell Rogers	6
100	Mercy Hospital	Minneapolis, MN	Jeffrey Chambers	6
105	Riverside Methodist Hospital	Columbus, OH	Steven Yakubov	14
110	NY Presbyterian	New York, NY	S. Chiu Wong	9
115	Ocala Regional Medical Center	Ocala, FL	Rakesh Prashad	10
124	Lutheran Hospital of IN	Fort Wayne, IN	Steven Orlow	16
126	Genesis Hospital	Davenport, IA	Jon Robken	1
187	Sacred Heart Medical Center	Spokane, WA	Michael Ring	7
264	Sinai Hospital	Baltimore, MD	Paul Gurbel	22
270	Henry Ford Hospital	Detroit, MI	Aaron Kugelmass	12
279	TexSAn Heart Hospital	San Antonio, TX	Chris Casey	5
			Total Enrollment	**436**

Table 2b. Clinical Follow-up Data Compliance (ITT)

Site	Index	30-Day Contact	6-Month Contact	9-Month Contact	12-Month Contact	24-Month Contact
4	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	94.44% (17/18)	88.89% (16/18)	94.44% (17/18)
6	100.0% (9/9)	100.0% (9/9)	88.89% (8/9)	88.89% (8/9)	88.89% (8/9)	88.89% (8/9)
8	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)
9	100.0% (10/10)	100.0% (10/10)	90.00% (9/10)	100.0% (10/10)	100.0% (10/10)	100.0% (10/10)
10	100.0% (46/46)	100.0% (46/46)	97.83% (45/46)	97.83% (45/46)	100.0% (46/46)	93.48% (43/46)
31	100.0% (26/26)	100.0% (26/26)	96.15% (25/26)	92.31% (24/26)	92.31% (24/26)	92.31% (24/26)
39	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)
42	100.0% (19/19)	100.0% (19/19)	100.0% (19/19)	100.0% (19/19)	100.0% (19/19)	94.74% (18/19)
43	100.0% (19/19)	100.0% (19/19)	100.0% (19/19)	94.74% (18/19)	84.21% (16/19)	78.95% (15/19)
44	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)
48	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)
63	100.0% (63/63)	98.41% (62/63)	96.83% (61/63)	95.24% (60/63)	96.83% (61/63)	96.83% (61/63)
65	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)
81	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
82	100.0% (11/11)	81.82% (9/11)	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)
86	100.0% (22/22)	100.0% (22/22)	100.0% (22/22)	100.0% (22/22)	90.91% (20/22)	95.45% (21/22)
90	100.0% (22/22)	100.0% (22/22)	100.0% (22/22)	95.45% (21/22)	95.45% (21/22)	90.91% (20/22)
91	100.0% (17/17)	94.12% (16/17)	100.0% (17/17)	100.0% (17/17)	100.0% (17/17)	100.0% (17/17)
95	100.0% (6/6)	100.0% (6/6)	100.0% (6/6)	100.0% (6/6)	100.0% (6/6)	100.0% (6/6)
100	100.0% (6/6)	83.33% (5/6)	83.33% (5/6)	83.33% (5/6)	83.33% (5/6)	83.33% (5/6)
105	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)
110	100.0% (9/9)	88.89% (8/9)	88.89% (8/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)
115	100.0% (10/10)	100.0% (10/10)	100.0% (10/10)	100.0% (10/10)	100.0% (10/10)	100.0% (10/10)
124	100.0% (16/16)	100.0% (16/16)	100.0% (16/16)	100.0% (16/16)	93.75% (15/16)	93.75% (15/16)
126	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
187	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)
264	100.0% (22/22)	100.0% (22/22)	95.45% (21/22)	100.0% (22/22)	100.0% (22/22)	95.45% (21/22)
270	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)
279	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	80.00% (4/5)
Total	100.0% (436/436)	98.62% (430/436)	97.94% (427/436)	97.48% (425/436)	96.56% (421/436)	95.18% (415/436)

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Table 2c. Angiographic/IVUS Follow-up Data Compliance (ITT)

Site	Baseline QCA	8-Month QCA	Baseline IVUS	8-Month IVUS
4	100.0% (18/18)	77.78% (14/18)	94.44% (17/18)	61.11% (11/18)
6	100.0% (9/9)	66.67% (6/9)	88.89% (8/9)	33.33% (3/9)
8	100.0% (9/9)	77.78% (7/9)	88.89% (8/9)	33.33% (3/9)
9	100.0% (10/10)	90.00% (9/10)	80.00% (8/10)	50.00% (5/10)
10	100.0% (46/46)	89.13% (41/46)	80.43% (37/46)	82.61% (38/46)
31	100.0% (26/26)	84.62% (22/26)	73.08% (19/26)	50.00% (13/26)
39	100.0% (14/14)	92.86% (13/14)	85.71% (12/14)	78.57% (11/14)
42	100.0% (19/19)	94.74% (18/19)	94.74% (18/19)	78.95% (15/19)
43	100.0% (19/19)	89.47% (17/19)	73.68% (14/19)	57.89% (11/19)
44	100.0% (9/9)	88.89% (8/9)	100.0% (9/9)	77.78% (7/9)
48	100.0% (8/8)	100.0% (8/8)	75.00% (6/8)	87.50% (7/8)
63	100.0% (63/63)	98.41% (62/63)	74.60% (47/63)	82.54% (52/63)
65	100.0% (5/5)	100.0% (5/5)	40.00% (2/5)	80.00% (4/5)
81	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
82	100.0% (11/11)	81.82% (9/11)	54.55% (6/11)	72.73% (8/11)
86	100.0% (22/22)	81.82% (18/22)	95.45% (21/22)	68.18% (15/22)
90	100.0% (22/22)	81.82% (18/22)	72.73% (16/22)	63.64% (14/22)
91	100.0% (17/17)	94.12% (16/17)	88.24% (15/17)	82.35% (14/17)
95	100.0% (6/6)	66.67% (4/6)	66.67% (4/6)	50.00% (3/6)
100	100.0% (6/6)	83.33% (5/6)	83.33% (5/6)	66.67% (4/6)
105	92.86% (13/14)	92.86% (13/14)	78.57% (11/14)	71.43% (10/14)
110	100.0% (9/9)	88.89% (8/9)	66.67% (6/9)	55.56% (5/9)
115	100.0% (10/10)	100.0% (10/10)	90.00% (9/10)	80.00% (8/10)
124	100.0% (16/16)	93.75% (15/16)	75.00% (12/16)	75.00% (12/16)
126	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
187	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	71.43% (5/7)
264	100.0% (22/22)	86.36% (19/22)	81.82% (18/22)	72.73% (16/22)
270	100.0% (12/12)	91.67% (11/12)	58.33% (7/12)	58.33% (7/12)
279	100.0% (5/5)	100.0% (5/5)	80.00% (4/5)	80.00% (4/5)
Total	99.77% (435/436)	89.45% (390/436)	79.82% (348/436)	70.41% (307/436)

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Table 3. Baseline Demographics and Clinical Characteristics (ITT)

Patient Characteristic	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Age (yrs)					
Mean±SD (n)	61.42±10.58 (323)	61.73±11.59 (113)	61.50±10.84 (436)	-0.30 [-2.63,2.03]	0.799
Range (min,max)	(34.00,86.00)	(37.00,83.00)	(34.00,86.00)		
Number of Men	65.3% (211/323)	81.4% (92/113)	69.5% (303/436)	-16.1% [-24.9%,-7.2%]	0.001
History of Smoking	66.5% (212/319)	75.2% (85/113)	68.8% (297/432)	-8.8% [-18.3%,0.7%]	0.098
Prior Percutaneous Coronary Revascularization	22.6% (73/323)	16.8% (19/113)	21.1% (92/436)	5.8% [-2.5%,14.1%]	0.228
Hyperlipidemia Requiring Treatment	83.5% (268/321)	86.7% (98/113)	84.3% (366/434)	-3.2% [-10.7%,4.2%]	0.455
Diabetes Mellitus	29.7% (96/323)	28.3% (32/113)	29.4% (128/436)	1.4% [-8.3%,11.1%]	0.811
Insulin Dependent	6.5% (21/322)	8.8% (10/113)	7.1% (31/435)	-2.3% [-8.2%,3.6%]	0.401
Hypertension Requiring Treatment	70.7% (227/321)	74.3% (84/113)	71.7% (311/434)	-3.6% [-13.1%,5.8%]	0.544
Prior MI	19.9% (64/321)	20.7% (23/111)	20.1% (87/432)	-0.8% [-9.5%,7.9%]	0.891
Premature CAD in First Degree Relative	52.0% (140/269)	45.3% (43/95)	50.3% (183/364)	6.8% [-4.9%,18.4%]	0.284
Prior CABG	5.3% (17/323)	8.0% (9/113)	6.0% (26/436)	-2.7% [-8.3%,2.9%]	0.355
Revascularization for Angina or MI	84.8% (274/323)	85.8% (97/113)	85.1% (371/436)	-1.0% [-8.5%,6.5%]	0.879
Worst One					0.776
Stable	43.1% (118/274)	40.2% (39/97)	42.3% (157/371)		
Unstable	51.1% (140/274)	55.7% (54/97)	52.3% (194/371)		
MI	5.8% (16/274)	4.1% (4/97)	5.4% (20/371)		
CCS Class III or IV†	59.3% (156/263)	55.9% (52/93)	58.4% (208/356)	3.4% [-8.3%,15.1%]	0.625
Positive Stress Test	92.0% (185/201)	92.1% (70/76)	92.1% (255/277)	-0.1% [-7.2%,7.1%]	1.000
Ethnicity					
Hispanic/Latino	3.4% (11/323)	1.8% (2/113)	3.0% (13/436)	1.6% [-1.5%,4.8%]	0.529
Race					0.387
White	92.3% (298/323)	90.3% (102/113)	91.7% (400/436)		
Black	3.7% (12/323)	3.5% (4/113)	3.7% (16/436)		
Asian	1.2% (4/323)	0.0% (0/113)	0.9% (4/436)		
Native Hawaiian or Other Pacific Islander	0.3% (1/323)	0.0% (0/113)	0.2% (1/436)		
American Indian or Alaska Native	1.2% (4/323)	2.7% (3/113)	1.6% (7/436)		
Other	1.2% (4/323)	3.5% (4/113)	1.8% (8/436)		
Number of diseased, native, major epicardial coronary vessels (>50% Stenosed)					0.403
Single	62.2% (201/323)	58.4% (66/113)	61.2% (267/436)		
Double	29.1% (94/323)	30.1% (34/113)	29.4% (128/436)		
Triple	8.7% (28/323)	11.5% (13/113)	9.4% (41/436)		
Ejection Fraction (%)					
Mean±SD (n)	55.66±9.11 (307)	56.28±9.28 (110)	55.82±9.15 (417)	-0.62 [-2.62,1.38]	0.540
Range (min,max)	(30.00,87.00)	(30.00,78.00)	(30.00,87.00)		

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value.
†CCS – Canadian Cardiovascular Society angina class.

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Table 4. Baseline Lesion Characteristics (ITT)

Lesion Characteristic	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Vessel Location					0.532
LAD	41.2% (133/323)	39.8% (45/113)	40.8% (178/436)		
LCX	23.2% (75/323)	28.3% (32/113)	24.5% (107/436)		
RCA	35.6% (115/323)	31.9% (36/113)	34.6% (151/436)		
LMCA	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)		
Lesion Location					0.707
Ostial	2.2% (7/323)	3.5% (4/113)	2.5% (11/436)		
Proximal	37.2% (120/323)	37.2% (42/113)	37.2% (162/436)		
Mid	53.3% (172/323)	49.6% (56/113)	52.3% (228/436)		
Distal	7.4% (24/323)	9.7% (11/113)	8.0% (35/436)		
Length					0.257
Discrete (< 10 mm)	20.8% (67/322)	29.5% (33/112)	23.0% (100/434)		
Tubular (10–19.9 mm)	59.3% (191/322)	50.0% (56/112)	56.9% (247/434)		
Diffuse (≥ 20 mm)	19.9% (64/322)	20.5% (23/112)	20.0% (87/434)		
Eccentric	51.4% (166/323)	49.6% (56/113)	50.9% (222/436)	1.8% [-8.9%,12.5%]	0.744
Bend					0.864
< 45 degrees	78.9% (255/323)	79.6% (90/113)	79.1% (345/436)		
≥ 45 degrees and < 90 degrees	19.8% (64/323)	19.5% (22/113)	19.7% (86/436)		
≥ 90 degrees	1.2% (4/323)	0.9% (1/113)	1.1% (5/436)		
Thrombus	3.4% (11/323)	2.7% (3/113)	3.2% (14/436)	0.8% [-2.8%,4.3%]	1.000
Tortuosity					0.286
None	91.6% (296/323)	94.7% (107/113)	92.4% (403/436)		
Moderate	6.2% (20/323)	4.4% (5/113)	5.7% (25/436)		
Severe	2.2% (7/323)	0.9% (1/113)	1.8% (8/436)		
Calcification					0.094
Mild	80.2% (259/323)	87.6% (99/113)	82.1% (358/436)		
Moderate	15.8% (51/323)	8.0% (9/113)	13.8% (60/436)		
Severe	4.0% (13/323)	4.4% (5/113)	4.1% (18/436)		
Ulcerated	6.5% (21/323)	1.8% (2/113)	5.3% (23/436)	4.7% [1.1%,8.4%]	0.053
Aneurysm	1.9% (6/323)	0.0% (0/113)	1.4% (6/436)	1.9% [0.4%,3.3%]	0.346
Intimal Flap	0.6% (2/323)	1.8% (2/113)	0.9% (4/436)	-1.2% [-3.7%,1.4%]	0.277
TIMI Flow					0.837
0	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)		
1	0.9% (3/323)	1.8% (2/113)	1.1% (5/436)		
2	4.0% (13/323)	2.7% (3/113)	3.7% (16/436)		
3	95.0% (307/323)	95.6% (108/113)	95.2% (415/436)		
Total Occlusion	0.9% (3/323)	1.8% (2/113)	1.1% (5/436)	-0.8% [-3.5%,1.8%]	0.608
Branch Vessel Disease	8.4% (27/323)	5.3% (6/113)	7.6% (33/436)	3.0% [-2.1%,8.2%]	0.408
Sidebranch Stenosis (%)					
Mean±SD (n)	23.18±30.97 (107)	10.92±22.11 (38)	19.97±29.34 (145)	12.26 [1.45,23.06]	0.010
Range (min,max)	(0.00,90.00)	(0.00,80.00)	(0.00,90.00)		
Modified ACC/AHA Lesion Class					0.058
A	3.7% (12/323)	7.1% (8/113)	4.6% (20/436)		
B1	29.1% (94/323)	36.3% (41/113)	31.0% (135/436)		
B2	38.7% (125/323)	32.7% (37/113)	37.2% (162/436)		
C	28.5% (92/323)	23.9% (27/113)	27.3% (119/436)		

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value. All data assessed by the Angiographic Core Laboratory.

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Table 5. Procedural Characteristics (ITT)

Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Pre-Stent Balloon Angioplasty					
Nominal Diameter (mm)					
Mean±SD (n)	2.61±0.36 (319)	2.68±0.37 (109)	2.63±0.36 (428)	-0.07 [-0.15,0.01]	0.081
Range (min,max)	(2.00,4.00)	(2.00,4.00)	(2.00,4.00)		
Maximum Pressure (atm)					
Mean±SD (n)	10.23±3.41 (316)	10.52±3.97 (109)	10.30±3.56 (425)	-0.30 [-1.07,0.48]	0.490
Range (min,max)	(4.00,24.00)	(4.00,33.00)	(4.00,33.00)		
Stenting Procedure					
Maximum Pressure (atm)					
Mean±SD (n)	13.57±2.52 (318)	14.52±2.89 (110)	13.81±2.65 (428)	-0.95 [-1.52,-0.38]	0.001
Range (min,max)	(5.00,21.00)	(8.00,22.00)	(5.00,22.00)		
1st Post-Stent Balloon Dilatation					
Nominal Diameter (mm)					
Mean±SD (n)	3.27±0.49 (166)	3.40±0.48 (62)	3.31±0.49 (228)	-0.12 [-0.27,0.02]	0.087
Range (min,max)	(2.00,4.50)	(2.50,4.50)	(2.00,4.50)		
Maximum Pressure (atm)					
Mean±SD (n)	15.42±3.31 (166)	15.87±3.03 (63)	15.55±3.24 (229)	-0.45 [-1.39,0.49]	0.347
Range (min,max)	(8.00,24.00)	(8.00,22.00)	(8.00,24.00)		
2nd Post-Stent Balloon Dilatation					
Nominal Diameter (mm)					
Mean±SD (n)	3.16±0.33 (22)	3.36±0.58 (14)	3.24±0.45 (36)	-0.20 [-0.51,0.11]	0.258
Range (min,max)	(2.50,4.00)	(2.50,4.50)	(2.50,4.50)		
Maximum Pressure (atm)					
Mean±SD (n)	15.59±2.86 (22)	15.23±4.59 (13)	15.46±3.53 (35)	0.36 [-2.19,2.91]	0.776
Range (min,max)	(12.00,22.00)	(2.00,20.00)	(2.00,22.00)		
Maximum Post Balloon Diameter (mm)					
Mean±SD (n)	3.28±0.47 (180)	3.39±0.50 (68)	3.31±0.48 (248)	-0.12 [-0.25,0.02]	0.083
Range (min,max)	(2.00,4.50)	(2.50,4.50)	(2.00,4.50)		
Maximum Post Balloon Pressure (atm)					
Mean±SD (n)	15.51±3.25 (181)	15.71±3.35 (69)	15.56±3.27 (250)	-0.20 [-1.12,0.71]	0.664
Range (min,max)	(8.00,24.00)	(2.00,22.00)	(2.00,24.00)		
GP IIb/IIIa Inhibitors	44.0% (142/323)	44.6% (50/112)	44.1% (192/435)	-0.7% [-11.4%,10.0%]	0.912

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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Table 6a. Quantitative Angiographic Analysis (ITT)

Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Pre-Procedure					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.75±0.46 (323)	2.79±0.46 (113)	2.76±0.46 (436)	-0.03 [-0.13,0.06]	0.489
Range (min,max)	(1.56,4.28)	(1.69,3.98)	(1.56,4.28)		
MLD (mm)					
Mean±SD (n)	0.92±0.41 (323)	0.90±0.39 (113)	0.91±0.40 (436)	0.02 [-0.06,0.11]	0.607
Range (min,max)	(0.10,2.48)	(0.11,2.24)	(0.10,2.48)		
% Stenosis					
Mean±SD (n)	66.81±12.40 (323)	67.91±12.42 (113)	67.10±12.40 (436)	-1.09 [-3.76,1.57]	0.421
Range (min,max)	(29.70,95.41)	(37.04,95.06)	(29.70,95.41)		
Lesion Length (mm)					
Mean±SD (n)	14.96±6.20 (322)	14.95±7.28 (112)	14.96±6.49 (434)	0.01 [-1.39,1.41]	0.987
Range (min,max)	(4.39,37.22)	(3.77,41.29)	(3.77,41.29)		
Post-Procedure					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.81±0.46 (323)	2.85±0.46 (113)	2.82±0.46 (436)	-0.04 [-0.14,0.06]	0.455
Range (min,max)	(1.76,4.37)	(1.96,4.32)	(1.76,4.37)		
In-Segment					
MLD (mm)					
Mean±SD (n)	2.27±0.45 (323)	2.28±0.47 (113)	2.27±0.46 (436)	-0.01 [-0.11,0.09]	0.836
Range (min,max)	(1.26,3.64)	(0.11,3.56)	(0.11,3.64)		
% Stenosis					
Mean±SD (n)	19.38±9.25 (323)	20.17±11.74 (113)	19.59±9.95 (436)	-0.78 [-2.92,1.36]	0.522
Range (min,max)	(1.87,47.61)	(3.53,94.55)	(1.87,94.55)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	2.67±0.42 (323)	2.67±0.40 (112)	2.67±0.42 (435)	0.00 [-0.09,0.09]	0.993
Range (min,max)	(1.62,3.87)	(1.92,3.83)	(1.62,3.87)		
Mean Diameter (mm)					
Mean±SD (n)	3.02±0.42 (323)	3.04±0.42 (112)	3.02±0.42 (435)	-0.02 [-0.11,0.07]	0.674
Range (min,max)	(1.90,4.19)	(2.19,4.56)	(1.90,4.56)		
% Stenosis					
Mean±SD (n)	4.33±9.77 (323)	5.92±9.07 (112)	4.74±9.61 (435)	-1.59 [-3.66,0.48]	0.132
Range (min,max)	(-30.96,34.60)	(-27.55,28.28)	(-30.96,34.60)		
Proximal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.77±0.54 (304)	2.83±0.55 (106)	2.79±0.54 (410)	-0.05 [-0.17,0.07]	0.400
Range (min,max)	(1.55,4.54)	(1.65,4.09)	(1.55,4.54)		
Mean Diameter (mm)					
Mean±SD (n)	2.96±0.52 (304)	3.02±0.55 (106)	2.98±0.53 (410)	-0.05 [-0.17,0.06]	0.374
Range (min,max)	(1.75,4.63)	(1.88,4.31)	(1.75,4.63)		
% Stenosis					
Mean±SD (n)	1.06±11.80 (304)	1.55±10.46 (106)	1.19±11.46 (410)	-0.49 [-3.03,2.05]	0.706
Range (min,max)	(-33.81,47.27)	(-24.21,28.74)	(-33.81,47.27)		
Distal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.39±0.53 (321)	2.42±0.49 (111)	2.40±0.52 (432)	-0.03 [-0.14,0.08]	0.621
Range (min,max)	(1.15,4.23)	(1.30,3.97)	(1.15,4.23)		
Mean Diameter (mm)					
Mean±SD (n)	2.62±0.52 (321)	2.64±0.50 (111)	2.62±0.52 (432)	-0.02 [-0.13,0.09]	0.695
Range (min,max)	(1.53,4.40)	(1.59,4.52)	(1.53,4.52)		
% Stenosis					
Mean±SD (n)	14.96±11.75 (321)	15.25±11.09 (111)	15.03±11.57 (432)	-0.29 [-2.80,2.21]	0.819
Range (min,max)	(-20.11,50.08)	(-2.33,41.74)	(-20.11,50.08)		

Table 6a. Quantitative Angiographic Analysis (ITT) (Continued)

Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
8 Month Follow-up					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.74±0.44 (277)	2.84±0.49 (94)	2.77±0.46 (371)	-0.10 [-0.20,0.01]	0.081
Range (min,max)	(1.71,3.95)	(1.95,4.68)	(1.71,4.68)		
In-Segment					
MLD (mm)					
Mean±SD (n)	1.91±0.53 (277)	2.16±0.50 (94)	1.97±0.53 (371)	-0.25 [-0.37,-0.13]	<0.001
Range (min,max)	(0.27,3.39)	(0.10,3.45)	(0.10,3.45)		
% Stenosis					
Mean±SD (n)	30.42±15.57 (277)	23.86±13.87 (94)	28.76±15.41 (371)	6.56 [3.01,10.12]	<0.001
Range (min,max)	(6.33,88.41)	(3.53,95.07)	(3.53,95.07)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	2.06±0.57 (277)	2.52±0.56 (94)	2.17±0.60 (371)	-0.46 [-0.60,-0.33]	<0.001
Range (min,max)	(0.27,3.39)	(0.10,3.75)	(0.10,3.75)		
Mean Diameter (mm)					
Mean±SD (n)	2.53±0.48 (277)	2.99±0.50 (93)	2.64±0.52 (370)	-0.46 [-0.58,-0.35]	<0.001
Range (min,max)	(0.84,3.73)	(2.01,4.61)	(0.84,4.61)		
% Stenosis					
Mean±SD (n)	24.90±17.45 (277)	11.01±15.91 (94)	21.38±18.09 (371)	13.89 [9.88,17.90]	<0.001
Range (min,max)	(-9.34,88.41)	(-12.20,95.07)	(-12.20,95.07)		
Proximal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.56±0.59 (265)	2.75±0.58 (87)	2.61±0.59 (352)	-0.19 [-0.33,-0.05]	0.010
Range (min,max)	(0.45,4.36)	(0.90,4.15)	(0.45,4.36)		
Mean Diameter (mm)					
Mean±SD (n)	2.80±0.55 (265)	2.96±0.56 (87)	2.84±0.56 (352)	-0.16 [-0.30,-0.03]	0.019
Range (min,max)	(1.51,4.76)	(1.60,4.35)	(1.51,4.76)		
% Stenosis					
Mean±SD (n)	6.67±15.58 (265)	3.76±12.75 (87)	5.95±14.96 (352)	2.91 [-0.72,6.54]	0.083
Range (min,max)	(-31.32,86.09)	(-28.68,60.61)	(-31.32,86.09)		
Distal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.25±0.49 (276)	2.35±0.51 (92)	2.27±0.49 (368)	-0.10 [-0.22,0.01]	0.081
Range (min,max)	(1.08,3.70)	(1.25,3.61)	(1.08,3.70)		
Mean Diameter (mm)					
Mean±SD (n)	2.47±0.48 (276)	2.57±0.51 (92)	2.49±0.49 (368)	-0.10 [-0.22,0.01]	0.083
Range (min,max)	(1.33,3.98)	(1.58,3.94)	(1.33,3.98)		
% Stenosis					
Mean±SD (n)	18.05±12.12 (276)	17.38±11.64 (92)	17.89±11.99 (368)	0.67 [-2.17,3.52]	0.642
Range (min,max)	(-9.94,57.36)	(-7.21,52.20)	(-9.94,57.36)		
Binary Restenosis					
In-Segment	12.3% (34/277)	4.3% (4/94)	10.2% (38/371)	8.0% [2.4%,13.6%]	0.029
Within the Stent	9.7% (27/277)	2.1% (2/94)	7.8% (29/371)	7.6% [3.1%,12.2%]	0.014
Proximal Edge	1.5% (4/265)	1.1% (1/87)	1.4% (5/352)	0.4% [-2.3%,3.0%]	1.000
Distal Edge	1.4% (4/276)	1.1% (1/92)	1.4% (5/368)	0.4% [-2.2%,2.9%]	1.000

Table 6a. Quantitative Angiographic Analysis (ITT) (Continued)

Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Acute Gain (mm)					
In-Segment					
Mean±SD (n)	1.35±0.48 (323)	1.38±0.49 (113)	1.36±0.49 (436)	-0.03 [-0.14,0.07]	0.535
Range (min,max)	(0.18,2.71)	(0.00,2.55)	(0.00,2.71)		
Within the Stent					
Mean±SD (n)	1.76±0.44 (323)	1.77±0.46 (112)	1.76±0.44 (435)	-0.02 [-0.11,0.08]	0.753
Range (min,max)	(0.67,2.89)	(0.78,3.20)	(0.67,3.20)		
8 Month Late Loss (mm)					
In-Segment					
Mean±SD (n)	0.36±0.46 (277)	0.13±0.33 (94)	0.30±0.44 (371)	0.24 [0.13,0.34]	<0.001
Range (min,max)	(-0.46,2.20)	(-0.58,1.15)	(-0.58,2.20)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	0.62±0.49 (277)	0.15±0.34 (94)	0.50±0.50 (371)	0.47 [0.36,0.58]	<0.001
Range (min,max)	(-0.26,2.51)	(-0.50,1.82)	(-0.50,2.51)		
Mean Diameter Late Loss					
Mean±SD (n)	0.50±0.33 (277)	0.06±0.23 (93)	0.39±0.36 (370)	0.44 [0.36,0.51]	<0.001
Range (min,max)	(-0.19,1.57)	(-0.57,0.58)	(-0.57,1.57)		
Within the Proximal Edge					
MLD (mm)					
Mean±SD (n)	0.24±0.44 (260)	0.10±0.40 (86)	0.20±0.44 (346)	0.14 [0.04,0.25]	0.009
Range (min,max)	(-0.72,3.15)	(-1.53,1.45)	(-1.53,3.15)		
Mean Diameter Late Loss					
Mean±SD (n)	0.18±0.34 (260)	0.08±0.35 (86)	0.16±0.34 (346)	0.10 [0.02,0.19]	0.015
Range (min,max)	(-0.57,1.79)	(-1.00,1.11)	(-1.00,1.79)		
Within the Distal Edge					
MLD (mm)					
Mean±SD (n)	0.15±0.37 (276)	0.09±0.35 (92)	0.14±0.36 (368)	0.06 [-0.02,0.15]	0.157
Range (min,max)	(-0.63,1.66)	(-0.94,1.31)	(-0.94,1.66)		
Mean Diameter Late Loss					
Mean±SD (n)	0.15±0.32 (276)	0.08±0.29 (92)	0.14±0.31 (368)	0.07 [-0.00,0.15]	0.054
Range (min,max)	(-0.86,1.17)	(-0.54,1.16)	(-0.86,1.17)		
Loss Index					
In-Segment					
Arithmetic					
Mean±SD (n)	0.25±0.39 (277)	0.12±0.48 (94)	0.22±0.42 (371)	0.14 [0.04,0.24]	0.012
Range (min,max)	(-1.52,1.80)	(-0.75,3.77)	(-1.52,3.77)		
Regression					
Coefficient ± SE	0.29±0.05	0.09±0.07	0.24±0.05	0.20[0.02,0.37]	
Within the Stent					
Arithmetic					
Mean±SD (n)	0.36±0.29 (277)	0.10±0.26 (94)	0.30±0.30 (371)	0.27 [0.20,0.33]	<0.001
Range (min,max)	(-0.22,1.80)	(-0.45,1.87)	(-0.45,1.87)		
Regression					
Coefficient ± SE	0.21±0.07	-0.03±0.08	0.15±0.06	0.24[0.04,0.44]	

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

All data assessed by the Angiographic Core Laboratory.

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Table 6b. Interpolated Angiographic Analysis (ITT)

Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Pre-Procedure					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.69±0.49 (323)	2.73±0.48 (113)	2.70±0.48 (436)	-0.04 [-0.14,0.07]	0.470
Range (min,max)	(1.60,4.27)	(1.81,3.87)	(1.60,4.27)		
MLD (mm)					
Mean±SD (n)	0.92±0.41 (323)	0.90±0.39 (113)	0.91±0.40 (436)	0.02 [-0.06,0.11]	0.607
Range (min,max)	(0.10,2.48)	(0.11,2.24)	(0.10,2.48)		
% Stenosis					
Mean±SD (n)	65.94±12.80 (323)	67.14±12.61 (113)	66.25±12.75 (436)	-1.19 [-3.93,1.54]	0.392
Range (min,max)	(27.41,95.09)	(36.22,95.06)	(27.41,95.09)		
Lesion Length (mm)					
Mean±SD (n)	14.96±6.20 (322)	14.95±7.28 (112)	14.96±6.49 (434)	0.01 [-1.39,1.41]	0.987
Range (min,max)	(4.39,37.22)	(3.77,41.29)	(3.77,41.29)		
Post-Procedure					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.77±0.50 (323)	2.82±0.47 (113)	2.78±0.49 (436)	-0.05 [-0.16,0.05]	0.335
Range (min,max)	(1.75,4.26)	(1.94,4.32)	(1.75,4.32)		
In-Segment					
MLD (mm)					
Mean±SD (n)	2.27±0.45 (323)	2.28±0.47 (113)	2.27±0.46 (436)	-0.01 [-0.11,0.09]	0.836
Range (min,max)	(1.26,3.64)	(0.11,3.56)	(0.11,3.64)		
% Stenosis					
Mean±SD (n)	17.80±9.36 (323)	19.13±12.16 (113)	18.14±10.17 (436)	-1.33 [-3.51,0.85]	0.291
Range (min,max)	(1.15,51.93)	(2.86,94.55)	(1.15,94.55)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	2.67±0.42 (323)	2.67±0.40 (112)	2.67±0.42 (435)	0.00 [-0.09,0.09]	0.993
Range (min,max)	(1.62,3.87)	(1.92,3.83)	(1.62,3.87)		
Mean Diameter (mm)					
Mean±SD (n)	3.02±0.42 (323)	3.04±0.42 (112)	3.02±0.42 (435)	-0.02 [-0.11,0.07]	0.674
Range (min,max)	(1.90,4.19)	(2.19,4.56)	(1.90,4.56)		
% Stenosis					
Mean±SD (n)	2.53±9.37 (323)	4.85±8.15 (112)	3.13±9.12 (435)	-2.33 [-4.28,-0.37]	0.020
Range (min,max)	(-41.54,30.65)	(-17.82,22.66)	(-41.54,30.65)		
Proximal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.77±0.54 (304)	2.83±0.55 (106)	2.79±0.54 (410)	-0.05 [-0.17,0.07]	0.400
Range (min,max)	(1.55,4.54)	(1.65,4.09)	(1.55,4.54)		
Mean Diameter (mm)					
Mean±SD (n)	2.96±0.52 (304)	3.02±0.55 (106)	2.98±0.53 (410)	-0.05 [-0.17,0.06]	0.374
Range (min,max)	(1.75,4.63)	(1.88,4.31)	(1.75,4.63)		
% Stenosis					
Mean±SD (n)	-1.50±18.48 (304)	-0.71±17.44 (106)	-1.30±18.20 (410)	-0.79 [-4.83,3.25]	0.700
Range (min,max)	(-51.20,43.00)	(-50.30,44.63)	(-51.20,44.63)		
Distal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.39±0.53 (321)	2.42±0.49 (111)	2.40±0.52 (432)	-0.03 [-0.14,0.08]	0.621
Range (min,max)	(1.15,4.23)	(1.30,3.97)	(1.15,4.23)		
Mean Diameter (mm)					
Mean±SD (n)	2.62±0.52 (321)	2.64±0.50 (111)	2.62±0.52 (432)	-0.02 [-0.13,0.09]	0.695
Range (min,max)	(1.53,4.40)	(1.59,4.52)	(1.53,4.52)		
% Stenosis					
Mean±SD (n)	13.39±11.18 (321)	14.16±11.58 (111)	13.59±11.27 (432)	-0.78 [-3.22,1.67]	0.533
Range (min,max)	(-18.57,48.18)	(-8.69,45.61)	(-18.57,48.18)		

Table 6b. Interpolated Angiographic Analysis (ITT) (Continued)

Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
8 Month Follow-up					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.54±0.47 (277)	2.79±0.55 (94)	2.60±0.50 (371)	-0.25 [-0.37,-0.14]	<0.001
Range (min,max)	(1.48,3.93)	(1.89,4.68)	(1.48,4.68)		
In-Segment					
MLD (mm)					
Mean±SD (n)	1.91±0.53 (277)	2.16±0.50 (94)	1.97±0.53 (371)	-0.25 [-0.37,-0.13]	<0.001
Range (min,max)	(0.27,3.39)	(0.10,3.45)	(0.10,3.45)		
% Stenosis					
Mean±SD (n)	24.68±16.25 (277)	22.17±14.03 (94)	24.04±15.73 (371)	2.51 [-1.18,6.19]	0.183
Range (min,max)	(1.39,86.15)	(-2.15,94.87)	(-2.15,94.87)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	2.06±0.57 (277)	2.52±0.56 (94)	2.17±0.60 (371)	-0.46 [-0.60,-0.33]	<0.001
Range (min,max)	(0.27,3.39)	(0.10,3.75)	(0.10,3.75)		
Mean Diameter (mm)					
Mean±SD (n)	2.53±0.48 (277)	2.99±0.50 (93)	2.64±0.52 (370)	-0.46 [-0.58,-0.35]	<0.001
Range (min,max)	(0.84,3.73)	(2.01,4.61)	(0.84,4.61)		
% Stenosis					
Mean±SD (n)	18.56±19.14 (277)	9.20±15.50 (94)	16.18±18.72 (371)	9.36 [5.06,13.65]	<0.001
Range (min,max)	(-26.59,86.15)	(-15.41,94.87)	(-26.59,94.87)		
Proximal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.56±0.59 (265)	2.75±0.58 (87)	2.61±0.59 (352)	-0.19 [-0.33,-0.05]	0.010
Range (min,max)	(0.45,4.36)	(0.90,4.15)	(0.45,4.36)		
Mean Diameter (mm)					
Mean±SD (n)	2.80±0.55 (265)	2.96±0.56 (87)	2.84±0.56 (352)	-0.16 [-0.30,-0.03]	0.019
Range (min,max)	(1.51,4.76)	(1.60,4.35)	(1.51,4.76)		
% Stenosis					
Mean±SD (n)	-1.56±20.89 (265)	0.96±18.88 (87)	-0.94±20.42 (352)	-2.52 [-7.48,2.44]	0.319
Range (min,max)	(-75.93,77.94)	(-51.60,64.57)	(-75.93,77.94)		
Distal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.25±0.49 (276)	2.35±0.51 (92)	2.27±0.49 (368)	-0.10 [-0.22,0.01]	0.081
Range (min,max)	(1.08,3.70)	(1.25,3.61)	(1.08,3.70)		
Mean Diameter (mm)					
Mean±SD (n)	2.47±0.48 (276)	2.57±0.51 (92)	2.49±0.49 (368)	-0.10 [-0.22,0.01]	0.083
Range (min,max)	(1.33,3.98)	(1.58,3.94)	(1.33,3.98)		
% Stenosis					
Mean±SD (n)	11.23±12.09 (276)	15.54±12.00 (92)	12.31±12.19 (368)	-4.31 [-7.17,-1.45]	0.003
Range (min,max)	(-59.88,55.39)	(-12.26,53.01)	(-59.88,55.39)		
Binary Restenosis					
In-Segment	10.8% (30/277)	4.3% (4/94)	9.2% (34/371)	6.6% [1.1%,12.1%]	0.063
Within the Stent	8.7% (24/277)	2.1% (2/94)	7.0% (26/371)	6.5% [2.1%,11.0%]	0.034
Proximal Edge	2.3% (6/265)	2.3% (2/87)	2.3% (8/352)	-0.0% [-3.7%,3.6%]	1.000
Distal Edge	0.7% (2/276)	1.1% (1/92)	0.8% (3/368)	-0.4% [-2.7%,2.0%]	1.000

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

All data assessed by the Angiographic Core Laboratory.

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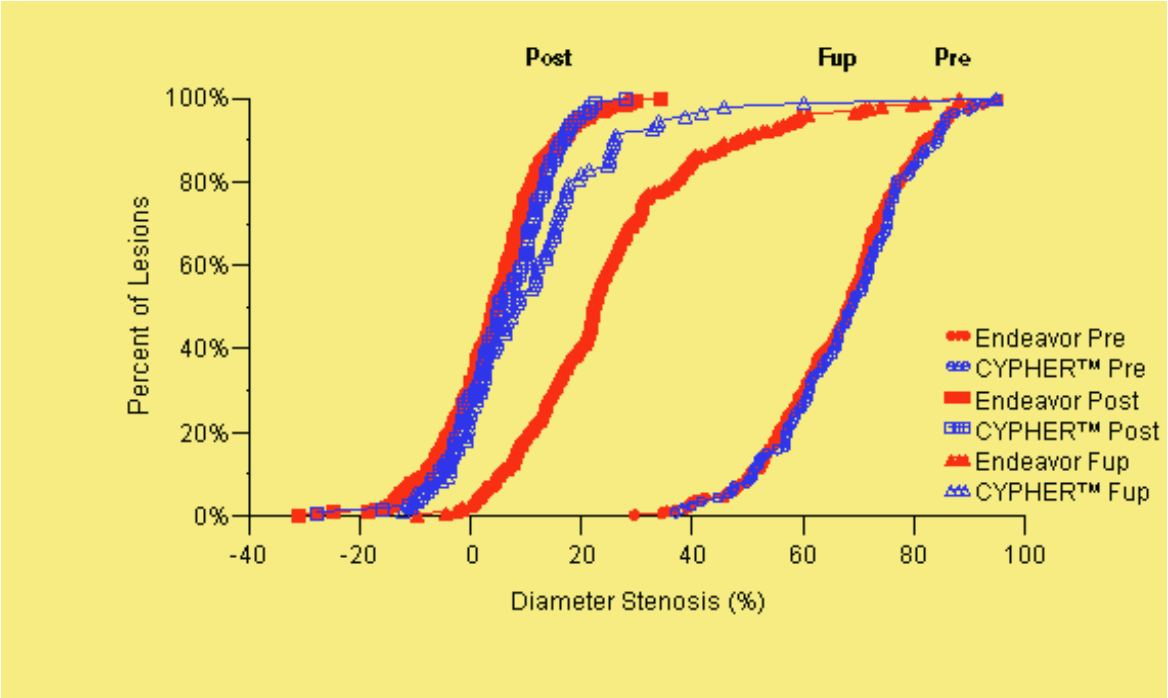
Figure 1. Cumulative Frequency Distribution of In-Stent Percent Diameter Stenosis (ITT)



	Pre-Procedure		Eight-Month Follow-up In-Stent		Post-Procedure In-Stent	
Measure	**Endeavor**	**CYPHER™**	**Endeavor**	**CYPHER™**	**Endeavor**	**CYPHER™**
Number	323	113	277	94	323	112
Median	68.1%	69.0%	22.3%	8.4%	4.4%	5.5%
Minimum	29.7%	37.0%	-9.3%	-12.2%	-31.0%	-27.6%
Maximum	95.4%	95.1%	88.4%	95.1%	34.6%	28.3%
Mean	66.8%	67.9%	24.9%	11.0%	4.3%	5.9%
SD	12.4%	12.4%	17.4%	15.9%	9.8%	9.1%
COV	18.6%	18.3%	70.1%	144.5%	225.5%	153.2%
Diff [CI]	-1.1%[-3.8%,1.6%]		13.9%[9.9%,17.9%]		-1.6%[-3.7%,0.5%]	

All data assessed by the Angiographic Core Laboratory.

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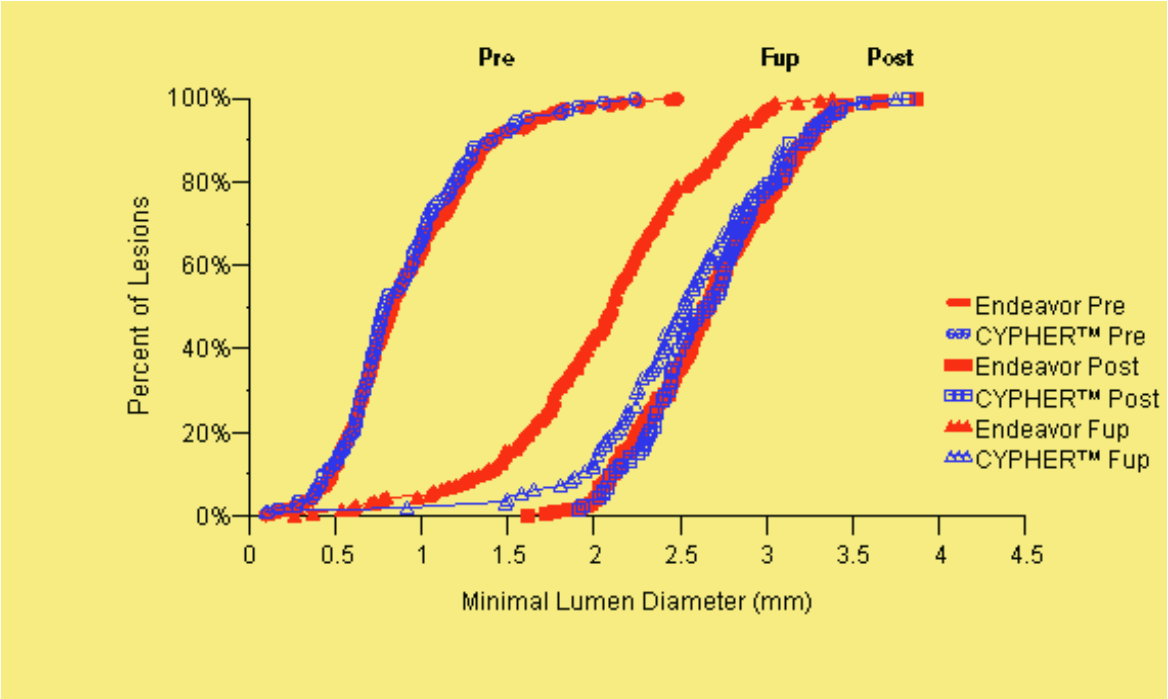
Figure 2. Cumulative Frequency Distribution of In-Stent Minimum Lumen Diameter (ITT)



	Pre-Procedure		Eight-Month Follow-up In-Stent		Post-Procedure In-Stent	
Measure	**Endeavor**	**CYPHER™**	**Endeavor**	**CYPHER™**	**Endeavor**	**CYPHER™**
Number	323	113	277	94	323	112
Median	0.84	0.79	2.11	2.53	2.66	2.67
Minimum	0.10	0.11	0.27	0.10	1.62	1.92
Maximum	2.48	2.24	3.39	3.75	3.87	3.83
Mean	0.92	0.90	2.06	2.52	2.67	2.67
SD	0.41	0.39	0.57	0.56	0.42	0.40
COV	44.1%	44.1%	27.7%	22.4%	15.8%	15.1%
Diff [CI]	0.02[-0.06,0.11]		-0.46[-0.60,-0.33]		0.00[-0.09,0.09]	

All data assessed by the Angiographic Core Laboratory.

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Table 7. Imputation Results for Primary Endpoint Analysis (ITT)

Lesion Characteristic	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [90% CI]	P-value*
Multiple Imputation					
Mean±SD (n)	0.35±0.50 (323)	0.17±0.74 (113)	0.31±0.54 (436)	0.18 [0.06,0.30]	0.607
Worst Case Imputation					
Mean±SD (n)	0.63±0.77 (323)	0.30±0.49 (113)	0.54±0.72 (436)	0.33 [0.20,0.45]	0.977
Range (min,max)	(-0.46,2.20)	(-0.58,1.15)	(-0.58,2.20)		
Available Case Analysis					
Mean±SD (n)	0.36±0.46 (277)	0.13±0.33 (94)	0.30±0.44 (371)	0.24 [0.15,0.32]	0.791
Range (min,max)	(-0.46,2.20)	(-0.58,1.15)	(-0.58,2.20)		

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N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.
*P-values are for the test of Non-Inferiority.
Multiple imputation was run using SAS v9. Covariates included: Age, Diabetes, Lesion Length, LAD, Procedure Success, Device Success, In Stent Late Loss, MACE, Angiographic binary restenosis, and Neointimal hyperplastic volume.
Note: The multiple imputation result must be interpreted with caution, given the relatively large number of patients with missing data.

Table 8. Acute Success (ITT)

Success	Endeavor	CYPHER™
Lesions Evaluable for Lesion Success	323	113
Patients Evaluable for Procedure Success	323	113
Lesions Evaluable for Device Success	323	113
Patients Evaluable for Device-Specific Procedure Success	323	113

Lesion	Endeavor	CYPHER™	Difference	95% CI
Success	323	112		
% Successful	100.0%	99.1%	0.9%	[-0.8%,2.6%]
Failure	0	1		
% Failed	0.0%	0.9%	-0.9%	[-2.6%,0.8%]

Procedure	Endeavor	CYPHER™	Difference	95% CI
Success	321	108		
% Successful	99.4%	95.6%	3.8%	[-0.1%,7.7%]
Failure	2	5		
% Failed	0.6%	4.4%	-3.8%	[-7.7%,0.1%]

Device	Endeavor	CYPHER™	Difference	95% CI
Success	319	107		
% Successful	98.8%	94.7%	4.1%	[-0.2%,8.4%]
Failure	4	6		
% Failed	1.2%	5.3%	-4.1%	[-8.4%,0.2%]

Device-Specific Procedure Success	Endeavor	CYPHER™	Difference	95% CI
Success	317	103		
% Successful	98.1%	91.2%	7.0%	[1.6%,12.4%]
Failure	6	10		
% Failed	1.9%	8.8%	-7.0%	[-12.4%,-1.6%]

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Table 9. Post-Procedure Morphology and Length of Stay (ITT)

Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Post-Procedure Hospital Length of Stay (days)					
Mean±SD (n)	1.1±0.5 (323)	1.2±0.7 (113)	1.2±0.6 (436)	-0.1 [-0.2,0.0]	0.263
Range (min,max)	(1.0,7.0)	(1.0,7.0)	(1.0,7.0)		
Median	1.0	1.0	1.0		
Interquartile Range (25%,75%)	(1.0,1.0)	(1.0,1.0)	(1.0,1.0)		
Diameter of stents implanted (per stent)					0.557
2.5 mm	21.9% (79/361)	17.4% (23/132)	20.7% (102/493)		
3.0 mm	40.2% (145/361)	42.4% (56/132)	40.8% (201/493)		
3.5 mm	38.0% (137/361)	40.2% (53/132)	38.5% (190/493)		
Pre-Stent Thrombus	3.4% (11/323)	2.7% (3/113)	3.2% (14/436)	0.8% [-2.8%,4.3%]	1.000
Post-Procedure Thrombus	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Post-Procedure Dissection					0.235
None	98.8% (319/323)	100.0% (113/113)	99.1% (432/436)		
Type A	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)		
Type B	0.9% (3/323)	0.0% (0/113)	0.7% (3/436)		
Type C	0.3% (1/323)	0.0% (0/113)	0.2% (1/436)		
Type D	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)		
Type E	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)		
Type F	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)		
Post-Procedure TIMI*					0.268
0	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)		
1	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)		
2	0.6% (2/323)	0.9% (1/113)	0.7% (3/436)		
3	99.4% (321/323)	98.2% (111/113)	99.1% (432/436)		

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.
*Patient 105-599 post-procedure TIMI = 1. Patient had lesion failure.
Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value.

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Table 10. Follow-up Morphology (ITT)

Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Eight-Month Follow-up					
Thrombus	0.0% (0/277)	0.0% (0/94)	0.0% (0/371)	0.0% [--,--]	--
TIMI Flow					0.744
0	0.0% (0/277)	0.0% (0/94)	0.0% (0/371)		
1	0.0% (0/277)	1.1% (1/94)	0.3% (1/371)		
2	0.7% (2/277)	0.0% (0/94)	0.5% (2/371)		
3	99.3% (275/277)	98.9% (93/94)	99.2% (368/371)		
Total Occlusion	0.0% (0/277)	1.1% (1/94)	0.3% (1/371)	-1.1% [-3.1%,1.0%]	0.253
In-stent Restenosis Pattern					0.021
IA	0.0% (0/34)	0.0% (0/4)	0.0% (0/38)		
IB	29.4% (10/34)	50.0% (2/4)	31.6% (12/38)		
IC	11.8% (4/34)	25.0% (1/4)	13.2% (5/38)		
ID	5.9% (2/34)	0.0% (0/4)	5.3% (2/38)		
II	52.9% (18/34)	0.0% (0/4)	47.4% (18/38)		
III	0.0% (0/34)	0.0% (0/4)	0.0% (0/38)		
IV	0.0% (0/34)	25.0% (1/4)	2.6% (1/38)		
ISR Length (mm)					
Mean±SD (n)	13.00±6.95 (34)	6.46±1.22 (4)	12.31±6.88 (38)	6.54 [-0.60,13.68]	<0.001
Range (min,max)	(4.09,26.79)	(5.00,7.90)	(4.09,26.79)		

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value.

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Table 11. Major Adverse Events In-Hospital (ITT)

In-Hospital Complications	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Death	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Myocardial Infarction (Q Wave or Non-Q Wave)	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Q Wave MI	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Non-Q Wave MI	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Emergent CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Lesion Revascularization	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TL-CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TL-PTCA	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Vessel Revascularization not involving the Target Lesion	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TV/non-TL-CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TV/non-TL-PTCA	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Vessel Revascularization	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Vessel Failure	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Perforation	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Early Stent Thrombosis	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Vascular Complications	1.9% (6/323)	3.5% (4/113)	2.3% (10/436)	-1.7% [-5.4%,2.0%]	0.292
Cerebrovascular Accident (CVA)	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Major Bleeding	1.9% (6/323)	4.4% (5/113)	2.5% (11/436)	-2.6% [-6.6%,1.5%]	0.162

N = the maximum number of eligible patients, denominators indicate the total number of patients with in-hospital information.

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Table 12a. Major Adverse Events Out-of-Hospital to 30 Days (ITT)

Out-of-Hospital Complications to 30 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Death	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Myocardial Infarction (Q Wave or Non-Q Wave)	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Q Wave MI	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Non-Q Wave MI	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Emergent CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Lesion Revascularization	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TL-CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TL-PTCA	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Vessel Revascularization not involving the Target Lesion	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)	-0.9% [-2.6%,0.8%]	0.259
TV/non-TL-CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TV/non-TL-PTCA	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)	-0.9% [-2.6%,0.8%]	0.259
Target Vessel Revascularization	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)	-0.9% [-2.6%,0.8%]	0.259
Target Vessel Failure	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)	-0.9% [-2.6%,0.8%]	0.259
Perforation	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Early Stent Thrombosis	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Vascular Complications	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)	-0.9% [-2.6%,0.8%]	0.259
Cerebrovascular Accident (CVA)	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Major Bleeding	0.3% (1/323)	0.9% (1/113)	0.5% (2/436)	-0.6% [-2.4%,1.3%]	0.452

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 25 days post index procedure or an event through 30 days.

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Table 12b. Major Adverse Events Out-of-Hospital to 180 Days (ITT)

Out-of-Hospital Complications to 180 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	2.2% (7/321)	1.8% (2/113)	2.1% (9/434)	0.4% [-2.5%,3.3%]	1.000
Death	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Myocardial Infarction (Q Wave or Non-Q Wave)	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Q Wave MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Non-Q Wave MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Emergent CABG	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Target Lesion Revascularization	2.2% (7/321)	1.8% (2/113)	2.1% (9/434)	0.4% [-2.5%,3.3%]	1.000
TL-CABG	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
TL-PTCA	1.6% (5/321)	1.8% (2/113)	1.6% (7/434)	-0.2% [-3.0%,2.6%]	1.000
Target Vessel Revascularization not involving the Target Lesion	0.9% (3/321)	1.8% (2/113)	1.2% (5/434)	-0.8% [-3.5%,1.8%]	0.609
TV/non-TL-CABG	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
TV/non-TL-PTCA	0.9% (3/321)	1.8% (2/113)	1.2% (5/434)	-0.8% [-3.5%,1.8%]	0.609
Target Vessel Revascularization	2.8% (9/321)	2.7% (3/113)	2.8% (12/434)	0.1% [-3.3%,3.6%]	1.000
Target Vessel Failure	2.8% (9/321)	2.7% (3/113)	2.8% (12/434)	0.1% [-3.3%,3.6%]	1.000
Perforation	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Early Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Vascular Complications	0.0% (0/321)	0.9% (1/113)	0.2% (1/434)	-0.9% [-2.6%,0.8%]	0.260
Cerebrovascular Accident (CVA)	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Major Bleeding	0.3% (1/321)	0.9% (1/113)	0.5% (2/434)	-0.6% [-2.4%,1.3%]	0.453

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 166 days post index procedure or an event through 180 days.

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Table 12c. Major Adverse Events Out-of-Hospital to 270 Days (ITT)

Out-of-Hospital Complications to 270 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	6.9% (22/321)	3.5% (4/113)	6.0% (26/434)	3.3% [-1.1%,7.7%]	0.253
Death	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Q Wave MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Non-Q Wave MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Emergent CABG	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Target Lesion Revascularization	6.2% (20/321)	3.5% (4/113)	5.5% (24/434)	2.7% [-1.6%,7.0%]	0.346
TL-CABG	0.9% (3/321)	0.0% (0/113)	0.7% (3/434)	0.9% [-0.1%,2.0%]	0.571
TL-PTCA	5.3% (17/321)	3.5% (4/113)	4.8% (21/434)	1.8% [-2.4%,6.0%]	0.612
Target Vessel Revascularization not involving the Target Lesion	5.9% (19/321)	5.3% (6/113)	5.8% (25/434)	0.6% [-4.3%,5.5%]	1.000
TV/non-TL-CABG	0.3% (1/321)	0.0% (0/113)	0.2% (1/434)	0.3% [-0.3%,0.9%]	1.000
TV/non-TL-PTCA	5.6% (18/321)	5.3% (6/113)	5.5% (24/434)	0.3% [-4.5%,5.1%]	1.000
Target Vessel Revascularization	11.2% (36/321)	8.0% (9/113)	10.4% (45/434)	3.3% [-2.8%,9.3%]	0.375
Target Vessel Failure	11.2% (36/321)	8.0% (9/113)	10.4% (45/434)	3.3% [-2.8%,9.3%]	0.375
Perforation	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Early Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Vascular Complications	0.0% (0/321)	1.8% (2/113)	0.5% (2/434)	-1.8% [-4.2%,0.7%]	0.067
Cerebrovascular Accident (CVA)	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
Major Bleeding	0.3% (1/321)	1.8% (2/113)	0.7% (3/434)	-1.5% [-4.0%,1.0%]	0.167

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 256 days post index procedure or an event through 270 days.

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Table 12d. Major Adverse Events Out-of-Hospital to 360 Days (ITT)

Out-of-Hospital Complications to 360 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	7.2% (23/320)	4.5% (5/112)	6.5% (28/432)	2.7% [-2.0%,7.5%]	0.379
Death	0.6% (2/320)	0.9% (1/112)	0.7% (3/432)	-0.3% [-2.2%,1.7%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Q Wave MI	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Non-Q Wave MI	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Emergent CABG	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Target Lesion Revascularization	6.6% (21/320)	3.6% (4/112)	5.8% (25/432)	3.0% [-1.4%,7.4%]	0.347
TL-CABG	0.9% (3/320)	0.0% (0/112)	0.7% (3/432)	0.9% [-0.1%,2.0%]	0.572
TL-PTCA	5.6% (18/320)	3.6% (4/112)	5.1% (22/432)	2.1% [-2.2%,6.3%]	0.465
Target Vessel Revascularization not involving the Target Lesion	6.6% (21/320)	5.4% (6/112)	6.3% (27/432)	1.2% [-3.8%,6.2%]	0.821
TV/non-TL-CABG	0.6% (2/320)	0.0% (0/112)	0.5% (2/432)	0.6% [-0.2%,1.5%]	1.000
TV/non-TL-PTCA	6.3% (20/320)	5.4% (6/112)	6.0% (26/432)	0.9% [-4.0%,5.8%]	0.822
Target Vessel Revascularization	12.2% (39/320)	8.0% (9/112)	11.1% (48/432)	4.2% [-2.0%,10.3%]	0.295
Target Vessel Failure	12.2% (39/320)	8.0% (9/112)	11.1% (48/432)	4.2% [-2.0%,10.3%]	0.295
Perforation	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Early Stent Thrombosis	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Vascular Complications	0.0% (0/320)	1.8% (2/112)	0.5% (2/432)	-1.8% [-4.2%,0.7%]	0.067
Cerebrovascular Accident (CVA)	0.6% (2/320)	0.0% (0/112)	0.5% (2/432)	0.6% [-0.2%,1.5%]	1.000
Major Bleeding	0.3% (1/320)	1.8% (2/112)	0.7% (3/432)	-1.5% [-4.0%,1.1%]	0.166

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 330 days post index procedure or an event through 360 days.

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Table 12e. Major Adverse Events Out-of-Hospital to 720 Days (ITT)

Out-of-Hospital Complications to 720 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	8.6% (27/313)	8.9% (10/112)	8.7% (37/425)	-0.3% [-6.4%,5.8%]	1.000
Death	1.6% (5/313)	4.5% (5/112)	2.4% (10/425)	-2.9% [-6.9%,1.2%]	0.138
Myocardial Infarction (Q Wave or Non-Q Wave)	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Q Wave MI	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Non-Q Wave MI	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Emergent CABG	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Target Lesion Revascularization	7.0% (22/313)	4.5% (5/112)	6.4% (27/425)	2.6% [-2.2%,7.3%]	0.498
TL-CABG	1.3% (4/313)	0.0% (0/112)	0.9% (4/425)	1.3% [0.0%,2.5%]	0.577
TL-PTCA	5.8% (18/313)	4.5% (5/112)	5.4% (23/425)	1.3% [-3.3%,5.9%]	0.808
Target Vessel Revascularization not involving the Target Lesion	8.3% (26/313)	6.3% (7/112)	7.8% (33/425)	2.1% [-3.4%,7.5%]	0.545
TV/non-TL-CABG	1.0% (3/313)	0.0% (0/112)	0.7% (3/425)	1.0% [-0.1%,2.0%]	0.570
TV/non-TL-PTCA	7.7% (24/313)	6.3% (7/112)	7.3% (31/425)	1.4% [-3.9%,6.8%]	0.832
Target Vessel Revascularization	13.7% (43/313)	9.8% (11/112)	12.7% (54/425)	3.9% [-2.8%,10.6%]	0.325
Target Vessel Failure	13.7% (43/313)	10.7% (12/112)	12.9% (55/425)	3.0% [-3.9%,9.9%]	0.512
Perforation	0.0% (0/313)	0.9% (1/112)	0.2% (1/425)	-0.9% [-2.6%,0.8%]	0.264
Early Stent Thrombosis	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Vascular Complications	0.0% (0/313)	1.8% (2/112)	0.5% (2/425)	-1.8% [-4.2%,0.7%]	0.069
Cerebrovascular Accident (CVA)	0.6% (2/313)	0.9% (1/112)	0.7% (3/425)	-0.3% [-2.2%,1.7%]	1.000
Major Bleeding	0.3% (1/313)	1.8% (2/112)	0.7% (3/425)	-1.5% [-4.0%,1.1%]	0.171

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 690 days post index procedure or an event through 720 days.

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Table 13a. Combined Major Adverse Events to 30 Days (ITT)

Combined Complications to 30 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Death	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Myocardial Infarction (Q Wave or Non-Q Wave)	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Q Wave MI	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Non-Q Wave MI	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Emergent CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Lesion Revascularization	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TL-CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TL-PTCA	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Target Vessel Revascularization not involving the Target Lesion	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)	-0.9% [-2.6%,0.8%]	0.259
TV/non-TL-CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TV/non-TL-PTCA	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)	-0.9% [-2.6%,0.8%]	0.259
Target Vessel Revascularization	0.0% (0/323)	0.9% (1/113)	0.2% (1/436)	-0.9% [-2.6%,0.8%]	0.259
Target Vessel Failure	0.6% (2/323)	4.4% (5/113)	1.6% (7/436)	-3.8% [-7.7%,0.1%]	0.014
Perforation	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Early Stent Thrombosis	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Vascular Complications	1.9% (6/323)	4.4% (5/113)	2.5% (11/436)	-2.6% [-6.6%,1.5%]	0.162
Cerebrovascular Accident (CVA)	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Major Bleeding	2.2% (7/323)	5.3% (6/113)	3.0% (13/436)	-3.1% [-7.6%,1.3%]	0.109

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 25 days post index procedure or an event through 30 days.

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Table 13b. Combined Major Adverse Events to 180 Days (ITT)

Combined Complications to 180 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	2.8% (9/321)	5.3% (6/113)	3.5% (15/434)	-2.5% [-7.0%,2.0%]	0.233
Death	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Myocardial Infarction (Q Wave or Non-Q Wave)	0.6% (2/321)	3.5% (4/113)	1.4% (6/434)	-2.9% [-6.4%,0.6%]	0.042
Q Wave MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Non-Q Wave MI	0.6% (2/321)	3.5% (4/113)	1.4% (6/434)	-2.9% [-6.4%,0.6%]	0.042
Emergent CABG	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Target Lesion Revascularization	2.2% (7/321)	1.8% (2/113)	2.1% (9/434)	0.4% [-2.5%,3.3%]	1.000
TL-CABG	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
TL-PTCA	1.6% (5/321)	1.8% (2/113)	1.6% (7/434)	-0.2% [-3.0%,2.6%]	1.000
Target Vessel Revascularization not involving the Target Lesion	0.9% (3/321)	1.8% (2/113)	1.2% (5/434)	-0.8% [-3.5%,1.8%]	0.609
TV/non-TL-CABG	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
TV/non-TL-PTCA	0.9% (3/321)	1.8% (2/113)	1.2% (5/434)	-0.8% [-3.5%,1.8%]	0.609
Target Vessel Revascularization	2.8% (9/321)	2.7% (3/113)	2.8% (12/434)	0.1% [-3.3%,3.6%]	1.000
Target Vessel Failure	3.4% (11/321)	6.2% (7/113)	4.1% (18/434)	-2.8% [-7.6%,2.1%]	0.270
Perforation	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Early Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Vascular Complications	1.9% (6/321)	4.4% (5/113)	2.5% (11/434)	-2.6% [-6.6%,1.5%]	0.164
Cerebrovascular Accident (CVA)	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Major Bleeding	2.2% (7/321)	5.3% (6/113)	3.0% (13/434)	-3.1% [-7.6%,1.3%]	0.110

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 166 days post index procedure or an event through 180 days.

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Table 13c. Combined Major Adverse Events to 270 Days (ITT)

Combined Complications to 270 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	7.5% (24/321)	7.1% (8/113)	7.4% (32/434)	0.4% [-5.1%,5.9%]	1.000
Death	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	0.6% (2/321)	3.5% (4/113)	1.4% (6/434)	-2.9% [-6.4%,0.6%]	0.042
Q Wave MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Non-Q Wave MI	0.6% (2/321)	3.5% (4/113)	1.4% (6/434)	-2.9% [-6.4%,0.6%]	0.042
Emergent CABG	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Target Lesion Revascularization	6.2% (20/321)	3.5% (4/113)	5.5% (24/434)	2.7% [-1.6%,7.0%]	0.346
TL-CABG	0.9% (3/321)	0.0% (0/113)	0.7% (3/434)	0.9% [-0.1%,2.0%]	0.571
TL-PTCA	5.3% (17/321)	3.5% (4/113)	4.8% (21/434)	1.8% [-2.4%,6.0%]	0.612
Target Vessel Revascularization not involving the Target Lesion	5.9% (19/321)	5.3% (6/113)	5.8% (25/434)	0.6% [-4.3%,5.5%]	1.000
TV/non-TL-CABG	0.3% (1/321)	0.0% (0/113)	0.2% (1/434)	0.3% [-0.3%,0.9%]	1.000
TV/non-TL-PTCA	5.6% (18/321)	5.3% (6/113)	5.5% (24/434)	0.3% [-4.5%,5.1%]	1.000
Target Vessel Revascularization	11.2% (36/321)	8.0% (9/113)	10.4% (45/434)	3.3% [-2.8%,9.3%]	0.375
Target Vessel Failure	11.8% (38/321)	11.5% (13/113)	11.8% (51/434)	0.3% [-6.5%,7.2%]	1.000
Perforation	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Early Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Vascular Complications	1.9% (6/321)	5.3% (6/113)	2.8% (12/434)	-3.4% [-7.8%,1.0%]	0.088
Cerebrovascular Accident (CVA)	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
Major Bleeding	2.2% (7/321)	6.2% (7/113)	3.2% (14/434)	-4.0% [-8.7%,0.7%]	0.058

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 256 days post index procedure or an event through 270 days.

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Table 13d. Combined Major Adverse Events to 360 Days (ITT)

Combined Complications to 360 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	7.8% (25/320)	8.0% (9/112)	7.9% (34/432)	-0.2% [-6.1%,5.6%]	1.000
Death	0.6% (2/320)	0.9% (1/112)	0.7% (3/432)	-0.3% [-2.2%,1.7%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	0.6% (2/320)	3.6% (4/112)	1.4% (6/432)	-2.9% [-6.5%,0.6%]	0.042
Q Wave MI	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Non-Q Wave MI	0.6% (2/320)	3.6% (4/112)	1.4% (6/432)	-2.9% [-6.5%,0.6%]	0.042
Emergent CABG	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Target Lesion Revascularization	6.6% (21/320)	3.6% (4/112)	5.8% (25/432)	3.0% [-1.4%,7.4%]	0.347
TL-CABG	0.9% (3/320)	0.0% (0/112)	0.7% (3/432)	0.9% [-0.1%,2.0%]	0.572
TL-PTCA	5.6% (18/320)	3.6% (4/112)	5.1% (22/432)	2.1% [-2.2%,6.3%]	0.465
Target Vessel Revascularization not involving the Target Lesion	6.6% (21/320)	5.4% (6/112)	6.3% (27/432)	1.2% [-3.8%,6.2%]	0.821
TV/non-TL-CABG	0.6% (2/320)	0.0% (0/112)	0.5% (2/432)	0.6% [-0.2%,1.5%]	1.000
TV/non-TL-PTCA	6.3% (20/320)	5.4% (6/112)	6.0% (26/432)	0.9% [-4.0%,5.8%]	0.822
Target Vessel Revascularization	12.2% (39/320)	8.0% (9/112)	11.1% (48/432)	4.2% [-2.0%,10.3%]	0.295
Target Vessel Failure	12.8% (41/320)	11.6% (13/112)	12.5% (54/432)	1.2% [-5.8%,8.2%]	0.868
Perforation	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Early Stent Thrombosis	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Vascular Complications	1.9% (6/320)	5.4% (6/112)	2.8% (12/432)	-3.5% [-7.9%,0.9%]	0.087
Cerebrovascular Accident (CVA)	0.6% (2/320)	0.0% (0/112)	0.5% (2/432)	0.6% [-0.2%,1.5%]	1.000
Major Bleeding	2.2% (7/320)	6.3% (7/112)	3.2% (14/432)	-4.1% [-8.8%,0.7%]	0.057

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 330 days post index procedure or an event through 360 days.

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Table 13e. Combined Major Adverse Events to 720 Days (ITT)

Combined Complications to 720 Days	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
MACE (Death, MI, Emergent CABG, TLR)	9.3% (29/313)	11.6% (13/112)	9.9% (42/425)	-2.3% [-9.1%,4.4%]	0.465
Death	1.6% (5/313)	4.5% (5/112)	2.4% (10/425)	-2.9% [-6.9%,1.2%]	0.138
Myocardial Infarction (Q Wave or Non-Q Wave)	0.6% (2/313)	3.6% (4/112)	1.4% (6/425)	-2.9% [-6.5%,0.6%]	0.044
Q Wave MI	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Non-Q Wave MI	0.6% (2/313)	3.6% (4/112)	1.4% (6/425)	-2.9% [-6.5%,0.6%]	0.044
Emergent CABG	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Target Lesion Revascularization	7.0% (22/313)	4.5% (5/112)	6.4% (27/425)	2.6% [-2.2%,7.3%]	0.498
TL-CABG	1.3% (4/313)	0.0% (0/112)	0.9% (4/425)	1.3% [0.0%,2.5%]	0.577
TL-PTCA	5.8% (18/313)	4.5% (5/112)	5.4% (23/425)	1.3% [-3.3%,5.9%]	0.808
Target Vessel Revascularization not involving the Target Lesion	8.3% (26/313)	6.3% (7/112)	7.8% (33/425)	2.1% [-3.4%,7.5%]	0.545
TV/non-TL-CABG	1.0% (3/313)	0.0% (0/112)	0.7% (3/425)	1.0% [-0.1%,2.0%]	0.570
TV/non-TL-PTCA	7.7% (24/313)	6.3% (7/112)	7.3% (31/425)	1.4% [-3.9%,6.8%]	0.832
Target Vessel Revascularization	13.7% (43/313)	9.8% (11/112)	12.7% (54/425)	3.9% [-2.8%,10.6%]	0.325
Target Vessel Failure	14.4% (45/313)	13.4% (15/112)	14.1% (60/425)	1.0% [-6.4%,8.4%]	0.875
Perforation	0.0% (0/313)	0.9% (1/112)	0.2% (1/425)	-0.9% [-2.6%,0.8%]	0.264
Early Stent Thrombosis	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Late Stent Thrombosis	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Vascular Complications	1.9% (6/313)	5.4% (6/112)	2.8% (12/425)	-3.4% [-7.9%,1.0%]	0.090
Cerebrovascular Accident (CVA)	0.6% (2/313)	0.9% (1/112)	0.7% (3/425)	-0.3% [-2.2%,1.7%]	1.000
Major Bleeding	2.2% (7/313)	6.3% (7/112)	3.3% (14/425)	-4.0% [-8.8%,0.8%]	0.060

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 690 days post index procedure or an event through 720 days.

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Table 14a. Hierarchical Major Adverse Events to 30 Days (ITT)

Complications	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Any MACE (Death, MI, Emergent CABG, TLR)	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Death	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Non-fatal Q Wave MI	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
Non-fatal Non-Q Wave MI without Q Wave MI	0.6% (2/323)	3.5% (4/113)	1.4% (6/436)	-2.9% [-6.4%,0.6%]	0.042
Emergent CABG without Death or MI	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TL-CABG without Death or MI	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--
TL-PTCA without Death, MI, or TL-CABG	0.0% (0/323)	0.0% (0/113)	0.0% (0/436)	0.0% [--,--]	--

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 25 days post index procedure or an event through 30 days.

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Table 14b. Hierarchical Major Adverse Events to 180 Days (ITT)

Complications	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Any MACE (Death, MI, Emergent CABG, TLR)	2.8% (9/321)	5.3% (6/113)	3.5% (15/434)	-2.5% [-7.0%,2.0%]	0.233
Death	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Non-fatal Q Wave MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Non-fatal Non-Q Wave MI without Q Wave MI	0.6% (2/321)	3.5% (4/113)	1.4% (6/434)	-2.9% [-6.4%,0.6%]	0.042
Emergent CABG without Death or MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
TL-CABG without Death or MI	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
TL-PTCA without Death, MI, or TL-CABG	1.6% (5/321)	1.8% (2/113)	1.6% (7/434)	-0.2% [-3.0%,2.6%]	1.000

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 166 days post index procedure or an event through 180 days.

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Table 14c. Hierarchical Major Adverse Events to 270 Days (ITT)

Complications	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Any MACE (Death, MI, Emergent CABG, TLR)	7.5% (24/321)	7.1% (8/113)	7.4% (32/434)	0.4% [-5.1%,5.9%]	1.000
Death	0.6% (2/321)	0.0% (0/113)	0.5% (2/434)	0.6% [-0.2%,1.5%]	1.000
Non-fatal Q Wave MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
Non-fatal Non-Q Wave MI without Q Wave MI	0.6% (2/321)	3.5% (4/113)	1.4% (6/434)	-2.9% [-6.4%,0.6%]	0.042
Emergent CABG without Death or MI	0.0% (0/321)	0.0% (0/113)	0.0% (0/434)	0.0% [--,--]	--
TL-CABG without Death or MI	0.9% (3/321)	0.0% (0/113)	0.7% (3/434)	0.9% [-0.1%,2.0%]	0.571
TL-PTCA without Death, MI, or TL-CABG	5.3% (17/321)	3.5% (4/113)	4.8% (21/434)	1.8% [-2.4%,6.0%]	0.612

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 256 days post index procedure or an event through 270 days.

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Table 14d. Hierarchical Major Adverse Events to 360 Days (ITT)

Complications	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Any MACE (Death, MI, Emergent CABG, TLR)	7.8% (25/320)	8.0% (9/112)	7.9% (34/432)	-0.2% [-6.1%,5.6%]	1.000
Death	0.6% (2/320)	0.9% (1/112)	0.7% (3/432)	-0.3% [-2.2%,1.7%]	1.000
Non-fatal Q Wave MI	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
Non-fatal Non-Q Wave MI without Q Wave MI	0.6% (2/320)	3.6% (4/112)	1.4% (6/432)	-2.9% [-6.5%,0.6%]	0.042
Emergent CABG without Death or MI	0.0% (0/320)	0.0% (0/112)	0.0% (0/432)	0.0% [--,--]	--
TL-CABG without Death or MI	0.9% (3/320)	0.0% (0/112)	0.7% (3/432)	0.9% [-0.1%,2.0%]	0.572
TL-PTCA without Death, MI, or TL-CABG	5.6% (18/320)	3.6% (4/112)	5.1% (22/432)	2.1% [-2.2%,6.3%]	0.465

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 330 days post index procedure or an event through 360 days.

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Table 14e. Hierarchical Major Adverse Events to 720 Days (ITT)

Complications	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Any MACE (Death, MI, Emergent CABG, TLR)	9.3% (29/313)	11.6% (13/112)	9.9% (42/425)	-2.3% [-9.1%,4.4%]	0.465
Death	1.6% (5/313)	4.5% (5/112)	2.4% (10/425)	-2.9% [-6.9%,1.2%]	0.138
Non-fatal Q Wave MI	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
Non-fatal Non-Q Wave MI without Q Wave MI	0.6% (2/313)	2.7% (3/112)	1.2% (5/425)	-2.0% [-5.2%,1.1%]	0.117
Emergent CABG without Death or MI	0.0% (0/313)	0.0% (0/112)	0.0% (0/425)	0.0% [--,--]	--
TL-CABG without Death or MI	1.3% (4/313)	0.0% (0/112)	0.9% (4/425)	1.3% [0.0%,2.5%]	0.577
TL-PTCA without Death, MI, or TL-CABG	5.8% (18/313)	4.5% (5/112)	5.4% (23/425)	1.3% [-3.3%,5.9%]	0.808

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 690 days post index procedure or an event through 720 days.

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Figure 3. Survival Free from MACE at 720 Days (ITT)

MACE	0	90	180	270	360	450	540	630	720
Endeavor									
# Entered	323	321	318	312	296	291	285	282	281
# Censored	0	2	0	1	4	6	0	0	114
# Incomplete	0	0	0	0	0	0	0	0	0
# Events	2	1	6	15	1	0	3	1	0
% Survived	99.4%	99.1%	97.2%	92.5%	92.2%	92.2%	91.2%	90.9%	90.9%
SE	0.4%	0.5%	0.9%	1.5%	1.5%	1.5%	1.6%	1.6%	2.1%
CYPHER™									
# Entered	113	109	108	107	105	103	103	103	101
# Censored	0	0	0	0	1	0	0	0	39
# Incomplete	0	0	0	0	0	0	0	0	0
# Events	4	1	1	2	1	0	0	2	2
% Survived	96.5%	95.6%	94.7%	92.9%	92.0%	92.0%	92.0%	90.2%	88.5%
SE	1.7%	1.9%	2.1%	2.4%	2.6%	2.6%	2.6%	2.8%	3.9%
Tests Between Groups									
	Test	Chi-Square	Deg Frdm	P-value					
	Wilcoxon	0.53	1	0.466					
	Log-Rank	0.54	1	0.464					

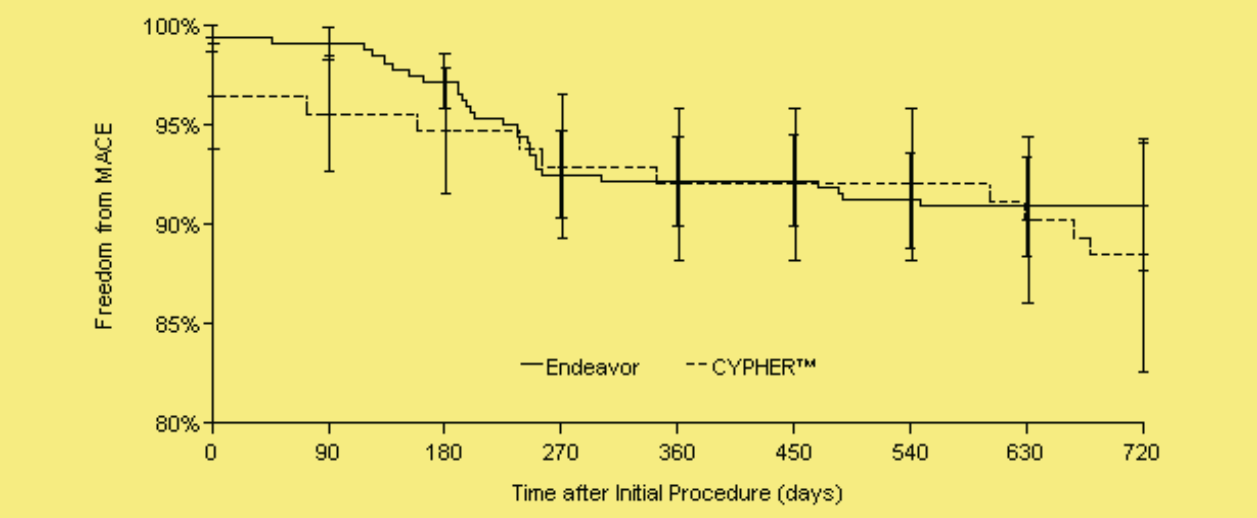

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Figure 4. Survival Free from Target Lesion Revascularization Event at 720 Days (ITT)

TLR	0	90	180	270	360	450	540	630	720
Endeavor									
# Entered	323	323	319	312	287	279	273	270	269
# Censored	0	3	1	10	7	6	0	0	106
# Incomplete	0	0	0	2	0	0	3	0	0
# Events	0	1	6	13	1	0	0	1	0
% Survived	100.0%	99.7%	97.8%	93.7%	93.4%	93.4%	93.4%	93.0%	93.0%
SE	0.0%	0.3%	0.8%	1.4%	1.4%	1.5%	1.5%	1.5%	1.9%
CYPHER™									
# Entered	113	113	112	111	109	107	107	106	104
# Censored	0	0	0	0	1	0	0	0	39
# Incomplete	0	0	0	0	1	0	1	2	1
# Events	0	1	1	2	0	0	0	0	1
% Survived	100.0%	99.1%	98.2%	96.5%	96.5%	96.5%	96.5%	96.5%	95.5%
SE	0.0%	0.9%	1.2%	1.7%	1.8%	1.8%	1.8%	1.8%	2.5%
Tests Between Groups									
	Test	Chi-Square	Deg Frdm	P-value					
	Wilcoxon	0.95	1	0.330					
	Log-Rank	0.93	1	0.336					

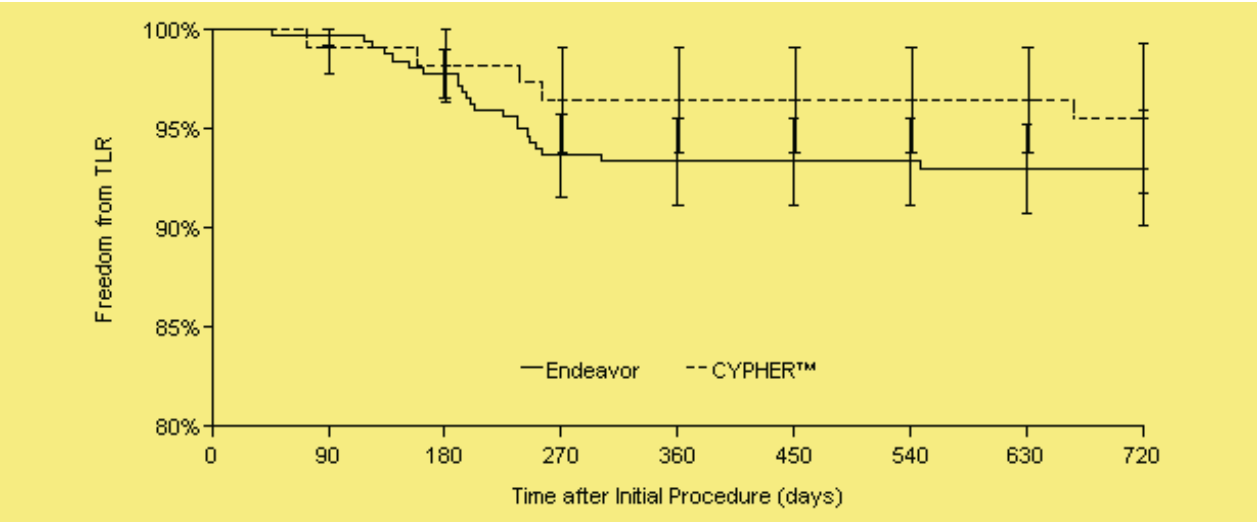

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Figure 5. Survival Free from Target Vessel Failure Event at 720 Days (ITT)

TVF	0	90	180	270	360	450	540	630	720
Endeavor									
# Entered	323	321	318	310	281	274	268	264	262
# Censored	0	2	0	2	4	6	3	0	102
# Incomplete	0	0	0	0	0	0	0	0	0
# Events	2	1	8	27	3	0	1	2	1
% Survived	99.4%	99.1%	96.6%	88.1%	87.2%	87.2%	86.9%	86.2%	85.8%
SE	0.4%	0.5%	1.0%	1.8%	1.9%	1.9%	1.9%	2.0%	2.6%
CYPHER™									
# Entered	113	109	107	106	100	98	97	97	95
# Censored	0	0	0	0	2	0	0	2	38
# Incomplete	0	0	0	0	0	0	0	0	0
# Events	4	2	1	6	0	1	0	0	1
% Survived	96.5%	94.7%	93.8%	88.5%	88.5%	87.6%	87.6%	87.6%	86.7%
SE	1.7%	2.1%	2.3%	3.0%	3.0%	3.1%	3.1%	3.2%	4.2%
Tests Between Groups									
	Test	Chi-Square	Deg Frdm	P-value					
	Wilcoxon	0.01	1	0.906					
	Log-Rank	0.03	1	0.867					

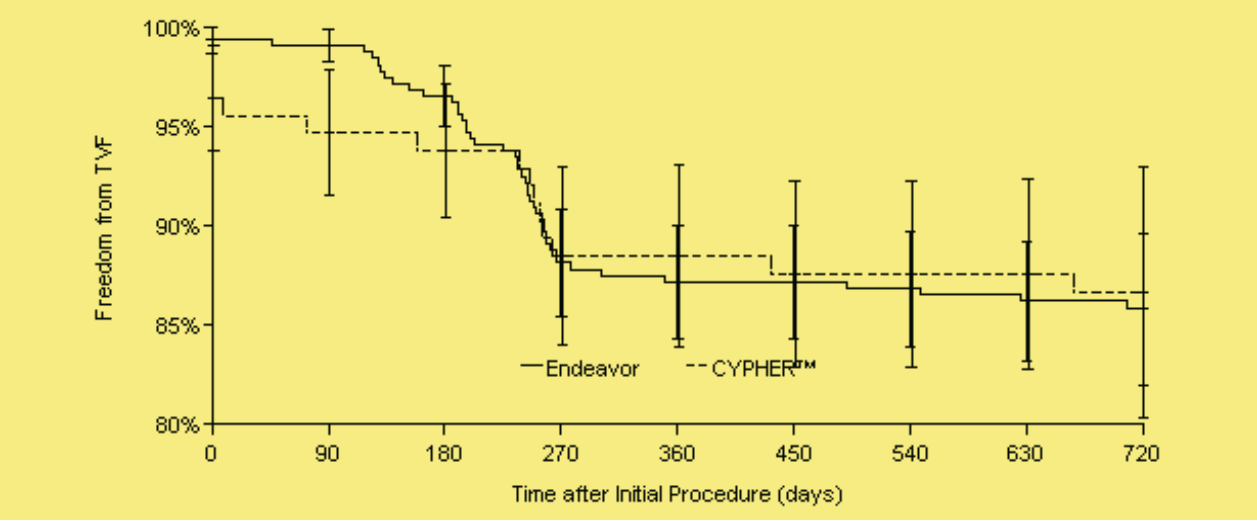

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Figure 6. Survival Free from Target Vessel Revascularization Event at 720 Days (ITT)

TVR	0	90	180	270	360	450	540	630	720
Endeavor									
# Entered	323	323	320	312	283	276	270	266	264
# Censored	0	2	0	0	4	6	0	0	103
# Incomplete	0	0	0	2	0	0	3	0	0
# Events	0	1	8	27	3	0	1	2	1
% Survived	100.0%	99.7%	97.2%	88.8%	87.8%	87.8%	87.5%	86.8%	86.4%
SE	0.0%	0.3%	0.9%	1.8%	1.8%	1.9%	1.9%	1.9%	2.5%
CYPHER™									
# Entered	113	113	111	110	104	102	101	100	98
# Censored	0	0	0	0	1	0	0	0	37
# Incomplete	0	0	0	0	1	0	1	2	1
# Events	0	2	1	6	0	1	0	0	1
% Survived	100.0%	98.2%	97.3%	92.0%	92.0%	91.1%	91.1%	91.1%	90.2%
SE	0.0%	1.2%	1.5%	2.5%	2.6%	2.7%	2.7%	2.7%	3.7%
Tests Between Groups									
	Test	Chi-Square	Deg Frdm	P-value					
	Wilcoxon	1.08	1	0.298					
	Log-Rank	1.06	1	0.304					

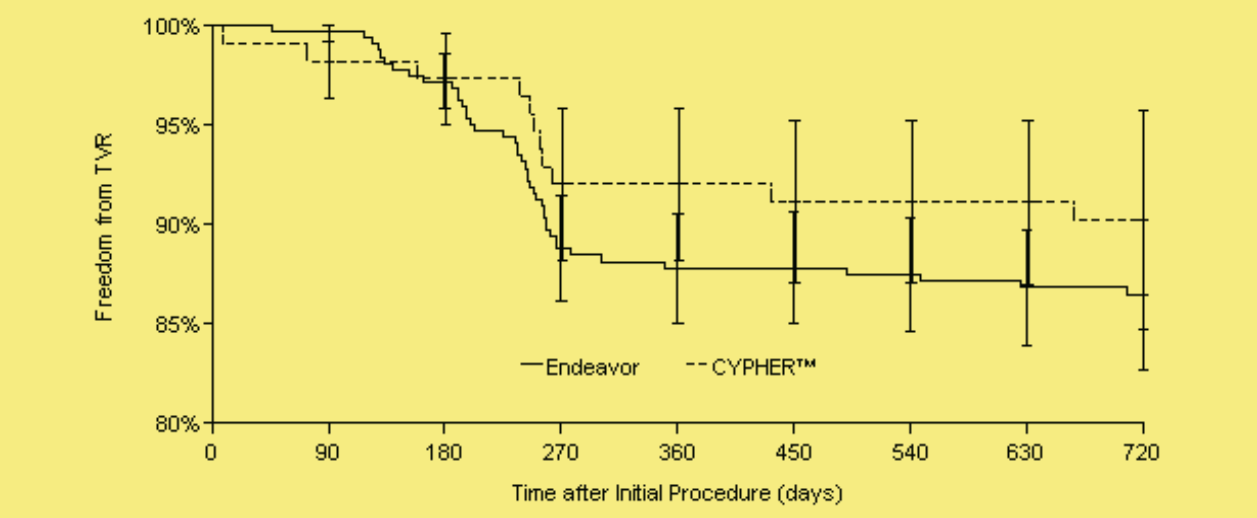

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Table 15. Total Stent Length Implanted per Patient (ITT)

			Endeavor (N=323 Patients)		CYPHER™ (N=113 Patients)	
Number of Stents Implanted	Total Stent Length Implanted (mm)	Length of Stents	Number of Patients	Number of Stents Implanted	Number of Patients	Number of Stents Implanted
0			6	0	2	0
1	8	1 8mm	1	1	0	0
	13	1 13mm	1	1	2	2
	14	1 14mm	2	2	0	0
	15	1 15mm	1	1	0	0
	16	1 16mm	0	0	1	1
	18	1 18mm	147	147	42	42
	23	1 23mm	0	0	24	24
	24	1 24mm	76	76	1	1
	25	1 25mm	1	1	0	0
	28	1 28mm	0	0	14	14
	30	1 30mm	50	50	0	0
	32	1 32mm	0	0	1	1
	33	1 33mm	0	0	8	8
2	26	1 8mm, 1 18mm	2	4	0	0
	26	2 13mm	0	0	1	2
	27	1 9mm, 1 18mm	6	12	0	0
	32	1 8mm, 1 24mm	1	2	0	0
	33	1 9mm, 1 24mm	5	10	0	0
	36	1 13mm, 1 23mm	0	0	2	4
	36	2 18mm	5	10	0	0
	38	1 8mm, 1 30mm	1	2	0	0
	39	1 9mm, 1 30mm	5	10	0	0
	41	1 13mm, 1 28mm	0	0	4	8
	41	1 18mm, 1 23mm	0	0	4	8
	41	1 8mm, 1 33mm	0	0	1	2
	42	1 18mm, 1 24mm	4	8	0	0
	48	1 18mm, 1 30mm	3	6	0	0
	48	2 24mm	1	2	0	0
	51	1 18mm, 1 33mm	0	0	2	4
	56	2 28mm	0	0	1	2
3	24	3 8mm	0	0	1	3
	34	2 8mm, 1 18mm	0	0	1	3
	45	1 9mm, 2 18mm	1	3	0	0
	50	1 8mm, 1 18mm, 1 24mm	1	3	0	0
	51	1 9mm, 1 18mm, 1 24mm	1	3	0	0
	54	1 8mm, 1 18mm, 1 28mm	0	0	1	3
	57	1 9mm, 1 18mm, 1 30mm	1	3	0	0
4	35	1 8mm, 3 9mm	1	4	0	0
		Total Stents Implanted	**323**	**361**	**113**	**132**

N = the maximum number of eligible patients.

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Table 16. Quantitative Intravascular Ultrasound Analysis Post-Stent Implantation (ITT)

Post-Stent	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
EEM Area (mm^2)					
Mean±SD (n)	13.92±4.64 (133)	13.90±4.56 (49)	13.92±4.60 (182)	0.01 [-1.51,1.54]	0.985
Range (min,max)	(5.91,31.44)	(6.53,23.67)	(5.91,31.44)		
EEM Volume (mm^3)					
Mean±SD (n)	328.17±138.64 (116)	328.49±159.52 (43)	328.26±144.06 (159)	-0.32 [-51.29,50.64]	0.990
Range (min,max)	(108.94,823.52)	(115.81,648.31)	(108.94,823.52)		
Mean Stent Area (mm^2)					
Mean±SD (n)	7.05±2.20 (212)	6.95±2.13 (81)	7.02±2.18 (293)	0.10 [-0.46,0.66]	0.731
Range (min,max)	(2.78,13.66)	(2.15,13.76)	(2.15,13.76)		
Stent Volume (mm^3)					
Mean±SD (n)	171.29±66.72 (185)	171.88±78.49 (70)	171.45±69.99 (255)	-0.59 [-19.97,18.79]	0.952
Range (min,max)	(60.80,436.72)	(58.37,428.79)	(58.37,436.72)		
Mean Lumen Area (mm^2)					
Mean±SD (n)	7.04±2.20 (212)	6.94±2.12 (81)	7.01±2.17 (293)	0.10 [-0.46,0.66]	0.720
Range (min,max)	(2.78,13.66)	(2.15,13.55)	(2.15,13.66)		
Minimal Lumen Area (mm^2)					
Mean±SD (n)	5.99±2.10 (207)	5.81±1.94 (81)	5.94±2.06 (288)	0.17 [-0.36,0.70]	0.524
Range (min,max)	(1.55,13.06)	(1.81,11.82)	(1.55,13.06)		
Lumen Volume (mm^3)					
Mean±SD (n)	170.90±66.70 (185)	171.18±77.83 (70)	170.98±69.77 (255)	-0.28 [-19.60,19.04]	0.977
Range (min,max)	(60.80,436.72)	(58.33,424.95)	(58.33,436.72)		
Plaque Volume (mm^3)					
Mean±SD (n)	160.44±78.90 (116)	164.03±92.68 (43)	161.41±82.56 (159)	-3.59 [-32.79,25.61]	0.809
Range (min,max)	(48.11,498.67)	(43.59,396.53)	(43.59,498.67)		
Neointimal Hyperplastic Volume (mm^3)					
Mean±SD (n)	N/A	0.05±0.40 (81)	N/A	N/A	N/A
Range (min,max)		(0.00,3.61)			

N = the maximum number of eligible patients, n = number of patients with evaluable data.

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Table 17. Quantitative Intravascular Ultrasound Analysis at 8 Months (ITT)

8-Month Follow-up	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
EEM Area (mm^2)					
Mean±SD (n)	14.80±4.57 (156)	13.75±3.84 (45)	14.57±4.43 (201)	1.06 [-0.42,2.53]	0.159
Range (min,max)	(4.85,28.56)	(7.09,23.99)	(4.85,28.56)		
EEM Volume (mm^3)					
Mean±SD (n)	336.82±121.68 (139)	332.27±163.86 (39)	335.82±131.57 (178)	4.55 [-42.63,51.73]	0.872
Range (min,max)	(113.39,756.00)	(127.89,754.28)	(113.39,756.00)		
Mean Stent Area (mm^2)					
Mean±SD (n)	7.24±2.15 (209)	7.27±1.86 (67)	7.25±2.08 (276)	-0.03 [-0.60,0.55]	0.929
Range (min,max)	(2.59,16.21)	(3.69,13.13)	(2.59,16.21)		
Stent Volume (mm^3)					
Mean±SD (n)	167.90±60.00 (187)	176.58±78.86 (61)	170.04±65.09 (248)	-8.68 [-27.59,10.23]	0.433
Range (min,max)	(59.77,407.89)	(66.52,413.53)	(59.77,413.53)		
Mean Lumen Area (mm^2)					
Mean±SD (n)	6.08±2.02 (209)	7.12±1.91 (67)	6.33±2.04 (276)	-1.04 [-1.59,-0.48]	<0.001
Range (min,max)	(1.79,11.77)	(3.53,13.08)	(1.79,13.08)		
Minimal Lumen Area (mm^2)					
Mean±SD (n)	4.89±1.96 (209)	5.77±1.97 (66)	5.10±2.00 (275)	-0.88 [-1.43,-0.34]	0.002
Range (min,max)	(1.19,11.77)	(1.96,11.29)	(1.19,11.77)		
Lumen Volume (mm^3)					
Mean±SD (n)	140.98±52.95 (187)	172.48±77.70 (61)	148.72±61.34 (248)	-31.50 [-48.91,-14.09]	0.004
Range (min,max)	(35.19,360.96)	(63.60,402.39)	(35.19,402.39)		
Mean NIH Area (mm^2)					
Mean±SD (n)	1.16±0.96 (209)	0.16±0.19 (67)	0.92±0.94 (276)	1.01 [0.78,1.24]	<0.001
Range (min,max)	(0.00,6.46)	(0.00,0.77)	(0.00,6.46)		
Plaque Volume (mm^3)					
Mean±SD (n)	194.22±81.24 (139)	169.01±94.72 (39)	188.70±84.74 (178)	25.21 [-4.95,55.37]	0.101
Range (min,max)	(50.19,498.17)	(55.57,452.62)	(50.19,498.17)		
Neointimal Hyperplastic Volume (mm^3)					
Mean±SD (n)	24.09±21.16 (209)	3.74±5.20 (67)	19.15±20.53 (276)	20.36 [15.21,25.50]	<0.001
Range (min,max)	(0.00,111.35)	(0.00,31.74)	(0.00,111.35)		
Volume Obstruction (%)					
Mean±SD (n)	15.94±10.94 (187)	2.66±3.11 (61)	12.67±11.19 (248)	13.27 [10.48,16.07]	<0.001
Range (min,max)	(0.00,67.31)	(0.00,15.30)	(0.00,67.31)		

N = the maximum number of eligible patients, n = number of patients with evaluable data.

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Table 18. Quantitative Intravascular Ultrasound Analysis - Difference Between Post-Stent Implantation and 8-Month Follow-up (ITT)

Difference (8-Month Follow-up - Final Post-Stent)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
EEM Area (mm^2)					
Mean±SD (n)	0.29±1.75 (82)	0.42±1.78 (21)	0.32±1.75 (103)	-0.13 [-0.98,0.72]	0.758
Range (min,max)	(-11.47,3.94)	(-5.42,5.00)	(-11.47,5.00)		
EEM Volume (mm^3)					
Mean±SD (n)	2.40±49.79 (74)	7.06±46.42 (20)	3.39±48.89 (94)	-4.66 [-29.24,19.93]	0.708
Range (min,max)	(-283.10,87.91)	(-92.38,144.07)	(-283.10,144.07)		
Mean Stent Area (mm^2)					
Mean±SD (n)	0.15±0.94 (138)	0.21±1.16 (46)	0.17±0.99 (184)	-0.07 [-0.40,0.27]	0.702
Range (min,max)	(-6.24,5.01)	(-3.92,5.54)	(-6.24,5.54)		
Stent Volume (mm^3)					
Mean±SD (n)	1.42±22.81 (124)	5.81±31.91 (42)	2.53±25.39 (166)	-4.38 [-13.33,4.57]	0.415
Range (min,max)	(-154.02,57.19)	(-94.25,140.96)	(-154.02,140.96)		
Mean Lumen Area (mm^2)					
Mean±SD (n)	-1.01±1.22 (138)	0.03±1.17 (46)	-0.75±1.28 (184)	-1.04 [-1.44,-0.63]	<0.001
Range (min,max)	(-6.46,1.59)	(-3.92,5.54)	(-6.46,5.54)		
Minimal Lumen Area (mm^2)					
Mean±SD (n)	-1.18±1.42 (135)	-0.26±1.25 (46)	-0.95±1.43 (181)	-0.91 [-1.38,-0.45]	<0.001
Range (min,max)	(-6.61,2.83)	(-4.06,4.73)	(-6.61,4.73)		
Lumen Volume (mm^3)					
Mean±SD (n)	-25.44±31.86 (124)	1.31±32.32 (42)	-18.67±33.95 (166)	-26.75 [-38.02,-15.48]	<0.001
Range (min,max)	(-159.09,49.84)	(-94.25,141.00)	(-159.09,141.00)		
Plaque Volume (mm^3)					
Mean±SD (n)	27.90±34.31 (74)	13.62±42.90 (20)	24.86±36.53 (94)	14.28 [-3.87,32.43]	0.122
Range (min,max)	(-124.01,122.52)	(-52.17,139.53)	(-124.01,139.53)		
Neointimal Hyperplastic Volume (mm^3)					
Mean±SD (n)	24.52±22.36 (138)	4.81±5.86 (46)	19.59±21.35 (184)	19.71 [13.13,26.30]	<0.001
Range (min,max)	(0.00,111.35)	(0.00,31.74)	(0.00,111.35)		

N = the maximum number of eligible patients, n = number of patients with evaluable data.

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Table 19. Quantitative Intravascular Ultrasound Analysis - Incomplete Stent Apposition (ITT)

Measures	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Incomplete Stent Apposition at Post Procedure	12.4% (31/251)	17.7% (17/96)	13.8% (48/347)	-5.4% [-14.0%,3.3%]	0.224
Incomplete Stent Apposition at 8 Month Follow-up	7.5% (17/226)	17.1% (13/76)	9.9% (30/302)	-9.6% [-18.7%,-0.4%]	0.025
Resolved	5.8% (11/189)	7.4% (5/68)	6.2% (16/257)	-1.5% [-8.6%,5.5%]	0.770
Persistent	7.9% (15/189)	11.8% (8/68)	8.9% (23/257)	-3.8% [-12.4%,4.7%]	0.332
Late Acquired	0.5% (1/189)	5.9% (4/68)	1.9% (5/257)	-5.4% [-11.0%,0.3%]	0.018

N = the maximum number of eligible patients, denominators indicate the total number of patients with available data for related parameter.

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Table 20a. Major Protocol Deviation by Site (ITT)

Site	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
4	1	0	1
6	1	0	1
8	3	1	4
10	2	0	2
31	1	1	2
39	5	1	6
42	1	0	1
43	6	0	6
63	2	0	2
65	1	0	1
82	0	1	1
95	1	0	1
100	2	0	2
105	0	1	1
124	1	0	1
264	3	2	5
279	1	0	1
Total	31	7	38

N = the maximum number of eligible patients.

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Table 20b. Major Protocol Deviation by Type (ITT)

Major Protocol Deviation	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
Female patients of childbearing potential must have a negative pregnancy test within seven (7) days before the procedure.	2	0	2
The patient has been informed of the nature of the study and agrees to its provisions and has provided written informed consent as approved by the Institutional Review Board of the respective clinical site.	1	0	1
The patient and the treating physician agree that the patient will return for all required post-procedure follow-up visits.	1	0	1
The target lesion must be a single de novo lesion that has not been previously treated with any interventional procedure.	1	0	1
The target vessel has a TIMI flow 2 or greater.	1	0	1
The target lesion must be >= 14 mm and <= 27 mm in length.	3	3	6
The target vessel reference diameter must be >= 2.5 mm and >= 3.5 mm. Note: Measurements may be made by careful visual estimate, on-line QCA, or intravascular ultrasound (IVUS).	2	0	2
A platelet count < 100,000 cells/mm³ or > 700,000 cells/mm³, or a WBC < 3,000 cells/mm³.	1	0	1
Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave myocardial infarction having creatine kinase (CK) enzymes >= 2X the upper laboratory normal with the presence of a creatine kinasemyocardial-band isoenzyme (CK-MB) elevated above the Institution's upper limit of normal).	3	0	3
Any previous or planned treatment of any vessel with a drug eluting stent.	1	1	2
Previous or planned percutaneous coronary intervention of any vessel within 30 days pre or post procedure.	1	1	2
Previous stenting anywhere in the target vessel.	2	0	2
During the index procedure, the target lesion requires treatment with a device other than PTCA prior to stent placement (such as, but not limited to, cutting balloon, directional coronary atherectomy, excimer laser, rotational atherectomy,thrombectomy, etc.).	2	0	2
A documented left ventricular ejection fraction < 30% at any time prior to index procedure.	0	1	1
Target vessel has other lesions with greater than 40% diameter stenosis based on visual estimate or on-line QCA.	6	0	6
The target vessel has evidence of thrombus.	2	0	2
The target vessel is excessively tortuous.	0	1	1
Incorrect version of consent provided to the patient	2	0	2
Total	31	7	38

N = the maximum number of eligible patients.

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Table 21a. Minor Protocol Deviation by Site (ITT)

Site	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
4	69	27	96
6	39	27	66
8	61	17	78
9	17	9	26
10	213	72	285
31	123	38	161
39	43	16	59
42	49	9	58
43	100	39	139
44	28	9	37
48	8	6	14
63	130	37	167
65	21	0	21
81	0	2	2
82	79	8	87
86	40	19	59
90	94	32	126
91	36	7	43
95	38	3	41
100	17	7	24
105	79	24	103
110	47	34	81
115	12	10	22
124	62	6	68
126	11	0	11
187	24	12	36
264	140	39	179
270	46	17	63
279	12	0	12
Total	1638	526	2164

N = the maximum number of eligible patients.

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Table 21b. Minor Protocol Deviation by Type (ITT)

Minor Protocol Deviation	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
Patient discharged on incorrect ASA dose	1	0	1
Ticlid/Plavix not given	6	4	10
ASA not given	10	4	14
NTG not given pre-stent	29	12	41
NTG not given post-stent	19	3	22
Patient did not take required ASA	62	24	86
Patient did not take required Ticlid/Plavix	5	4	9
Ticlid/Plavix not taken for 12 weeks	4	1	5
Incorrect medication given	5	2	7
Pre-procedure CBC with diff. not done	57	34	91
Post-procedure CBC with diff. not done (30 day)	91	17	108
Pre-procedure Chemistry not done	167	49	216
Pre-procedure labs (CBC and/or chemistry) done out of window	17	8	25
Pre-procedure CK/CK-MB not done	30	8	38
Pre-procedure CK/CK-MB taken outside protocol time frame	12	6	18
Post-procedure CK/CK-MB not done	62	22	84
Post-procedure CK/CK-MB taken outside protocol time frame	136	36	172
Pre-procedure ECG not done	6	1	7
Pre-procedure ECG done outside protocol specifications	9	4	13
Post procedure/discharge ECG not done	2	1	3
Stent deployed above rated burst pressure	11	0	11
Treatment performed outside protocol	43	12	55
No Pre-dilatation done	2	4	6
Patient randomized but no study stent was attempted/tried to implant	2	1	3
Randomization assignment not followed	1	2	3
Bare metal or non-study stent used	4	1	5
ACT measurements not obtained	54	19	73
Follow-up phone call/visit outside protocol time frame	248	82	330
Follow-up 30 days not done as office visit	20	5	25
Follow-up 6 months not done	7	2	9
Follow-up 8 months not done as office visit.	43	13	56
Follow-up 9 months not done	10	0	10
Follow-up 12 months not done	2	2	4
Follow-up annual not done	5	1	6
Follow-up angiogram not done	40	20	60
Follow-up angiogram done outside protocol time frame	60	12	72
Follow-up IVUS not done	54	21	75
Follow-up IVUS done outside protocol time frame	36	10	46
Other	163	45	208
Blinding noncompliance	103	34	137
Total	1638	526	2164

N = the maximum number of eligible patients.
The protocol deviation type of other were specified in Table 21c.

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Table 21c. Minor Protocol Deviation by Type - Other

Site	Patient	Minor Protocol Deviation by Type - Other Specification
4	-----	ACT<250 SEC
4	-----	UNDERSIZED CYPHER STENT USED - LENGTH ACCEPTABLE
4	-----	PRE DIL BALLOON NOT 0.5 SMALLER THAN STENT
4	-----	SAE NOT REPORTED PER PROTOCOL
6	-----	IVUS NOT DONE POST STENT IMPLANTATION
8	-----	SAE NOT REPORTED IN PROTOCOL TIME FRAME
8	-----	
8	-----	
8	-----	
9	-----	INTENT TO TREAT W/IVUS IVUS NOT PERFORMED POST STENT
9	-----	PER I STAT ACT WAS 207 NOT IN RANGE
9	-----	POST DIL BALLOON WAS 4.5 TAKEN TO 12 ATM - THIS IS > .5 MM
9	-----	FOLLOW UP WAS PERFORMED AT THE REFERRING MD OFFICE.
10	-----	SAE NOT REPORTED WITHIN 24 HRS.
10	-----	PRE DILATION BALLOON DIAMETER NOT SMALLER THAN RVD
10	-----	CRF 1 + 5 NOT FAXED W/IN 24 HOURS
10	-----	PRE BALLOON EQUAL TO RVD
10	-----	ENZMES 1 HR LATE
10	-----	SAE NOT REPORTED IN 24 HRS
10	-----	CRF 1 + 5 NOT FAXED W/IN 24 HOURS
10	-----	NOT REPORTED WITHIN 24 HRS
10	-----	CRF 1 + 5 NOT FAXED W/IN 24 HOURS
10	-----	ACT NOT TO LEVEL PRIOR TO STENT
10	-----	PGS 1 & 5 NOT FAXED W/IN 24 HRS
10	-----	PAGES 1 AND 5 NOT FAX'D W/IN 24 HRS.
10	-----	PG 1 & 5 NO FAXED W/IN 24 HRS
10	-----	NO RE-IVUS DUE TO FAILURE EQUIPMENT
10	-----	PAGES 1 + 5 NOT FAXED IN 24 HRS
10	-----	SAE NOT REPORTED
10	-----	COORDINATOR NOT ON DELEGATION OF AUTHORITY
10	-----	ACT NOT @ 250 @ DEPLOYMENT
10	-----	DIDN'T RECEIVE RANDOMIZED TX, CORRECT SIZE STENT WAS NOT AVAILABLE AT TIME OF RANDOMIZATION
10	-----	SAE REPORTED OUT OF TIME FRAME
10	-----	POST DILATED WITH STENT DELIVERY SYSTEM COORDINATOR WAS UNAIVERE
10	-----	30 DAY VISIT DONE BY NON STUDY DOCTOR
31	-----	PRE DILATION EQUAL TO REFERENCE DIAMETER OF LESION
31	-----	
31	-----	SAE NOT FAXED WITHIN 24 HRS OF EVENT
31	-----	
31	-----	
31	-----	30 DAY CBC DONE OUT OF WINDOW
31	-----	
31	-----	SAE NOT FAXED TO SPONSOR
31	-----	UNABLE TO CONTACT PATIENT FOR 8 MONTH VISIT
31	-----	
31	-----	SAE NOT REPORTED TO SPONSOR WITHIN 24 HOURS
31	-----	ACT DID NOT REACH THERAPEUTIC LEVELS DURING THE CASE DESPITE NUMEROUS BOLUSES
31	-----	SAE NOT REPORTED WITHIN 24 HOURS OF EVENT KNOWLEDGE

Table 21c. Minor Protocol Deviation by Type - Other (Continued)

Site	Patient	Minor Protocol Deviation by Type - Other Specification
31	-----	STENT BALLOON NOT INFLATED AT NOMINAL PRESSURE AT DELIVERY OF STENT
31	-----	IVUS NOT PERFORMED POST PROCEDURE
31	-----	SAE NOT FAXED TO SPONSOR WITHIN 24 HRS OF KNOWLEDGE OF EVENT
31	-----	
31	-----	
31	-----	POST PROCEDURE IVUS NOT DONE
31	-----	
31	-----	BASELINE PLAVIX ORDERED AND NOTED "GIVEN IN CATH LAB" HOWEVER NO SIGNATURE OR TIME IS FOUND
39	-----	
39	-----	PRE-DIL. BALLOON SAME DIAMETER AS REF. VESSEL DIAMETER
39	-----	BALLOON (PRE-DIL) SAME SIZE AS REF. VESSEL DIAMETER
39	-----	REFERENCE VESSEL OF PRE-DIL BALLOON SAME AS TARGET VESSEL
39	-----	PRE DIL BALLOON SAME DIAMETER AS TARGET LESION
39	-----	LEARNED OF BACK SURGERY @ 2 YEAR PHONE CALL, AWAITING OUTSIDE NOTES. NOTIFICATION TO HCRI > 24 HOURS.
39	-----	This was reported greater than 24 hours to HCRI
39	-----	THIS WAS REPORTED GREATER THAN 24 HOURS TO HCRI
39	-----	PT. SEEN BY CARDIOLOGIST NOT ONSITE RESP. LOG
39	-----	
42	-----	POST PROCEDURE CBC WITH DIFF 1 DAY EARLY.
42	-----	8 MONTH NOT DONE
42	-----	ACT RESULT AFTER STENT PLACEMENT, BASELINE ACT
42	-----	ACT DRAWN AFTER STENT PLACEMENT.
42	-----	STENT CHOSEN WAS NOT 3MM LONGER THAN LESION.
42	-----	FOLLOW-UP CBC WITH DIFF DONE, BUT OUTSIDE THE WINDOW.
43	-----	IVUS NOT DONE POST STENT IMPLANT
43	-----	PATIENT NOT CONTACTED FOR 8 MONTH FOLLOW-UP
43	-----	
43	-----	
43	-----	
43	-----	
43	-----	30-DAY CBC WITH DIFF DONE OUT OF PROTOCOL
43	-----	
43	-----	
43	-----	CBC WITH DIFF DONE OUT OF PROTOCOL OF TIME FRAME
43	-----	PT EVALUATED BY AN UNTRAINED TRIAL PHYSICIAN
44	-----	
48	-----	IVUS NOT DONE
63	-----	CRF PAGES 1 + 5 NOT FAXED WITHIN 24 HRS.
63	-----	IVUS PROCEDURE NOT PERFORMED AFTER PROCEDURE
63	-----	TECHNICAL PROBLEMS WITH IVUS EQUIPMENT - COULD NOT DO IVUS POST
63	-----	CRF PAGES 1 & 5 NOT FAXED WITHIN 24 HRS.
63	-----	SAE NOT REPORTED TO HCRI W/IN 24 HOURS
63	-----	SAE NOT REPORTED TO HCRI WITH/IN 24 HOURS
63	-----	
63	-----	
63	-----	PREDIL BALLOON WAS SAME DIAMETER AS REFERENCE DIAMETER OF TARGET VESSEL
63	-----	SAE INADVERTENTLY NOT REPORTED TO HCRI OR SPONSOR BUT WAS REPORTED TO IRB WITHIN 24 HRS
63	-----	
63	-----	SAE NOT REPORTED WITH/IN 24 HOURS TO HCRI

Table 21c. Minor Protocol Deviation by Type - Other (Continued)

Site	Patient	Minor Protocol Deviation by Type - Other Specification
63	-----	
63	-----	ENROLLMENT NOT FAXED IN 24 HOUR
65	-----	FOLLOW-UP OFFICE VISIT (8 MONTH) DONE BY NON INVESTIGATOR
65	-----	FOLLOW-UP OFFICE VISIT (8 MONTH) DONE BY NON-INVESTIGATOR
81	-----	OFFICE EXAM DONE BY NON-STUDY PHYSICIAN
82	-----	IVUS NOT PERFORMED
82	-----	FOLLOWUP LABS NOT DONE @ MD'S OFFICE
82	-----	30 DAY FOLLOW UP NOT DONE
82	-----	9 MONTH VISIT DONE OUT OF TIME FRAME
82	-----	ACT NOT GREATER THAN 250.
82	-----	IVUS NOT PERFORM. PHYSICAN THOUGHT SUBJECT NOT ENROLLED.
82	-----	
86	-----	SAE REPORTED TO HCRI > 24 HRS
86	-----	FOLLOW-UP CATH DONE BY NON-INVESTIGATOR
90	-----	30 D LABS OUT OF WINDOW
90	-----	OFFICE VISIT DONE BY OUTSIDE PHYSICIAN
90	-----	
90	-----	30 DAY LABS OUTSIDE OF WINDOW
90	-----	PT CONTACT NOT WITH STUDY PERSONNEL
90	-----	MISSED VISIT
90	-----	PRE-CKMB NOT DONE
90	-----	30-DAY FU VISIT DNE BY PHYSICIAN OF THE
90	-----	PRE-PROCEDURE CKMD
90	-----	30 D CBC WITH DIFF DONE OUT OF WINDOW
90	-----	
90	-----	IVUS NOT DONE PAST STENTING
90	-----	PT. PREFERENCE NON STUDY PHYSICIAN DID FOLLOW UP
90	-----	PRE-PROCEDURE CK MB
90	-----	PRE CK-MB NOT DONE
90	-----	FOLLOW UP BY NON-STUDY PHYSICIAN
90	-----	NON-STUDY MD DID F/U
90	-----	ACT <250
90	-----	CKMD PRE PROCEDURE NOT DONE
90	-----	8 MO FOLLOW-UP VISIT MISSED
90	-----	PRE-CKMB NOT DONE
91	-----	PREDILATION BALLOON SAME SIZE AS STENT (3.5)
91	-----	8 MONTH FOLLOW-UP NOT DONE.
91	-----	SAE NOTIFICATION GREATER THAN 24 HOURS OF KNOWLEDGE.
100	-----	
100	-----	
100	-----	IVUS WAS NOT PERFORMED AFTER STENT PLACEMENT
100	-----	NO SHOW FOLLOWUP VISIT, UNABLE TO REACH PT. VIA TELEPHONE AND OTHER CONTACT.
105	-----	SAE NOT FAXED WITHIN 24 HOURS
105	-----	SAE NO REPORTED WITHIN 24 HRS
105	-----	8 MO F/U NOT DONE
105	-----	SAE NOT REPORTED WITHIN 24 HRS
105	-----	SAE NOT REPORTED TO SPONSOR WITHIN 24 HRS
105	-----	SAE NOT REPORTED TO SPONSOR WITHIN 24 HRS
105	-----	SAE NOT REPORTED WITHIN 24 HOURS

Table 21c. Minor Protocol Deviation by Type - Other (Continued)

Site	Patient	Minor Protocol Deviation by Type - Other Specification
105	-----	SAE NOT FAXED WITHIN 24 HRS
105	-----	POST DILATION BALLOON NOT < 3 MM SMALLER THAN STENT MD ERROR
105	-----	SAE NOTIFICATION FORM NOT SENT W/IN 24 HRS.
105	-----	UNABLE TO PASS GUIDE WIRE
105	-----	
105	-----	SAE NOT REPORTED WITHIN 24 HOURS
105	-----	NO AUTOMATTED IVUS PULL BACK
105	-----	SAE NOTIFICATION NOT SENT W/IN 24 HRS
105	-----	SAE NOT REPORTED WITHIN 24 HRS
110	-----	GGT NOT DONE
110	-----	IVUS NOT PERFORMED POST STENT
110	-----	STENT DEPLOYED BELOW MINIMUN DEPLOYMENT ATM PER PROTOCOL
110	-----	PRE-DILITATION DONE WITH SAME DIAMETER BALLOON AS TARGET LESION STENT
115	-----	IVUS NOT PERFORMED POST PCI
124	-----	PAGE 5 (CRF) NOT FAXED WITHIN 24 HOURS
124	-----	PRE-DILATATION BALLOON NOT .5 MM < TARGET VESSEL DIAM.
124	-----	POST STENT IMPLANTATION IVUS NOT DONE
124	-----	SAE REPORTED LATE TO IRB
124	-----	POST-STENT IMPLANT IVUS NOT DONE
124	-----	REFERENCE VESSEL DIAMETER NO .5MM DIFFERENT THAN STENT
124	-----	PREDILITATION BALLOON NOT LESS THAN REFERENCE VESSEL DIAMETER.
124	-----	PRE DILITATION BALLOON NOT.5MM LESS THAN REFERENCE VESSEL DIAMETER.
126	-----	DR KEYES NOT SIGNED ON AS SUB I. WILL PROCEDE WITH PAPERWORK.
126	-----	SAE NOT REPORTED WITHIN 24 HRS
187	-----	30 DAY CBC W/DIFF DONE OUT OF WINDOW
187	-----	SEE NARRATIVE
187	-----	POST-DIL BALLOON LONGER THAN STENT LENGTH
187	-----	N/A
264	-----	PRE-DILATATION BALLOON NOT 0.5 MM SMALLER THAN STENT
264	-----	TARGET ACT NOT REACHED PRIOR TO PROCEDURE
264	-----	PRE-DIE BALLOON NOT < 0.5 MM SMALLER THANT STENT
264	-----	STENT SIZE NOT >= 3 M LONGER THAN LESION LENGTH
264	-----	STENT NOT GREATER THAN OR EQUAL TO 3MM LONGER THAT LESION
264	-----	PRE DILATION BALLOON NOT <0.5 MM THAN LESION
264	-----	
264	-----	ACT <250 AT STENT DEPLOYMENT
264	-----	PRE-DIL BALLOON LONGER THAN STENT STENT >3MM LONGER THAN LESION
264	-----	SAE NOT REPORTED WITHIN TIME FRAME
264	-----	LATE NOTIFICATION OF SAE
264	-----	PRE-DIL BALLOON NOT <0.5MM THAN STENT
264	-----	PRE-DIL. BALLOON NOT <0.5 MM THAN STENT
264	-----	F/U PERFORMED BY NON-APPROVED CRC
264	-----	ACT < 250 AT STENT DEPLOYMENT
264	-----	NO BASELINE CK, CK MB, ALT, AST, ALK. PHOS, GGT
264	-----	PRE-DIL BALLOON NOT 0.5 MM SMALLER THAN STENT DIAMETER
264	-----	NO IVUS OR TVTG USED POST STENT DEPLOYMENT
264	-----	PRE-DIL BALLOON LONGER THAN LESION LENGTH
264	-----	PRE-DILATATION BALLOON NOT 0.5MM LESS THAN STENT
264	-----	PRE-DIL. BALLOON NOT <0.5MM FROM STENT

Table 21c. Minor Protocol Deviation by Type - Other (Continued)

Site	Patient	Minor Protocol Deviation by Type - Other Specification
264	-----	SAE NOT REPORTED TO SPONSOR WITHIN 24 HRS.
264	-----	PRE-DIL BALLOON NOT < 0.5 MM THAN STENT DIAM.
264	-----	SAE NOT REPORTED TO SPONSOR WITHIN 24 HRS
264	-----	ACT <250 AT TIME OF STENT DEPLOYMENT
264	-----	ACT < 250 AT STENT DEPLOYMENT
264	-----	PRE-DILATATION BALLOON NOT < 0.5 MM SMALLER THAN STENT PLACED
264	-----	PRE-DIL BALLOON WAS LONGER THAN STENT LENGTH AND NOT < 0.5 MM SMALLER THAN STENT DIAMETER
270	-----	2.5 PRE-DIL BALLOON USED, NOT 2.0
270	-----	ACT NOT 200 PRE STENT (ACTUAL ACT 198)
270	-----	
270	-----	
279	-----	PREDILATION BALLOON DIAMETER NOT 0.5 MM LESS THAN STENT
279	-----	SUBJECT NOT CONSENTED W/MOST RECENT APPROVED CONSENT.

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Table 22a. Adverse Events to 720 Days (ITT)

Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
TOTAL	*280(86.7%)*	*94(83.2%)*	*374(85.8%)*
BLOOD AND LYMPHATIC SYSTEM DISORDERS	*12(3.7%)*	*4(3.5%)*	*16(3.7%)*
ANAEMIA	9(2.8%)	3(2.7%)	12(2.8%)
LEUKOCYTOSIS	1(0.3%)	0(0.0%)	1(0.2%)
LEUKOPENIA	1(0.3%)	0(0.0%)	1(0.2%)
NORMOCHROMIC NORMOCYTIC ANAEMIA	1(0.3%)	1(0.9%)	2(0.5%)
REFRACTORY ANAEMIA	1(0.3%)	1(0.9%)	2(0.5%)
THROMBOCYTOPENIA	1(0.3%)	0(0.0%)	1(0.2%)
CARDIAC DISORDERS	*161(49.8%)*	*51(45.1%)*	*212(48.6%)*
ACUTE MYOCARDIAL INFARCTION	0(0.0%)	1(0.9%)	1(0.2%)
ANGINA PECTORIS	126(39.0%)	36(31.9%)	162(37.2%)
ANGINA UNSTABLE	6(1.9%)	0(0.0%)	6(1.4%)
ARRHYTHMIA	2(0.6%)	1(0.9%)	3(0.7%)
ARTERIOSPASM CORONARY	4(1.2%)	0(0.0%)	4(0.9%)
ATRIAL FIBRILLATION	8(2.5%)	3(2.7%)	11(2.5%)
ATRIAL FLUTTER	1(0.3%)	0(0.0%)	1(0.2%)
ATRIOVENTRICULAR BLOCK COMPLETE	1(0.3%)	0(0.0%)	1(0.2%)
BRADYCARDIA	4(1.2%)	1(0.9%)	5(1.1%)
CHEST PAIN	0(0.0%)	1(0.9%)	1(0.2%)
CORONARY ARTERY DISEASE	7(2.2%)	3(2.7%)	10(2.3%)
CORONARY ARTERY DISSECTION	11(3.4%)	6(5.3%)	17(3.9%)
CORONARY ARTERY OCCLUSION	1(0.3%)	3(2.7%)	4(0.9%)
CORONARY ARTERY STENOSIS	7(2.2%)	0(0.0%)	7(1.6%)
EXTRASYSTOLES	0(0.0%)	1(0.9%)	1(0.2%)
MYOCARDIAL INFARCTION	8(2.5%)	6(5.3%)	14(3.2%)
MYOCARDIAL ISCHAEMIA	2(0.6%)	0(0.0%)	2(0.5%)
PALPITATIONS	8(2.5%)	0(0.0%)	8(1.8%)
RHYTHM IDIOVENTRICULAR	1(0.3%)	0(0.0%)	1(0.2%)
SINUS ARRHYTHMIA	0(0.0%)	1(0.9%)	1(0.2%)
SUPRAVENTRICULAR TACHYCARDIA	1(0.3%)	0(0.0%)	1(0.2%)
TACHYCARDIA	1(0.3%)	0(0.0%)	1(0.2%)
VENTRICULAR ASYSTOLE	1(0.3%)	0(0.0%)	1(0.2%)
VENTRICULAR FIBRILLATION	2(0.6%)	0(0.0%)	2(0.5%)
VENTRICULAR TACHYCARDIA	4(1.2%)	2(1.8%)	6(1.4%)
EAR AND LABYRINTH DISORDERS	*2(0.6%)*	*2(1.8%)*	*4(0.9%)*
EAR HAEMORRHAGE	1(0.3%)	0(0.0%)	1(0.2%)
VERTIGO	1(0.3%)	2(1.8%)	3(0.7%)
EYE DISORDERS	*5(1.5%)*	*1(0.9%)*	*6(1.4%)*
CATARACT	1(0.3%)	0(0.0%)	1(0.2%)
DACRYOSTENOSIS ACQUIRED	1(0.3%)	0(0.0%)	1(0.2%)
DIPLOPIA	0(0.0%)	1(0.9%)	1(0.2%)
VISION BLURRED	2(0.6%)	0(0.0%)	2(0.5%)
VITREOUS HAEMORRHAGE	1(0.3%)	0(0.0%)	1(0.2%)
GASTROINTESTINAL DISORDERS	*50(15.5%)*	*25(22.1%)*	*75(17.2%)*
ABDOMINAL PAIN	8(2.5%)	2(1.8%)	10(2.3%)
ABDOMINAL PAIN UPPER	4(1.2%)	1(0.9%)	5(1.1%)
COLITIS ULCERATIVE	0(0.0%)	2(1.8%)	2(0.5%)
COLONIC POLYP	1(0.3%)	0(0.0%)	1(0.2%)
CONSTIPATION	1(0.3%)	0(0.0%)	1(0.2%)
DIARRHOEA	3(0.9%)	0(0.0%)	3(0.7%)
DIVERTICULITIS	1(0.3%)	0(0.0%)	1(0.2%)
DIVERTICULUM	0(0.0%)	1(0.9%)	1(0.2%)
DYSPEPSIA	4(1.2%)	4(3.5%)	8(1.8%)
DYSPHAGIA	1(0.3%)	0(0.0%)	1(0.2%)
FAECAL INCONTINENCE	1(0.3%)	0(0.0%)	1(0.2%)

Table 22a. Adverse Events to 720 Days (ITT) (Continued)

Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
GASTRIC DISORDER	1(0.3%)	0(0.0%)	1(0.2%)
GASTRIC ULCER	0(0.0%)	1(0.9%)	1(0.2%)
GASTRITIS	0(0.0%)	1(0.9%)	1(0.2%)
GASTROINTESTINAL DISORDER	1(0.3%)	1(0.9%)	2(0.5%)
GASTROINTESTINAL HAEMORRHAGE	6(1.9%)	2(1.8%)	8(1.8%)
GASTROINTESTINAL UPSET	0(0.0%)	1(0.9%)	1(0.2%)
GASTROOESOPHAGEAL REFLUX DISEASE	1(0.3%)	0(0.0%)	1(0.2%)
HAEMATEMESIS	1(0.3%)	0(0.0%)	1(0.2%)
HALITOSIS	1(0.3%)	0(0.0%)	1(0.2%)
INGUINAL HERNIA	1(0.3%)	0(0.0%)	1(0.2%)
INTESTINAL OBSTRUCTION	1(0.3%)	0(0.0%)	1(0.2%)
LOOSE STOOLS	1(0.3%)	1(0.9%)	2(0.5%)
MELAENA	1(0.3%)	1(0.9%)	2(0.5%)
NAUSEA	7(2.2%)	2(1.8%)	9(2.1%)
OESOPHAGEAL DISCOMFORT	1(0.3%)	0(0.0%)	1(0.2%)
OESOPHAGEAL STENOSIS ACQUIRED	1(0.3%)	0(0.0%)	1(0.2%)
PANCREATITIS	1(0.3%)	0(0.0%)	1(0.2%)
PANCREATITIS ACUTE	1(0.3%)	0(0.0%)	1(0.2%)
RECTAL HAEMORRHAGE	2(0.6%)	1(0.9%)	3(0.7%)
RETROPERITONEAL HAEMORRHAGE	1(0.3%)	2(1.8%)	3(0.7%)
STOMACH DISCOMFORT	0(0.0%)	1(0.9%)	1(0.2%)
TOOTHACHE	1(0.3%)	1(0.9%)	2(0.5%)
UPPER GASTROINTESTINAL HAEMORRHAGE	2(0.6%)	0(0.0%)	2(0.5%)
VOMITING	3(0.9%)	2(1.8%)	5(1.1%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	*86(26.6%)*	*27(23.9%)*	*113(25.9%)*
ADVERSE DRUG REACTION	2(0.6%)	2(1.8%)	4(0.9%)
ASTHENIA	4(1.2%)	2(1.8%)	6(1.4%)
CHEST DISCOMFORT	14(4.3%)	3(2.7%)	17(3.9%)
CHEST PAIN	6(1.9%)	1(0.9%)	7(1.6%)
DEATH	3(0.9%)	1(0.9%)	4(0.9%)
FATIGUE	12(3.7%)	3(2.7%)	15(3.4%)
HERNIA PAIN	1(0.3%)	0(0.0%)	1(0.2%)
INJECTION SITE BRUISING	3(0.9%)	1(0.9%)	4(0.9%)
INJECTION SITE DISCOMFORT	2(0.6%)	1(0.9%)	3(0.7%)
INJECTION SITE HAEMORRHAGE	12(3.7%)	5(4.4%)	17(3.9%)
INJECTION SITE INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
INJECTION SITE OEDEMA	1(0.3%)	0(0.0%)	1(0.2%)
INJECTION SITE PAIN	6(1.9%)	1(0.9%)	7(1.6%)
LETHARGY	1(0.3%)	0(0.0%)	1(0.2%)
MUCOSAL INFLAMMATION	1(0.3%)	0(0.0%)	1(0.2%)
NON CARDIAC CHEST PAIN	20(6.2%)	6(5.3%)	26(6.0%)
NON-CARDIAC CHEST PAIN	4(1.2%)	0(0.0%)	4(0.9%)
OEDEMA	6(1.9%)	1(0.9%)	7(1.6%)
OEDEMA PERIPHERAL	11(3.4%)	3(2.7%)	14(3.2%)
PAIN	1(0.3%)	1(0.9%)	2(0.5%)
PITTING OEDEMA	1(0.3%)	0(0.0%)	1(0.2%)
PYREXIA	4(1.2%)	1(0.9%)	5(1.1%)
RIGORS	2(0.6%)	0(0.0%)	2(0.5%)
HEPATOBILIARY DISORDERS	*2(0.6%)*	*0(0.0%)*	*2(0.5%)*
CHOLECYSTITIS ACUTE	1(0.3%)	0(0.0%)	1(0.2%)
CHOLELITHIASIS	1(0.3%)	0(0.0%)	1(0.2%)
IMMUNE SYSTEM DISORDERS	*1(0.3%)*	*0(0.0%)*	*1(0.2%)*
HYPERSENSITIVITY	1(0.3%)	0(0.0%)	1(0.2%)
INFECTIONS AND INFESTATIONS	*50(15.5%)*	*14(12.4%)*	*64(14.7%)*
ABSCESS	1(0.3%)	0(0.0%)	1(0.2%)

Table 22a. Adverse Events to 720 Days (ITT) (Continued)

Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
APPENDICITIS	1(0.3%)	0(0.0%)	1(0.2%)
BLADDER INFECTION	3(0.9%)	1(0.9%)	4(0.9%)
BRONCHITIS	7(2.2%)	0(0.0%)	7(1.6%)
BRONCHITIS ACUTE	1(0.3%)	0(0.0%)	1(0.2%)
CELLULITIS	5(1.5%)	1(0.9%)	6(1.4%)
FUNGAL INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
FUNGAL RASH	0(0.0%)	1(0.9%)	1(0.2%)
GASTROENTERITIS	0(0.0%)	1(0.9%)	1(0.2%)
GASTROENTERITIS VIRAL	1(0.3%)	0(0.0%)	1(0.2%)
HERPES ZOSTER	0(0.0%)	1(0.9%)	1(0.2%)
IMPLANT SITE INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
INFECTION	1(0.3%)	2(1.8%)	3(0.7%)
INFLUENZA	2(0.6%)	0(0.0%)	2(0.5%)
JOINT ABSCESS	1(0.3%)	0(0.0%)	1(0.2%)
KIDNEY INFECTION	2(0.6%)	0(0.0%)	2(0.5%)
NASOPHARYNGITIS	4(1.2%)	1(0.9%)	5(1.1%)
OESOPHAGEAL CANDIDIASIS	1(0.3%)	0(0.0%)	1(0.2%)
ORAL INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
OSTEOMYELITIS	2(0.6%)	0(0.0%)	2(0.5%)
OTITIS EXTERNA	1(0.3%)	0(0.0%)	1(0.2%)
PHARYNGITIS STREPTOCOCCAL	1(0.3%)	0(0.0%)	1(0.2%)
PNEUMONIA	8(2.5%)	2(1.8%)	10(2.3%)
PNEUMONIA PRIMARY ATYPICAL	1(0.3%)	0(0.0%)	1(0.2%)
PSEUDOMONAS INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
RESPIRATORY TRACT INFECTION	2(0.6%)	0(0.0%)	2(0.5%)
SEPSIS	1(0.3%)	0(0.0%)	1(0.2%)
SINUSITIS	2(0.6%)	2(1.8%)	4(0.9%)
STAPHYLOCOCCAL INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
TOOTH ABSCESS	1(0.3%)	0(0.0%)	1(0.2%)
TOOTH INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
UPPER RESPIRATORY TRACT INFECTION	3(0.9%)	3(2.7%)	6(1.4%)
URINARY TRACT INFECTION	5(1.5%)	1(0.9%)	6(1.4%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	*33(10.2%)*	*6(5.3%)*	*39(8.9%)*
ACCIDENTAL OVERDOSE	1(0.3%)	0(0.0%)	1(0.2%)
ANKLE FRACTURE	2(0.6%)	0(0.0%)	2(0.5%)
BACK INJURY	1(0.3%)	0(0.0%)	1(0.2%)
CONTUSION	3(0.9%)	1(0.9%)	4(0.9%)
CORONARY ARTERY RESTENOSIS	4(1.2%)	0(0.0%)	4(0.9%)
FALL	1(0.3%)	0(0.0%)	1(0.2%)
FOOT FRACTURE	1(0.3%)	0(0.0%)	1(0.2%)
HIP FRACTURE	0(0.0%)	1(0.9%)	1(0.2%)
INCISION SITE COMPLICATION	1(0.3%)	1(0.9%)	2(0.5%)
INJECTION SITE PAIN	1(0.3%)	0(0.0%)	1(0.2%)
JOINT INJURY	3(0.9%)	0(0.0%)	3(0.7%)
JOINT SPRAIN	1(0.3%)	0(0.0%)	1(0.2%)
LIMB INJURY	3(0.9%)	0(0.0%)	3(0.7%)
MYOCARDIAL REPERFUSION INJURY	2(0.6%)	1(0.9%)	3(0.7%)
NECK INJURY	1(0.3%)	0(0.0%)	1(0.2%)
OPEN WOUND	2(0.6%)	0(0.0%)	2(0.5%)
RADIUS FRACTURE	1(0.3%)	0(0.0%)	1(0.2%)
RIB FRACTURE	2(0.6%)	0(0.0%)	2(0.5%)
SKIN LACERATION	1(0.3%)	0(0.0%)	1(0.2%)
STENT OCCLUSION	4(1.2%)	0(0.0%)	4(0.9%)
STERNAL FRACTURE	1(0.3%)	0(0.0%)	1(0.2%)
SUBDURAL HAEMATOMA	0(0.0%)	2(1.8%)	2(0.5%)

Table 22a. Adverse Events to 720 Days (ITT) (Continued)

Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
TONGUE INJURY	1(0.3%)	0(0.0%)	1(0.2%)
UPPER LIMB FRACTURE	1(0.3%)	0(0.0%)	1(0.2%)
INVESTIGATIONS	*30(9.3%)*	*4(3.5%)*	*34(7.8%)*
ANGIOGRAM PERIPHERAL	0(0.0%)	1(0.9%)	1(0.2%)
ARTERIOGRAM CORONARY ABNORMAL	1(0.3%)	0(0.0%)	1(0.2%)
BIOPSY STOMACH	1(0.3%)	0(0.0%)	1(0.2%)
BLOOD CHOLESTEROL INCREASED	1(0.3%)	0(0.0%)	1(0.2%)
BLOOD CREATINE PHOSPHOKINASE ABNORMAL	1(0.3%)	0(0.0%)	1(0.2%)
BLOOD CREATINE PHOSPHOKINASE INCREASED	1(0.3%)	0(0.0%)	1(0.2%)
BLOOD CREATINE PHOSPHOKINASE MB INCREASED	6(1.9%)	1(0.9%)	7(1.6%)
BLOOD GLUCOSE INCREASED	1(0.3%)	0(0.0%)	1(0.2%)
BLOOD IN STOOL	2(0.6%)	0(0.0%)	2(0.5%)
BLOOD PRESSURE INCREASED	0(0.0%)	1(0.9%)	1(0.2%)
CARDIAC ENZYMES INCREASED	4(1.2%)	0(0.0%)	4(0.9%)
COLONOSCOPY	1(0.3%)	0(0.0%)	1(0.2%)
FAECAL OCCULT BLOOD POSITIVE	1(0.3%)	0(0.0%)	1(0.2%)
FEMORAL BRUIT	2(0.6%)	0(0.0%)	2(0.5%)
FULL BLOOD COUNT DECREASED	1(0.3%)	0(0.0%)	1(0.2%)
HAEMATOCRIT DECREASED	1(0.3%)	0(0.0%)	1(0.2%)
HAEMOGLOBIN DECREASED	3(0.9%)	0(0.0%)	3(0.7%)
HEART RATE DECREASED	1(0.3%)	0(0.0%)	1(0.2%)
INTERNATIONAL NORMALISED RATIO INCREASED	1(0.3%)	0(0.0%)	1(0.2%)
LABORATORY TEST ABNORMAL	0(0.0%)	1(0.9%)	1(0.2%)
PROSTATIC SPECIFIC ANTIGEN INCREASED	1(0.3%)	0(0.0%)	1(0.2%)
PULSE ABNORMAL	2(0.6%)	0(0.0%)	2(0.5%)
TROPONIN INCREASED	2(0.6%)	0(0.0%)	2(0.5%)
WHITE BLOOD CELL COUNT DECREASED	1(0.3%)	0(0.0%)	1(0.2%)
METABOLISM AND NUTRITION DISORDERS	*15(4.6%)*	*5(4.4%)*	*20(4.6%)*
CACHEXIA	0(0.0%)	1(0.9%)	1(0.2%)
DEHYDRATION	4(1.2%)	0(0.0%)	4(0.9%)
DIABETES MELLITUS	2(0.6%)	1(0.9%)	3(0.7%)
DIABETES MELLITUS INADEQUATE CONTROL	2(0.6%)	0(0.0%)	2(0.5%)
FLUID OVERLOAD	1(0.3%)	0(0.0%)	1(0.2%)
GOUT	0(0.0%)	1(0.9%)	1(0.2%)
HYPERGLYCAEMIA	3(0.9%)	0(0.0%)	3(0.7%)
HYPERKALAEMIA	2(0.6%)	0(0.0%)	2(0.5%)
HYPERLIPIDAEMIA	0(0.0%)	1(0.9%)	1(0.2%)
HYPOALBUMINAEMIA	1(0.3%)	0(0.0%)	1(0.2%)
HYPOGLYCAEMIA	3(0.9%)	1(0.9%)	4(0.9%)
HYPOKALAEMIA	3(0.9%)	0(0.0%)	3(0.7%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	*72(22.3%)*	*10(8.8%)*	*82(18.8%)*
ARTHRALGIA	15(4.6%)	1(0.9%)	16(3.7%)
ARTHRITIS	1(0.3%)	0(0.0%)	1(0.2%)
AXILLARY MASS	1(0.3%)	0(0.0%)	1(0.2%)
BACK PAIN	20(6.2%)	1(0.9%)	21(4.8%)
BONE SPUR	0(0.0%)	1(0.9%)	1(0.2%)
BUTTOCK PAIN	2(0.6%)	0(0.0%)	2(0.5%)
CHEST WALL PAIN	2(0.6%)	0(0.0%)	2(0.5%)
COSTOCHONDRITIS	1(0.3%)	0(0.0%)	1(0.2%)
INTERVERTEBRAL DISC DISORDER	1(0.3%)	0(0.0%)	1(0.2%)
INTERVERTEBRAL DISC PROTRUSION	3(0.9%)	0(0.0%)	3(0.7%)
JOINT STIFFNESS	0(0.0%)	1(0.9%)	1(0.2%)
JOINT SWELLING	2(0.6%)	1(0.9%)	3(0.7%)
LOCALISED OSTEOARTHRITIS	1(0.3%)	0(0.0%)	1(0.2%)
MUSCLE CRAMP	1(0.3%)	1(0.9%)	2(0.5%)

Table 22a. Adverse Events to 720 Days (ITT) (Continued)

Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
MUSCLE HAEMORRHAGE	1(0.3%)	0(0.0%)	1(0.2%)
MUSCLE SPASMS	1(0.3%)	0(0.0%)	1(0.2%)
MUSCULOSKELETAL CHEST PAIN	1(0.3%)	0(0.0%)	1(0.2%)
MUSCULOSKELETAL DISCOMFORT	1(0.3%)	0(0.0%)	1(0.2%)
MUSCULOSKELETAL PAIN	1(0.3%)	0(0.0%)	1(0.2%)
MUSCULOSKELETAL STIFFNESS	1(0.3%)	0(0.0%)	1(0.2%)
MYALGIA	7(2.2%)	0(0.0%)	7(1.6%)
MYOPATHY	1(0.3%)	0(0.0%)	1(0.2%)
NECK PAIN	3(0.9%)	0(0.0%)	3(0.7%)
PAIN IN EXTREMITY	18(5.6%)	5(4.4%)	23(5.3%)
PAIN IN JAW	4(1.2%)	0(0.0%)	4(0.9%)
ROTATOR CUFF SYNDROME	2(0.6%)	0(0.0%)	2(0.5%)
SHOULDER BLADE PAIN	1(0.3%)	0(0.0%)	1(0.2%)
SPINAL OSTEOARTHRITIS	1(0.3%)	0(0.0%)	1(0.2%)
TENDONITIS	1(0.3%)	0(0.0%)	1(0.2%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	*7(2.2%)*	*4(3.5%)*	*11(2.5%)*
COLON NEOPLASM	1(0.3%)	0(0.0%)	1(0.2%)
LUNG NEOPLASM MALIGNANT	2(0.6%)	3(2.7%)	5(1.1%)
NON SMALL CELL LUNG CANCER	0(0.0%)	1(0.9%)	1(0.2%)
PANCREATIC CARCINOMA	1(0.3%)	0(0.0%)	1(0.2%)
SKIN CARCINOMA	1(0.3%)	0(0.0%)	1(0.2%)
SQUAMOUS CELL CARCINOMA OF SKIN	1(0.3%)	0(0.0%)	1(0.2%)
THROAT CANCER	1(0.3%)	0(0.0%)	1(0.2%)
THYMOMA	1(0.3%)	0(0.0%)	1(0.2%)
NERVOUS SYSTEM DISORDERS	*46(14.2%)*	*15(13.3%)*	*61(14.0%)*
APHASIA	1(0.3%)	0(0.0%)	1(0.2%)
ARACHNOID CYST	1(0.3%)	0(0.0%)	1(0.2%)
BALANCE DISORDER	1(0.3%)	0(0.0%)	1(0.2%)
CAROTID ARTERY STENOSIS	1(0.3%)	0(0.0%)	1(0.2%)
CEREBROVASCULAR ACCIDENT	2(0.6%)	1(0.9%)	3(0.7%)
COMA	0(0.0%)	1(0.9%)	1(0.2%)
DIZZINESS	11(3.4%)	5(4.4%)	16(3.7%)
DIZZINESS POSTURAL	1(0.3%)	0(0.0%)	1(0.2%)
DYSARTHRIA	1(0.3%)	0(0.0%)	1(0.2%)
DYSGEUSIA	1(0.3%)	0(0.0%)	1(0.2%)
HEADACHE	10(3.1%)	4(3.5%)	14(3.2%)
HYPOAESTHESIA	7(2.2%)	2(1.8%)	9(2.1%)
LUMBAR SPINAL STENOSIS	1(0.3%)	0(0.0%)	1(0.2%)
MENTAL IMPAIRMENT	1(0.3%)	0(0.0%)	1(0.2%)
MIGRAINE	1(0.3%)	0(0.0%)	1(0.2%)
NEUROPATHY PERIPHERAL	1(0.3%)	0(0.0%)	1(0.2%)
PARAESTHESIA	1(0.3%)	0(0.0%)	1(0.2%)
SOMNOLENCE	1(0.3%)	0(0.0%)	1(0.2%)
SYNCOPE	5(1.5%)	2(1.8%)	7(1.6%)
SYNCOPE VASOVAGAL	1(0.3%)	1(0.9%)	2(0.5%)
TRANSIENT ISCHAEMIC ATTACK	3(0.9%)	0(0.0%)	3(0.7%)
PSYCHIATRIC DISORDERS	*10(3.1%)*	*4(3.5%)*	*14(3.2%)*
ANXIETY	1(0.3%)	3(2.7%)	4(0.9%)
CONFUSIONAL STATE	1(0.3%)	0(0.0%)	1(0.2%)
DEPRESSION	4(1.2%)	0(0.0%)	4(0.9%)
INSOMNIA	0(0.0%)	1(0.9%)	1(0.2%)
MAJOR DEPRESSION	1(0.3%)	0(0.0%)	1(0.2%)
MENTAL STATUS CHANGES	1(0.3%)	0(0.0%)	1(0.2%)
NERVOUSNESS	1(0.3%)	0(0.0%)	1(0.2%)
STRESS SYMPTOMS	1(0.3%)	0(0.0%)	1(0.2%)

Table 22a. Adverse Events to 720 Days (ITT) (Continued)

Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
SUICIDE ATTEMPT	0(0.0%)	1(0.9%)	1(0.2%)
RENAL AND URINARY DISORDERS	*8(2.5%)*	*7(6.2%)*	*15(3.4%)*
CALCULUS URETERIC	0(0.0%)	1(0.9%)	1(0.2%)
CALCULUS URINARY	0(0.0%)	1(0.9%)	1(0.2%)
DYSURIA	0(0.0%)	1(0.9%)	1(0.2%)
NEPHROLITHIASIS	1(0.3%)	3(2.7%)	4(0.9%)
POLLAKIURIA	1(0.3%)	0(0.0%)	1(0.2%)
RENAL ARTERY STENOSIS	2(0.6%)	0(0.0%)	2(0.5%)
RENAL FAILURE ACUTE	0(0.0%)	1(0.9%)	1(0.2%)
RENAL IMPAIRMENT	1(0.3%)	0(0.0%)	1(0.2%)
RENAL INSUFFICIENCY	4(1.2%)	1(0.9%)	5(1.1%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	*4(1.2%)*	*2(1.8%)*	*6(1.4%)*
BREAST MASS	1(0.3%)	0(0.0%)	1(0.2%)
ERECTILE DYSFUNCTION	1(0.3%)	1(0.9%)	2(0.5%)
METRORRHAGIA	1(0.3%)	0(0.0%)	1(0.2%)
TESTICULAR PAIN	1(0.3%)	0(0.0%)	1(0.2%)
VAGINAL HAEMORRHAGE	0(0.0%)	1(0.9%)	1(0.2%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	*47(14.6%)*	*19(16.8%)*	*66(15.1%)*
ACUTE PULMONARY OEDEMA	1(0.3%)	0(0.0%)	1(0.2%)
ACUTE RESPIRATORY FAILURE	0(0.0%)	1(0.9%)	1(0.2%)
ASTHMA	0(0.0%)	1(0.9%)	1(0.2%)
BRONCHITIS ACUTE	1(0.3%)	0(0.0%)	1(0.2%)
BRONCHOSPASM	1(0.3%)	0(0.0%)	1(0.2%)
CARDIO-RESPIRATORY ARREST	0(0.0%)	1(0.9%)	1(0.2%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	1(0.3%)	1(0.9%)	2(0.5%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE EXACERBATED	3(0.9%)	2(1.8%)	5(1.1%)
COUGH	7(2.2%)	1(0.9%)	8(1.8%)
DIAPHRAGMATIC DISORDER	0(0.0%)	1(0.9%)	1(0.2%)
DYSPNOEA	32(9.9%)	10(8.8%)	42(9.6%)
DYSPNOEA EXACERBATED	0(0.0%)	1(0.9%)	1(0.2%)
DYSPNOEA EXERTIONAL	2(0.6%)	2(1.8%)	4(0.9%)
EPISTAXIS	2(0.6%)	1(0.9%)	3(0.7%)
HAEMOPTYSIS	1(0.3%)	0(0.0%)	1(0.2%)
HAEMOTHORAX	0(0.0%)	1(0.9%)	1(0.2%)
HYPOXIA	1(0.3%)	0(0.0%)	1(0.2%)
NOCTURNAL DYSPNOEA	1(0.3%)	0(0.0%)	1(0.2%)
ORTHOPNOEA	1(0.3%)	0(0.0%)	1(0.2%)
PHARYNGOLARYNGEAL PAIN	1(0.3%)	0(0.0%)	1(0.2%)
PNEUMONIA ASPIRATION	1(0.3%)	0(0.0%)	1(0.2%)
PULMONARY EMBOLISM	1(0.3%)	0(0.0%)	1(0.2%)
RESPIRATORY DISTRESS	1(0.3%)	0(0.0%)	1(0.2%)
RESPIRATORY FAILURE	1(0.3%)	2(1.8%)	3(0.7%)
SINUS PAIN	1(0.3%)	0(0.0%)	1(0.2%)
SNORING	1(0.3%)	0(0.0%)	1(0.2%)
WHEEZING	3(0.9%)	0(0.0%)	3(0.7%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	*19(5.9%)*	*7(6.2%)*	*26(6.0%)*
ALOPECIA	1(0.3%)	0(0.0%)	1(0.2%)
CELLULITIS	1(0.3%)	0(0.0%)	1(0.2%)
DERMATITIS	0(0.0%)	1(0.9%)	1(0.2%)
DERMATITIS ALLERGIC	1(0.3%)	0(0.0%)	1(0.2%)
DERMATITIS CONTACT	1(0.3%)	0(0.0%)	1(0.2%)
ECCHYMOSIS	4(1.2%)	0(0.0%)	4(0.9%)
ERYTHEMA	2(0.6%)	0(0.0%)	2(0.5%)
HYPERHIDROSIS	0(0.0%)	1(0.9%)	1(0.2%)
INCREASED TENDENCY TO BRUISE	0(0.0%)	1(0.9%)	1(0.2%)

Table 22a. Adverse Events to 720 Days (ITT) (Continued)

Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
LOCALISED EXFOLIATION	1(0.3%)	0(0.0%)	1(0.2%)
NAIL HYPERTROPHY	1(0.3%)	0(0.0%)	1(0.2%)
NIGHT SWEATS	3(0.9%)	0(0.0%)	3(0.7%)
RASH	4(1.2%)	4(3.5%)	8(1.8%)
SKIN DISORDER	0(0.0%)	1(0.9%)	1(0.2%)
SKIN LESION	1(0.3%)	0(0.0%)	1(0.2%)
URTICARIA	1(0.3%)	0(0.0%)	1(0.2%)
SURGICAL AND MEDICAL PROCEDURES	*61(18.9%)*	*16(14.2%)*	*77(17.7%)*
ANGIOPLASTY	1(0.3%)	0(0.0%)	1(0.2%)
ARTERIAL BYPASS OPERATION	1(0.3%)	0(0.0%)	1(0.2%)
BLADDER REPAIR	1(0.3%)	0(0.0%)	1(0.2%)
BLOOD PRODUCT TRANSFUSION	0(0.0%)	1(0.9%)	1(0.2%)
CARDIAC PACEMAKER INSERTION	1(0.3%)	0(0.0%)	1(0.2%)
CARDIAC PACEMAKER REPLACEMENT	1(0.3%)	0(0.0%)	1(0.2%)
CARPAL TUNNEL DECOMPRESSION	1(0.3%)	0(0.0%)	1(0.2%)
CATARACT EXTRACTION	2(0.6%)	1(0.9%)	3(0.7%)
CHOLECYSTECTOMY	3(0.9%)	0(0.0%)	3(0.7%)
CORONARY ARTERY SURGERY	1(0.3%)	0(0.0%)	1(0.2%)
CORONARY REVASCULARISATION	31(9.6%)	8(7.1%)	39(8.9%)
HEART VALVE REPLACEMENT	1(0.3%)	0(0.0%)	1(0.2%)
HERNIA REPAIR	1(0.3%)	0(0.0%)	1(0.2%)
HIP ARTHROPLASTY	1(0.3%)	1(0.9%)	2(0.5%)
HOSPITALISATION	5(1.5%)	5(4.4%)	10(2.3%)
HYSTERECTOMY	1(0.3%)	0(0.0%)	1(0.2%)
KNEE ARTHROPLASTY	3(0.9%)	1(0.9%)	4(0.9%)
KNEE OPERATION	1(0.3%)	1(0.9%)	2(0.5%)
MITRAL VALVE REPAIR	1(0.3%)	0(0.0%)	1(0.2%)
PACKED RED BLOOD CELL TRANSFUSION	1(0.3%)	0(0.0%)	1(0.2%)
PANCREATIC OPERATION	1(0.3%)	0(0.0%)	1(0.2%)
PERICARDIAL DRAINAGE	1(0.3%)	0(0.0%)	1(0.2%)
PERIPHERAL REVASCULARISATION	4(1.2%)	0(0.0%)	4(0.9%)
ROTATOR CUFF REPAIR	1(0.3%)	0(0.0%)	1(0.2%)
SURGERY	1(0.3%)	0(0.0%)	1(0.2%)
VASCULAR DISORDERS	*43(13.3%)*	*14(12.4%)*	*57(13.1%)*
AORTIC ANEURYSM	2(0.6%)	0(0.0%)	2(0.5%)
AORTIC STENOSIS	1(0.3%)	0(0.0%)	1(0.2%)
ARTERIOVENOUS FISTULA ACQUIRED	1(0.3%)	1(0.9%)	2(0.5%)
BLOOD PRESSURE INADEQUATELY CONTROLLED	1(0.3%)	0(0.0%)	1(0.2%)
DEEP VEIN THROMBOSIS	3(0.9%)	0(0.0%)	3(0.7%)
HAEMATOMA	10(3.1%)	4(3.5%)	14(3.2%)
HAEMORRHAGE	1(0.3%)	2(1.8%)	3(0.7%)
HYPERAEMIA	1(0.3%)	0(0.0%)	1(0.2%)
HYPERTENSION	10(3.1%)	1(0.9%)	11(2.5%)
HYPOTENSION	12(3.7%)	5(4.4%)	17(3.9%)
ILIAC ARTERY STENOSIS	1(0.3%)	0(0.0%)	1(0.2%)
ORTHOSTATIC HYPOTENSION	1(0.3%)	0(0.0%)	1(0.2%)
PERIPHERAL ARTERY DISSECTION	1(0.3%)	0(0.0%)	1(0.2%)
RENAL ARTERY STENOSIS	1(0.3%)	0(0.0%)	1(0.2%)
THROMBOPHLEBITIS	0(0.0%)	1(0.9%)	1(0.2%)
THROMBOSIS	1(0.3%)	0(0.0%)	1(0.2%)
VASCULAR PSEUDOANEURYSM	2(0.6%)	2(1.8%)	4(0.9%)
VENOUS THROMBOSIS LIMB	1(0.3%)	0(0.0%)	1(0.2%)

N = the maximum number of eligible patients.

NOS - Not Otherwise Specified.
NOTE: AEs missing event dates are included in this listing.

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Table 22b. Adverse Events by Site (ITT)

Site	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
4	1.32% (19/1436)	1.91% (8/418)	1.46% (27/1854)
6	0.63% (9/1436)	2.39% (10/418)	1.02% (19/1854)
8	1.25% (18/1436)	1.20% (5/418)	1.24% (23/1854)
9	2.58% (37/1436)	1.44% (6/418)	2.32% (43/1854)
10	5.99% (86/1436)	8.37% (35/418)	6.53% (121/1854)
31	2.51% (36/1436)	2.39% (10/418)	2.48% (46/1854)
39	7.17% (103/1436)	5.74% (24/418)	6.85% (127/1854)
42	3.27% (47/1436)	0.72% (3/418)	2.70% (50/1854)
43	4.11% (59/1436)	5.26% (22/418)	4.37% (81/1854)
44	0.84% (12/1436)	2.87% (12/418)	1.29% (24/1854)
48	2.99% (43/1436)	1.20% (5/418)	2.59% (48/1854)
63	21.52% (309/1436)	21.77% (91/418)	21.57% (400/1854)
65	1.53% (22/1436)	0.00% (0/418)	1.19% (22/1854)
81	0.00% (0/1436)	0.96% (4/418)	0.22% (4/1854)
82	6.89% (99/1436)	1.91% (8/418)	5.77% (107/1854)
86	5.36% (77/1436)	5.50% (23/418)	5.39% (100/1854)
90	2.23% (32/1436)	3.83% (16/418)	2.59% (48/1854)
91	3.83% (55/1436)	5.02% (21/418)	4.10% (76/1854)
95	0.49% (7/1436)	0.00% (0/418)	0.38% (7/1854)
100	0.49% (7/1436)	2.15% (9/418)	0.86% (16/1854)
105	4.39% (63/1436)	1.67% (7/418)	3.78% (70/1854)
110	2.09% (30/1436)	2.15% (9/418)	2.10% (39/1854)
115	3.13% (45/1436)	5.98% (25/418)	3.78% (70/1854)
124	2.23% (32/1436)	1.91% (8/418)	2.16% (40/1854)
126	0.77% (11/1436)	0.00% (0/418)	0.59% (11/1854)
187	1.32% (19/1436)	0.96% (4/418)	1.24% (23/1854)
264	5.57% (80/1436)	6.94% (29/418)	5.88% (109/1854)
270	1.95% (28/1436)	2.15% (9/418)	2.00% (37/1854)
279	3.55% (51/1436)	3.59% (15/418)	3.56% (66/1854)

N = the maximum number of eligible patients.

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Table 23a. Serious Adverse Events (to 720 Days) (ITT)

Serious Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
TOTAL	*186(57.6%)*	*54(47.8%)*	*240(55.0%)*
BLOOD AND LYMPHATIC SYSTEM DISORDERS	*6(1.9%)*	*3(2.7%)*	*9(2.1%)*
ANAEMIA	5(1.5%)	3(2.7%)	8(1.8%)
IRON DEFICIENCY ANAEMIA	1(0.3%)	0(0.0%)	1(0.2%)
NORMOCHROMIC NORMOCYTIC ANAEMIA	1(0.3%)	0(0.0%)	1(0.2%)
CARDIAC DISORDERS	*93(28.8%)*	*30(26.5%)*	*123(28.2%)*
ANGINA PECTORIS	68(21.1%)	18(15.9%)	86(19.7%)
ANGINA UNSTABLE	4(1.2%)	0(0.0%)	4(0.9%)
AORTIC VALVE INCOMPETENCE	1(0.3%)	0(0.0%)	1(0.2%)
ARRHYTHMIA	0(0.0%)	1(0.9%)	1(0.2%)
ARTERIOSPASM CORONARY	1(0.3%)	0(0.0%)	1(0.2%)
ATRIAL FIBRILLATION	6(1.9%)	2(1.8%)	8(1.8%)
ATRIAL FLUTTER	1(0.3%)	1(0.9%)	2(0.5%)
ATRIOVENTRICULAR BLOCK COMPLETE	1(0.3%)	0(0.0%)	1(0.2%)
BRADYCARDIA	1(0.3%)	0(0.0%)	1(0.2%)
CARDIAC FAILURE CONGESTIVE	2(0.6%)	0(0.0%)	2(0.5%)
CARDIAC FLUTTER	1(0.3%)	0(0.0%)	1(0.2%)
CORONARY ARTERY ANEURYSM	1(0.3%)	0(0.0%)	1(0.2%)
CORONARY ARTERY DISEASE	7(2.2%)	3(2.7%)	10(2.3%)
CORONARY ARTERY DISSECTION	4(1.2%)	0(0.0%)	4(0.9%)
CORONARY ARTERY OCCLUSION	2(0.6%)	0(0.0%)	2(0.5%)
CORONARY ARTERY STENOSIS	5(1.5%)	2(1.8%)	7(1.6%)
MYOCARDIAL INFARCTION	14(4.3%)	7(6.2%)	21(4.8%)
MYOCARDIAL ISCHAEMIA	1(0.3%)	0(0.0%)	1(0.2%)
PALPITATIONS	2(0.6%)	0(0.0%)	2(0.5%)
SINUS ARRHYTHMIA	0(0.0%)	1(0.9%)	1(0.2%)
SUPRAVENTRICULAR TACHYCARDIA	1(0.3%)	0(0.0%)	1(0.2%)
TACHYCARDIA	0(0.0%)	1(0.9%)	1(0.2%)
VENTRICULAR BIGEMINY	1(0.3%)	0(0.0%)	1(0.2%)
VENTRICULAR FIBRILLATION	1(0.3%)	0(0.0%)	1(0.2%)
VENTRICULAR TACHYCARDIA	2(0.6%)	1(0.9%)	3(0.7%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	*0(0.0%)*	*1(0.9%)*	*1(0.2%)*
ARTERIOVENOUS MALFORMATION	0(0.0%)	1(0.9%)	1(0.2%)
GASTROINTESTINAL DISORDERS	*16(5.0%)*	*13(11.5%)*	*29(6.7%)*
ABDOMINAL DISCOMFORT	1(0.3%)	0(0.0%)	1(0.2%)
ABDOMINAL DISTENSION	1(0.3%)	0(0.0%)	1(0.2%)
ABDOMINAL PAIN	1(0.3%)	0(0.0%)	1(0.2%)
COLITIS ISCHAEMIC	1(0.3%)	0(0.0%)	1(0.2%)
COLITIS ULCERATIVE	0(0.0%)	2(1.8%)	2(0.5%)
DIARRHOEA	1(0.3%)	1(0.9%)	2(0.5%)
DIVERTICULITIS	2(0.6%)	1(0.9%)	3(0.7%)
DIVERTICULUM	0(0.0%)	1(0.9%)	1(0.2%)
FAECES DISCOLOURED	0(0.0%)	1(0.9%)	1(0.2%)
GASTRITIS	0(0.0%)	1(0.9%)	1(0.2%)
GASTROINTESTINAL HAEMORRHAGE	4(1.2%)	2(1.8%)	6(1.4%)
HIATUS HERNIA	0(0.0%)	1(0.9%)	1(0.2%)
LOWER GASTROINTESTINAL HAEMORRHAGE	1(0.3%)	0(0.0%)	1(0.2%)
MELAENA	0(0.0%)	1(0.9%)	1(0.2%)
PANCREATITIS	1(0.3%)	0(0.0%)	1(0.2%)
PANCREATITIS ACUTE	1(0.3%)	0(0.0%)	1(0.2%)
RECTAL HAEMORRHAGE	1(0.3%)	2(1.8%)	3(0.7%)
REFLUX OESOPHAGITIS	1(0.3%)	0(0.0%)	1(0.2%)
RETROPERITONEAL HAEMORRHAGE	1(0.3%)	2(1.8%)	3(0.7%)
SMALL INTESTINAL OBSTRUCTION	1(0.3%)	0(0.0%)	1(0.2%)
UPPER GASTROINTESTINAL HAEMORRHAGE	1(0.3%)	0(0.0%)	1(0.2%)

Table 23a. Serious Adverse Events (to 720 Days) (ITT) (Continued)

Serious Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
VOMITING	2(0.6%)	0(0.0%)	2(0.5%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	*34(10.5%)*	*10(8.8%)*	*44(10.1%)*
ADVERSE DRUG REACTION	2(0.6%)	0(0.0%)	2(0.5%)
ASTHENIA	5(1.5%)	1(0.9%)	6(1.4%)
CHEST DISCOMFORT	2(0.6%)	0(0.0%)	2(0.5%)
CHEST PAIN	2(0.6%)	0(0.0%)	2(0.5%)
DEATH	4(1.2%)	5(4.4%)	9(2.1%)
FATIGUE	1(0.3%)	0(0.0%)	1(0.2%)
FEELING HOT	1(0.3%)	0(0.0%)	1(0.2%)
GAIT ABNORMAL	1(0.3%)	0(0.0%)	1(0.2%)
INJECTION SITE BRUISING	1(0.3%)	0(0.0%)	1(0.2%)
INJECTION SITE HAEMORRHAGE	4(1.2%)	1(0.9%)	5(1.1%)
INJECTION SITE PAIN	1(0.3%)	0(0.0%)	1(0.2%)
MUCOSAL INFLAMMATION	1(0.3%)	0(0.0%)	1(0.2%)
NON-CARDIAC CHEST PAIN	14(4.3%)	3(2.7%)	17(3.9%)
OEDEMA PERIPHERAL	3(0.9%)	0(0.0%)	3(0.7%)
PAIN	0(0.0%)	1(0.9%)	1(0.2%)
PYREXIA	1(0.3%)	0(0.0%)	1(0.2%)
ULCER HAEMORRHAGE	1(0.3%)	0(0.0%)	1(0.2%)
HEPATOBILIARY DISORDERS	*5(1.5%)*	*1(0.9%)*	*6(1.4%)*
CHOLECYSTITIS	1(0.3%)	0(0.0%)	1(0.2%)
CHOLECYSTITIS ACUTE	1(0.3%)	0(0.0%)	1(0.2%)
CHOLECYSTITIS CHRONIC	0(0.0%)	1(0.9%)	1(0.2%)
CHOLELITHIASIS	2(0.6%)	1(0.9%)	3(0.7%)
GALLBLADDER DISORDER	1(0.3%)	0(0.0%)	1(0.2%)
INFECTIONS AND INFESTATIONS	*20(6.2%)*	*4(3.5%)*	*24(5.5%)*
ABSCESS LIMB	1(0.3%)	0(0.0%)	1(0.2%)
APPENDICITIS	1(0.3%)	0(0.0%)	1(0.2%)
BRONCHITIS	2(0.6%)	0(0.0%)	2(0.5%)
BRONCHITIS ACUTE	1(0.3%)	0(0.0%)	1(0.2%)
BURSITIS INFECTIVE	0(0.0%)	1(0.9%)	1(0.2%)
CELLULITIS	5(1.5%)	0(0.0%)	5(1.1%)
GASTROENTERITIS	0(0.0%)	1(0.9%)	1(0.2%)
INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
OSTEOMYELITIS	1(0.3%)	0(0.0%)	1(0.2%)
OSTEOMYELITIS ACUTE	1(0.3%)	0(0.0%)	1(0.2%)
PHARYNGITIS STREPTOCOCCAL	1(0.3%)	0(0.0%)	1(0.2%)
PNEUMONIA	7(2.2%)	2(1.8%)	9(2.1%)
PNEUMONIA PRIMARY ATYPICAL	1(0.3%)	0(0.0%)	1(0.2%)
SKIN INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
UPPER RESPIRATORY TRACT INFECTION	1(0.3%)	1(0.9%)	2(0.5%)
URINARY TRACT INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
WOUND INFECTION	1(0.3%)	0(0.0%)	1(0.2%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	*16(5.0%)*	*4(3.5%)*	*20(4.6%)*
ACCIDENTAL EXPOSURE	1(0.3%)	0(0.0%)	1(0.2%)
ANKLE FRACTURE	2(0.6%)	0(0.0%)	2(0.5%)
CONTUSION	1(0.3%)	0(0.0%)	1(0.2%)
CORONARY ARTERY RESTENOSIS	2(0.6%)	0(0.0%)	2(0.5%)
FOREARM FRACTURE	1(0.3%)	0(0.0%)	1(0.2%)
HAEMOTHORAX	0(0.0%)	1(0.9%)	1(0.2%)
HIP FRACTURE	0(0.0%)	1(0.9%)	1(0.2%)
POLYTRAUMATISM	1(0.3%)	0(0.0%)	1(0.2%)
RIB FRACTURE	1(0.3%)	0(0.0%)	1(0.2%)
ROAD TRAFFIC ACCIDENT	2(0.6%)	0(0.0%)	2(0.5%)
STENT OCCLUSION	6(1.9%)	0(0.0%)	6(1.4%)

Table 23a. Serious Adverse Events (to 720 Days) (ITT) (Continued)

Serious Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
STERNAL FRACTURE	1(0.3%)	0(0.0%)	1(0.2%)
SUBDURAL HAEMATOMA	0(0.0%)	2(1.8%)	2(0.5%)
INVESTIGATIONS	*11(3.4%)*	*3(2.7%)*	*14(3.2%)*
BLOOD CREATINE PHOSPHOKINASE MB INCREASED	2(0.6%)	0(0.0%)	2(0.5%)
BLOOD CREATININE INCREASED	1(0.3%)	0(0.0%)	1(0.2%)
CARDIAC ENZYMES INCREASED	2(0.6%)	0(0.0%)	2(0.5%)
CATHETERISATION CARDIAC	1(0.3%)	0(0.0%)	1(0.2%)
FULL BLOOD COUNT DECREASED	2(0.6%)	0(0.0%)	2(0.5%)
HAEMATOCRIT DECREASED	0(0.0%)	1(0.9%)	1(0.2%)
HAEMOGLOBIN DECREASED	1(0.3%)	2(1.8%)	3(0.7%)
TROPONIN I INCREASED	1(0.3%)	0(0.0%)	1(0.2%)
TROPONIN INCREASED	1(0.3%)	0(0.0%)	1(0.2%)
WHITE BLOOD CELL COUNT DECREASED	0(0.0%)	1(0.9%)	1(0.2%)
METABOLISM AND NUTRITION DISORDERS	*7(2.2%)*	*1(0.9%)*	*8(1.8%)*
CACHEXIA	0(0.0%)	1(0.9%)	1(0.2%)
DEHYDRATION	3(0.9%)	0(0.0%)	3(0.7%)
DIABETES MELLITUS	1(0.3%)	0(0.0%)	1(0.2%)
DIABETES MELLITUS INADEQUATE CONTROL	1(0.3%)	0(0.0%)	1(0.2%)
HYPERGLYCAEMIA	1(0.3%)	0(0.0%)	1(0.2%)
HYPOGLYCAEMIA	1(0.3%)	0(0.0%)	1(0.2%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	*15(4.6%)*	*1(0.9%)*	*16(3.7%)*
ARTHRALGIA	3(0.9%)	0(0.0%)	3(0.7%)
BACK PAIN	3(0.9%)	0(0.0%)	3(0.7%)
GROIN PAIN	0(0.0%)	1(0.9%)	1(0.2%)
INTERVERTEBRAL DISC DISORDER	1(0.3%)	0(0.0%)	1(0.2%)
LOCALISED OSTEOARTHRITIS	1(0.3%)	0(0.0%)	1(0.2%)
MUSCLE HAEMORRHAGE	1(0.3%)	0(0.0%)	1(0.2%)
NECK PAIN	2(0.6%)	0(0.0%)	2(0.5%)
PAIN IN EXTREMITY	2(0.6%)	0(0.0%)	2(0.5%)
ROTATOR CUFF SYNDROME	2(0.6%)	0(0.0%)	2(0.5%)
SHOULDER BLADE PAIN	1(0.3%)	0(0.0%)	1(0.2%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	*7(2.2%)*	*4(3.5%)*	*11(2.5%)*
BREAST CANCER	1(0.3%)	0(0.0%)	1(0.2%)
COLON NEOPLASM	1(0.3%)	0(0.0%)	1(0.2%)
LUNG CANCER METASTATIC	0(0.0%)	1(0.9%)	1(0.2%)
LUNG NEOPLASM MALIGNANT	2(0.6%)	3(2.7%)	5(1.1%)
PANCREATIC CARCINOMA	1(0.3%)	0(0.0%)	1(0.2%)
THROAT CANCER	1(0.3%)	0(0.0%)	1(0.2%)
THYMOMA	1(0.3%)	0(0.0%)	1(0.2%)
NERVOUS SYSTEM DISORDERS	*19(5.9%)*	*4(3.5%)*	*23(5.3%)*
ARACHNOID CYST	1(0.3%)	0(0.0%)	1(0.2%)
CAROTID ARTERY STENOSIS	1(0.3%)	0(0.0%)	1(0.2%)
CEREBROVASCULAR ACCIDENT	1(0.3%)	1(0.9%)	2(0.5%)
COMA	1(0.3%)	0(0.0%)	1(0.2%)
DIZZINESS	3(0.9%)	0(0.0%)	3(0.7%)
DYSARTHRIA	2(0.6%)	0(0.0%)	2(0.5%)
HAEMORRHAGIC STROKE	1(0.3%)	0(0.0%)	1(0.2%)
HEADACHE	0(0.0%)	1(0.9%)	1(0.2%)
HYPOAESTHESIA	1(0.3%)	0(0.0%)	1(0.2%)
LUMBAR SPINAL STENOSIS	1(0.3%)	0(0.0%)	1(0.2%)
NEUROPATHY PERIPHERAL	1(0.3%)	0(0.0%)	1(0.2%)
SYNCOPE	5(1.5%)	2(1.8%)	7(1.6%)
TRANSIENT ISCHAEMIC ATTACK	3(0.9%)	0(0.0%)	3(0.7%)
PSYCHIATRIC DISORDERS	*5(1.5%)*	*1(0.9%)*	*6(1.4%)*
ANXIETY	1(0.3%)	0(0.0%)	1(0.2%)

Table 23a. Serious Adverse Events (to 720 Days) (ITT) (Continued)

Serious Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
DEPRESSION	2(0.6%)	0(0.0%)	2(0.5%)
INTENTIONAL SELF-INJURY	0(0.0%)	1(0.9%)	1(0.2%)
MAJOR DEPRESSION	1(0.3%)	0(0.0%)	1(0.2%)
MENTAL STATUS CHANGES	2(0.6%)	0(0.0%)	2(0.5%)
RENAL AND URINARY DISORDERS	*5(1.5%)*	*6(5.3%)*	*11(2.5%)*
CALCULUS URETERIC	0(0.0%)	1(0.9%)	1(0.2%)
NEPHROLITHIASIS	0(0.0%)	1(0.9%)	1(0.2%)
RENAL ARTERY STENOSIS	3(0.9%)	1(0.9%)	4(0.9%)
RENAL COLIC	0(0.0%)	1(0.9%)	1(0.2%)
RENAL FAILURE ACUTE	0(0.0%)	1(0.9%)	1(0.2%)
RENAL IMPAIRMENT	1(0.3%)	0(0.0%)	1(0.2%)
RENAL INSUFFICIENCY	2(0.6%)	1(0.9%)	3(0.7%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	*12(3.7%)*	*5(4.4%)*	*17(3.9%)*
ACUTE RESPIRATORY DISTRESS SYNDROME	1(0.3%)	0(0.0%)	1(0.2%)
ACUTE RESPIRATORY FAILURE	0(0.0%)	1(0.9%)	1(0.2%)
BRONCHOSPASM	1(0.3%)	0(0.0%)	1(0.2%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	1(0.3%)	1(0.9%)	2(0.5%)
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE EXACERBATED	2(0.6%)	2(1.8%)	4(0.9%)
DYSPNOEA	7(2.2%)	2(1.8%)	9(2.1%)
DYSPNOEA EXERTIONAL	2(0.6%)	0(0.0%)	2(0.5%)
HAEMOPTYSIS	1(0.3%)	0(0.0%)	1(0.2%)
LUNG CONSOLIDATION	0(0.0%)	1(0.9%)	1(0.2%)
PLEURAL EFFUSION	0(0.0%)	1(0.9%)	1(0.2%)
PLEURITIC PAIN	0(0.0%)	1(0.9%)	1(0.2%)
PULMONARY EMBOLISM	1(0.3%)	0(0.0%)	1(0.2%)
PULMONARY OEDEMA	1(0.3%)	0(0.0%)	1(0.2%)
RESPIRATORY DISTRESS	1(0.3%)	0(0.0%)	1(0.2%)
RESPIRATORY FAILURE	0(0.0%)	1(0.9%)	1(0.2%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	*3(0.9%)*	*0(0.0%)*	*3(0.7%)*
ERYTHEMA	1(0.3%)	0(0.0%)	1(0.2%)
LOCALISED EXFOLIATION	1(0.3%)	0(0.0%)	1(0.2%)
PRURITUS	1(0.3%)	0(0.0%)	1(0.2%)
RASH	1(0.3%)	0(0.0%)	1(0.2%)
SURGICAL AND MEDICAL PROCEDURES	*113(35.0%)*	*27(23.9%)*	*140(32.1%)*
ABDOMINAL HERNIA REPAIR	1(0.3%)	0(0.0%)	1(0.2%)
AORTIC ANEURYSM REPAIR	1(0.3%)	0(0.0%)	1(0.2%)
AORTIC VALVE REPLACEMENT	2(0.6%)	0(0.0%)	2(0.5%)
ARTERIAL BYPASS OPERATION	1(0.3%)	0(0.0%)	1(0.2%)
ARTERIOVENOUS FISTULA OPERATION	0(0.0%)	1(0.9%)	1(0.2%)
BLADDER REPAIR	2(0.6%)	0(0.0%)	2(0.5%)
CARCINOMA EXCISION	1(0.3%)	0(0.0%)	1(0.2%)
CARDIAC ABLATION	0(0.0%)	1(0.9%)	1(0.2%)
CARDIAC PACEMAKER INSERTION	3(0.9%)	0(0.0%)	3(0.7%)
CARDIAC PACEMAKER REVISION	1(0.3%)	0(0.0%)	1(0.2%)
CAROTID ENDARTERECTOMY	1(0.3%)	0(0.0%)	1(0.2%)
CORONARY ARTERY SURGERY	8(2.5%)	0(0.0%)	8(1.8%)
CORONARY REVASCULARISATION	78(24.1%)	22(19.5%)	100(22.9%)
DIABETES MELLITUS MANAGEMENT	1(0.3%)	0(0.0%)	1(0.2%)
HIP ARTHROPLASTY	2(0.6%)	1(0.9%)	3(0.7%)
HOSPITALISATION	2(0.6%)	0(0.0%)	2(0.5%)
HYSTERECTOMY	1(0.3%)	0(0.0%)	1(0.2%)
IMPLANTABLE DEFIBRILLATOR INSERTION	1(0.3%)	1(0.9%)	2(0.5%)
KNEE ARTHROPLASTY	6(1.9%)	2(1.8%)	8(1.8%)
KNEE OPERATION	1(0.3%)	1(0.9%)	2(0.5%)
LEG AMPUTATION	1(0.3%)	0(0.0%)	1(0.2%)

Table 23a. Serious Adverse Events (to 720 Days) (ITT) (Continued)

Serious Adverse Events (to 720 Days)	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
LUNG LOBECTOMY	1(0.3%)	0(0.0%)	1(0.2%)
MITRAL VALVE REPLACEMENT	1(0.3%)	0(0.0%)	1(0.2%)
PANCREATIC OPERATION	1(0.3%)	0(0.0%)	1(0.2%)
PERICARDIAL DRAINAGE	1(0.3%)	0(0.0%)	1(0.2%)
PERIPHERAL REVASCULARISATION	8(2.5%)	0(0.0%)	8(1.8%)
REHABILITATION THERAPY	1(0.3%)	0(0.0%)	1(0.2%)
ROTATOR CUFF REPAIR	2(0.6%)	0(0.0%)	2(0.5%)
SPINAL LAMINECTOMY	1(0.3%)	0(0.0%)	1(0.2%)
STERNOTOMY	1(0.3%)	0(0.0%)	1(0.2%)
SURGERY	3(0.9%)	0(0.0%)	3(0.7%)
TOE AMPUTATION	1(0.3%)	0(0.0%)	1(0.2%)
TUMOUR EXCISION	1(0.3%)	0(0.0%)	1(0.2%)
UMBILICAL HERNIA REPAIR	1(0.3%)	0(0.0%)	1(0.2%)
URETERAL STENT INSERTION	0(0.0%)	1(0.9%)	1(0.2%)
VASCULAR DISORDERS	*21(6.5%)*	*3(2.7%)*	*24(5.5%)*
AORTIC ANEURYSM	1(0.3%)	0(0.0%)	1(0.2%)
AORTIC STENOSIS	1(0.3%)	0(0.0%)	1(0.2%)
ARTERIOVENOUS FISTULA, ACQUIRED	0(0.0%)	1(0.9%)	1(0.2%)
ARTERY DISSECTION	0(0.0%)	1(0.9%)	1(0.2%)
DEEP VEIN THROMBOSIS	2(0.6%)	0(0.0%)	2(0.5%)
EMBOLISM	1(0.3%)	0(0.0%)	1(0.2%)
HAEMATOMA	3(0.9%)	0(0.0%)	3(0.7%)
HAEMORRHAGE	2(0.6%)	0(0.0%)	2(0.5%)
HYPOTENSION	0(0.0%)	1(0.9%)	1(0.2%)
ILIAC ARTERY STENOSIS	3(0.9%)	0(0.0%)	3(0.7%)
INTERMITTENT CLAUDICATION	2(0.6%)	0(0.0%)	2(0.5%)
INTRACARDIAC THROMBUS	1(0.3%)	0(0.0%)	1(0.2%)
PERIPHERAL REVASCULARISATION	2(0.6%)	0(0.0%)	2(0.5%)
THROMBOPHLEBITIS SUPERFICIAL	2(0.6%)	0(0.0%)	2(0.5%)
VASCULAR PSEUDOANEURYSM	1(0.3%)	0(0.0%)	1(0.2%)

N = the maximum number of eligible patients.

NOS - Not Otherwise Specified.
NOTE: SAEs missing event dates are included in this listing.

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Table 23b. Serious Adverse Events by Site (ITT)

Site	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)
4	1.68% (10/595)	4.73% (8/169)	2.36% (18/764)
6	1.51% (9/595)	5.92% (10/169)	2.49% (19/764)
8	1.51% (9/595)	0.59% (1/169)	1.31% (10/764)
9	2.86% (17/595)	2.96% (5/169)	2.88% (22/764)
10	5.88% (35/595)	15.38% (26/169)	7.98% (61/764)
31	6.22% (37/595)	5.33% (9/169)	6.02% (46/764)
39	5.55% (33/595)	1.18% (2/169)	4.58% (35/764)
42	3.36% (20/595)	1.78% (3/169)	3.01% (23/764)
43	2.02% (12/595)	0.00% (0/169)	1.57% (12/764)
44	0.67% (4/595)	2.37% (4/169)	1.05% (8/764)
48	2.18% (13/595)	0.00% (0/169)	1.70% (13/764)
63	20.00% (119/595)	17.75% (30/169)	19.50% (149/764)
65	1.18% (7/595)	0.00% (0/169)	0.92% (7/764)
82	4.37% (26/595)	2.96% (5/169)	4.06% (31/764)
86	8.57% (51/595)	12.43% (21/169)	9.42% (72/764)
90	2.35% (14/595)	2.96% (5/169)	2.49% (19/764)
91	1.51% (9/595)	4.73% (8/169)	2.23% (17/764)
95	1.51% (9/595)	0.00% (0/169)	1.18% (9/764)
100	0.00% (0/595)	1.18% (2/169)	0.26% (2/764)
105	7.73% (46/595)	2.96% (5/169)	6.68% (51/764)
110	2.52% (15/595)	4.14% (7/169)	2.88% (22/764)
115	1.01% (6/595)	1.78% (3/169)	1.18% (9/764)
124	3.36% (20/595)	4.14% (7/169)	3.53% (27/764)
126	1.18% (7/595)	0.00% (0/169)	0.92% (7/764)
187	1.18% (7/595)	0.00% (0/169)	0.92% (7/764)
264	6.22% (37/595)	2.96% (5/169)	5.50% (42/764)
270	2.52% (15/595)	0.00% (0/169)	1.96% (15/764)
279	1.34% (8/595)	1.78% (3/169)	1.44% (11/764)

N = the maximum number of eligible patients.

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Table 24. Site Reported Major Adverse Events to 720 Days (ITT)

Complications	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Mace (Death, Emergent CABG, MI, TLR)	15.2% (49/323)	14.2% (16/113)	14.9% (65/436)	1.0% [-6.5%,8.5%]	0.879
Death	1.9% (6/323)	4.4% (5/113)	2.5% (11/436)	-2.6% [-6.6%,1.5%]	0.162
Emergent CABG	0.9% (3/323)	0.0% (0/113)	0.7% (3/436)	0.9% [-0.1%,2.0%]	0.572
MI	5.0% (16/323)	7.1% (8/113)	5.5% (24/436)	-2.1% [-7.4%,3.2%]	0.471
Q Wave MI	0.3% (1/323)	1.8% (2/113)	0.7% (3/436)	-1.5% [-4.0%,1.0%]	0.166
Non-Q Wave MI	4.6% (15/323)	5.3% (6/113)	4.8% (21/436)	-0.7% [-5.4%,4.1%]	0.800
TLR	9.0% (29/323)	3.5% (4/113)	7.6% (33/436)	5.4% [0.8%,10.1%]	0.064
TVR not Involve the Target Lesion	10.8% (35/323)	7.1% (8/113)	9.9% (43/436)	3.8% [-2.1%,9.6%]	0.278
Major Bleeding Events	2.8% (9/323)	3.5% (4/113)	3.0% (13/436)	-0.8% [-4.6%,3.1%]	0.749
Major Vascular Events	0.9% (3/323)	0.9% (1/113)	0.9% (4/436)	0.0% [-2.0%,2.1%]	1.000
CVA	1.9% (6/323)	0.9% (1/113)	1.6% (7/436)	1.0% [-1.3%,3.2%]	0.683

N = the maximum number of eligible patients, denominators indicate the total number of patients.
Among the 65 MACEs that were reported by sites, 37 of them were adjudicated as MACE by the CEC.

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Table 25. Laboratory - Cardiac Enzymes Findings (ITT)

Laboratory - CK, CKMB	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
CK					
Pre-Procedure Peak>2 ULN	1.3% (4/312)	0.0% (0/110)	0.9% (4/422)	1.3% [0.0%,2.5%]	0.577
Post-Procedure Peak>2 ULN	2.2% (7/322)	5.4% (6/112)	3.0% (13/434)	-3.2% [-7.6%,1.3%]	0.108
Post-Procedure Peak>3 ULN	0.6% (2/322)	1.8% (2/112)	0.9% (4/434)	-1.2% [-3.8%,1.4%]	0.275
Post-Procedure Peak>4 ULN	0.3% (1/322)	0.9% (1/112)	0.5% (2/434)	-0.6% [-2.4%,1.3%]	0.450
Post-Procedure Peak>5 ULN	0.3% (1/322)	0.9% (1/112)	0.5% (2/434)	-0.6% [-2.4%,1.3%]	0.450
CKMB					
Pre-Procedure Peak>1 ULN	2.7% (8/291)	3.9% (4/103)	3.0% (12/394)	-1.1% [-5.3%,3.0%]	0.521
Post-Procedure Peak>1 ULN	16.5% (51/309)	21.1% (23/109)	17.7% (74/418)	-4.6% [-13.3%,4.1%]	0.307
Post-Procedure Peak>2 ULN	4.9% (15/309)	13.8% (15/109)	7.2% (30/418)	-8.9% [-15.8%,-2.0%]	0.004
Post-Procedure Peak>3 ULN	1.6% (5/309)	6.4% (7/109)	2.9% (12/418)	-4.8% [-9.6%,0.0%]	0.017
Post-Procedure Peak>4 ULN	1.0% (3/309)	5.5% (6/109)	2.2% (9/418)	-4.5% [-9.0%,-0.1%]	0.012
Pre-Procedure CK>2 ULN and CKMB>1 ULN	1.0% (3/288)	0.0% (0/102)	0.8% (3/390)	1.0% [-0.1%,2.2%]	0.570
Post-Procedure CK>2 ULN and CKMB>1 ULN	1.6% (5/309)	4.6% (5/108)	2.4% (10/417)	-3.0% [-7.2%,1.2%]	0.135
Pre- and Post-Procedure CK>2 ULN and CKMB>1 ULN	1.1% (3/281)	0.0% (0/100)	0.8% (3/381)	1.1% [-0.1%,2.3%]	0.570

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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Table 26. Medication - Anti-coagulants Use (ITT)

Anti-coagulant	Endeavor (N= 323 Patients)	CYPHER™ (N= 113 Patients)	All Patients (N= 436 Patients)	Difference [95% CI]	P-value
Pre-Procedure					
Aspirin	99.7% (322/323)	100.0% (112/112)	99.8% (434/435)	-0.3% [-0.9%,0.3%]	1.000
Clopidogrel	80.8% (261/323)	87.5% (98/112)	82.5% (359/435)	-6.7% [-14.2%,0.8%]	0.114
IIb/IIIa	7.7% (25/323)	10.7% (12/112)	8.5% (37/435)	-3.0% [-9.4%,3.5%]	0.330
During Procedure					
Aspirin	6.5% (21/323)	8.8% (10/113)	7.1% (31/436)	-2.3% [-8.2%,3.5%]	0.400
IIb/IIIa	44.0% (142/323)	44.6% (50/112)	44.1% (192/435)	-0.7% [-11.4%,10.0%]	0.912
Post Procedure					
Aspirin	88.5% (286/323)	87.5% (98/112)	88.3% (384/435)	1.0% [-6.0%,8.1%]	0.736
Clopidogrel	93.8% (302/322)	89.3% (100/112)	92.6% (402/434)	4.5% [-1.8%,10.8%]	0.141
Ticlopidine	0.8% (1/127)	2.7% (1/37)	1.2% (2/164)	-1.9% [-7.4%,3.5%]	0.401
IIb/IIIa	40.6% (131/323)	40.2% (45/112)	40.5% (176/435)	0.4% [-10.2%,10.9%]	1.000
Aspirin and (Clopidogrel or Ticlopidine)	87.6% (283/323)	86.6% (97/112)	87.4% (380/435)	1.0% [-6.2%,8.3%]	0.745
At Discharge					
Aspirin	100.0% (323/323)	100.0% (113/113)	100.0% (436/436)	0.0% [--,--]	--
Clopidogrel	99.4% (321/323)	99.1% (112/113)	99.3% (433/436)	0.3% [-1.7%,2.2%]	1.000
Ticlopidine	1.6% (2/129)	2.7% (1/37)	1.8% (3/166)	-1.2% [-6.8%,4.5%]	0.533
IIb/IIIa	0.0% (0/323)	0.0% (0/112)	0.0% (0/435)	0.0% [--,--]	--
Aspirin and (Clopidogrel or Ticlopidine)	100.0% (323/323)	100.0% (113/113)	100.0% (436/436)	0.0% [--,--]	--
At 30-Days					
Aspirin	95.9% (304/317)	98.2% (110/112)	96.5% (414/429)	-2.3% [-5.6%,1.0%]	0.373
Clopidogrel	94.6% (298/315)	95.5% (107/112)	94.8% (405/427)	-0.9% [-5.5%,3.6%]	0.808
Ticlopidine	6.3% (4/64)	10.7% (3/28)	7.6% (7/92)	-4.5% [-17.4%,8.4%]	0.431
Aspirin and (Clopidogrel or Ticlopidine)	94.0% (298/317)	94.7% (107/113)	94.2% (405/430)	-0.7% [-5.6%,4.2%]	1.000
At 6-Month					
Aspirin	95.9% (303/316)	95.5% (106/111)	95.8% (409/427)	0.4% [-4.0%,4.8%]	0.790
Clopidogrel	90.1% (264/293)	89.0% (89/100)	89.8% (353/393)	1.1% [-5.9%,8.1%]	0.707
Ticlopidine	6.1% (2/33)	0.0% (0/12)	4.4% (2/45)	6.1% [-2.1%,14.2%]	1.000
Aspirin and (Clopidogrel or Ticlopidine)	81.6% (258/316)	78.4% (87/111)	80.8% (345/427)	3.3% [-5.5%,12.0%]	0.484
At 9-Month					
Aspirin	97.4% (304/312)	96.4% (108/112)	97.2% (412/424)	1.0% [-2.9%,4.9%]	0.525
Clopidogrel	85.7% (78/91)	91.2% (31/34)	87.2% (109/125)	-5.5% [-17.4%,6.5%]	0.554
Ticlopidine	0.0% (0/9)	0.0% (0/4)	0.0% (0/13)	0.0% [--,--]	--
Aspirin and (Clopidogrel or Ticlopidine)	24.4% (76/312)	26.8% (30/112)	25.0% (106/424)	-2.4% [-11.9%,7.1%]	0.613
At 12-Month					
Aspirin	95.8% (295/308)	97.2% (106/109)	96.2% (401/417)	-1.5% [-5.3%,2.3%]	0.772
Clopidogrel	83.8% (57/68)	73.1% (19/26)	80.9% (76/94)	10.7% [-8.4%,29.9%]	0.252
Ticlopidine	0.0% (0/8)	0.0% (0/2)	0.0% (0/10)	0.0% [--,--]	--
Aspirin and (Clopidogrel or Ticlopidine)	17.5% (54/308)	16.5% (18/109)	17.3% (72/417)	1.0% [-7.1%,9.2%]	0.883
At 24-Month					
Aspirin	91.1% (277/304)	92.6% (100/108)	91.5% (377/412)	-1.5% [-7.4%,4.4%]	0.841
Clopidogrel	69.2% (18/26)	76.9% (10/13)	71.8% (28/39)	-7.7% [-36.7%,21.3%]	0.719
Ticlopidine	0.0% (0/3)	0.0% (0/1)	0.0% (0/4)	0.0% [--,--]	--
Aspirin and (Clopidogrel or Ticlopidine)	5.6% (17/304)	9.3% (10/108)	6.6% (27/412)	-3.7% [-9.7%,2.4%]	0.183

N = the maximum number of eligible patients, denominators indicate the total number of patients with available data for related parameter.

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Table 27. Summary of Device Performance

Coronary Stent System Device Performance	ENDEAVOR III	CYPHER™	Group Unknown
Stent Delivery Failure	**1**	**3**	**2**
Never Delivered	0	2*	2
1st attempt, with subsequent success	1	1**	
Other Device Malfunction	**1**	**0**	**1**
Delivery Balloon	1	0	1
Failure Outcome			
Failed stent withdrawn	1**	1**	
Stent deployed at unintended site	0	1	
Stent embolization	0	0	
Failure Treatment	**0**	**2**	**0**
Non-study stent implanted	0	2*	
PTCA only	0	0	
CABG surgery	0	0	
Associated Adverse Event	1	1	

*No enrollment received but group B per source document.
**"Subsequent success with study stent but utilized stent lengths not sized according to lesion length and thus represents a protocol device failure."
Note: An internal HCRI MD or the Clinical Reviewer adjudicated all device events.

Table 28. Narrative Summaries of Device Performance

Site	Pt	Treatment Group	Summary
----------		CYPHER™	Assigned Strategy Not Attempted On 06/18/2004 the patient underwent the index procedure for treatment of a lesion in the mid RCA. The site reported that after pre-dilatation "the vessel had spiraled into a split dissection." The patient was in the process of IVRS system randomization when a Taxus™ stent was delivered to ensure "the patient remained stable clinically," since the site did not have the appropriately sized stent for the assigned treatment arm. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/19/2004 on ASA and clopidogrel.
----------		CYPHER™	Device Failure per Protocol, Stent Delivered to Unintended Site On 03/01/2004 the patient underwent the index procedure with delivery of the assigned stent in the mid RCA. There was failure to deliver the assigned stent to the target lesion. The assigned stent was deployed proximal to the target site. Two bare metal stents were subsequently deployed at the target site. The site reported a 0% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The Angiographic Core Lab reported a 14% final in-lesion residual stenosis with TIMI 3 flow and no dissection. The post-procedure course was uncomplicated and the patient was discharged on 03/02/2004 on ASA and clopidogrel.
----------		Endeavor	Assigned Strategy Not Attempted On 04/13/2004 the patient was randomized to the assigned treatment based on a visual estimate. The patient underwent pre-procedure IVUS study which revealed a target lesion diameter of 4.0 mm, thus not meeting the protocol inclusion criteria. The investigator decided to follow the patient for "intent to treat". The study stent was not opened or implanted. The investigator implanted a non-study stent in the distal RCA. The site reported a 0% final residual stenosis, no dissection, and unknown TIMI flow. The Angiographic Core Lab reported an 18% final in-lesion residual stenosis with TIMI 3 flow and no dissection. The post-procedure course was complicated by hypotension requiring unspecified drug treatment. The patient was discharged on 04/14/2004 on ASA, clopidogrel and coumadin.

Site	Pt	Treatment Group	Summary
----------		CYPHER™	Device Failure per Protocol On 03/23/2004 the patient underwent the index procedure with predilatation of the lesion followed by an unsuccessful attempt to cross the lesion in the mid LAD with the assigned stent and the stent was withdrawn. Additional balloon inflations were performed and a second attempt to cross the lesion with the assigned stent failed and the stent was withdrawn. A site reported "modular technique" was employed and three 8 mm assigned stents were successfully delivered. The site reported a final grade C dissection. The Angiographic Core Lab reported a 40% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/24/2004 on ASA and clopidogrel.
----------		Endeavor	Assigned Strategy Not Attempted On 05/31/2004 the patient was randomized. The investigator determined the patient did not meet the protocol inclusion/exclusion criteria. The site reported the patient underwent placement of a non-study stent in the mid RCA. After pre-dilatation, a 75% stenosis with a site reported grade A dissection after pre-treatment was reported. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/01/2004 on ASA and clopidogrel.

Site	Pt	Treatment Group	Summary
----------		Endeavor	Device Failure per Protocol On 03/15/2004 the patient underwent the index procedure with predilatation of the lesion in the proximal LAD; however attempts to cross the lesion with the assigned stent were unsuccessful and the stent was withdrawn. Balloon inflations were performed; however, further attempts to deliver the stent were unsuccessful and the stent was withdrawn. Additional balloon angioplasty was performed and two 9 mm assigned stents were successfully deployed. Post-treatment IVUS was then attempted. There was inability to cross the lesion with two IVUS catheters. The patient subsequently complained of left arm pain. Further angiography revealed a dissection of the LM and proximal CX. Two additional assigned stents were placed; one in the proximal CX, the other in the "LM/LAD." Additional balloon inflations were performed using the kissing balloon technique in the CX and LAD with good results. The Angiographic Core Lab noted "after PCI in the LAD" there was a grade D dissection in the LAD and LM requiring added stents in both the LM and CX, and a 27% final residual in-lesion stenosis, no dissection and TIMI 3 flow.
----------		Endeavor	Delivery Balloon Rupture On 05/12/2004 the patient underwent the index procedure with placement of the assigned stent in the proximal LAD. The site reported the balloon on the stent delivery catheter ruptured at 12 atm after 17 seconds. Stent placement was completed successfully with a NC Stormer balloon. There were no clinical sequelae. The site reported a 0% final residual stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/13/2004 on ASA and clopidogrel.
----------		CYPHER™	Assigned Strategy Not Attempted On 09/09/2004 the patient underwent the index procedure with placement of 3.0 x 18 mm stent in the 2nd OM. The site reported the Investigator was mistakenly given the "wrong stent" in the catheterization lab, apparently a stent from the other treatment arm. The Angiographic Core Lab reported a 19% final in-lesion residual stenosis with TIMI 3 flow and no dissection. The post-procedure course was uncomplicated and the patient was discharged on 09/10/2004 on ASA and clopidogrel.

Site	Pt	Treatment Group	Summary
----------		Endeavor	**Delivery Balloon Failure** On 05/14/2004 the patient underwent the index procedure with placement of the assigned stent in the distal CX. The site reported a delivery balloon leak. Further information has been requested. The site reported a 0% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The Angiographic Core Lab report is not available. The patient was discharged on 05/15/2004 on ASA and clopidogrel.
----------		CYPHER™	**Assigned Strategy Not Attempted** On 07/16/2004 the patient was randomized to the assigned treatment. The site reported an inability to pass a guide wire due to tortuosity of the CX. The study treatment was not delivered. The Angiographic Core Lab confirmed the failed attempt to cross the lesion and reported a final 95% target lesion stenosis with TIMI 1 flow. An EPS study was performed on 07/30/2004 for a long standing history of arrhythmias. An AICD was implanted on 08/03/2004. The patient was discharged on 08/04/2004 on ASA and clopidogrel.
----------		CYPHER™	**Device Failure per Protocol, Stent Delivery Failure** On 04/19/2004 the patient underwent an attempted index procedure in the distal RCA. Pre-dilation of the target lesion was performed. The site reported an inability to cross the lesion with two 3.0 mm diameter assigned stents, first an 18 mm, followed by a 13 mm. An unsuccessful attempt was then made to deliver a Taxus stent to the lesion, and success was finally achieved when a Driver 3.0 x 18 mm stent was successfully deployed. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/20/2004 on ASA and clopidogrel.

Site	Pt	Treatment Group	Summary
----------		Endeavor	Assigned Strategy Not Attempted On 04/28/2004 the patient underwent the index procedure. After completion of the telephone randomization of the patient, the site discovered the length of the target lesion was 10 mm. Since the patient did not qualify for the study, the investigator elected to treat the patient with a non-study stent. The patient underwent the successful placement of one Taxus™ stent in the proximal LAD. The Angiographic Core Lab reported a 30% final in-lesion residual stenosis with TIMI 3 flow and no dissection. The post-procedure course was uncomplicated and the patient was discharged on 04/30/2004 on ASA and clopidogrel.

Table 29. Narrative Summaries of Major Adverse Events to 720 days[5]

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	Cardiac Death, 513 days post-procedure; FDA defined Non-Q wave MI, day of procedure
			The patient was a 71 year-old man with a history of hypertension and dyslipidemia who presented with CCS Class II angina and a positive functional ischemia study. On 07/23/2004 he underwent the index procedure with placement of the assigned stent in the proximal RCA. The Angiographic Core Lab reported a final 23% in-stent residual stenosis with TIMI 3 flow and no dissection. Post-procedure, he experienced a "vasovagal episode" with a systolic blood pressure of 60 mmHg during bedpan use, requiring treatment with atropine and IV normal saline. Acute renal failure was also reported post-procedure. On 07/22/2004 the pre-procedure creatinine was 1.9 mg/dL. On 07/24/2004 the post-procedure creatinine was 2.9 mg/dL. The patient underwent IV fluid administration, discontinuation of medications that may have "exacerbated the renal failure," and a renal consultation was obtained. The patient was discharged on 07/25/2004 on ASA and clopidogrel with outpatient nephrology follow-up. On 07/23/2004 the pre-procedure CK was 95 (nl 174, ratio <1) with a CKMB of 2.9 (nl 4, ratio <1). On 07/24/2004 at 00:37 the CK was 282 (nl 174, ratio 1.6) with a CKMB of 2.8 (nl 4, ratio <1). On 07/24/2004 at 06:41 the CK was 906 (nl 174, ratio 5.2) with a CKMB of 6.6 (nl 4, ratio 1.6). On 07/24/2004 at 17:20 the CK was 1725 (nl 174, ratio 9.9) with a CKMB of 16.8 (nl 4, ratio 4.2). On 07/25/2004 at 01:00 the CK was 1568 (nl 174, ratio 9.0) with a CKMB of 14.5 (nl 4, ratio 3.6). On 07/25/2004 at 09:00 the CK was 1293 (nl 174, ratio 7.4) with a CKMB of 11.6 (nl 4.0, ratio 2.9). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The site reported these values were "probably representative of myositis secondary to atorvastatin use," which was discontinued. In January 2006, the investigative site received a phone call from the patient's wife stating that the patient had undergone elective back surgery in December 2005 and was discharged on 12/18/2005. On the same day, he reportedly "fell at home and became unconscious." Emergency medical personnel were summoned but were unable to successfully resuscitate him. Per the investigator, the Death Certificate indicated that the cause of death was "cardiac arrest." An autopsy was not performed.

[5] Please note: Table 29 includes narratives on patient 010-188, 115-209, and 063-225 who had events on days 729, 721, and 966, respectively. These events are not included in the Index Procedure to 720 day analysis; the events will be captured in the clinical study report that analyzes events through 1080 days.

Site	Pt	Treatment Group	Case Summary
---------		Endeavor	Non-cardiac Death, 246 days post-procedure The patient was a 73 year-old woman with a history of dyslipidemia and hypertension who presented with a positive functional ischemia study. On 07/07/2004 she underwent the index procedure with placement of the assigned stent in the proximal RCA. The Angiographic Core Lab reported a 30% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 07/08/2004 on ASA and clopidogrel. On 01/13/2005 the patient was diagnosed with liver and pancreatic cancer. Chemotherapy was administered, but on 03/10/2005 she died at home. An autopsy was not performed.
---------		CYPHER™	Non-cardiac Death, 678 days post-procedure The patient was a 79 year-old man with a history of a prior MI , hypertension, hyperlipidemia, former smoking and known three-vessel CAD who presented with syncope, but without angina, evidence of acute MI, nor a positive recent stress test. On 06/07/2004 he underwent the index procedure with successful delivery of the assigned treatment in the distal CX. The Angiographic Core Lab reported a 14% final residual in-stent stenosis with no dissection and TIMI 3 flow. The post-procedure course was complicated by episodes of sinus node dysfunction, which prompted the insertion of a permanent pacemaker, delaying discharge until 06/09/2004. At the time of the twelve-month contact on 06/30/2005, clopidogrel and aspirin had been discontinued. In November 2005, he was admitted with shortness of breath, pneumonia and a left pleural effusion. Pleural nodules were first noted on CT scan in January 2006. On 03/22/2006, the patient was readmitted, underwent thoracoscopy, and was subsequently diagnosed with metastatic squamous cell carcinoma of the lung. He was discharged to home with hospice care and died on 04/16/2006. The official cause of death was reported as "lung cancer." An autopsy was not performed.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Non-cardiac Death, 488 days post-procedure The patient was a 52 year-old man with a history of hyperlipidemia and current smoking who presented with CCS Class 3 angina and a positive functional study. On 03/09/2004 he underwent the index procedure with successful delivery of one assigned stent in the 2nd OM. The Angiographic Core Lab reported a 36% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/10/2004. At the 8-month follow-up, the patient was without symptoms and the Angiographic Core Lab reported a widely patent stent in the target lesion. At the time of the attempted two-year contact, a social security death index search revealed that the patient had died on 07/10/2005. The information was verified by a family member and the official cause of death was reported as "auto accident." An autopsy was not performed.
----------		Endeavor	Non-cardiac Death, 729 days post-procedure The patient was a 64 year-old man with a history of a recent MI, hypertension and hyperlipidemia who presented with unstable angina and a positive functional study. On 04/16/2004 he underwent the index procedure with successful delivery of the assigned treatment in the mid LAD. The Angiographic Core Lab reported a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/17/2004. Protocol-mandated repeat angiography on 12/21/2004 revealed mild neointimal hyperplasia with a 38% in-stent restenosis, as reported by the Core Lab. On approximately 03/10/2006 the patient was in China when he was admitted to a local hospital with a cough and dyspnea. On 03/13/2006, a supplied ICU consultation note reported tachypnea, cyanosis and hypotension. He was diagnosed with "multiple organ dysfunction syndrome" and his condition was classified as critical. A dopamine infusion was administered and the patient was receiving three IV antibiotics. On the fourth ICU day, he continued to require mechanical ventilation and plans were made to transfer the patient to a "Respiratory centre." Further hospital records are not available. Per report from the patient's wife, he died in the hospital in April, but the exact date was unknown. The investigator reported the cause of death as "ARDS, multiple organ failure." It was unknown if an autopsy was performed.

Site	Pt	Treatment Group	Case Summary
----------	----------	CYPHER™	Non-cardiac Death, 343 days post-procedure
			The patient was a 67 year-old man with a history of diabetes, hyperlipidemia and former smoking who presented on 06/16/2004 with CCS Class 2 angina and a positive functional study. One assigned stent was successfully deployed during the index procedure and the Angiographic Core Lab reported a 13% final in-lesion residual stenosis with TIMI 3 flow and no dissection. The patient had experienced no recurrent angina through the eight-month visit, and protocol-mandated repeat angiography revealed a widely patent stent. On 05/24/2005 the patient was readmitted from the Emergency Room with complaints of abdominal pain following his chemotherapy and was started on morphine via a PCA pump. He subsequently developed chest pain. An ECG was reported to reveal "some evidence of myocardial infarction, age indeterminate." Cardiac enzymes were ordered, but results were not reported. Per a supplied discharge summary, the covering physician was subsequently "notified that the patient had passed away with arrhythmias noted on the Telemetry strip." The Certificate of Death reported that the patient died of cardiopulmonary arrest due to non-small cell lung cancer. An autopsy was not performed.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Non-cardiac Death, 481 days post procedure
			The patient was a 77 year-old man with a history of hypertension, hyperlipidemia, COPD and lung cancer who presented with stable angina and a positive functional study. On 07/22/2004 he underwent the index procedure with successful delivery of the assigned treatment in the 1st OM. The Angiographic Core Lab reported a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 07/23/2004. No significant restenosis was reported by the Angiographic Core Lab at the time of a 03/23/2005 follow-up. The patient was admitted to an outlying hospital on 04/04/2005 with dyspnea. Cardiac enzymes were within normal limits, a VQ scan was negative and bilateral lower extremity Doppler studies were negative for the presence of DVT, per the investigator's report. He was readmitted on 10/18/2005 with pneumonia and progressive shortness of breath that was unresponsive to outpatient steroid therapy. Infiltrates in the right upper and middle lobes and a left-sided pleural effusion was revealed by chest X-ray. He was discharged after six days. He was rehospitalized again on 11/02/2005 after an accidental overdose of Darvocet for chronic back pain. He responded to treatment with naloxone, but was noted to have recurrent pneumonia with persistent hypercapnia and acidosis. He was treated with BiPAP, intravenous antibiotics and steroids. A "do not resuscitate" order was requested by the patient's family. On the morning of 11/03/2005, the patient was noted to be lethargic with an increased respiratory effort. After reconfirming the patient's and the family's wishes, all treatments were withdrawn and the patient died later on 11/03/2005. Pneumonia was reported as the official cause of death. An autopsy was not performed.

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	Non-cardiac Death, 627 days post-procedure
			The patient was a 73 year-old woman with a history of hypertension, dyslipidemia, diabetes and former smoking who presented with CCS Class II angina. On 09/08/2004 she underwent the index procedure with placement of the assigned stent in the proximal LAD. The Angiographic Core Lab reported a 10% final residual stenosis with no dissection and TIMI 3 flow. On 09/09/2004 at 08:15 the CK was 216 (nl 250, ratio <1) with a peak CKMB of 36.4 (nl 5.8, ratio 6.2). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The post-procedure course was complicated by "atypical chest pain" which resolved with drug treatment. The patient was discharged on 09/09/2004 at 09:55 on ASA and clopidogrel. At the time of the six-month contact, the investigator reported "severe refractory anemia" of unknown etiology. The patient experienced a syncopal episode and was transfused for a Hct of 24.3 and a Hgb of 8.2. At the time of the attempted two-year contact, the patient's husband reported that she was diagnosed with lung cancer in (approximately) March 2006 and died in May 2006. A site-supplied Certificate of Death reported that the patient died on 05/28/2006 and that the primary cause of death was "metastatic lung cancer." An autopsy was not performed.

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	Non-cardiac Death, 600 days post-procedure
			The patient was a 57 year-old man with a history of insulin-dependant diabetes, hypertension, hyperlipidemia and former smoking who presented with a positive functional study. On 06/01/2004 he underwent the index procedure with successful delivery of the assigned treatment in the proximal RCA. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/02/2004. At the time of the one-month contact, the patient reported that a PET scan had been performed which was consistent with lung cancer, and a biopsy was scheduled to confirm the diagnosis. In September 2004 he was admitted and underwent a thoracotomy with a segmental resection of the left upper lobe. The post-operative course was complicated by renal failure which required short-term hemodialysis, and which eventually progressed to end-stage renal disease. He had multiple readmissions during the following year for complications related to the lung cancer, including respiratory failure, pleural effusions and a hemothorax. On 01/22/2006, the patient died at a skilled nursing facility. Contributing factors were noted as "lung cancer, bacteremia and renal failure." An autopsy was not performed.

Site	Pt	Treatment Group	Case Summary
	----------	Endeavor	Non-cardiac Death, 250 days post-procedure; CVA, 250 days post-procedure
			The patient was a 59 year-old man with a history of hypertension, dyslipidemia and former smoking who presented with CCS Class II angina and a positive functional ischemia study. On 05/12/2004 he underwent the index procedure with placement of the assigned stent in the proximal LAD. The site reported the balloon on the stent delivery catheter ruptured at 12 atm after 17 seconds. Stent placement was completed successfully with an additional balloon. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/13/2004 on ASA and clopidogrel. Protocol re-study on 01/05/2005 in the absence of recurrent angina or a functional ischemia study revealed a 14% in-lesion restenosis reported by the Angiographic Core Lab with the notation "study stent is patent." No revascularization was performed. On 01/17/2005 the patient was rehospitalized urgently in the early morning after becoming obtunded and then unresponsive. A CT scan revealed a "massive, inoperable intracerebral hemorrhage." He was admitted to an ICU and maintained on "life support" for possible organ donation. An Anesthesia Examination for Brain Death Criteria revealed no response to painful stimuli, flaccid extremities, no deep tendon reflexes, no Babinski response, and fixed, dilated pupils. The patient was declared brain dead at 17:45 and expired later the same day. A discharge summary reported hemorrhage-induced diabetes insipidus. The categorical cause of death was non-cardiac. The official cause of death was a CVA. An autopsy was not performed.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Non-cardiac Death, 721 days post-procedure
			The patient was an 80 year-old woman with a history of a MI in 2000, a prior PCI, hypertension, hyperlipidemia, former smoking who presented with CCS Class III angina. On 04/12/2004 she underwent the index procedure with successful delivery of the assigned treatment in the proximal LAD. Post-deployment IVUS was not performed due to an inability to cross the stent with multiple IVUS catheters. The Angiographic Core Lab reported a 29% final residual in-lesion/stent stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/14/2004. During the first year of follow-up, she complained of bilateral upper extremity pain and occasional chest pressure. On 12/01/2005, she was admitted with an "acute abdomen" and obstructive jaundice. She was found to have "impacted gallstones" and was treated with ERCP, but recovery was complicated by an episode of sepsis, for which she received IV antibiotics. On 02/15/2006, she was readmitted with pneumonia. Sputum cultures grew MRSA. She was retreated with antibiotics and was discharged to a rehabilitation facility on 02/23/2006. On 03/24/2006, she was admitted with "altered mental status." No acute changes were revealed on a head CT scan. Intermittent hypotension and confusion were reported throughout the admission. Per a supplied narrative, the patient "was thought to have a malfunction of an intrathecal morphine pump with overdose." The pump was surgically replaced on 03/30/2006. She suffered a cardiopulmonary arrest on 04/03/2006 and expired. An autopsy was not performed.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Non-cardiac Death, 484 days post-procedure
			The patient was an 86 year-old woman with a history of hypertension and former smoking who presented with CCS Class 2 angina and a positive functional study. On 08/04/2004 she underwent the index procedure with successful delivery of the assigned stent in the distal CX. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 08/05/2004. On 04/02/2005 she was admitted with complaints of abdominal pain. Chest pain unrelieved by NTG was denied. Two sets of cardiac enzymes were drawn. Although the troponin was reported as "elevated" on the first sample, no quantified measurement was reported. The peak CK was 63 (nl 195, ratio <1) and CKMB was 1.9 (nl 15, ratio <1).. Per a supplied narrative, the treating physician stated in the discharge summary "? non-ST segment elevation myocardial infarction," but also noted that no ECGs were in the patient's chart. A CT scan performed for the evaluation of her abdominal pain revealed a left lower lobe lung mass which was found to be a small cell carcinoma on biopsy. The patient was discharged on 04/05/2005. Hospice care was instituted in May 2005 and the patient died on 12/01/2005. An autopsy was not performed.
----------		Endeavor	Death, 966 days post-procedure (awaiting data for CEC adjudication)
			The patient was a 54 year-old man with a history of hypertension and former smoking who presented with a positive functional study. On 04/15/2004 he underwent the index procedure with the successful delivery of the assigned treatment in the proximal RCA. The Angiographic Core Lab reported a 12% final in-lesion residual stenosis with TIMI 3 flow and no dissection. The post-procedure course was uneventful and the patient was discharged on 04/16/2004. Protocol-mandate repeat angiography on 12/23/2004 revealed a patent target lesion with a maximum 24% in-stent restenosis. Per two unmonitored Reports of Serious Adverse Event, the patient was involved in a motorcycle accident on 10/30/2006 and subsequently underwent an amputation of the left lower extremity at an outlying hospital. He was discharged on 11/9/2006. On 1/10/2007, the investigative site was informed that the patient had died on 12/07/2006, but no details were available to the investigator at the time of the report. No additional information regarding the death has been submitted since the initial report.

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	FDA Defined Non-Q wave MI, day of procedure The patient is a 77 year-old woman with a history of hypertension and dyslipidemia who presented with CCS Class I angina. On 05/03/2004 she underwent the index procedure with placement of the assigned stent in the mid LAD with administration of eptifibatide. The site reported the procedure was complicated by "transient no-reflow" after post-dilation of the study stent. An IVUS study revealed a "well-opposed stent." IC NTG was administered with TIMI 3 flow restored through the lesion, per the investigator's report. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and a final TIMI 2 flow with the presence of abrupt closure and no reflow. The patient was discharged on 05/06/2004 on ASA and clopidogrel. The pre-procedure CK and CKMB drawn on 05/03/2004 at 10:40 were 62 (nl 180, ratio <1) and 3.1 (nl 15, ratio <1) respectively. On 05/04/2004 at 02:10 the CK peaked at 553 (nl 160, ratio 3.3) with a CKMB of 99.4 (nl 15, ratio 6.6). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves.
----------		Endeavor	FDA defined Non-Q wave MI, day of procedure The patient is a 50 year-old man with a history of hypertension and dyslipidemia who presented with CCS Class III angina. On 07/23/2004 at 11:10 hours he underwent the index procedure with placement of the assigned stent in the distal RCA. The Angiographic Core Lab reported a final 17% in-lesion residual stenosis with TIMI 3 flow and no dissection. There were no further post-procedure complications and the patient was discharged on 07/25/2004 on ASA and clopidogrel. On 07/23/2004 at 07:00 the pre-procedure CK was 62 (nl 180, ratio <1) with a CKMB of 1.4 (nl 15, ratio <1). On 07/23/2004 at 19:04 the CK was 67 (nl 180, ratio <1) with a CKMB of 7.9 (nl 15, ratio <1). On 07/24/2004 at 02:00 the CK was 238 (nl 180, ratio <1) with a CKMB of 18.4 (nl 15, ratio 1.2). On 07/24/2004 at 08:00 the CK was 418 (nl 180, ratio 2.3) with a CKMB of 14.3 (nl 15, ratio <1). On 7/24/2004 at 13:25 the CK was 457 (nl 180, ratio 2.5) with a CKMB of 12.2 (nl 15, ratio 1.2). On 07/24/2004 at 22:55 the CK was 377 (nl 180, ratio 2) with a CKMB of 8.5 (nl 15, ratio <1). No additional CK enzymes were measured. The ECG Core Lab reported new inferior T wave inversions and no new Q waves.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	FDA Defined Non-Q wave MI, day of procedure
			The patient is an 85 year-old man with a history of MI on 08/24/2004, hypertension and former smoking who presented with CCS Class IV angina. The site reported the pre-procedure CK enzymes did not meet protocol specified requirements to exclude the patient; therefore the patient was enrolled. On 08/25/2004 at 19:38 he underwent the index procedure with placement of the assigned stent in the proximal LAD. The second assigned stent was placed proximal to the target lesion to stabilize the lesion. The Angiographic Core Lab reported a final 42% in-lesion residual stenosis with TIMI 3 flow and no dissection. The patient was discharged on 08/26/2004 at 12:27 on ASA and clopidogrel. On 08/25/2004 at 20:01 the pre-procedure CK was 90 (nl 329, ratio <1) with a CKMB of 5.6 (nl 5, ratio 1.1). CK enzymes were not measured at 6-8 hours post-procedure. On 08/26/2004 at 11:00 the CK was 790 (nl 329, ratio 2.4) with a CKMB of 133.8 (nl 5, ration 26.7). CK enzymes were not measured at 12-16 hours post-procedure. The ECG Core Lab reported new inferolateral ST depressions and no new Q waves. .
----------		CYPHER™	FDA defined Non-Q wave MI, day of procedure
			The patient is a 49 year-old man with a history of dyslipidemia and current smoking who presented with CCS Class IV angina and a positive functional ischemia study. On 03/25/2004 he underwent the index procedure with placement of the assigned stent in the mid LAD. The index procedure was complicated by chest pain. An interventional catheterization report revealed "some compromise to a very small secondary diagonal branch." The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was also complicated by chest pain which resolved with an unspecified drug treatment. The patient was discharged on 03/26/2004 on ASA and clopidogrel. The pre-procedure CK on 03/25/2004 at 11:15 was 176 (nl 225, ratio <1) and 1.1 (nl 5, ratio <1). On 03/25/2004 at 19:00 the CK was 244 (nl 225, ratio 1.08) with a ratio of 9.9 (nl 5, ratio 1.8). On 03/26.2004 at 02:10 the CK was 465 (nl 225, ratio 2.06) with a CKMB of 28.8 (nl 5, ratio 5.6). On 03/26/2004 at 09:05 the CK was 475 (nl 225, ratio 2.1) with a CKMB of 24 (nl 5, ratio 4.8). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves, but noted inadequate tracing quality due to lead misplacement.

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	FDA defined Non-Q wave MI, day of procedure
			The patient is an 80 year-old woman with a history of diabetes, hypertension and dyslipidemia who presented with CCS Class III angina and a positive functional ischemia study. On 06/15/2004 she underwent placement of the assigned stent in the mid LAD. An interventional catheterization report revealed a "small diagonal II was lost during stent deployment." In addition, the same report noted "subsequent IVUS evaluation of the stent revealed a well deployed stent without evidence of a dissection proximal to or distal to the stent." The Angiographic Core Lab confirmed a post-procedure 100% occlusion of the 2nd diagonal, and reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow in the mid LAD. The pre-procedure CK drawn on 06/15/2004 at 10:55 hours was 148 (nl 232, ratio <1) with a CKMB of 2.9 (nl 5.7, ratio <1). On 06/16/2004 at 00:55 hours the CK was 177 (nl 232, ratio <1) with a CKMB of 19 (nl 5.7, ratio 3.3). On 06/16/2004 at 08:10 hours the CK was 438 (nl 232, ratio 1.8) with a CKMB of 69.1 (nl 5.7, ratio 12.1). On 06/16/2004 at 18:40 hours the CK was 657 (nl 232, ratio 2.8) with a CKMB of 97.4 (nl 5.7, ratio 17). On 06/17/2004 at 11:45 hours the CK decreased to 261 (nl 232, ratio 1.1) with a CKMB of 26.2 (nl 5.7, ratio 4.5). No further CK enzymes are available. The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The site reported cardiac enzymes were elevated post-procedure due to the loss of the small diagonal branch. The post-procedure course was complicated by a 10 minute episode of unresponsiveness which resolved after the administration of naloxone hydrochloride. The patient was discharged on 06/17/2004 on ASA and clopidogrel.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-CABG, 164 days post-procedure The patient is a 70 year-old woman with a history of diabetes, hypertension, and dyslipidemia who presented with CCS Class IV angina and a positive functional ischemia study. On 04/05/2004 she underwent the index procedure with placement of the assigned stent in the proximal CX. The Angiographic Core Lab reported a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/06/2004 on ASA and clopidogrel. Repeat angiography on 09/14/2004 in the setting of recurrent angina with a positive functional ischemia study revealed an 82% in-lesion restenosis reported by the Angiographic Core Lab with the notation "M1 is taken from the final; type 2 ISR, no PCI." On 09/16/2004 the patient underwent CABG surgery with grafts placed to the proximal CX and Ramus, reported as target lesion/target vessel revascularization. The patient was discharged on 09/20/2004.
----------		Endeavor	Target Lesion Revascularization-CABG, Target Vessel Revascularization-CABG, 193 days post-procedure The patient is a 57 year-old man with a history of hypertension, diabetes, dyslipidemia and current smoking who presented with CCS Class II angina. On 07/02/2004 he underwent the index procedure with placement of the assigned stent in the mid LAD. The site reported a 0% final residual stenosis. The Angiographic Core Lab reported a 40% final in-lesion residual stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 07/03/2004 on ASA and clopidogrel. On 1/5/2005 the patient presented to his local cardiologist's office with complaints of recurrent chest pain. Repeat angiography on 1/5/2005 revealed a 99% target lesion in-stent restenosis as well as "critical 3-vessel disease," per the investigator's report. The patient underwent a CABG procedure on 01/11/2005 where grafts were placed to the proximal, mid and distal LAD, the 1st diagonal, the proximal CX and the 1st OM. The patient experienced no post-operative complications and was discharged on 1/17/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-CABG, 548 days post-procedure The patient is a 48 year-old woman with a history of hyperlipidemia, hypertension, smoking and early familial CAD who presented on 03/13/2004 with CCS Class III angina. She underwent the index procedure on 03/16/2004. A target vessel Grade B dissection was noted by the investigator after pre-treatment balloon angioplasty. The first assigned stent was delivered to the mid LAD without difficulty and the dissection was then treated with the deployment of one stent proximal and one stent distal to the primary target lesion stent. The Angiographic Core Lab reported a final 44% in-lesion residual stenosis with TIMI 3 flow and no dissection. Over the following year, she underwent four interventions, three involving the RCA and the other involving the proximal CX. Per the Angiographic Core Lab, repeat angiography on 02/08/2005 revealed "moderate intimal hyperplasia" with a 43% target lesion restenosis. On 08/02/2005, she underwent repeat angiography for recurrent angina and a percutaneous intervention was performed in the RCA. Also revealed was "a significant ostial circumflex lesion" and 60-70% stenosis in the mid LAD, per site report. The Angiographic Core Lab reported a 52% target lesion restenosis on 08/02/2005 and noted an RCA intervention on that date. On 08/12/2005 she was admitted with slurred speech and disequilibrium. Per the investigator's report, a head CT was unremarkable and carotid duplex ultrasound revealed no significant stenoses. All symptoms resolved within 24 hours of onset. A CVA was "ruled out'" and the patient was started on low-molecular weight heparin and warfarin. On 09/13/2005, she was readmitted with chest pain, and per site report, a "review of the cath done in August" led to a surgical revascularization on 09/15/2005 during which a LIMA graft was placed to the distal LAD and SVGs were placed to the R-PDA, the 1st OM and the Ramus. The post-operative recovery was unremarkable and she was discharged on 09/20/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-CABG, 124 days post-procedure
			The patient is a 51 year-old man with a history of MI on 02/17/2004; prior CABG surgery in 1996 with LIMA to LAD, SVG to intermediate and OM; dyslipidemia and current smoking who presented with CCS Class I angina. On 03/26/2004 he underwent the index procedure with placement of the assigned stent in the proximal LAD. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/27/2004 on ASA and clopidogrel. On 07/17/2004 the patient was admitted with angina, reported as a non-ST elevation MI on an operative report. CK enzymes were not measured. The troponin was <0.20 (nl <0.20). The ECG Core Lab reported new anterolateral/apical T wave inversions and no new Q waves. Repeat angiography on 07/19/2004 for recurrent angina/ischemic symptoms without a positive functional ischemia study revealed a 69.7% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1B ISR; no PCI was done." An interventional catheterization report revealed a "widely patent stent" in the mid LAD with 70% occlusion; a 100% occlusion in the LIMA to LAD; 100% occlusion in the SVG to 2nd OM; and 100% occlusion in the RAMUS. On 07/28/2004 the patient underwent CABG surgery with a left radial artery graft placed to the mid LAD and a reverse SVG was placed to the Ramus intermedius, reported as a target lesion/target vessel revascularization. The patient was discharged on 08/02/2004.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization – CABG, 587 days post-procedure; Target Lesion Revascularization – PTCA, 250 days post-procedure
			The patient is a 68 year-old man with a history of MI in 1986, dyslipidemia, hypertension and former smoking who presented with a positive functional ischemia study and no angina. On 04/29/2004 he underwent the index procedure with placement of the study stent in 1st OM. The Angiographic Core Lab reported a 25% final in-stent residual stenosis with no dissection and TIMI 3 flow. The patient was discharged on 04/30/2004 on ASA and clopidogrel. The patient underwent a protocol restudy on 01/4/2005 in the setting of recurrent angina. Angiography revealed a 74% in-stent restenosis reported by the Angiographic Core Lab, as opposed to 95% restenosis reported by the site. The patient underwent a successful unspecified percutaneous intervention involving the 1st OM. One month later, repeat angiography for continuing chest pain revealed a widely patent target lesion, and a non-target lesion in the LAD was successfully treated with balloon angioplasty and deployment of one stent. The patient underwent repeat angiography on 11/18/2005 for recurrent angina, which revealed significant three vessel disease but without restenosis of the target lesion stent, per the investigator's report. (No cine is available for submission to the Angiographic Core Lab.) The patient was scheduled for elective CABG surgery in mid-December, but on 12/05/2005 he presented with severe chest pain and was admitted. A CABG procedure was performed on 12/7/2005, with grafts placed to the R-PDA, the mid LAD, the 2nd OM and the Ramus. The post-operative period was uneventful and he was discharged on 12/16/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization - CABG, 354 days post-procedure; Target Vessel Revascularization – PTCA, 350 and 354 days post-procedure
			The patient is a 45 year-old man with a history of a MI on 07/12/2004, diabetes, hypertension, dyslipidemia and current smoking who presented with CCS Class II angina and a positive stress test. On 08/23/2004 he underwent the index procedure with successful delivery of the assigned treatment in the proximal RCA The Angiographic Core Lab reported a 26% final residual in-stent stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 08/24/2004. On 08/08/2005 the patient was without angina or a positive functional study and belatedly underwent protocol-mandated repeat angiography. The investigator reported a widely patent target lesion stent with 0% restenosis, but two-vessel disease was noted and one stent was deployed in the distal RCA. Cine from 08/08/2005 is not available to Core Lab for analysis. After treatment of the RCA lesion, the patient developed chest pain, and a critical lesion was noted in the LAD. A NTG infusion was administered and the patient was transferred to the ICU. An elective CABG was scheduled. On 08/12/2005, he underwent a CABG procedure with a LIMA graft placed to the LAD and a SVG was placed to the first diagonal. The patient returned to the ICU post-operatively but three hours later developed recurrent ventricular fibrillation associated with "inferior ST elevation with right ventricular involvement," reported an a non-Q wave MI by the investigator. No cardiac enzyme values were obtained. The ECG Core Lab, referring to a series of tracings from 08/08/2005 through 08/14/2005, reported isolated VPBs, an intermittent complete RBBB, new intermittent anterior and inferior ST elevations and T wave inversions, and loss of amplitude in the anterior R waves. The patient returned to the catheterization lab where an acute total occlusion of the RCA was revealed. The Angiographic Core Lab confirmed a thrombotic occlusion of the target vessel on 08/12/2005 with the note "abrupt occlusion of the target vessel. Status post CABG; PCI for failed procedure. Unable to restore blood flow in the vein." Multiple balloons and wires were passed down the vessel but antegrade flow was not immediately re-established. A distal wire perforation at the bifurcation of the R-PDA and RPL was reported by the site, which was successfully sealed with a prolonged balloon inflation. The balloon ruptured after approximately one minute of inflation, and the investigator reported persistent occlusion of the target vessel. An Export catheter was then employed and TIMI 1 flow was restored, albeit with a persistent heavy thrombotic burden. The patient emergently returned to the operating room on 08/12/2005 for a second CABG procedure with placement of a SVG to distal RCA/PDA.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-PTCA, Target Vessel Revascularization-PTCA, 197 days post-procedure The patient is a 47 year-old man with a history of MI on 03/09/2004 and current smoking who presented with CCS Class IV angina. On 03/15/2004 he underwent the index procedure with placement of the assigned stent in the mid RCA. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/16/2004 on ASA and clopidogrel. Protocol re-study on 09/28/2004 in the presence of recurrent angina and in the absence of a positive functional ischemia study revealed a 61% in-lesion re-stenosis reported by the Angiographic Core Lab. An interventional catheterization report revealed a "70% focal area of ISRS proximal/mid RCA; 70% mid/distal RCA" stenosis. The patient underwent balloon angioplasty with placement of Cypher™ stents in the mid and distal RCA, the mid LAD and the 1st diagonal.
---------		CYPHER™	Target Lesion Revascularization-PTCA, 73 days post-procedure; Target Vessel Revascularization-PTCA, 73 days post-procedure The patient is a 74 year-old woman with a history of diabetes, hypertension, hyperlipidemia and prior CABG who presented with CCS Class II angina and a positive functional study. On 05/10/2004 she underwent the index procedure with placement of one assigned study stent in the proximal CX. "After predilatation and stent deployment and on viewing the angiogram it was found that the lesion extends proximally into the CX artery and partially into the OM." A second stent was deployed with post-dilatation and IVUS. The Angiographic Core Lab reported a final 38% in-lesion residual stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/11/2004 on ASA and clopidogrel. Repeat angiography on 07/22/2004 for recurrent angina with a positive functional ischemia study revealed a 95% in-stent restenosis of the target lesion with TIMI 1 flow, as reported by the Angiographic Core Lab. Per a supplied interventional catheterization report, the patient underwent delivery of drug-eluting stents in the proximal and mid CX as well as balloon angioplasty in the "retrograde segment" of the SVG to OM2.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-PTCA 134,245,364 and 705 days post-procedure; Target Vessel Revascularization-PTCA,156 days post-procedure
			The patient is 58 year-old man with a history of hypertension and former smoking who presented with a positive functional ischemia study and without angina. On 06/30/2004 he underwent the index procedure with placement of the assigned stent in the mid RCA. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 07/01/2004 on ASA and clopidogrel. On 11/11/2004 the patient was rehospitalized with "unstable coronary syndrome." The CK peaked at 116 (nl 220, ratio <1) with a CKMB of 7 (nl 7, ratio 1). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves, but noted lead misplacement. A discharge summary reported a "non-ST segment elevation MI due to severe, in-stent restenosis of the RCA stent, placed on 06/30/2004." On 03/30/2005 the CEC ruled the event did no meet the criteria for a non-Q wave MI. Repeat angiography on 11/11/2004 for recurrent angina without a functional ischemia study revealed an 80% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 in-stent restenosis; PCI for ISR; target lesion revascularization." An interventional catheterization report revealed "tandem 95% stenosis, which appeared to be approximately at the proximal and distal ends of the previously placed stents." The patient underwent balloon angioplasty with placement of a Taxus™ stent in the mid RCA. The catheterization report also noted an "area slightly distal to the (new) stent, which was irregular and appeared to have at least a 60% narrowing, which did not resolve after multiple doses of IC NTG." A second Taxus™ stent was implanted. The patient was discharged on 11/12/2004 on ASA and clopidogrel for a minimum of six months. Repeat angiography on 12/03/2004 for recurrent angina without a functional ischemia study revealed a 25% in-lesion restenosis reported by the Angiographic Core Lab with the notation "study stent patent." An interventional catheterization report revealed an "80-90% stenosis before a large right postero-lateral branch" and a "95% stenosis of the mid-nondominant CX before a small postero-lateral branch." The patient underwent "primary stenting" with delivery of a Taxus™ stent in the distal RCA and balloon angioplasty with TAXUS™ stent placement in the distal CX artery. The site reported a target vessel revascularization. The patient was discharged on 12/04/2004. Protocol-mandated repeat angiography on 03/02/2005 in the setting of recurrent CCS Class III angina revealed a 69% in-lesion restenosis, reported by the Angiographic Core Lab as "Type 1B ISR." The patient underwent successful deployment of one 3.5 mm Cypher™ stent in the mid RCA. The post-procedure course was uneventful and the patient was discharged the following day. On 6/29/2005 the patient was rehospitalized for recurrent angina and fatigue. Repeat angiography on 6/29/2005 for recurrent angina without a positive functional ischemia study revealed a 59% focal in-stent restenosis reported by the Angiographic Core Lab. The lesion was successfully treated with the deployment of one Cypher™ stent. The post-procedure course was uneventful and the patient was discharged to home on 6/30/2005. On 06/05/2006 the patient underwent repeat angiography in the setting of recurrent angina and a positive functional study. Angiography revealed two discrete 70% stenoses in the mid portion of the RCA, per the investigator's report. One Cypher™ stent was successfully deployed within the lesion with "no significant residual narrowing" reported. The Angiographic Core Lab reported a 56% in-stent restenosis on 06/05/2006 with the note, "ISR Type 2, PCI-TLR, 1 stent."

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	Target Lesion Revascularization-PTCA, 237 days post-procedure
			The patient is a 70 year-old man with a history of prior CABG surgery, diabetes, dyslipidemia and hypertension who presented with CCS Class II angina and a positive functional ischemia study. On 02/27/2004 he underwent the index procedure with placement of the assigned stent in the distal CX. The Angiographic Core Lab reported on a lesion in the 1st OM, revealing a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 02/28/2004 on ASA and clopidogrel. Repeat angiography on 10/13/2004 in the setting of recurrent angina (per the 8-month contact form) revealed a 58% in-lesion restenosis as reported by the Angiographic Core Lab, with the notation "MLD is at proximal edge of the study stent; 1B ISR." The investigator reported the stenosis as a new lesion proximal to the study stent. The patient returned on 10/21/2004 and underwent a planned percutaneous procedure with one Cypher™ stent placed in the distal CX, reported by the investigator as a target vessel revascularization. The patient was discharged on 10/22/2004.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization – PTCA, 294 days post-procedure, subsequent PCI to non target lesion The patient is a 53 year-old man with a history of diabetes, dyslipidemia, hypertension and former smoking who presented with CCS Class III angina. On 05/12/2004 he underwent the index procedure with placement of the assigned stent in the distal CX, per site report. The Angiographic Core Lab, referring to the L-AV as the target lesion, reported a 31% final residual in-lesion stenosis with no dissection and a final TIMI 2 flow. The CK peaked at 218 (nl 236, ratio <1) with a CKMB peak of 7.1 (nl 5, ratio 1.4); The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The post-procedure course was otherwise uncomplicated and the patient was discharged on 05/13/2004 on ASA and clopidogrel. Repeat angiography on 7/21/2004 for recurrent angina without a functional ischemia study revealed a 46% in-lesion restenosis in the 3rd OM reported by the Angiographic Core Lab with the notation "type 2 ISR; PCI for ISR: TLR." The site reported a 55% in-stent restenosis and a 75% restenosis "proximal to study stent." The patient underwent balloon angioplasty and placement of an Express™ stent in the distal CX, reported as a target lesion revascularization. (The Clinical Events Committee, on 2/23/2005, determined that the intervention was not clinically driven.) On 03/1/2005 the patient presented with recurrent CCS Class III angina and dyspnea on exertion. Repeat angiography on 03/02/2005 revealed an 82% restenosis of the target lesion, per the Angiographic Core Lab. Two Taxus™ Express stents were successfully deployed in the distal CX, per the investigator. Serial cardiac enzymes were within normal limits and the patient was discharged the following day. He was readmitted on 04/04/2005 with chest pain and underwent revascularization of the LAD on 04/05/2005 with the deployment of one stent.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-PTCA, 117 and 586 days post-procedure The patient is a 61 year-old man with a history of hypertension, dyslipidemia and former smoking who presented with CCS Class I angina and a positive functional ischemia study. On 06/03/2004 he underwent the index procedure with placement of the assigned stent in the mid LAD. The Angiographic Core Lab reported a 19% final residual in-lesion lesion with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/04/2004 on ASA and clopidogrel. Repeat angiography on 09/28/2004 for recurrent angina without a functional ischemia study revealed a 27% in-lesion restenosis reported by the Angiographic Core Lab with the notation "stent patent; balloon dilatation of the side branch and target vessel only." An interventional catheterization report revealed "an ostial diagonal which is approximately 99% stenosed and is jailed by this prior placed stent." The patient underwent placement of a 2.5 a 13 mm Cypher™ stent in the 1st diagonal and placement of a 3.0 x 23 mm Cypher™ stent in the LAD, using a crush technique, reported as target vessel revascularization. The patient was discharged on 09/29/2004. On 01/12/2005 the Clinical Events Committee determined the above revascularization involved only the target lesion segment of the target vessel and was clinically driven. On 01/07/2006, the patient presented to an outlying hospital with recurrent angina and a positive functional study. He was subsequently transferred to the investigative site for a possible intervention. On 01/10/2006 repeat angiography revealed the target lesion stent to be widely patent per the investigator's report, and stents were delivered to the proximal and distal LAD and balloon angioplasty was performed in the first diagonal artery. The Angiographic Core Lab reported a 76% in-lesion restenosis on 01/10/2006 and noted "ISR in LAD and ostial diagonal with TLR; new stent in diagonal, final dilitation in LAD." The patient returned two weeks later with recurrent chest pain. Repeat angiography was again performed on 01/24/2006 where the target lesion remained widely patent. The pain was felt to be related to coronary artery spasm, and no intervention was performed.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-PTCA, 225 days post-procedure
			The patient is a 64 year-old man with a history of hypertension, dyslipidemia and former smoking who presented with CCS Class IV angina. On 05/04/2004 he underwent the index procedure with placement of the assigned stent in the distal RCA. The procedure was complicated by angina which resolved after drug treatment. The Angiographic Core Lab reported an 8% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The CK peaked at 170 (nl 200, ratio <1) with a CKMB of 17 (nl 9, ratio 1.8). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The post-procedure course was complicated by chest and left arm pain, diaphoresis and shortness of breath. Oxygen, IV morphine sulfate and sublingual NTG were administered. Repeat angiography on 05/04/2004 revealed a 13% re-narrowing of the target lesion. No revascularization was performed. Further chest pain was not reported. The patient was discharged on 05/05/2004 on ASA and clopidogrel. On 12/15/2004 repeat angiography in the presence of recurrent angina revealed a site-reported 75% restenosis, as compared to a 56% in-lesion restenosis reported by the Angiographic Core Lab. The patient underwent balloon angioplasty and placement of one Taxus™ stent in the distal RCA, reported as a target lesion revascularization.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization – PTCA, 255 days post-procedure
			The patient is a 61 year-old man with a history of diabetes, hypertension and hyperlipidemia who presented with CCS Class III angina and a positive functional study. On 07/13/2004 he underwent the index procedure with successful delivery of two assigned stents in the proximal CX. The Angiographic Core Lab reported a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 07/14/2004. Protocol-mandated repeat angiography on 03/25/2005 without recurrent angina or a positive functional study revealed a 95% in-stent restenosis and a distinct 95% lesion in the proximal CX, as reported by the investigator. The Angiographic Core Lab (from a CEC-requested second analysis of the supplied cine) reported an 88% in-stent restenosis on 03/25/2005, and noted "Type 1D ISR. PCI for ISR. TLR." Per a supplied progress note, the patient underwent successful balloon angioplasty in the index stent, as well as deployment of one drug-eluting stent in the proximal CX "in the area near the initial drug-eluting stent." The intervention was reported as both a target lesion and a target vessel revascularization. The patient experienced no complications and was discharged on 03/26/2005.

Site	Pt	Treatment Group	Case Summary
---------		Endeavor	Target Lesion Revascularization-PTCA, 203 days post-procedure; Target Vessel Revascularization-PTCA, 546 days post-procedure The patient is a 58 year-old man with a history of MI, prior CABG surgery, diabetes, hypertension, dyslipidemia and former smoking who presented with CCS Class III angina. On 03/12/2004 he underwent the index procedure with successful placement of the assigned stent in the Ramus. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/13/2004 on ASA and clopidogrel. Repeat angiography on 09/24/2004 for recurrent angina without a functional ischemia study revealed a 73% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 2 ISR; no procedure was done." The patient returned on 10/01/2004 for elective treatment of the target lesion, which was reported by the investigator as a 95% restenosis. The Angiographic Core Lab reported an 88% in-stent restenosis on 10/01/2004. During the subsequent intervention, predilitation balloon angioplasty resulted in an unquantified dissection and aneurysm formation (without visible free peroration), as reported by with Core Lab. Two stents were successfully deployed in the Ramus. Per a follow-up report from the Angiographic Core Lab, repeat angiography on 12/17/2004 revealed a "significant aneurysm of the target vessel, distal to the study stent" and a recurrent 72% in-stent restenosis. A revascularization was not reported by the Core Lab or by the investigator on that date. On 09/09/2005 the patient underwent repeat angiography for recurrent angina. The Angiographic Core Lab reported a total occlusion of the target lesion in the Ramus and reported that a percutaneous intervention was performed in the LMCA and the LAD, described as a "protected LM PCI, status-post CABG." The investigator reported that only the LMCA was treated with a drug-eluting stent, and the intervention did not involve the target lesion or the target vessel.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-PTCA, 139 days post-procedure
			The patient is a 73 year-old woman with a history of hypertension and dyslipidemia who presented with CCS Class II angina. On 04/13/2004 she underwent the index procedure with placement of the assigned stent in the proximal LAD. The Angiographic Core Lab reported on a lesion in the mid LAD, revealing a 19% final residual stenosis with no dissection and TIMI 3 flow. The post-procedure course was complicated by nausea and emesis which resolved without treatment. The patient was discharged on 04/14/2004 on ASA and clopidogrel. Repeat angiography on 08/30/2004 for recurrent angina without a functional ischemia study revealed a 52% in-lesion restenosis in the mid LAD reported by the Angiographic Core Lab with the notation "type 1b ISR; PCI for ISR; TLR." An interventional catheterization report revealed a 70% de novo stenosis in the "proximal portion of the segment." The patient underwent successful balloon angioplasty and placement of a Cypher™ stent in the mid LAD, reported as a target vessel revascularization. On 02/23/2005 the CEC ruled the event met the criteria for a clinically driven target lesion revascularization.
----------		CYPHER™	Target Lesion Revascularization – PTCA, 666 days post-procedure
			The patient is a 53 year-old man with a history of an MI, a prior PCI, hypertension, hyperlipidemia and current smoking who presented with CCS Class 2 angina. On 04/15/2004 he underwent the index procedure with successful delivery of the assigned stent in the proximal LAD. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/16/2004. Repeat angiographies in 06/2004, 01/2005 and 06/2005 for recurrent angina all revealed a patent target lesion stent without significant restenosis, as reported by the Angiographic Core Lab. On 02/8/2006 he was readmitted with recurrent angina and underwent repeat angiography which revealed a site-reported 70% target lesion restenosis. On 02/10/2006, one stent was successfully deployed at the proximal edge of the study stent, per the investigator's report. The Angiographic Core Lab reported a 32% target lesion restenosis, and also noted thrombus in the target vessel and narrowing at the proximal edge of the stent, quantified as less than 50%.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization - PTCA, 244 days post-procedure
			The patient is a 73 year-old man with a history of diabetes, hypertension, hyperlipidemia, and former smoking who presented with CCS Class II angina. On 08/03/2004 he underwent the index procedure with successful delivery of the assigned stent in the proximal CX. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 08/04/2004. Repeat angiography on 4/4/2005 for recurrent angina revealed a 50.5% in-stent restenosis reported by the Angiographic Core Lab, with the note "moderate neointimal hyperplasia inside of study stent...PCI performed in target lesion." The patient underwent successful cutting balloon angioplasty and deployment of one drug-eluting stent in the proximal CX, per the investigator's report. He was discharged home on 04/05/2005 in good condition.
----------		CYPHER™	Target Lesion Revascularization - PTCA, 255 days post-procedure
			The patient is a 55 year-old woman with a history of a prior CABG, diabetes, hypertension, and hyperlipidemia who presented with unstable angina. On 07/13/2004 she underwent the index procedure with successful delivery of one assigned stent in the mid LAD. The investigator reported a 0% final residual stenosis with TIMI 3 flow and no dissection. Other than noting right groin pain with ambulation, the post-procedure course was uneventful and the patient was discharged on 07/15/2004. Protocol-mandated repeat angiography on 03/25/2005 in the setting of recurrent angina and a negative functional study revealed a 5% target lesion restenosis, as reported by the investigator. The Angiographic Core Lab reported a 52% restenosis at the distal stent margin, and noted a target lesion revascularization. Per an SAE form, "another lesion" was revealed by IVUS and was subsequently treated with the deployment of one stent. The Revascularization Form notes that only the mid LAD was treated, but it was also reported by the investigator that both a target lesion and a target vessel revascularization were performed. The patient was admitted overnight and was discharged on 03/26/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization – PTCA, 237 days post-procedure The patient is a 68 year-old woman with a history of hyperlipidemia and current smoking who presented with CCS Class III angina and a positive functional study. On 08/31/2004 she underwent the index procedure with successful delivery of the first assigned stent in the mid RCA. After placement, "it was noted there was plaque shifting distally," and a second identical study stent was deployed. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was complicated by persistent access site oozing. The patient remained in the hospital for an additional day to ensure the bleeding had ceased, prior to discharge on 09/2/2004. Protocol-mandated repeat angiography on 04/25/2005 in the absence of recurrent angina or a positive functional study revealed an 80% in-stent restenosis, as reported by the Angiographic Core Lab. The patient underwent a successful revascularization of the mid RCA target lesion, but details regarding the intervention were not supplied.
----------		CYPHER™	Target Lesion Revascularization–PTCA, 158 days post-procedure The patient is a 45 year-old man with a history of MI in 1998, hypertension, dyslipidemia and current smoking who presented with CCS Class III angina and a positive functional ischemia study. On 04/29/2004 he underwent the index procedure with placement of two assigned stents in the distal RCA. The second assigned stent was placed distal to the first assigned stent to stabilize the target lesion. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/30/2004 on ASA and clopidogrel. Repeat angiography on 10/04/2004 for recurrent angina without a functional ischemia study revealed a 60% in-stent restenosis in the target lesion, as reported by the Angiographic Core Lab. The patient underwent a percutaneous intervention during which one drug-eluting stent was successfully deployed in the distal RCA. The patient was discharged on 10/15/2004.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-PTCA, 46 days post-procedure
			The patient is a 65 year-old man with a history of current smoking who presented with CCS Class II angina. On 07/9/2004 he underwent the index procedure with placement of the assigned stent in the distal CX. The Angiographic Core Lab reported on a lesion in the proximal CX, revealing a 41% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "moderate stenosis left uncovered in the proximal study stent." The post-procedure course was complicated by hypotension (post morphine sulfate administration for sheath removal) which resolved with the infusion of IV fluids. The patient was discharged on 07/10/2004 on ASA and clopidogrel. Repeat angiography on 08/24/2004 for recurrent angina without a functional ischemia study revealed a 56% in-lesion restenosis in the proximal CX reported by the Angiographic Core Lab with the notation "progression of the residual lesion; type 1B ISR; PCI for ISR; TLR." An interventional catheterization report revealed "the proximal CX from the ostium for approximately 8mm to the previously placed stent contains an eccentric, bulky calcific 80% stenosis; the previously placed stent was without stenosis." The patient underwent direct Cypher™ stent placement in the proximal CX, reported as a target vessel revascularization. On 02/23/2005 the CEC ruled the event met the criteria for a clinically driven target lesion revascularization.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-PTCA, 153 days post-procedure
			The patient is a 63 year-old man with a history of hypertension and dyslipidemia who presented with CCS Class III angina and a positive functional ischemia study. On 04/13/2004 he underwent the index procedure with placement of the assigned stent in the R-PDA. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The patient was discharged on 04/15/2004. The patient experienced dizziness in the elevator post-discharge and was admitted later the same day for observation and hydration. The site reported CK enzymes were negative; laboratory work was within normal limits, and there were no reported ECG changes. The patient was discharged on 04/16/2004. Repeat angiography on 09/13/2004 for recurrent angina without a functional ischemia study revealed a 50.1% in-lesion restenosis reported by the Angiographic Core Lab with the notation "type 1B ISR." An interventional catheterization report revealed "the stent is widely patent, there is a 70% focal restenosis of the proximal margin... given recurrent symptoms revascularization of the ongoing LAD lesion and proximal RCA stent margin restenosis are indicated." The patient underwent revascularization in the R-PDA, mid LAD, 2nd diagonal and 1st OM The site reported a non-Q wave MI on 09/14/2004. The CK peaked at 313 (nl 266, ratio 1.1) with a CKMB of 23.8 (nl 5, ratio 4.7). Supplied ECGs reveal no major ST or T wave changes, and no evidence of a MI per reading by the ECG Core Lab.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-PTCA, 301 days post-procedure The patient is a 69 year-old woman with a history of hypertension and dyslipidemia who presented with CCS Class III angina. On 04/09/2004 she underwent the index procedure with placement of two assigned stents in the mid RCA. The second stent was placed to stabilize and fully cover the target lesion. The Angiographic Core Lab reported a 9% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/10/2004 on ASA and clopidogrel. On 02/04/2005 the patient had experienced recurrent chest pain and returned for the protocol repeat angiography. The investigator reported a widely patent target lesion with 10% in-stent stenosis and an "80% blockage just distal to [the] study stents." The Angiographic Core Lab reported a 54% in-lesion restenosis on 02/04/2005 and noted that a target lesion intervention had been performed. The investigator treated the distal lesion with balloon angioplasty and the deployment of one stent, which overlapped the more distal of the two index stents. The post-procedure course was uneventful and the patient was discharged on 02/05/2005.
----------		Endeavor	Target Lesion Revascularization -PTCA, 236 days post-procedure The patient is a 78 year-old man with a history of a MI in 1982, diabetes, hypertension, hyperlipidemia and former smoking who presented with CCS Class IV angina and a positive functional study. On 09/08/2004 he underwent the index procedure with successful delivery of the assigned treatment in the proximal CX. The Angiographic Core Lab reported an 11% final residual in-stent stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/09/2004. Protocol repeat angiography on 05/02/2005 in the setting of recurrent angina and a positive functional study revealed a 71% type 1C in-stent restenosis, as reported by the Angiographic Core Lab. The patient underwent successful balloon angioplasty and deployment of one stent in the proximal CX target site on 05/02/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization-PTCA, 200 and 368 days post-procedure
			The patient is a 60 year-old man with a history of hypertension, dyslipidemia and former smoking who presented with CCS Class II angina. On 06/25/2004 he underwent the index procedure with placement of the assigned stent in the 1st diagonal. The site reported a 0% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The Angiographic Core Lab reported a 45% final in-lesion residual stenosis with TIMI 3 flow and no dissection. The post-procedure course was uncomplicated and the patient was discharged on 06/26/2004 on ASA and clopidogrel. Protocol re-study on 01/11/2005 in the presence of recurrent angina and in the absence of a positive functional ischemia study revealed a site reported 90% restenosis versus the Angiographic Core Lab report of 74% in-stent restenosis. An interventional catheterization report revealed a "very long area of restenosis involving the stent in the first major diagonal to at least 90% with at least 70-80% stenosis extending beyond the proximal edge of the stent." The patient underwent successful balloon angioplasty and placement of a Taxus™ stent in the 1st diagonal, reported as a target lesion revascularization. On 06/28/2005 the patient underwent repeat angiography for recurrent angina, which revealed an 82% in-stent restenosis, as reported by the Angiographic Core Lab. The patient underwent successful balloon angioplasty and brachytherapy in the diagonal/LAD, reported as a target lesion revascularization by the Core Lab. An unspecified intervention was also performed in the RCA at that setting. No complications were reported and the patient was discharged the following day.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization – PTCA, 190 days post-procedure The patient is an 85 year-old man with a history of a prior a target vessel PCI in 1994, hyperlipidemia and former smoking who presented with CCS Class III angina. On 09/08/2004 he underwent the index procedure with successful delivery of the assigned treatment in the proximal LAD. The Angiographic Core Lab reported a 42% final residual in-lesion stenosis with no dissection and TIMI 3 flow. Twenty hours post-procedure, the CK peaked at 164 (nl 225, ratio <1) with a non-concurrent CKMB of 15.2 (nl 5.1, ratio 2.98). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The patient was discharged on 09/09/2004. Repeat angiography on 03/17/2005 for recurrent angina revealed a 71% in-stent restenosis, as reported by the Angiographic Core Lab. The patient underwent successful deployment of one stent in the proximal LAD on 03/17/2005. The post-procedure course was uneventful and the patient was discharged on 03/18/2005.
----------		Endeavor	Target Lesion Revascularization – PTCA, 190 days post-procedure The patient is a 68 year-old man with a history of a CABG, hypertension, and hyperlipidemia who presented with CCS Class II and a positive functional study. On 04/29/2004 he underwent the index procedure with successful delivery of the assigned stent in the proximal RCA. No procedural complications were noted and the Angiographic Core Lab reported a 2% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/30/2004. Repeat angiography on 11/05/2004 in the setting of recurrent angina and a positive functional study revealed a 58% in-stent restenosis, as reported by the Angiographic Core Lab. The investigator reported the occurrence of subacute closure of the target lesion on the Angiography Form. However, there was a maximum 90% restenosis per site report and there was no other documentation of target vessel occlusion. Only TIMI 3 flow was reported by the Core Lab. The patient underwent successful balloon angioplasty and deployment of one Taxus™ stent in the proximal RCA and was discharged the following day, on 11/06/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization - PTCA, 245 days post-procedure
			The patient is a 49 year-old woman with a history of hypertension, diabetes and dyslipidemia who presented with CCS Class IV angina and a positive functional ischemia study. On 06/01/2004 she underwent the index procedure with placement of the assigned stent in the mid LAD. The site reported a 0% final residual stenosis with no dissection and TIMI 3 flow. The Angiographic Core Lab reported an 8% final in-lesion residual stenosis with TIMI 3 flow and no dissection. The post-procedure course was uncomplicated and the patient was discharged in 06/02/2004 on ASA and clopidogrel. Protocol repeat angiography on 01/31/2005 in the presence of recurrent angina without a positive functional ischemia study revealed a 52% diameter in-stent restenosis of the target lesion, as reported by the Angiographic Core Lab. On 02/01/2005, the Core Lab reported a 58% restenosis of the lesion and the patient underwent balloon angioplasty and brachytherapy in the mid LAD, reported as a target lesion revascularization.

Site	Pt	Treatment Group	Case Summary
---------		CYPHER™	Target Vessel Revascularization – PTCA, 432 days post-procedure The patient is a 55 year-old man with a history of hypertension and hyperlipidemia who presented with CCS Class 4 angina and a positive functional study. On 07/07/2004 he underwent the index procedure with successful delivery of one assigned stent in the mid LAD. The Angiographic Core Lab reported an 8% final residual in-stent stenosis with no dissection and TIMI 3 flow. The CK peaked at 204 (nl 170, ratio 1.2) with a peak CKMB of 7.0 (nl 2.6, ratio 2.7). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The patient was discharged on 07/08/2004. Protocol-mandated repeat angiography on 03/14/2005 in the setting of recurrent CCS Class 2 angina revealed a 30% restenosis of the target lesion per the investigator's report. The proximal CX was treated at that setting with an unspecified PCI. On 09/12/2005 the patient underwent repeat angiography in the setting of recurrent angina and an abnormal stress test. Angiography revealed a site site-reported 85% stenosis in the proximal LAD, referred to as "progressive disease proximal to the previous stent." The Angiographic Core Lab reported a 13% target lesion restenosis on 09/12/2005 and noted that the patient underwent "PCI for proximal LAD lesion. Remote TVR." The patient's recovery was uneventful and he was discharged on 09/13/2005. On 04/19/2006, after undergoing an out-patient urological procedure, he presented to an outlying facility with severe chest pain and was diagnosed with a site-reported acute lateral wall Q-wave MI. On 4/20/2006 the peak CK was 3061 (nl 232, ratio 13.2) with a peak CKMB of 371.6 (nl 3.6, ratio 103). Per the investigator's report, he subsequently underwent PCI of the proximal CX. He developed recurrent chest pain and was urgently transferred to the investigative site where repeat angiography on 04/20/2006 revealed the study stent to be patent, per the Angiographic Core Lab. His medical therapy was maximized and he was subsequently discharged to home in stable condition.

Site	Pt	Treatment Group	Case Summary
	---------	CYPHER™	Target Vessel Revascularization-PTCA, 245 days post-procedure
			The patient is a 75 year-old woman with a history of MI, hypertension and dyslipidemia who presented with a positive functional ischemia study and no angina. On 04/13/2004 she underwent the index procedure with placement of the assigned stent in the mid RCA. The Angiographic Core Lab reported on a lesion in the distal RCA, revealing a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The CK peaked at 314 (nl 230, ratio 1.3) with a CKMB of 10.7 (nl 5, ratio 2.4). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The post-procedure course was uncomplicated and the patient was discharged on 04/16/2004 on ASA and clopidogrel. Protocol re-study on 12/14/2004 in the absence of recurrent angina or a functional ischemia study revealed a widely patent stent with a 19% in-lesion restenosis reported by the Angiographic Core Lab. However, per the investigator's report, there was "significantly advanced plaque burden" noted in the proximal RCA as well as an 80% proximal PDA stenosis. PTCA was successfully performed in the ostial and proximal PDA. Intravascular ultrasound then demonstrated ulcerated plaque and deterioration of the proximal RCA lesion which was stabilized with balloon angioplasty and the deployment of one Vision stent. The investigator reported no significant final residual stenosis, TIMI 3 flow and no dissection.
	---------	Endeavor	Target Vessel Revascularization - PTCA, 258 days post-procedure
			The patient is a 58 year-old man with a history of a hypertension and hyperlipidemia who presented with CCS Class III angina. On 09/15/2004 he underwent the index procedure with successful delivery of the assigned stent in the mid RCA. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/16/2004. Protocol-mandated repeat angiography on 05/31/2005 in the absence of angina or a positive functional study revealed a 60% in-stent restenosis at the proximal edge of the index stent, as reported by the Angiographic Core Lab, with the note "TLR as well as TVR; angioplasty and stent placement in CASS 1." The investigator reported a "70% lesion in the proximal, mid and distal" RCA, and noted that a stent was deployed to treat each lesion. No complications were reported and the patient was discharged the following day.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization-PTCA, 267 days post-procedure
			The patient is a 53 year-old man with a history of dyslipidemia who presented with CCS Class II angina and a positive functional ischemia study. On 03/15/2004 he underwent the index procedure with placement of the assigned stent in the mid LAD. The Angiographic Core Lab reported on a lesion in the proximal LAD, revealing a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The CK peaked at 259 (nl 225, ratio 1.15) with a CKMB of 28 (nl 16, ratio 1.75). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The post-procedure course was uncomplicated and the patient was discharged on 03/16/2004 on ASA and clopidogrel. Protocol re-study on 12/07/2004 in the absence of recurrent angina or a functional ischemia study revealed a 29% in-lesion restenosis in the mid LAD target lesion, as reported by the Angiographic Core Lab. The Core Lab made no comment regarding the occurrence or lack of revascularization. The site reported the "previous proximal [study] stent was patent" and noted a 75% stenosis in a more distal segment of the mid LAD. The patient underwent successful stent placement in the mid LAD.
----------		Endeavor	Target Vessel Revascularization-PTCA, 130 days post-procedure
			The patient is a 72 year-old man with a history of PCI of a non-target vessel, dyslipidemia, hypertension and former smoking who presented with a positive stress test and no angina. On 03/29/2004 he underwent the index procedure with placement of one assigned stent in the mid LAD. Following treatment of the target lesion and IVUS, a second assigned stent was deployed distal to the target lesion to treat a previously unrecognized 70% stenosis. The Angiographic Core Lab reported on a lesion in the proximal LAD, revealing 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/30/2004 on ASA and clopidogrel. Repeat angiography on 08/06/2004 for recurrent angina without a functional ischemia study revealed a 28% in-lesion restenosis in the proximal LAD reported by the Angiographic Core Lab with the note "study stent is patent." The patient underwent successful percutaneous revascularization in the 1st diagonal, reported as a target vessel revascularization.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization-PTCA, 129 days post-procedure
			The patient is a 51 year-old man with a history of MI in 1991, diabetes, dyslipidemia, hypertension and former smoking who presented with CCS Class III angina and a positive functional ischemia study. On 03/16/2004 he underwent the index procedure with placement of the assigned stent in the mid LAD. The Angiographic Core Lab reported a 27% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/17/2004 on ASA and clopidogrel. Repeat angiography on 07/23/2004 for recurrent angina with a positive functional ischemia study revealed a 28% in-lesion restenosis reported by the Angiographic Core Lab with the notation "study stent is patent." An interventional catheterization report revealed a "borderline significant lesion in the distal LAD." The patient underwent balloon angioplasty in the LAD, reported as a target vessel revascularization. The patient was discharged on 07/24/2004.
----------		Endeavor	Target Vessel Revascularization - PTCA, 242 days post-procedure
			The patient is a 75 year-old man with a history of recent MI on 03/04/2004, PCI of a non-target vessel, dyslipidemia, hypertension and prior smoking who presented with CCS Class IV angina and a positive functional ischemia study. On 03/04/2004 he underwent the index procedure with successful delivery of the assigned stent in the distal RCA. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The patient was discharged on 03/05/2004 on ASA and clopidogrel. Protocol re-study on 11/01/2004 in the presence of recurrent angina and in the absence of a functional ischemia study revealed a 21% in-stent restenosis reported by the Angiographic Core Lab. An interventional catheterization report revealed a 70% lesion in the mid RCA. The patient underwent successful balloon angioplasty and placement of a Taxus™ stent in the mid RCA, reported as a target vessel revascularization. IC NTG was administered during and after stent implantation to "alleviate intracoronary spasm and facilitate stent implantation."

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization-PTCA, 257 days post-procedure
			The patient is a 64 year-old man with a history of diabetes, hypertension, dyslipidemia and former smoking who presented with a positive functional ischemia study and no angina. On 03/18/2004 he underwent the index procedure with placement of the assigned stent in the proximal RCA. The Angiographic Core Lab reported a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/19/2004 on ASA and clopidogrel. Protocol re-study on 11/30/2004 in the presence of recurrent angina and a positive functional study revealed a 40% in-lesion restenosis reported by the Angiographic Core Lab with the notation " moderate residual lesion left distal to the segment of analysis; PCI for distal RCA; remote TLR." An interventional catheterization report noted a 90% stenosis in the R-PDA and a 70% lesion in the mid RCA. The patient underwent balloon angioplasty and placement of two Taxus™ stents in the R-PDA. A third Taxus™ stent was placed in the mid RCA. The site reported a target lesion/target vessel revascularization.
----------		Endeavor	Target Vessel Revascularization-PTCA, 196 days post-procedure
			The patient is a 75 year-old man with a history of diabetes, hypertension and former smoking who presented with CCS Class III angina and a positive functional ischemia study. On 05/14/2004 he underwent the index procedure with placement of the assigned stent in the mid LAD. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The CK peaked at 108 (nl 236, ratio <1) with a CKMB peak of 5.8 (nl 5, ratio1.16). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The post-procedure course was uncomplicated and the patient was discharged on 05/15/2004 on ASA and clopidogrel. Repeat angiography on 11/26/2004 for unstable angina without a functional ischemia study revealed a 16% in-lesion restenosis, as reported by the Angiographic Core Lab. The site reported "progression of disease in the mid LAD with a significant lesion beyond the previously placed stent." The 70% distal stenosis was treated with the deployment of one Taxus™ stent "with an excellent result." The investigator reported the intervention as a target vessel revascularization, which was confirmed by the Core Lab. The patient was discharged on 11/27/2004.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization – PTCA, 235 days post-procedure
			The patient is a 57 year-old man with a history of hypertension, dyslipidemia and current smoking who presented with CCS Class IV angina and a positive functional ischemia study. On 04/05/2004 he underwent the index procedure with placement of the assigned stent in the mid RCA. The site reported a 0% final residual stenosis with no dissection and TIMI 3 flow. The Angiographic Core Lab reported a final 27% in-lesion residual stenosis with TIMI 3 flow and no dissection. The Core Lab also noted that significant residual disease was left untreated in the distal RCA. The post-procedure course was uncomplicated and the patient was discharged on 04/06/2004 on ASA and clopidogrel. Protocol re-study on 11/26/2004 in the absence of recurrent angina or a functional ischemia study revealed a 35% diameter restenosis of the mid RCA target lesion, as reported by the Angiographic Core Lab. An interventional catheterization report revealed a new 80-90% stenosis in the distal RCA. The patient underwent direct stenting with two Taxus™ stents in the distal RCA, reported as a target vessel revascularization.
----------		Endeavor	Target Vessel Revascularization – PTCA, 259 days post-procedure
			The patient is a 69 year-old woman with a history of hypertension, dyslipidemia and former smoking who presented with CCS Class III angina. On 05/03/2004 she underwent the index procedure with placement of the assigned stent in the proximal RCA. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was complicated by a vasovagal episode which resolved with unspecified drug treatment. The patient was discharged on 05/04/2004 on ASA and clopidogrel. Protocol re-study on 01/17/2005 in the presence of recurrent angina and in the absence of a functional ischemia study revealed a 23% in-lesion restenosis reported by the Angiographic Core Lab. An interventional catheterization report revealed a "widely patent stent proximally and a distal 70% narrowing." The patient underwent direct stenting in the distal RCA with a Cypher™ stent and balloon angioplasty with Cypher™ stent placement in the distal CX. The patient was discharged on 01/18/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization – PTCA, 249 days post-procedure
			The patient is a 59 year-old man with a history of diabetes who presented with CCS Class IV angina. On 05/03/2004 he underwent the index procedure with placement of the assigned stent in the proximal LAD. The Angiographic Core Lab reported a 39% final in-lesion residual stenosis with no dissection and TIMI 3 flow, with the notation that a moderate stenosis remained distal to the analyzed segment. The post-procedure course was uncomplicated and the patient was discharged on 05/04/2004 on ASA and clopidogrel. Protocol re-study on 01/07/2005 in the absence of recurrent angina or a functional ischemia study revealed a site reported 0% diameter stenosis of the target lesion. The Angiographic Core Lab reported a 36% stenosis in the target lesion and "progression of the mid LAD lesion...TVR." The site quantified the mid LAD stenosis as 90% at the take-off of the 1st diagonal, and also reported a 65% stenosis in the proximal CX. The patient underwent revascularization and placement of Cypher™ stents in the mid LAD, the 1st diagonal and proximal CX. The post-procedure course was uneventful and the patient was discharged on 01/08/2005.
----------		Endeavor	Target Vessel Revascularization – PTCA, 185 days post-procedure
			The patient is a 71 year-old woman with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class IV angina and a positive functional ischemia study. On 03/29/2004 she underwent the index procedure with placement of the assigned stent in the mid LAD. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/30/2004 on ASA and clopidogrel. Repeat angiography on 09/20/2004 for recurrent angina without a functional ischemia study revealed a 16% in-lesion restenosis reported by the Angiographic Core Lab. The site reported a "75% mid/distal [stenosis] beyond stent." Additional angiography on 09/30/2004 revealed a 22% in-lesion restenosis reported by the Angiographic Core Lab with the notation "study stent is patent; PCI for CASS 14." The patient underwent balloon angioplasty and placement of an Express stent in the distal LAD, reported as a target vessel revascularization.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization-PTCA, 257 days post-procedure The patient is a 54 year-old man with a history of hypertension and current smoking who presented with a positive functional study. On 07/21/2004 he underwent the index procedure for treatment of a newly-revealed lesion in the distal RCA. Pre-treatment balloon angioplasty resulted in a site-reported Grade F dissection with associated TIMI 0 flow, chest pain, hypotension, bradycardia and ischemic ECG changes. An eptifibatide infusion was started. The assigned stent was successfully delivered to the target lesion, and two additional assigned stents were deployed proximally to stabile the dissection. The investigator reported abrupt closure, slow or no reflow and coronary artery spasm during the procedure. The Angiographic Core Lab reported a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow. On 07/22/2004 the patient was discharged on aspirin and clopidogrel. Protocol re-study on 04/04/2005 without the presence of angina and without a positive functional ischemia study revealed a 30% in-lesion restenosis reported by the Angiographic Core Lab with the notation "remote target vessel revascularization, angioplasty and stent placement in the proximal RCA." The site reported an 80% lesion in the proximal RCA and noted "restenosis in the target vessel at site of bailout stent." The patient underwent repeat revascularization with balloon angioplasty and placement of one Taxus™ Stent in the proximal RCA. A narrative noted that the patient experienced ventricular asystole during the catheterization procedure and defibrillation with "combo pads" was performed. The site reported elevated cardiac enzymes with two post-procedure readings. On 04/05/2005 at 06:20 the CK peaked at 1136 (nl 170, ratio 6.7) with a CKMB of 11.1 (nl 4, ratio 2.8). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The site reported the patient remained hospitalized for an additional day.

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	Target Vessel Revascularization -PTCA, 248 days post-procedure The patient is a 42 year old with a history of CABG surgery in a non-target vessel, hypertension, dyslipidemia and current smoking who presented with CCS Class III angina. On 04/26/2004 he underwent the index procedure with placement of one assigned stent in the mid RCA. The site reported a 0% final residual stenosis with no dissection and TIMI 3 flow. The Angiographic Core Lab reported a final 21% in-lesion residual stenosis with TIMI 3 flow and no dissection, and noted that the target lesion was in the mid portion of the mid RCA. The post-procedure course was uncomplicated and the patient was discharged on 04/27/2004 on ASA and clopidogrel. On 12/28/2004 the patient underwent protocol-mandated repeat angiography in the absence of angina or a positive functional study. Angiography revealed a 13% target lesion restenosis, per the Angiographic Core Lab, and the occurrence of an intervention was neither confirmed nor denied. Site-supplied catheterization and interventional reports noted a 75% stenosis in the proximal RCA and an 80-85% de novo stenosis in the mid portion of the mid RCA. An intervention was not performed on 12/28/2004, but on 12/30/2004, one Vision stent was successfully deployed in the proximal RCA, and one Cypher™ stent was successfully delivered to the mid RCA lesion. The investigator reported a 0% residual stenosis in both stents, but cines from the 12/30/2004 intervention were not available for submission to the Core Lab. At the conclusion of the intervention an AV fistula between the right femoral artery and vein was noted. On follow-up on 1/12/2005 a bruit was reported over the right femoral access site and an ultrasound study was subsequently performed. On 01/13/2005 the patient was admitted and underwent a surgical repair of the right femoral AV fistula. The post-operative course was uneventful and the patient was discharged on 01/14/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization – PTCA, 625 days post-procedure
			The patient is a 79 year-old woman with a history of prior CABG surgery in a non-target vessel, dyslipidemia and former smoking who presented with CCS Class III angina. On 04/27/2004 she underwent the index procedure with placement of the assigned stent in the distal CX. The Angiographic Core Lab reported a 9% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/28/2004 on ASA and clopidogrel. Repeat angiography on 10/19/2004 for recurrent angina without a functional ischemia study revealed a 45% in-lesion restenosis reported by the Angiographic Core Lab with the notation "DS<50% in the segment of analysis; PCI performed in the study stent/balloon; moderate neo-intimal hyperplasia inside of the study stent." She underwent percutaneous intervention in the distal CX, reported as a target lesion revascularization. The patient was discharged on 10/20/2004. The Clinical Events Committee ruled that the intervention was not clinically driven. The patient was admitted with recurrent angina and weakness on 01/06/2006. Repeat angiography revealed a 36% target lesion restenosis, per the Angiographic Core Lab, and the investigator reported a "significant lesion of the left main." She was discharged, subsequently readmitted on 01/12/2006 and underwent an "elective PCI with DES" of LMCA.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization-PTCA, 708 days post-procedure The patient is a 78 year-old man with a history of a PCI in a non-target vessel, hypertension and hyperlipidemia who presented with stable angina without a positive functional study. On 07/08/2004 he underwent the index procedure with successful delivery of the assigned treatment in the distal LAD. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 07/09/2004. He presented to an outlying hospital on 06/10/2006 with chest pain. Cardiac enzymes were negative and an echo cardiogram was reported as unremarkable. Diagnostic repeat angiography on 06/12/2006 for recurrent angina revealed a 20% target lesion restenosis reported by the investigator. The patient was transferred to a second facility and on 06/16/2006, and underwent an unspecified percutaneous intervention in the 2nd diagonal, per the investigator's report. The Angiographic Core Lab reported a 37% target lesion restenosis on 6/16/2006 and noted "moderate neointimal hyperplasia. Remote TVR of mid LAD and 2nd diagonal."
----------		Endeavor	Target Vessel Revascularization – PTCA, 491 days post-procedure The patient is a 67 year-old man with a history of a MI in 1969, hypertension, hyperlipidemia and former smoking who presented with CCS Class 3 angina. On 09/13/2004 he underwent the index procedure with successful delivery of the assigned treatment in the mid LAD. The Angiographic Core Lab reported on a lesion in the proximal LAD and noted a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/14/2004. Repeat angiography on 01/17/2006 for recurrent angina revealed a 26% in-stent restenosis, as reported by the Angiographic Core Lab with the note, "Remote TVR. The new deployed stent comes over segment of analysis." The investigator reported an unquantified de novo lesion in the distal LAD, unrelated to the prior stent placement.

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	Target Vessel Revascularization -PTCA, 253 days post-procedure
			The patient is a 68 year-old man with a history of hypertension, dyslipidemia and current smoking who presented with CCS Class III angina and a positive functional study. On 07/01/2004 he underwent the index procedure for treatment of a lesion in the mid RCA which was complicated by a grade B dissection after pre-dilitation, as reported by the investigator. Two assigned stents were successfully deployed, the first for primary treatment of the target lesion and the second to stabilize the proximal dissection. The Angiographic Core Lab reported a 7% final residual in-lesion stenosis with no dissection and TIMI 3 flow. Other than an episode of chest pain that was responsive to drug treatment, the post-procedure course was uneventful and the patient was discharged on 07/02/2004 on aspirin and clopidogrel. On 03/10/2005 the patient was without angina or a positive functional ischemia study and underwent the protocol-mandated 8-month repeat angiography. The Angiographic Core Lab reported a 9% in-lesion restenosis on 03/10/2005. Per the investigator's report, a significant lesion distal to the widely patent target lesion stent was also revealed which was note reported by the Core Lab. The following day, on 03/11/2005, the patient underwent balloon angioplasty and the deployment of at least one stent to treat lesions in both the proximal and distal RCA per site report, reported as a target vessel revascularization by the Core Lab. The patient was discharged on 03/12/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization - PTCA, 239 days post procedure
			The patient is a 51 year-old man with a history of diabetes, hyperlipidemia and former smoking who presented with CCS Class IV angina and a positive functional study. On 07/13/2004 he underwent the index procedure with successful delivery of two assigned stents in the mid LAD. The Angiographic Core Lab reported a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 07/14/2004. On 03/09/2005 the patient was without angina or a positive functional study and underwent the protocol-mandated repeat angiography. The Angiographic Core Lab reported a 41% restenosis and noted "study stent patent, mild neointimal hyperplasia; significant stenosis distal to the segment of analysis. Remote TVR." The investigator reported the lesion in the distal LAD to contain a 75% stenosis by angiography, but 90% by IVUS. During IVUS interrogation of the lesion, the patient developed chest pain and ST elevations that were unresponsive to NTG. A Taxus™ drug-eluting stent was emergently and successfully deployed to treat the distal lesion, and balloon angioplasty was performed within the target lesion to treat a site-reported 50% restenosis. The patient was observed overnight and was discharged on 03/10/2005.

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	Target Vessel Revascularization-PTCA, 7 days post-procedure
			The patient is a 53 year-old man with a history of prior CABG in non-target vessel, diabetes, dyslipidemia, hypertension and former smoking who presented with CCS Class III angina. On 04/19/2004 the patient underwent an attempted index procedure in the distal RCA. Pre-dilation of the target lesion was performed. The site reported an inability to cross the lesion with two 3.0 mm diameter assigned stents, first an 18 mm, followed by a 13 mm. An unsuccessful attempt was then made to deliver a non-study drug-eluting stent to the lesion, and success was finally achieved when a bare metal 3.0 x 18 mm stent was successfully deployed. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/20/2004 on ASA and clopidogrel. Repeat angiography on 04/26/2004 for recurrent angina without a functional ischemia study revealed a 5% in-lesion restenosis reported by the Angiographic Core Lab with the notation "study stent patent; PCI through SVG for PDA lesion; non-target vessel revascularization." The patient underwent the successful deployment of one Taxus™ stent in the R-PDA for treatment of a site-reported a 75% stenosis. The patient was discharged on 04/28/2004.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization – PTCA, 277 days post-procedure; CVA, 185 days post-procedure The patient is a 67 year-old woman with a history of MI in 2004, hypertension, dyslipidemia and current smoking who presented with CCS Class IV angina. On 06/04/2004 she underwent the index procedure with placement of the assigned stent in the mid RCA. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/06/2004 on ASA and clopidogrel. On 12/02/2004 the patient underwent bilateral angioplasty and stenting in the right and left common iliac arteries. Post-procedure, lethargy was noted after morphine administration for leg pain. She was discharged home on 12/03/2004 on continuing ASA and clopidogrel. Her family noted the patient continued to be sleepy and lethargic over several days and also had difficulty with sentence completion and word finding. On 12/06/2004 she was rehospitalized. A MRI scan revealed a left putamen territory infarct. An electroencephalogram revealed slowing in the left brain pathways, but no epilepsy patterns. A head CT scan revealed "mild cerebral atrophy and small vessel ischemic disease; no acute intracranial pathology is identified." Carotid studies did not reveal "any significant abnormalities." On 12/06/2004 she was discharged home with continuing speech therapy. On 01/31/2005 the Angiographic Core Lab reported a 18% in-lesion restenosis in the mid RCA. On 03/08/2005 the patient underwent repeat angiography in the setting of two to four weeks of recurrent chest pain. Angiography revealed a widely patent target lesion with "progression of RCA stenosis." The proximal RCA was treated on 03/08/2005 with the successful deployment of one stent. The post-procedure course was uneventful and the patient was discharged on 03/09/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization – PTCA, 266 days post-procedure
			The patient is a 44 year-old man with a history of dyslipidemia and current smoking who presented with CCS Class II angina and a positive functional ischemia study. On 04/29/2004 he underwent the index procedure with placement of the assigned stent in the proximal LAD. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The patient was discharged on 04/30/2004 on ASA and clopidogrel. Protocol re-study on 01/10/2005 in the presence of recurrent angina and in the absence of a functional ischemia study revealed a 14% in-lesion stenosis with the note "study stent is patent." An interventional catheterization report revealed an "80% mid LAD stenosis distal to the patent stent." An intervention was recommended. On 01/20/2005 additional angiography revealed a 13% in-lesion stenosis with the notation "target vessel revascularization was done distal" to the study stent. He underwent balloon angioplasty and placement of a Taxus™ stent in the proximal LAD, reported as a target vessel revascularization. In addition, the catheterization report revealed a 70-80% narrowing at the bifurcation of the principal diagonal branch. Post-angioplasty, a 10% stenosis remained at the bifurcation. A "very hard" calcified lesion was reported, which did not fully dilate despite 20 atmospheres of balloon. The diagonal suffered some "snowplow effect" and "kissing balloon angioplasty restored diagonal flow to normal" TIMI 3 flow.
----------		CYPHER™	Target Vessel Revascularization–PTCA, 262 days post-procedure
			The patient is a 51 year-old man with a history of hypertension, diabetes, dyslipidemia and former smoking who presented with CCS Class III angina. On 04/19/2004 underwent the index procedure with placement of the assigned stent in the mid LAD. The Angiographic Core Lab reported a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/20/2004 on ASA and clopidogrel. Protocol re-study on 01/06/2005 in the presence of recurrent angina and in the absence of a functional ischemia study revealed a 26% in-lesion restenosis reported by the Angiographic Core Lab with the notation "PTCA and stent placement of non-target lesion; distal LAD as well as proximal RCA." The investigator confirmed that successful balloon angioplasty and stent placement was performed in the distal LAD and RCA. The patient was discharged on 01/07/2005.

Site	Pt	Treatment Group	Case Summary
----------		Endeavor	Target Vessel Revascularization-PTCA, 244 days post-procedure
			The patient is a 67 year-old man with a history of hypertension and dyslipidemia who presented with CCS Class I angina and a positive functional ischemia study. On 05/14/2004 she underwent the index procedure with delivery of the assigned stent in the proximal RCA. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/15/2004 on ASA and clopidogrel. Protocol re-study on 01/13/2005 for possible chest pain (present per a supplied Procedure Report, but denied on Angiography Form) revealed a 24% in-lesion restenosis reported by the Angiographic Core Lab with the notation "angioplasty and stent placement in non-target lesion CASS 2." The patient underwent balloon angioplasty and deployment of one Taxus™ stent in the distal RCA for treatment of a site-reported 80-89% "tubular lesion," reported as a target vessel revascularization.
----------		Endeavor	Target Vessel Revascularization-PTCA, 261 days post-procedure
			The patient is an 80 year-old woman who presented with CCS Class I angina and a positive functional ischemia study. On 06/07/2004 she underwent the index procedure with placement of the assigned stent in the mid LAD. The Angiographic Core Lab reported on a lesion in the proximal LAD, revealing a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/08/2004 on ASA and clopidogrel. On 02/23/2005 the patient had been free of chest pain and underwent the 8-month protocol repeat angiography which revealed a 36% restenosis of the target lesion, per the Angiographic Core Lab. A new significant lesion was revealed in the distal LAD which was successfully treated with an unspecified percutaneous intervention, per the site report. The patient experienced an episode of ventricular fibrillation during the procedure and was successfully defibrillated. Chest pain and ST elevations were denied. Eight hours post-procedure, the CKMB was elevated to 15.9 (nl 2.1, ratio 7.6). CK levels were not measured. The event was reported in the Discharge Summary as a non-Q wave MI. The patient was discharged on 02/25/2005 in stable condition.

Site	Pt	Treatment Group	Case Summary
----------		CYPHER™	CVA, 569 days post-procedure
			The patient is a 83 year-old man with a history of diabetes, hypertension, hyperlipidemia and former smoking who presented with CCS Class II angina. On 07/26/2004 s/he underwent the index procedure with successful delivery of the assigned treatment in the proximal LAD. The Angiographic Core Lab reported a 6% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 07/27/2004. In February 2006 (exact date unknown) while the patient was on vacation, he experienced left-sided weakness and presented to a local hospital. Although detailed records are not available to the investigator, the patient was reported to have had altered mental status with sensory, motor and coordination deficits which involved the upper and lower extremities. Unspecified residual deficits were present five months after the acute event, per a member of the patient's family.

Event censored due to prior not clinically driven intervention

Site	Patient	Treatment Group	Case Summary
----------		Endeavor	Target Lesion Revascularization – PTCA, 294 days post-procedure, subsequent PCI to non target lesion The patient is a 53 year-old man with a history of diabetes, dyslipidemia, hypertension and former smoking who presented with CCS Class III angina. On 05/12/2004 he underwent the index procedure with placement of the assigned stent in the distal CX, per site report. The Angiographic Core Lab, referring to the L-AV as the target lesion, reported a 31% final residual in-lesion stenosis with no dissection and a final TIMI 2 flow. The CK peaked at 218 (nl 236, ratio <1) with a CKMB peak of 7.1 (nl 5, ratio 1.4); The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The post-procedure course was otherwise uncomplicated and the patient was discharged on 05/13/2004 on ASA and clopidogrel. Repeat angiography on 7/21/2004 for recurrent angina without a functional ischemia study revealed a 46% in-lesion restenosis in the 3rd OM reported by the Angiographic Core Lab with the notation "type 2 ISR; PCI for ISR: TLR." The site reported a 55% in-stent restenosis and a 75% restenosis "proximal to study stent." The patient underwent balloon angioplasty and placement of an Express™ stent in the distal CX, reported as a target lesion revascularization. (The Clinical Events Committee, on 2/23/2005, determined that the intervention was not clinically driven.) On 03/1/2005 the patient presented with recurrent CCS Class III angina and dyspnea on exertion. Repeat angiography on 03/02/2005 revealed an 82% restenosis of the target lesion, per the Angiographic Core Lab. Two Taxus™ Express stents were successfully deployed in the distal CX, per the investigator. Serial cardiac enzymes were within normal limits and the patient was discharged the following day. He was readmitted on 04/04/2005 with chest pain and underwent revascularization of the LAD on 04/05/2005 with the deployment of one stent.

Listing 1. Detailed Patient Listing

Appendix A: Methods for Qualifying Angiograms

Ascertainment of Qualifying Angiograms

1. Identify patients in the angiographic subset.
2. Identify experimental lesions in the angiographic subset; discard non-experimental lesions:
    a. Compare post and pre films to see if the CASS numbers match;
    b. Compare the FU with baseline. If any CASS numbers do not match, then issue query and await resolution.
3. Reconcile duplicate QCA readings or inappropriate QCA readings (e.g., follow-up reads on baseline CRF's). The angiographic core laboratory will receive queries regarding duplicate or inappropriate QCA readings. Once the readings are reconciled, the duplicate or inappropriate readings will be discarded.
4. Perform all analyses as lesion-based, NOT patient or vessel-based.
5. Exemptions from Angiographic F/U:
    a. Intent to Treat analyses:
        i. Peri-procedural CABG (within 14 days);
        ii. Death before F/U QCA due in the absence of a qualifying angiogram.
    b. Per-protocol analyses:
        i. Patients who withdraw consent for further follow-up, including angiograms;
        ii. Lesion never successfully treated with assigned device strategy.
6. Define the upper window that will be acceptable for qualifying angiograms. Three Hundred Sixty (360) days is the upper window for 8-month follow-up.
7. All QCA ≤ 14 days post-procedure and instances of subacute closure will not be included for analysis of restenosis.
8. All QCA after any TVR (clinically indicated or NOT) that occurs >14 days post-procedure are censored; TVR changes natural history of the lesion. TVRs occurring within the first 14 days post-procedure should NOT be used for excluding subsequent QCA's (unless it's a CABG, which exempts the patient).
9. Define a date cut-off as the earliest acceptable date for qualifying angiograms:
    a. One Hundred Fifty (150) days is the cut-off for 8-month follow-up.
    b. If QCA between days 15-150 and in-segment QCADS ≥70%, angiogram qualifies as restenosis.
    c. If QCA between days 15-150 and in-segment QCADS <50% and NO clinically-driven TLR occurred within a reasonable time window (vide infra), the angiogram is censored.
    d. If QCA between days 15-150 and in-segment QCADS <50% but is associated with a TLR that the CEC has deemed clinically-driven (despite the fact that the QCADS <50%), then this angiogram should be considered *qualified* and should NOT be censored. This lesion will have undergone a clinically-driven TLR in the absence of angiographic restenosis.
    e. If QCA between days 15-150 and in-segment QCADS 50-69.9% and a TVR (clinically indicated or NOT) occurs within a reasonable time window (e.g., 30 days after the QCA), the angiogram qualifies as restenosis.
    f. If QCA between days 15-150 and QCADS 50-69.9% and NO TVR occurs within a reasonable time window, the angiogram is censored.
10. In case of multiple qualifying angiograms, first take the one associated with TVR and/or TLR, whichever occurs first, then use the one closest to the follow-up date, and then take the latest one (to allow for vessel remodeling).
11. If a QCA has an in-lesion diameter stenosis which qualifies (e.g., in-lesion DS 53% with TVR at day 60), then the entire angiogram should qualify, even if the in-stent diameter stenosis <50%.
12. If the in-lesion MLD is 0 (total occlusion) upstream (proximal to) the experimental stent, then the in-stent MLD should be set to zero. The two situations where in-stent MLD is not zero (even if in-lesion MLD is zero) are in cases where no stent was deployed during the index procedure or where the total occlusion is distal to the stent (in which case the in-stent MLD should be available and >0).

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APPENDIX 5

Endeavor IV 9 Month Report

(Table 27. Detailed Patient Listing was Provided Electronically to FDA)

A Randomized, Controlled Trial of the Medtronic Endeavor Drug (ABT-578) Eluting Coronary Stent§ System versus the Taxus™ * Paclitaxel-Eluting Coronary Stent System in *De Novo* Native Coronary Artery Lesions

The ENDEAVOR IV Study

8/9-Month Report

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Date:	August 29, 2007
Version:	1.3 FINAL

This report has undergone the quality control process at HCRI.

§Endeavor Zotarolimus-Eluting Coronary Stent System.
*Taxus is a trademark of the Boston Scientific Corporation.

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Section I: Primary Results

Structured Abstract

Title: A Randomized, Controlled Trial of the Medtronic Endeavor Drug (ABT-578) Eluting Coronary Stent System versus the Taxus Paclitaxel-Eluting Coronary Stent System in *De Novo* Native Coronary Artery Lesions.

Design: The ENDEAVOR IV Trial was a prospective, multi-center, randomized, two-arm, single-blind trial. The Endeavor Zotarolimus-Eluting Coronary Stent System (Endeavor) is intended for use in patients with symptomatic ischemic heart disease due to *de novo* stenotic lesions of native coronary arteries with a RVD between 2.5 mm and 3.5 mm and lesion length ≤27 mm that are amenable to percutaneous treatment with stenting.

Purpose: The primary objective of this study was to assess the non-inferior safety and efficacy of the Endeavor stent when compared to the Taxus Paclitaxel-Eluting Coronary Stent System (Taxus) for the treatment of single *de novo* lesions in native coronary arteries with a reference vessel diameter of 2.5-3.5 mm.

Enrollment: A total of 1,548 subjects were enrolled in this trial. The trial had a proposed randomization ratio of 1:1. The Endeavor arm enrolled 773 subjects and the Taxus arm enrolled 775 subjects. This study enrolled an angiographic and intravascular ultrasound (IVUS) cohort consisting of 328 consecutively enrolled subjects from all participating study sites.

Clinical Sites: This trial was conducted at 80 study sites across the United States.

Methods: Baseline clinical and angiographic data were collected on standardized case report forms by study personnel at the clinical sites. Clinical follow-up assessments were performed during follow-up visits/assessments at 30 days and 6 and 9 months post-procedure Additional follow-up assessments are to be performed at 12 months and then annually for 5 years from the index procedure.

An independent Angiographic Core Laboratory and an independent IVUS Core Laboratory analyzed all baseline angiograms and IVUS images. Follow-up angiography and IVUS evaluations were scheduled at 8 months for the first 328 consecutively patients enrolled. Angiographic films were qualified at follow-up based on the qualification scheme in Section IV. The results of the analysis of these data are included in this report. An additional subset of subjects had treatment of the target lesion with 2 or more stents during the index procedure. These subjects were also required to have angiographic and IVUS evaluations immediately post-procedure and at 8 month post-procedure. The results of the analysis of the data from this subgroup will be presented in the 12-month report.

The primary endpoint to be evaluated in this non-inferiority study is target vessel failure (TVF) rate at 9 months post-procedure. Specifically, the null (H_o) and alternative (H_a) hypotheses are:

$$H_o: \pi_A \geq \pi_C + \delta$$
$$H_a: \pi_A < \pi_C + \delta$$

Where π_A is the true TVF rate for the Endeavor stent and π_C is the true TVF rate for the control stent (Taxus stent), and delta (δ) signifies the pre-specified non-inferiority limit of 3.8%

Additionally, the Angio/IVUS subset cohort was used to test the hypothesis of non-inferiority of in-segment late loss at 8 months. Specifically, the null (Ho) and alternative (Ha) hypotheses are:

$$H_o: \mu_{Endeavor} \geq \mu_{Taxus} + \delta$$
$$H_a: \mu_{Endeavor} < \mu_{Taxus} + \delta$$

Where $\mu_{Endeavor}$ is the mean in-segment late lumen loss for Endeavor and μ_{Taxus} is the mean in-segment late lumen loss for the control stent, Taxus and $\delta = 0.2$ mm was the non-inferiority margin.

Additional, pre-specified secondary endpoints for this study were:
1) Acute success (device, lesion, and procedure);
2) 8-month in-stent and in-segment angiographic measures of:
   a) Percent diameter stenosis (%DS);
   b) Late lumen loss;
   c) Late loss index;
   d) Angiographic binary restenosis (ABR) rate;
   e) Minimum luminal diameter (MLD);
3) Major adverse cardiac event (MACE) rate at 30 days, 6, 9, and 12 months post-procedure;
4) Neointimal hyperplastic volume and percent volume obstruction (%VO) at 8 months post-procedure as measured by intravascular ultrasound (IVUS);
5) Clinically-driven target lesion revascularization (TLR) rate at 9 months post-procedure;
6) Clinically-driven target vessel revascularization (TVR) rate at 9 months post-procedure.

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Demographics: The baseline demographics and clinical characteristics of the 1548 subjects enrolled in the study are reported in Section III, Table 3. In the Endeavor arm the mean age of the subjects was 63.5 years compared with 63.6 years in the Taxus arm. In the Endeavor arm 66.9% (517/773) of the subjects were male compared with 68.5% (531/775) in the Taxus arm. In the Endeavor arm 28.2% (218/773) of subjects had prior percutaneous coronary revascularization compared with 29.5% (229/775) of subjects in the Taxus arm. In the Endeavor arm 31.2% (241/773) of subjects had a history of diabetes mellitus compared with 30.5% (236/775) of subjects in the Taxus arm. No statistically significant differences were observed in any of the baseline demographics and clinical characteristics measured.

Results:

Clinical Results

The primary endpoint of this study was TVF at 9 months post-procedure. In the Endeavor arm the TVF rate was 6.8% (50/740) compared with 7.4% (54/734) in the Taxus arm. The upper limit of the 90% Confidence Interval of the difference is 1.6% (Table 12) and is below the protocol specified non-inferiority margin of 3.8%. The p-value of the test of the null hypothesis that the TVF rate in the Endeavor arm is greater than in the Taxus arm was 0.0005. Therefore, the non-inferiority of Endeavor to Taxus with respect to TVF rate was demonstrated in this study.

The upper limit of the 95% Confidence Interval is below the protocol specified non-inferiority

The results of the statistical tests comparing MACE and TVF rates between the two treatment arms are summarized below and in Table 1a. In-hospital MACE and MACE and TVF rates at 30 days were statistically significantly different between the treatment arms while the rates at 180 and 270 days were not.

1. The in-hospital MACE rate in the Endeavor arm was 0.9% (7/773) compared with 2.6% (20/775) in the Taxus arm (p=0.018).
2. The cumulative MACE rate at 30 days in the Endeavor arm was 1.2% (9/770) compared with 3.0% (23/771) in the Taxus arm (p=0.019).
3. The TVF rate at 30 days in the Endeavor arm was 1.0% (8/770) compared with 3.0% (23/771) in the Taxus arm (p=0.010).
4. The MACE rate at 6 months post-procedure in the Endeavor arm was 3.0% (23/766) compared with 4.3% (33/759) in the Taxus arm (p=0.175).
5. The MACE rate at 9 months post-procedure in the Endeavor arm was 5.7% (42/740) compared with 5.7% (42/734) in the Taxus arm (p=1.0)
6. The TLR rate at 9 months in the Endeavor arm was 4.2% (31/740) compared with 2.7% (20/734) in the Taxus arm (p=0.154).
7. The TVR rate at 9 months in the Endeavor arm was 5.5% (41/740) compared with 5.0% (37/734) in the Taxus arm (p=0.727)

Procedural-related Results

No statistically significant differences were observed between arms with respect to the rate of lesion success, device success and device-specific procedure success. The results were as follows:

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1. The lesion success rate in the Endeavor arm was 99.6% (767/770) compared with 99.2% (766/772) in the Taxus arm.
2. The device success rate in the Endeavor arm was 97.3% (751/772) compared with 97.9% (757/773) in the Taxus arm.
3. The device-specific procedure success rate, defined as device success and no in-hospital MACE, was 96.5% (745/772) in the Endeavor arm compared with 95.6% (739/773) in the Taxus arm.

A statistically significant difference was observed in the procedure success rates in the two treatment arms. The procedure success rate in the Endeavor arm was 98.7% (760/770) compared with 96.8% (747/772) in the Taxus arm (p=0.015).

Safety Results
Through 270 days, 773 subjects randomized to the Endeavor stent experienced a total of 606 (78.4%) adverse events. Similarly, 775 subjects randomized to the Taxus stent experienced a total of 616 adverse events (79.5%) through 270 days. A total of 270 serious adverse events were reported for each the Endeavor and Taxus arms (34.9% and 34.8% respectively) through 270 days. No new safety concerns were identified during this study and the safety profile remains consistent between the two subject populations.

Angiographic and IVUS Results
Of the 328 subjects enrolled in the angiographic/IVUS cohort, qualifying 8 month angiograms were available for 85.1% (279/328) of the subjects; Neointimal hyperplastic volume and percent volume obstruction obtained from the 8 months IVUS were available for 46% (151/328) of the subjects.

8-Month Follow-up In-Segment Late Loss (mm)

Two statistical tests were performed for in-segment late loss. The first (Table 6a) tested the null hypothesis that the mean in-segment late-loss was the same in the two treatment groups. The 95% Confidence Interval of the difference and the p-value for this test are presented below. The mean in-segment late-loss in the Taxus arm was statistically significantly lower than in the Endeavor arm (p=0.023).

	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
Mean±SD (n)	0.36±0.47 (143)	0.23±0.45 (135)	0.30±0.46 (278)	0.13 [0.02, 0.23]	0.023
Range (Min,Max)	(-0.48,1.90)	(-0.78,2.45)	(-0.78,2.45)		

The number of subjects with evaluable angiographic/IVUS data for each parameter is reported in parentheses.

In addition, the secondary objective of demonstrating non-inferiority of Endeavor to Taxus with respect to in-segment late loss was tested using a standard non-inferiority hypothesis test (Table 12). The p-value for testing the null hypothesis that Endeavor is inferior to Taxus with respect to

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in-segment late loss was 0.0890 and the upper limit of the 90% Confidence Interval for the difference was 0.22. Therefore the inferiority hypothesis could not be rejected and the secondary endpoint was not met.

The post-procedure angiographic and the 8-month in-stent and in-segment angiographic binary restenosis rates are presented in Table 1a. None of the differences between the treatment arms were statistically significant with respect to these parameters.

Summary of Results

The primary objective of the ENDEAVOR IV study was to assess the non-inferior safety and efficacy of the Endeavor stent when compared with the Taxus stent for the treatment of single *de novo* lesions in native coronary arteries with a reference vessel diameter of 2.5-3.5 mm. Study results show that the two treatment arms were comparable with respect to baseline demographics and clinical characteristics. Clinical data were available on 99.5% (N=1541), 98.5% (N=1525), and 95.2% (N=1474) of subjects at 30, 180, and 270 days, respectively (Table 1a). Baseline quantitative coronary analysis (QCA) was performed in 99.9% (N=1546) of subjects. For the Angiographic/IVUS cohort, 85.1% (279/328) of the subjects had follow-up QCA available at 8-months post-procedure, and 46.0% (151/328) had IVUS data available for the assessment of the two pre-specified IVUS effectiveness endpoints.

The 9-month post-procedure TVF rate in the Endeavor arm was 6.8% compared with 7.4% in the Taxus arm with an observed difference of -0.6% and a 95% Confidence Interval of the difference of [-3.2%, 2.0%]. The upper limit of the one sided 95% Confidence Interval of the difference is 1.6% (Table 12) and is below the protocol specified non-inferiority margin of 3.8%. The p-value of the test of the null hypothesis that the TVF rate in the Endeavor arm is greater than in the Taxus arm was 0.0005. Therefore, the non-inferiority of Endeavor to Taxus with respect to TVF rate was demonstrated in this study.

This study showed that the safety profiles of the two study devices are comparable; the Endeavor device showed statistically significantly lower in-hospital MACE, 30-day MACE and 30-day TVF. No statistically significant differences were observed for 6- and 9-month MACE and 9-month TLR and TVR.

The secondary objective of demonstrating non-inferiority of Endeavor to Taxus for in-segment late loss was not met. However in-segment late loss, in-stent late loss, % DS (both in-segment and in-stent), angiographic binary restenosis (both in-segment and in-stent) and minimal lumen diameter (in-segment and in-stent) at 8 months post-procedure are all within accepted clinical ranges. The detailed results are reported in Table 1a below.

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Table 1a. Principal Effectiveness and Safety Results - ITT Set

Effectiveness Measure	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Lesion Success	99.6% (767/770)	99.2% (766/772)	99.4% (1533/1542)	0.4% [-0.4%, 1.1%]	0.507
Device Success	97.3% (751/772)	97.9% (757/773)	97.6% (1508/1545)	-0.7% [-2.2%, 0.9%]	0.412
Device Specific Procedure Success	96.5% (745/772)	95.6% (739/773)	96.1% (1484/1545)	0.9% [-1.0%, 2.8%]	0.433
Procedure Success	98.7% (760/770)	96.8% (747/772)	97.7% (1507/1542)	1.9% [0.5%, 3.4%]	0.015
Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.62±0.43 (763)	2.61±0.44 (763)	2.62±0.44 (1526)	0.01 [-0.04, 0.05]	0.703
Range (Min,Max)	(1.52,3.90)	(0.00,3.76)	(0.00,3.90)		
Post-Procedure In-Stent Percent Diameter Stenosis (% DS)					
Mean±SD (n)	5.50±9.61 (763)	5.01±10.49 (763)	5.25±10.06 (1526)	0.48 [-0.53, 1.49]	0.348
Range (Min,Max)	(-31.25,35.70)	(-43.23,100.00)	(-43.23,100.00)		
Post-Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.22±0.47 (770)	2.19±0.50 (772)	2.21±0.48 (1542)	0.03 [-0.02, 0.08]	0.196
Range (Min,Max)	(0.97,3.47)	(0.00,3.52)	(0.00,3.52)		
Post-Procedure In-Segment Percent Diameter Stenosis (% DS)					
Mean±SD (n)	20.47±9.54 (770)	20.97±11.12 (772)	20.72±10.36 (1542)	-0.50 [-1.53, 0.54]	0.344
Range (Min,Max)	(-3.55,69.38)	(-1.65,100.00)	(-3.55,100.00)		
8-Month Follow-up In-Stent Minimal Lumen Diameter (mm)					
Mean±SD (n)	1.95±0.61 (143)	2.25±0.61 (135)	2.10±0.63 (278)	-0.30 [-0.45, -0.16]	<.001
Range (Min,Max)	(0.00,3.66)	(0.24,3.75)	(0.00,3.75)		
8-Month Follow-up In-Stent Percent Diameter Stenosis (%)					
Mean±SD (n)	26.41±19.74 (143)	16.09±17.99 (135)	21.40±19.57 (278)	10.32 [5.85, 14.79]	<.001
Range (Min,Max)	(-9.60,100.00)	(-28.57,91.92)	(-28.57,100.00)		
8-Month Follow-up In-Segment Minimal Lumen Diameter (mm)					
Mean±SD (n)	1.80±0.55 (144)	1.98±0.56 (135)	1.89±0.56 (279)	-0.18 [-0.31, -0.05]	0.008
Range (Min,Max)	(0.00,2.99)	(0.24,3.29)	(0.00,3.29)		
8-Month Follow-up In-Segment Percent Diameter Stenosis (%)					
Mean±SD (n)	32.28±17.02 (144)	26.61±15.52 (135)	29.54±16.53 (279)	5.68 [1.83, 9.52]	0.004
Range (Min,Max)	(6.21,100.00)	(5.83,91.92)	(5.83,100.00)		
8-Month Follow-up Late Loss In-Stent (mm)					
Mean±SD (n)	0.67±0.49 (142)	0.42±0.50 (135)	0.55±0.51 (277)	0.25 [0.13, 0.37]	<.001
Range (Min,Max)	(-0.42,2.31)	(-0.74,2.75)	(-0.74,2.75)		
8-Month Follow-up Late Loss In-Segment (mm)					
Mean±SD (n)	0.36±0.47 (143)	0.23±0.45 (135)	0.30±0.46 (278)	0.13 [0.02, 0.23]	0.023
Range (Min,Max)	(-0.48,1.90)	(-0.78,2.45)	(-0.78,2.45)		
8-Month In-Stent Binary Restenosis	13.3% (19/143)	6.7% (9/135)	10.1% (28/278)	6.6% [-0.4%, 13.6%]	0.075
8-Month In-Segment Binary Restenosis	15.3% (22/144)	10.4% (14/135)	12.9% (36/279)	4.9% [-2.9%, 12.7%]	0.284

Safety Measure (to 30 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
In-Hospital MACE	0.9% (7/773)	2.6% (20/775)	1.7% (27/1548)	-1.7% [-3.0%, -0.4%]	0.018
Out-of-Hospital MACE to 30 Days	0.3% (2/770)	0.4% (3/771)	0.3% (5/1541)	-0.1% [-0.7%, 0.4%]	1.000
MACE to 30 Days	1.2% (9/770)	3.0% (23/771)	2.1% (32/1541)	-1.8% [-3.2%, -0.4%]	0.019
Death	0.3% (2/770)	0.0% (0/771)	0.1% (2/1541)	0.3% [-0.1%, 0.6%]	0.250
Cardiac Death	0.1% (1/770)	0.0% (0/771)	0.1% (1/1541)	0.1% [-0.1%, 0.4%]	0.500
Vascular Complications	0.4% (3/770)	0.8% (6/771)	0.6% (9/1541)	-0.4% [-1.1%, 0.4%]	0.507
Early Stent Thrombosis	0.4% (3/770)	0.1% (1/771)	0.3% (4/1541)	0.3% [-0.2%, 0.8%]	0.374
Acute Stent Thrombosis	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/770)	0.1% (1/771)	0.3% (4/1541)	0.3% [-0.2%, 0.8%]	0.374
Cerebrovascular Accident (CVA)	0.1% (1/770)	0.0% (0/771)	0.1% (1/1541)	0.1% [-0.1%, 0.4%]	0.500
Perforation	0.1% (1/770)	0.4% (3/771)	0.3% (4/1541)	-0.3% [-0.8%, 0.2%]	0.625
Target Vessel Revascularization	0.4% (3/770)	0.9% (7/771)	0.6% (10/1541)	-0.5% [-1.3%, 0.3%]	0.342
Target Lesion Revascularization	0.4% (3/770)	0.8% (6/771)	0.6% (9/1541)	-0.4% [-1.1%, 0.4%]	0.507
Target Vessel Failure	1.0% (8/770)	3.0% (23/771)	2.0% (31/1541)	-1.9% [-3.3%, -0.5%]	0.010

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Table 1a. (Continued) Principal Effectiveness and Safety Results - ITT Set

Safety Measure (to 180 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Out-of-Hospital MACE to 180 Days	2.1% (16/766)	1.7% (13/759)	1.9% (29/1525)	0.4% [-1.0%, 1.7%]	0.708
MACE to 180 Days	3.0% (23/766)	4.3% (33/759)	3.7% (56/1525)	-1.3% [-3.2%, 0.5%]	0.175
Death	0.5% (4/766)	0.5% (4/759)	0.5% (8/1525)	-0.0% [-0.7%, 0.7%]	1.000
Cardiac Death	0.3% (2/766)	0.3% (2/759)	0.3% (4/1525)	-0.0% [-0.5%, 0.5%]	1.000
Vascular Complications	0.4% (3/766)	0.8% (6/759)	0.6% (9/1525)	-0.4% [-1.2%, 0.4%]	0.340
Stent Thrombosis	0.8% (6/766)	0.1% (1/759)	0.5% (7/1525)	0.7% [-0.0%, 1.3%]	0.124
Acute Stent Thrombosis	0.0% (0/766)	0.0% (0/759)	0.0% (0/1525)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/766)	0.1% (1/759)	0.3% (4/1525)	0.3% [-0.3%, 0.8%]	0.625
Late Stent Thrombosis	0.4% (3/766)	0.0% (0/759)	0.2% (3/1525)	0.4% [-0.1%, 0.8%]	0.250
Cerebrovascular Accident (CVA)	0.7% (5/766)	0.3% (2/759)	0.5% (7/1525)	0.4% [-0.3%, 1.1%]	0.452
Perforation	0.1% (1/766)	0.4% (3/759)	0.3% (4/1525)	-0.3% [-0.8%, 0.2%]	0.372
Target Vessel Revascularization	2.1% (16/766)	2.8% (21/759)	2.4% (37/1525)	-0.7% [-2.2%, 0.9%]	0.410
Target Lesion Revascularization	1.7% (13/766)	1.6% (12/759)	1.6% (25/1525)	0.1% [-1.2%, 1.4%]	1.000
Target Vessel Failure	3.1% (24/766)	5.1% (39/759)	4.1% (63/1525)	-2.0% [-4.0%, -0.0%]	0.054

Safety Measure (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Out-of-Hospital MACE to 270 Days	4.7% (35/740)	3.0% (22/734)	3.9% (57/1474)	1.7% [-0.2%, 3.7%]	0.104
MACE to 270 Days	5.7% (42/740)	5.7% (42/734)	5.7% (84/1474)	-0.0% [-2.4%, 2.3%]	1.000
Death	0.7% (5/740)	0.8% (6/734)	0.7% (11/1474)	-0.1% [-1.0%, 0.7%]	0.773
Cardiac Death	0.4% (3/740)	0.3% (2/734)	0.3% (5/1474)	0.1% [-0.5%, 0.7%]	1.000
Vascular Complications	0.5% (4/740)	0.8% (6/734)	0.7% (10/1474)	-0.3% [-1.1%, 0.6%]	0.546
Stent Thrombosis	0.8% (6/740)	0.1% (1/734)	0.5% (7/1474)	0.7% [-0.0%, 1.4%]	0.124
Acute Stent Thrombosis	0.0% (0/740)	0.0% (0/734)	0.0% (0/1474)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/740)	0.1% (1/734)	0.3% (4/1474)	0.3% [-0.3%, 0.8%]	0.625
Late Stent Thrombosis	0.4% (3/740)	0.0% (0/734)	0.2% (3/1474)	0.4% [-0.1%, 0.9%]	0.250
Cerebrovascular Accident (CVA)	0.7% (5/740)	0.5% (4/734)	0.6% (9/1474)	0.1% [-0.7%, 0.9%]	1.000
Perforation	0.1% (1/740)	0.4% (3/734)	0.3% (4/1474)	-0.3% [-0.8%, 0.3%]	0.372
Target Vessel Revascularization	5.5% (41/740)	5.0% (37/734)	5.3% (78/1474)	0.5% [-1.8%, 2.8%]	0.727
Target Lesion Revascularization	4.2% (31/740)	2.7% (20/734)	3.5% (51/1474)	1.5% [-0.4%, 3.3%]	0.154
Target Vessel Failure	6.8% (50/740)	7.4% (54/734)	7.1% (104/1474)	-0.6% [-3.2%, 2.0%]	0.685

Kaplan-Meier Estimate	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	P-Value
TLR-Free at 270 days	95.8%	97.3%	96.6%	0.127
TVR-Free at 270 days	94.4%	95.0%	94.7%	0.682
TVF-Free at 270 days	93.3%	92.8%	93.0%	0.626
MACE-Free at 270 days	94.4%	94.5%	94.4%	0.952

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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Table 1b. Principal Effectiveness and Safety Results – PP Set

Effectiveness Measure	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
Lesion Success	100.0% (747/747)	99.9% (749/750)	99.9% (1496/1497)	0.1% [-0.1%, 0.4%]	1.000
Device Success	99.7% (745/747)	99.9% (749/750)	99.8% (1494/1497)	-0.1% [-0.6%, 0.3%]	0.624
Device Specific Procedure Success	98.9% (739/747)	97.6% (732/750)	98.3% (1471/1497)	1.3% [0.0%, 2.6%]	0.073
Procedure Success	99.2% (741/747)	97.6% (732/750)	98.4% (1473/1497)	1.6% [0.3%, 2.9%]	0.022
Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.62±0.43 (747)	2.62±0.44 (750)	2.62±0.43 (1497)	0.00 [-0.04, 0.05]	0.873
Range (Min,Max)	(1.52,3.90)	(0.00,3.76)	(0.00,3.90)		
Post-Procedure In-Stent Percent Diameter Stenosis (% DS)					
Mean±SD (n)	5.52±9.57 (747)	4.89±10.42 (750)	5.21±10.01 (1497)	0.63 [-0.38, 1.64]	0.223
Range (Min,Max)	(-31.25,35.70)	(-43.23,100.00)	(-43.23,100.00)		
Post-Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)					
Mean±SD (n)	2.23±0.46 (747)	2.20±0.48 (750)	2.22±0.47 (1497)	0.02 [-0.02, 0.07]	0.313
Range (Min,Max)	(0.97,3.47)	(0.00,3.52)	(0.00,3.52)		
Post-Procedure In-Segment Percent Diameter Stenosis (% DS)					
Mean±SD (n)	20.20±9.17 (747)	20.50±10.36 (750)	20.35±9.78 (1497)	-0.30 [-1.29, 0.69]	0.556
Range (Min,Max)	(-3.55,55.40)	(-1.65,100.00)	(-3.55,100.00)		
8-Month Follow-up In-Stent Minimal Lumen Diameter (mm)					
Mean±SD (n)	1.93±0.59 (140)	2.27±0.59 (133)	2.10±0.61 (273)	-0.34 [-0.48, -0.20]	<.001
Range (Min,Max)	(0.00,3.66)	(0.24,3.75)	(0.00,3.75)		
8-Month Follow-up In-Stent Percent Diameter Stenosis (%)					
Mean±SD (n)	26.76±19.67 (140)	15.35±17.01 (133)	21.20±19.25 (273)	11.40 [7.01, 15.79]	<.001
Range (Min,Max)	(-9.60,100.00)	(-28.57,91.92)	(-28.57,100.00)		
8-Month Follow-up In-Segment Minimal Lumen Diameter (mm)					
Mean±SD (n)	1.80±0.55 (140)	2.00±0.55 (133)	1.89±0.55 (273)	-0.20 [-0.33, -0.07]	0.003
Range (Min,Max)	(0.00,2.99)	(0.24,3.29)	(0.00,3.29)		
8-Month Follow-up In-Segment Percent Diameter Stenosis (%)					
Mean±SD (n)	32.13±16.84 (140)	26.03±14.81 (133)	29.16±16.14 (273)	6.10 [2.31, 9.88]	0.002
Range (Min,Max)	(6.21,100.00)	(5.83,91.92)	(5.83,100.00)		
8-Month Follow-up Late Loss In-Stent (mm)					
Mean±SD (n)	0.68±0.49 (139)	0.41±0.49 (133)	0.55±0.51 (272)	0.27 [0.16, 0.39]	<.001
Range (Min,Max)	(-0.42,2.31)	(-0.74,2.75)	(-0.74,2.75)		
8-Month Follow-up Late Loss In-Segment (mm)					
Mean±SD (n)	0.36±0.47 (139)	0.22±0.43 (133)	0.29±0.46 (272)	0.14 [0.03, 0.25]	0.010
Range (Min,Max)	(-0.48,1.90)	(-0.78,2.45)	(-0.78,2.45)		
8-Month In-Stent Binary Restenosis	13.6% (19/140)	5.3% (7/133)	9.5% (26/273)	8.3% [1.5%, 15.1%]	0.023
8-Month In-Segment Binary Restenosis	15.0% (21/140)	9.0% (12/133)	12.1% (33/273)	6.0% [-1.7%, 13.6%]	0.141

Safety Measure (to 30 days)	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
In-Hospital MACE	0.8% (6/748)	2.3% (17/752)	1.5% (23/1500)	-1.5% [-2.7%, -0.2%]	0.033
Out-of-Hospital MACE to 30 Days	0.3% (2/745)	0.3% (2/748)	0.3% (4/1493)	0.0% [-0.5%, 0.5%]	1.000
MACE to 30 Days	1.1% (8/745)	2.5% (19/748)	1.8% (27/1493)	-1.5% [-2.8%, -0.1%]	0.050
Death	0.3% (2/745)	0.0% (0/748)	0.1% (2/1493)	0.3% [-0.1%, 0.6%]	0.249
Cardiac Death	0.1% (1/745)	0.0% (0/748)	0.1% (1/1493)	0.1% [-0.1%, 0.4%]	0.499
Vascular Complications	0.4% (3/745)	0.8% (6/748)	0.6% (9/1493)	-0.4% [-1.2%, 0.4%]	0.506
Early Stent Thrombosis	0.4% (3/745)	0.1% (1/748)	0.3% (4/1493)	0.3% [-0.3%, 0.8%]	0.373
Acute Stent Thrombosis	0.0% (0/745)	0.0% (0/748)	0.0% (0/1493)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/745)	0.1% (1/748)	0.3% (4/1493)	0.3% [-0.3%, 0.8%]	0.373
Cerebrovascular Accident (CVA)	0.1% (1/745)	0.0% (0/748)	0.1% (1/1493)	0.1% [-0.1%, 0.4%]	0.499
Perforation	0.1% (1/745)	0.3% (2/748)	0.2% (3/1493)	-0.1% [-0.6%, 0.3%]	1.000
Target Vessel Revascularization	0.3% (2/745)	0.5% (4/748)	0.4% (6/1493)	-0.3% [-0.9%, 0.4%]	0.687
Target Lesion Revascularization	0.3% (2/745)	0.4% (3/748)	0.3% (5/1493)	-0.1% [-0.7%, 0.5%]	1.000
Target Vessel Failure	0.9% (7/745)	2.5% (19/748)	1.7% (26/1493)	-1.6% [-2.9%, -0.3%]	0.028

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Table 1b. (Continued) Principal Effectiveness and Safety Results – PP Set

Safety Measure (to 180 days)	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
Out-of-Hospital MACE to 180 Days	2.2% (16/741)	1.6% (12/736)	1.9% (28/1477)	0.5% [-0.9%, 1.9%]	0.568
MACE to 180 Days	3.0% (22/741)	3.9% (29/736)	3.5% (51/1477)	-1.0% [-2.8%, 0.9%]	0.322
Death	0.5% (4/741)	0.5% (4/736)	0.5% (8/1477)	-0.0% [-0.8%, 0.7%]	1.000
Cardiac Death	0.3% (2/741)	0.3% (2/736)	0.3% (4/1477)	-0.0% [-0.5%, 0.5%]	1.000
Vascular Complications	0.4% (3/741)	0.8% (6/736)	0.6% (9/1477)	-0.4% [-1.2%, 0.4%]	0.341
Stent Thrombosis	0.8% (6/741)	0.1% (1/736)	0.5% (7/1477)	0.7% [-0.0%, 1.4%]	0.124
Acute Stent Thrombosis	0.0% (0/741)	0.0% (0/736)	0.0% (0/1477)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/741)	0.1% (1/736)	0.3% (4/1477)	0.3% [-0.3%, 0.8%]	0.624
Late Stent Thrombosis	0.4% (3/741)	0.0% (0/736)	0.2% (3/1477)	0.4% [-0.1%, 0.9%]	0.250
Cerebrovascular Accident (CVA)	0.7% (5/741)	0.1% (1/736)	0.4% (6/1477)	0.5% [-0.1%, 1.2%]	0.218
Perforation	0.1% (1/741)	0.3% (2/736)	0.2% (3/1477)	-0.1% [-0.6%, 0.3%]	0.623
Target Vessel Revascularization	2.0% (15/741)	2.4% (18/736)	2.2% (33/1477)	-0.4% [-1.9%, 1.1%]	0.602
Target Lesion Revascularization	1.6% (12/741)	1.2% (9/736)	1.4% (21/1477)	0.4% [-0.8%, 1.6%]	0.661
Target Vessel Failure	3.1% (23/741)	4.8% (35/736)	3.9% (58/1477)	-1.7% [-3.6%, 0.3%]	0.109

Safety Measure (to 270 days)	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
Out-of-Hospital MACE to 270 Days	4.9% (35/716)	2.8% (20/711)	3.9% (55/1427)	2.1% [0.1%, 4.1%]	0.053
MACE to 270 Days	5.7% (41/716)	5.2% (37/711)	5.5% (78/1427)	0.5% [-1.8%, 2.9%]	0.727
Death	0.7% (5/716)	0.8% (6/711)	0.8% (11/1427)	-0.1% [-1.1%, 0.8%]	0.773
Cardiac Death	0.4% (3/716)	0.3% (2/711)	0.4% (5/1427)	0.1% [-0.5%, 0.8%]	1.000
Vascular Complications	0.6% (4/716)	0.8% (6/711)	0.7% (10/1427)	-0.3% [-1.2%, 0.6%]	0.546
Stent Thrombosis	0.8% (6/716)	0.1% (1/711)	0.5% (7/1427)	0.7% [-0.0%, 1.4%]	0.124
Acute Stent Thrombosis	0.0% (0/716)	0.0% (0/711)	0.0% (0/1427)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/716)	0.1% (1/711)	0.3% (4/1427)	0.3% [-0.3%, 0.8%]	0.624
Late Stent Thrombosis	0.4% (3/716)	0.0% (0/711)	0.2% (3/1427)	0.4% [-0.1%, 0.9%]	0.249
Cerebrovascular Accident (CVA)	0.7% (5/716)	0.4% (3/711)	0.6% (8/1427)	0.3% [-0.5%, 1.1%]	0.726
Perforation	0.1% (1/716)	0.3% (2/711)	0.2% (3/1427)	-0.1% [-0.6%, 0.3%]	0.623
Target Vessel Revascularization	5.6% (40/716)	4.6% (33/711)	5.1% (73/1427)	0.9% [-1.3%, 3.2%]	0.471
Target Lesion Revascularization	4.2% (30/716)	2.3% (16/711)	3.2% (46/1427)	1.9% [0.1%, 3.8%]	0.050
Target Vessel Failure	6.8% (49/716)	6.9% (49/711)	6.9% (98/1427)	-0.0% [-2.7%, 2.6%]	1.000

Kaplan-Meier Estimate	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	P-Value
TLR-Free at 270 days	95.8%	97.8%	96.8%	0.039
TVR-Free at 270 days	94.4%	95.4%	94.9%	0.423
TVF-Free at 270 days	93.2%	93.3%	93.2%	0.950
MACE-Free at 270 days	94.4%	95.0%	94.7%	0.674

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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Section II: Detailed Summary

A. Definitions and Acronyms/Abbreviations

ACUTE CLOSURE

Acute Closure. Defined as the occurrence of new (during the index procedure) severely reduced flow (TIMI grade 0-1) within the target vessel that persisted and required rescue by stenting or other treatment, or resulted in myocardial infarction or death. Abrupt closure requires proven association with a mechanical dissection of the treatment site or instrumented vessel, coronary thrombus, or severe spasm. Abrupt closure does not connote "no reflow" (due to microvascular flow limitation), in which the epicardial artery is patent but had reduced flow. Abrupt closure also does not connote transient closure with reduced flow in which the index treatment application does reverse the closure.

Subacute Closure. Defined as abrupt closure that occurred after the index procedure is completed (and the patient left the catheterization laboratory) and before the 30-day follow-up evaluation.

Threatened Acute Closure. Defined as a grade B dissection and ≥50% diameter stenosis or any dissection of grade C or higher.

ACUTE GAIN

Defined as the immediate dimensional change in minimal luminal diameter (mm) that occurred after the final post-dilatation as compared to the minimal luminal diameter at baseline and measured by quantitative coronary angiography from the average of 2 orthogonal views.

ACUTE SUCCESS[1]

Device Success: Attainment of <50% residual stenosis of the target lesion using only the assigned device.

Lesion Success: Attainment of <50% residual stenosis of the target lesion using any percutaneous method.

Procedure Success: Attainment of <50% residual stenosis of the target lesion and no in-hospital MACE.

Device-Specific Procedure Success[2]: Device success and no in-hospital MACE.

ADVERSE EFFECT

An adverse event which was or may have been caused by a device.

ADVERSE EVENT

An adverse event is any undesirable medical occurrence in a clinical study patient, whether it is considered to be related to the device or not, that includes a clinical sign, symptom, or condition and/or an observation of a near incident.

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[1] All analyses to determine acute success measures were conducted utilizing *in-stent* residual stenosis values. When in-stent % residual stenosis was not available, in-lesion % residual stenosis was used to complete the analysis.
[2] Device-Specific Procedure Success is utilized to account for procedural successes/failures that are related to the implanted device.

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ANGIOGRAPHIC BINARY RESTENOSIS (ABR) RATE
Percent of patients with a follow-up percent diameter stenosis of ≥50%.

ANTICIPATED ADVERSE EVENT
Any undesirable experience (sign, symptom, illness, abnormal laboratory value, or other medical event) occurring to a patient, whether or not considered related to the investigational product(s) or drug regimen prescribed as part of the clinical protocol, predefined in the clinical protocol and/or IFU, that is identified or worsens during a clinical study.

BLEEDING COMPLICATION
Defined as a procedure related hemorrhagic event that requires a transfusion or surgical repair. These may include a hematoma requiring treatment, retroperitoneal bleed.

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION (CCSC) OF ANGINA

Class I Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation.

Class II Slight limitation of ordinary activity. Angina upon walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the first hours after awakening. Angina if walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.

Class III Marked limitations of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace.

Class IV Inability to carry on any physical activity without discomfort. Angina syndrome may be present at rest.

CLINICALLY-DRIVEN TARGET SITE REVASCULARIZATION (TSR)
Revascularization at the target site associated with positive functional ischemia study or ischemic symptoms AND an angiographic minimal lumen diameter stenosis ≥50% by QCA, or revascularization of a target site with diameter stenosis ≥70% by QCA without either angina or a positive functional study.

CLINICALLY-DRIVEN TARGET VESSEL REVASCULARIZATION (TVR)
Revascularization in the target vessel associated with positive functional ischemia study or ischemic symptoms AND an angiographic minimal lumen diameter stenosis ≥50% by QCA, or revascularization of a target vessel with diameter stenosis ≥70% by QCA without either angina or a positive functional study.

COMPLETE BLOOD COUNT (CBC)
See laboratory panel.

CEREBROVASCULAR ACCIDENT (CVA) (see Stroke)
The occurrence of cerebral infarction (ischemic stroke) and intracerebral hemorrhage and subarachnoid hemorrhage (hemorrhagic stroke).

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CROSSOVER

When a patient is treated with a study stent other than the randomized treatment assignment.

De novo LESION

Defined as a native coronary artery lesion not previously treated.

DEATH

Divided into 2 categories:

Cardiac death is defined as death due to any of the following:

1. Acute MI
2. Cardiac perforation/pericardial tamponade
3. Arrhythmia or conduction abnormality
4. Stroke within 30 days of the procedure or stroke suspected of being related to the procedure
5. Death due to complication of the procedure, including bleeding, vascular repair, transfusion reaction, or bypass surgery
6. Any death in which a cardiac cause cannot be excluded

Non-cardiac death is defined as a death not due to cardiac causes (as defined above).

DEVICE RELATED ADVERSE EVENT

A device related adverse event is defined as any adverse event for which a causal relationship between the device and the event is at least a reasonable possibility, i.e., the relationship cannot be excluded.

Device Failure: A device has failed if it is used in accordance with the IFU, but does not perform according to IFU and negatively impacts the treatment.

Device Malfunction: A device malfunction is an unexpected change to the device that is contradictory to the IFU and may or may not affect device performance.

Near Incident: Malfunction or deterioration in the characteristics and/or performance of the device which might have led to death or serious deterioration in health; incident occurred and is such that if it occurred again, it might lead to death or serious deterioration in health.

Device Misuse: A misused device (one that is used by the Investigator in a manner that is contradictory to the IFU) will not be considered a malfunction.

DEVICE SUCCESS

Attainment of <50% residual stenosis of the target lesion using only the assigned device.

DEVICE SPECIFIC PROCEDURE SUCCESS

Device success and no in-hospital MACE.

DIABETES MELLITUS

Three ways to diagnose diabetes are possible, and each must be confirmed, on a subsequent day, by any one of the three methods given:

1. Symptoms of diabetes plus casual plasma glucose concentration >200 mg/dl (11.1

mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.

2. Fasting plasma glucose (FPG) ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 hours.
3. Two hour post-load glucose (PG) ≥200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Heath Organization (WHO), using a glucose load containing the equivalent of 75 gm anhydrous glucose dissolved in water.

In the absence of unequivocal hyperglycemia with acute metabolic decompensation, these criteria should be confirmed by repeat testing on a different day. The third measure, OGTT, is not recommended for routine clinical use.

DISSECTION, NHLBI (National Heart, Lung, and Blood Institute) CLASSIFICATION

Grade A Small radiolucent area within the lumen of the vessel disappearing with the passage of the contrast material.

Grade B Appearance of contrast medium parallel to the lumen of the vessel disappearing within a few cardiac cycles.

Grade C Dissection protruding outside the lumen of the vessel persisting after passage of the contrast material.

Grade D Spiral shaped filling defect with or without delayed run-off of the contrast material in the antegrade flow.

Grade E Persistent luminal filling defect with delayed run-off of the contrast material in the distal lumen.

Grade F Filling defect accompanied by total coronary occlusion.

DISTAL EMBOLIZATION

Defined as a new abrupt cut off or filling defect distal to the treated lesion.

EMERGENT BYPASS SURGERY

Defined as coronary bypass surgery performed on an urgent or emergent basis for severe vessel dissection or closure, or treatment failure resulting in new ischemia.

INCOMPLETE APPOSITION

Failure of the stent to completely appose to the vessel wall after placement is defined as one or more stent struts separated from the vessel wall with evidence of blood speckles behind the strut in the ultrasound image.

IN-SEGMENT MEASUREMENT

Defined as the measurements either within the stented segment or within 5 mm proximal and distal to the stent edges.

IN-STENT MEASUREMENT

Defined as the measurements within the boundaries of the stent.

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LABORATORY PANEL

Chemistry Panel	Complete Blood Count	Lipid Panel	Liver Function Tests
• Blood urea nitrogen (BUN) • Calcium • Chloride • Creatinine • Glucose • Sodium • Potassium	• Hematocrit (HCT) • Hemoglobin (HGB) • Platelet (Plt) count • Red blood cell (RBC) count • White blood cell (WBC) count • WBC differential (including eosinophils)	• Cholesterol (total) • High density lipoprotein (HDL) • Low density lipoprotein (LDL) • Triglycerides	• Alanine aminotransferase (ALT) or serum glutamic pyruvic transaminase (SGPT) • Alkaline phosphatase (ALP) • Aspartate aminotransferase (AST) or serum glutamic oxaloacetic transaminase (SGOT) • Gamma glutamyl transferase (GGT)

LATE INCOMPLETE APPOSITION

Incomplete apposition of the stent at follow-up which was not present post-procedure. See also incomplete apposition.

LATE LOSS INDEX

Defined as the ratio of late loss to acute gain.

LATE LUMEN/LUMINAL LOSS

Defined as the difference between the post-procedure minimal lumen diameter (MLD) and the follow-up angiography MLD.

LESION CLASS (American College of Cardiology/American Heart Association Class)

Type A Lesions: Minimally complex, discrete (length <10 mm), concentric, readily accessible, non angulated segment (<45°), smooth contour, little or no calcification, less than totally occlusive, not ostial in location, no major side branch involvement, and an absence of thrombus.

Type B Lesions: Moderately complex, tubular (length 10 to 20 mm), eccentric, moderate tortuosity of proximal segment, moderately angulated segment (>45°, <90°), irregular contour, moderate or heavy calcification, total occlusions <3 months old, ostial in location, bifurcation lesions requiring double guidewires, and some thrombus present.

Type C Lesions: Severely complex, diffuse (length >20 mm), excessive tortuosity of proximal segment, extremely angulated segments >90°, total occlusions >3 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions.

LESION SUCCESS

Attainment of <50% residual stenosis of the target lesion using any percutaneous method.

MAJOR ADVERSE CARDIAC EVENTS (MACE)

Defined as death, MI[3] (Q wave and non-Q wave), emergent cardiac bypass surgery, or target site revascularization (repeat PTCA or CABG).

[3] Myocardial infarction that has been adjudicated by the Clinical Events Committee as being clearly related to a non-target vessel will not be considered a MACE.

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MINIMAL LUMINAL DIAMETER (MLD)

The average of two orthogonal views (when possible) of the narrowest point within the area of assessment – in lesion, in stent or in segment. MLD is visually estimated during angiography by the Investigator; it is measured during QCA by the Angiographic Core Laboratory.

MYOCARDIAL INFARCTION

A positive diagnosis of myocardial infarction is made when one of the following criteria is met:

Q wave MI (QWMI): will require one of the following criteria:

- Chest pain or other acute symptoms consistent with myocardial ischemia and new pathological Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC, in the absence of timely cardiac enzyme data.
- New pathologic Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC and elevation of cardiac enzymes. In the absence of ECG data the CEC may adjudicate Q wave MI based on the clinical scenario and appropriate cardiac enzyme data.

Non-Q Wave MI (NQWMI): for this study NQWMI will be defined as elevated CK ≥2X the upper laboratory normal with the presence of elevated CK-MB (any amount above the institution's upper limit of normal) in the absence of new pathological Q waves.

NO REFLOW

Defined as a sustained or transient reduction in antegrade flow that is not associated with an obstructive lesion at the treatment site.

PERCENT DIAMETER STENOSIS

The value calculated as 100 x (RVD – MLD)/RVD using the mean values from two orthogonal views (when possible) by QCA.

PERCENT VOLUME OBSTRUCTION

Defined as stent intimal hyperplasia and calculated as 100 x (Stent Volume (SV) – Lumen Volume (LV))/SV.

PERFORATION

Perforations will be classified as follows:

Angiographic perforation: perforation detected by the clinical site or the core laboratory at any point during the procedure.

Clinical perforation: perforation requiring additional treatment (including efforts to seal the perforation or pericardial drainage), or resulting in significant pericardial effusion, acute closure, myocardial infarction, or death.

Pericardial hemorrhage/tamponade: perforation resulting in cardiac tamponade.

PERCUTANEOUS CORONARY INTERVENTION (PCI)

Refers to all interventional cardiology methods for treatment of coronary artery disease.

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PERSISTING DISSECTION
Dissection at follow-up that was present post-procedure.

PERSISTING INCOMPLETE APPOSITION
Incomplete apposition at follow-up that was present post-procedure. See also "incomplete apposition."

PROCEDURE SUCCESS
Attainment of <50% residual stenosis of the target lesion and no in-hospital MACE.

RESTENOTIC LESION
Defined as a lesion in a vessel segment that has undergone prior percutaneous treatment with or without a stent placement.

REFERENCE VESSEL DIAMETER (RVD)
Defined as the average of normal segments within 10 mm proximal and distal to the target lesion from 2 orthogonal views using QCA.

SERIOUS ADVERSE EVENT
A study-related adverse event that is fatal, life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, requires intervention to prevent permanent impairment/damage, results in persistent or significant disability or results in a congenital anomaly/birth defect.

STENT THROMBOSIS
Defined as angiographic thrombus or subacute closure within the stented vessel at the time of the clinically driven angiographic restudy for documented ischemia (chest pain and ECG changes). Any death not attributed to a non-cardiac cause within the first 30 days is considered a surrogate for stent thrombosis in the absence of documented angiographic stent patency. Late Stent Thrombosis is reported according to the following criteria[4]:

Definite Late Stent Thrombosis. Myocardial Infarction >30 days after index and attributable to the target vessel, angiographic documentation (site reported or by QCA) of thrombus or total occlusion at the target site, and freedom from interim revascularization of the target vessel.

Possible Late Stent Thrombosis. Myocardial Infarction >30 days after index and attributable to the target vessel, no identifiable culprit lesion elsewhere, freedom from interim revascularization of the target lesion, and freedom from interim bypass grafting of the target vessel.

STROKE
Defined as sudden onset of vertigo, numbness, dysphasia, weakness, visual field defects, dysarthria or other focal neurological deficits due to vascular lesions of the brain such as hemorrhage, embolism, thrombosis, or rupturing aneurysm, that persists >24 hours.

STUDY DEVIATION

[4] Medtronic Vascular utilizes stent thrombosis definitions that are consistent with the Harvard Clinical Research Institute Clinical Events Committee's standard definitions.

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An incident where the Investigator or site personnel did not conduct the study according to the clinical protocol or the Investigator agreement.

Major deviation: Any deviation from patient inclusion and exclusion criteria or patient informed consent procedures.

Minor deviation: Deviation from a clinical protocol requirement such as incomplete/inadequate patient testing procedures, non-compliance with medication regimens, follow-ups performed outside specified time windows, etc.

TARGET LESION

The lesion intended to be treated with the treatment device.

TARGET LESION/SITE REVASCULARIZATION (TLR/TSR)

Repeat PCI or CABG to the target lesion/site.

TARGET VESSEL FAILURE (TVF)

The composite endpoint comprised of cardiac death, myocardial infarction, or clinically-driven target vessel revascularization.

Target vessel failure includes any target vessel revascularization and MI. Target vessel failure will be reported when:

- MI occurs in territory not clearly attributed to a vessel other than the target vessel.
- Target vessel revascularization is performed.

TARGET VESSEL REVASCULARIZATION (TVR)

Repeat PCI or CABG of the target vessel. See also clinically-driven target vessel revascularization.

THROMBOLYSIS IN MYOCARDIAL INFARCTION (TIMI) CLASSIFICATION

TIMI 0 No perfusion.

TIMI 1 Penetration with minimal perfusion. Contrast fails to opacify the entire bed distal to the stenosis for the duration of the cine run.

TIMI 2 Partial perfusion. Contrast opacifies the entire coronary bed distal to the stenosis. However, the rate of entry and/or clearance is slower in the coronary bed distal to the obstruction than in comparable areas not perfused by the dilated vessel.

TIMI 3 Complete perfusion. Filling and clearance of contrast equally rapid in the coronary bed distal to stenosis as in other coronary beds.

UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

An UADE is defined as any adverse effect on health or safety or any life-threatening problem or death that is caused by or associated with an investigational device. The effect must have not been previously identified in nature, severity or degree of incidence in the clinical protocol, Investigator's Brochure or Instructions for Use. Other serious problems associated with the device that affects the rights or welfare of study patients may also be considered UADEs.

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VASCULAR COMPLICATIONS

Vascular complications may include the following:

1. Pseudoaneurysm
2. AVF
3. Peripheral ischemia/nerve injury
4. Vascular event requiring transfusion or surgical repair

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Acronyms and/or Abbreviations

Acronym / Abbreviation	Term
% DS	Percent diameter stenosis
% VO	Percent volume obstruction
µg	Microgram
ABR	Angiographic binary restenosis
ACC	American College of Cardiology
ACT	Activated clotting time
AE	Adverse event
AHA	American Heart Association
ALP	Alkaline phosphatase
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
atm	Atmospheric pressure
AVF	Arteriovenous fistula
BUN	Blood urea nitrogen
CABG	Coronary artery bypass graft
CBC	Complete blood count
CCSC	Canadian Cardiovascular Society Classification
CEC	Clinical Events Committee
CFR	Code of Federal Regulations
CFR	Coronary flow reserve
CK	Creatine kinase
CK-MB	Creatine kinase myocardial-band isoenzyme
cm	Centimeter
CRF	Case report form
CRO	Contract Research Organization
CVA	Cerebrovascular accident
DCA	Directional coronary atherectomy
DFU	Directions for Use
dL	Deciliter
DS	Diameter stenosis
DSMB	Data Safety Monitoring Board
ECG	Electrocardiogram
EC	Ethics Committee
FFR	Fractional flow reserve
FIM	First-in-man
FPG	Fasting plasma glucose
GCP	Good Clinical Practices
GGT	Gamma glutamyl transferase
GI	Gastrointestinal
gm	Gram
GP	Glycoprotein
HCRI	Harvard Clinical Research Institute

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Acronym / Abbreviation	Term
HCT	Hematocrit
HDL	High density lipoprotein
HGB	Hemoglobin
HHS	Health and Human Services (Department of)
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonization
IFU	Instructions for Use
in	Inch
IRB	Institutional Review Board
ITT	Intent-to-treat
IVRS	Interactive Voice Response System
IVUS	Intravascular ultrasound
L/l	Liter
LAD	Left anterior descending coronary artery
LCX	Left circumflex coronary artery
LDL	Low density lipoprotein
LIMA	Left internal mammary artery
LV	Lumen volume
LVEF	Left ventricular ejection fraction
MACE	Major adverse cardiac event
mg	Milligram
MI	Myocardial infarction
MLA	Minimal lumen area
MLD	Minimum luminal/lumen diameter
mm	Millimeter
mmol	Millimole
mRNA	Messenger ribonucleic acid
mTOR	Mammalian target of rapamycin
NHLBI	National Heart, Lung, and Blood Institute [Dissection Grade Classification]
NQWMI	Non-Q wave myocardial infarction
NTG	Nitroglycerin
OGTT	Oral glucose tolerance test
PC	Phosphorylcholine
PCI	Percutaneous coronary intervention
PG	Post-load glucose
Plt	Platelet
PTCA	Percutaneous transluminal coronary angioplasty
QCA	Quantitative coronary angiography
QWMI	Q wave myocardial infarction
RBC	Red blood cell
RCA	Right coronary artery
RIMA	Right internal mammary artery
RVD	Reference vessel diameter
SAE	Serious adverse event

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Acronym / Abbreviation	Term
SD	Standard deviation
SGOT	Serum glutamic oxaloacetic transaminase
SGPT	Serum glutamic pyruvic transaminase
SV	Stent volume
TIA	Transient ischemic attack
TIMI	Thrombolysis in myocardial infarction
TLR	Target lesion revascularization
™	Trademark
TPD	Therapeutic Products Directorate
TSR	Target site revascularization
TVF	Target vessel failure
TVR	Target vessel revascularization
UADE	Unanticipated adverse device effect
US	United States
USFDA	United States Food and Drug Administration
VO	Volume obstruction
WBC	White blood cell
WHO	World Health Organization

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B. Study Design

The ENDEAVOR IV Trial was a prospective, multi-center, randomized, two-arm, single-blind trial. The Endeavor Zotarolimus-Eluting Coronary Stent System is intended for use in patients with symptomatic ischemic heart disease due to *de novo* stenotic lesions of native coronary arteries with a RVD between 2.5 mm and 3.5 mm and lesion length ≤27 mm that are amenable to percutaneous treatment with stenting. A cohort of 328 consecutively enrolled patients was consented and prospectively assigned for protocol mandated angiographic and IVUS re-study at 8 months post-procedure. This report presents results of these angiographic and IVUS measures at 8 months post-procedure, as well as the primary clinical endpoint through 9 months post-procedure.

Subject Selection Criteria

This trial included 1,548 subjects with *de novo* native coronary artery lesions who agreed to participate in the study. Patients were considered for inclusion if the all inclusion criteria and no exclusion criteria conditions (including specific angiographic criteria) were met.

General Inclusion Criteria

1. The patient was ≥18 years of age.
2. The patient had clinical evidence of ischemic heart disease, stable or unstable angina, silent ischemia, or a positive functional study.
3. The patient was an acceptable candidate for PTCA, stenting, and emergent CABG surgery.
4. Female patients of childbearing potential must have had a negative pregnancy test within 7 days before the procedure.
5. The patient or patient's legal representative had been informed of the nature of the study and agreed to its provisions and provided written informed consent as approved by the Institutional Review Board/Ethics Committee (IRB/EC) of the respective clinical site.
6. The patient agreed to return to the same research facility for all required post-procedure follow-up visits.

Angiographic Inclusion Criteria

The target lesion/vessel met the following criteria:

1. The target lesion was a single *de novo* lesion in a native coronary artery.
2. The target lesion was ≤27 mm in length.
3. The target lesion had a stenosis of ≥50% and <100%.
4. The target vessel had a thrombolysis in myocardial infarction (TIMI) flow 2 or greater.
5. The target vessel reference diameter was ≥2.5 mm and ≤3.5 mm.

Note: Measurements were made by careful visual estimate, on-line QCA, or IVUS.

General Exclusion Criteria

Candidates were excluded from the study if any of the following conditions were present:

1. A known hypersensitivity or contraindication to aspirin, heparin or bivalirudin, ticlopidine or clopidogrel, cobalt, nickel, chromium, molybdenum, polymer coatings (e.g., Phosphorylcholine or Translute), or a sensitivity to contrast media, which could not be adequately pre-medicated.
2. History of an allergic reaction or significant sensitivity to drugs such as ABT-578,

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rapamycin, tacrolimus, everolimus, or any other analogue or derivative.

3. History of an allergic reaction or significant sensitivity to paclitaxel or drugs in similar class.
4. A platelet count <100,000 cells/mm³ or >700,000 cells/mm³, or a white blood cell (WBC) count <3,000 cells/mm³.
5. A serum creatinine level >2.0 mg/dl within seven days prior to index procedure.
6. Evidence of an acute MI within 72 hours of the intended index procedure (defined as: QWMI or non-Q wave myocardial infarction (NQWMI) having CK enzymes ≥2X the upper laboratory normal with the presence of a CK-MB elevated above the Institution's upper limit of normal).
   Note: Patients with evidence or suspicion of an acute MI had CK and CK-MB labs drawn and the results reviewed prior to randomization.
7. Previous PCI of the target vessel within 9 months pre-procedure.
8. Planned PCI of any vessel within 30 days post-procedure.
9. During the index procedure, the target lesion required treatment with a device other than PTCA prior to stent placement (including but not limited to, cutting balloon, any atherectomy, any laser, thrombectomy, etc.).
10. History of a stroke or transient ischemic attack (TIA) within the prior 6 months.
11. Active peptic ulcer or upper gastrointestinal (GI) bleeding within the prior 6 months.
12. History of bleeding diathesis or coagulopathy or refused blood transfusions.
13. Concurrent medical condition with a life expectancy of less than 12 months.
14. Any previous or planned treatment of the target vessel with anti-restenotic therapies including, but not limited to brachytherapy.
15. Currently participating in an investigational drug or another device study that had not completed the primary endpoint or that clinically interfered with the current study endpoints; or requires coronary angiography, IVUS or other coronary artery imaging procedures.
    Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, were not considered investigational trials.
16. Documented left ventricular ejection fraction (LVEF) <30% at most recent evaluation.

Angiographic Exclusion Criteria

Candidates were excluded from the study if any of the following conditions were met:

1. Target lesion was located in a native vessel distal to anastomosis with a saphenous vein graft or a left/right internal mammary artery (LIMA/RIMA) bypass with more than 40% diameter stenosis anywhere within the graft.
2. Previous stenting (drug-eluting or bare metal) in the target vessel unless the following conditions were met:
   a) It had been at least 9 months since the previous stenting, and
   b) The target lesion was at least 15 mm away from the previously placed stent.
3. Target vessel had other lesions with greater than 40% diameter stenosis based on visual estimate or on-line QCA.
4. The target vessel had evidence of thrombus.
5. The target vessel was excessively tortuous.
6. The target lesion had any of the following characteristics:
   a) Lesion location was aorto-ostial, an unprotected left main lesion, or within 5 mm of

the origin of the left anterior descending (LAD), left circumflex (LCX), or right coronary artery (RCA)

b) Involved a side branch >2.0 mm in diameter
c) Was at or distal to a >45º bend in the vessel
d) Was severely calcified
e) Involved a bifurcation

7. Unprotected left main coronary artery disease (an obstruction greater than 50% in the left main coronary artery).

Criteria for Staging Procedures

The study design and eligibility criteria permitted for only one target lesion to be treated during the index procedure. If a patient presented with multiple lesions, the most complex lesion (e.g., the lesion with the highest diameter stenosis, longest lesion length, etc. at the physician's discretion) was treated. During the index procedure any other lesion identified in the target vessel was specified for treatment at least 9 months after the index procedure with any approved stent. Any lesion in another vessel was specified for treatment at least 30 days after the index procedure with any approved stent (see Staging Criteria Table below).

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Staging Criteria

Time point	Target vessel	Other vessel(s)
>9 months prior to index procedure	Any approved stent • Target lesion must be ≥15 mm away from previously placed stent • No more than 40% stenosis anywhere in the vessel other than the target lesion	Any approved stent
9 months to 30 days prior to index procedure	No interventions	Any approved stent Except Taxus stent
30 days to >24 hours prior to index procedure	No interventions	Any bare metal stent, provided: • No MACE events resulted, if ≤30 days from the index procedure • Two (2) post-procedural serial CK or CK-MB measures below the upper limits of normal, if ≤72 hours from the index procedure
≤24 hours prior to index procedure	No interventions	No interventions
During index procedure	• Only one target lesion • Single vessel treated	No interventions
≤30 days post-procedure	No interventions*	No interventions
>30 days – 9 months post-procedure	No interventions**	Any approved stent
>9 months post-procedure	Any approved treatment for the intended indication.	Any approved treatment for the intended indication.
Note:	Previous or planned (at the time of procedure) interventional radiotherapy at any time is excluded	Previous or planned (at the time of procedure) interventional radiotherapy at any time is excluded

* In case of acute/subacute closure (within 30 days post-procedure), target lesion/segment should have been treated with randomized device assigned for index procedure.
** In cases of target lesion/vessel restenosis, the target lesion/vessel may have been treated according to physician's discretion.

Patient Screening

All patients evaluated for potential PCI of the native coronary arteries were screened for study eligibility. A qualified member of the Institution's research team assigned to the ENDEAVOR IV Trial reviewed the patient's medical and cardiac history to screen for study eligibility. A screening log was provided to study sites to maintain a log of all screened patients by the sites. Clinical research sites were instructed to complete and fax screening logs to Medtronic on a weekly basis.

Enrollment

All subjects who signed an informed consent form were asked to participate. A total of 1,548 patients were enrolled. The treatment groups for the intent-to-treat population after randomization numbered 773 for the Endeavor arm and 775 for the Taxus arm.

Patient Withdrawal

Study subjects had the right to discontinue participation at any time without penalty or loss of benefits to which the subject was otherwise entitled. Withdrawn subjects were not replaced.

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Schedule of Treatments and Assessments

Event	Index Hospitalization					Follow-up				
	Screening/Pre-procedure			Procedure	Post-procedure[1]	30 Day	6 Month	8 Month	9 Month	1-5 Years Annually
	Prior to procedure	Prior to procedure within: 7 days	Prior to procedure within: 72 hrs.			Clinic Visit	Patient Contact[2]	Clinic Visit[3]	Clinic Visit	Patient Contact
Informed Consent signed	X									
Medical and cardiac history	X									
Angina status	X					X	X	X	X	X
Pregnancy test[4]		X								
Chemistry panel		X								
CBC with differential (including eosinophils)		X				X				
Lipid panel		X								
Liver function test		X								
12 lead ECG		X			X Within 24 hours					
CK and CK-MB			X		X 6-8 hours 12-16 hours 20-24 hours[5]					
ACT measurements				X						
Clinically-driven revascularization verification								X[6]		
QCA	X			X				X		
IVUS				X[3]				X		
AE monitoring				X	X	X	X	X	X	X SAEs only
Medication regimen[7]	X Within 24 hours			X	X	X	X	X	X	X[8]

1. Post-procedure was defined as removal of the last catheter.
2. Patient contact includes phone calls, email, and/or office visit.
3. For Angiographic/IVUS and Multi-stent subsets only.
4. For women of childbearing potential only.
5. If a patient was discharged prior to 20 hours, the 20-24 hour blood draw may not have been performed.
6. Functional study/stress test, FFR, or IVUS should have been conducted prior to diagnostic imaging for Angiographic/IVUS and Multi-stent subsets.
7. See Concomitant Medication Regimen section.
8. Antiplatelet/anticoagulation medications only.

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C. Objectives

Primary Objective

The primary objective of this study was to assess the non-inferior safety and efficacy of the Endeavor Zotarolimus-Eluting Coronary Stent System when compared to the Taxus Paclitaxel-Eluting Coronary Stent System for the treatment of single *de novo* lesions in native coronary arteries with a reference vessel diameter of 2.5-3.5 mm.

Study Endpoints

Primary Endpoint

The primary endpoint of this study was TVF rate at 9 months post-procedure.

Secondary Endpoints

The secondary endpoints of this study were:

- Acute success (device, lesion, and procedure)
- Angiographic parameters (in-stent and in-segment) in a subset of patients at 8 months post-procedure including:
  - Percent diameter stenosis (%DS)
  - Late lumen loss
  - Late loss index
  - Angiographic binary restenosis (ABR) rate
  - Minimum luminal diameter (MLD)
- Major adverse cardiac event (MACE) rate at 30 days, 6, 9, and 12 months post-procedure
- Neointimal hyperplastic volume and percent volume obstruction (%VO) at 8 months post-procedure as measured by intravascular ultrasound (IVUS) in a subset of patients
- Target site revascularization (TSR) rate and clinically-driven TSR rate at 9 months post-procedure
- Target vessel revascularization (TVR) rate and clinically-driven TVR rate at 9 months post-procedure

Additional Parameters

Angiography

Baseline and index procedure angiograms were evaluated by the Angiographic Core Laboratory. Follow-up angiograms were scheduled for 8 months after the procedure to determine angiographic outcomes in the Angiographic/IVUS and Multi-stent (patients who received two or more stents at the target lesion) subsets. Any coronary angiograms performed during the study follow-up period were forwarded to the Angiographic Core Laboratory for analysis. Subjects involved in the Angiographic cohort and Multi-stent subset were required to complete all assigned follow-up visits, including protocol mandated angiographic re-study. Patients involved in the Angiographic cohort and Multi-stent subset were exempt from the protocol mandated Angiographic follow-up repeat study only if TLR was sustained after the 30 day follow-up visit.

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Intravascular Ultrasound

Patients who participated in the IVUS cohort underwent IVUS imaging post-procedure upon attainment of optimal stent placement (as determined by angiography). Follow-up IVUS imaging was scheduled for 8 months after the index procedure. All IVUS recordings were analyzed by the IVUS Core Laboratory to determine stent apposition and plaque growth.

Subjects involved in the IVUS cohort were required to complete all assigned follow-up visits, including protocol mandated IVUS re-study. Subjects involved in the IVUS cohort were exempt from the protocol mandated IVUS follow-up repeat study only if they sustained TLR after the 30 day follow-up visit.

Safety Analyses

Adverse Events

Adverse events were coded according to the Medical Dictionary for Regulatory Activities (MedDRA™) dictionary, version 8.0. Adverse events were summarized through Month 9. The number and percentage of subjects with an event are presented for each treatment group by MedDRA™ System Organ Class and Preferred Term.

Serious adverse events (SAEs) are summarized by tabulating the number and percentage of subjects for each treatment group with an event through Month 9 for each treatment group by System Organ Class (e.g., cardiovascular, GI system) (SOC) and Preferred Term (PT) using the MedDRA™ dictionary. System Organ Classes are presented in alphabetical order; within each SOC, PTs are sorted in alphabetical order.

Table 24 summarizes the adjudicated device delivery failures and resulting treatment outcome. Counts for each type of delivery failure are presented.

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D. Study Phases and Procedures

I. Baseline and Screening

A. Patient Screening

All patients evaluated for potential PCI of the native coronary arteries were screened for study eligibility. A qualified member of the Institution's research team assigned to the ENDEAVOR IV Trial reviewed the patient's medical and cardiac history to initially screen patients for study eligibility. A screening log was provided to study sites to maintain a log of all the patients screened by the sites. Clinical research sites were instructed to complete and fax screening logs to Medtronic on a weekly basis.

B. Clinical Laboratory Procedures and Tests

Performed for all patients prior to the procedure to ascertain eligibility:

1. *Obtained and results reviewed within seven days before the procedure:*
   - A laboratory panel including: a complete blood count (CBC) with differential (including eosinophil counts), chemistry panel, liver function tests, and lipid panel
   - A pregnancy test (serum or urine) for women of childbearing potential was obtained
   - A 12 lead ECG was obtained

2. *Within 72 hours prior to the procedure,* CK and CK-MB isoenzyme test results were obtained.

Summary of Concomitant Medical Therapy

Time point	Medication	Regimen
Prior to Procedure	Heparin or bivalirudin	As needed
	Aspirin	A minimum of 75 mg daily (within 24 hours prior to procedure)
	Clopidogrel	≥300 mg loading dose within 24 hours prior to procedure No loading dose is required if the patient has taken at least 3 doses (75 mg/dose) of clopidogrel within 72 hours of the procedure.
During Procedure	Heparin or bivalirudin	To maintain ACT ≥250 seconds (or 200-250 seconds if GP IIb/IIIa receptor blocker is administered)
	Intracoronary nitroglycerin	50-200 μg prior to stenting and post-intervention angiograms
Post-Procedure	Heparin or bivalirudin	As needed
	Aspirin	A minimum of 75 mg daily indefinitely
	Clopidogrel	≥300 mg loading dose immediately post-procedure (typically within 30 minutes after removal of the last catheter), if not administered pre-procedure 75 mg daily (for ≥6 months)

All medications should have been documented from 24 hours pre-procedure through the 9 month follow-up assessment. Nutritional supplements such as niacin for control of hyperlipidemia should also have been documented on the Concomitant Medication Log case report form (CRF).

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C. Informed Consent

All potential patients were consented prior to undergoing any study specific procedures and prior to receiving study specific medications. All potential patients received both the Endeavor and Taxus Patient Guide prior to making an informed decision. Once the Investigator determined the patient's eligibility for the study, the background of the proposed study and the benefits and risks of the procedures and study was explained to the patient. Only patients or their legally authorized representatives who signed the site's IRB/EC approved informed consent prior to participation were eligible to be in the study. There were twelve instances (see Table 17b) where the wrong version of the informed consent form was provided to the patient or the patient did not date the form.

II. Randomization Phase

Randomization occurred after confirming the signed informed consent had been obtained, the patient and target lesion met all of the inclusion and none of the exclusion criteria, and prior to any percutaneous treatment to the target lesion. Eligible patients were randomized in a blinded fashion to one of the two treatment arms:

1. Endeavor Zotarolimus-Eluting Coronary Stent System OR
2. Taxus Paclitaxel-Eluting Coronary Stent System

Randomization was accomplished at each site using an IVRS. Patients were stratified by diabetic status and subsequently randomized to receive either the Endeavor or Taxus stent in a 1:1 ratio. A diabetic patient in this protocol was defined as an individual who is taking insulin, oral antidiabetic agents, or on a modified diet to treat diabetes mellitus.

Randomized patients who were not treated with the assigned study stent were followed-up for safety purposes and were included in the ITT set. Patients included in the ITT set were followed throughout the primary endpoint period and underwent the follow-up assessments through the 9 month follow-up assessment.

The ITT population consisted of 773 patients randomized to the Endeavor stent and 775 patients randomized to the Taxus stent.

III. Procedural Phase

The Procedural Phase began after the diagnostic angiogram. The Procedural Phase included the study stent implantation, collection of ACTs, final angiograms, and IVUS images.

Angiogram Procedure

Preparation and Angiography

i. Using standard procedures for balloon angioplasty, an introducer sheath of at least 6 French (0.064 in/1.63 mm) was introduced using the standard approach.
ii. The guiding catheter used during the stent procedure must have had a minimum internal diameter of 6 French (0.064 in/1.63 mm) and the guide wire diameter must not have been larger than 0.014 in (0.36 mm).
iii. Heparin or bivalirudin, with or without a GP IIb/IIIa receptor blocker, was administered and supplemented as needed to maintain anticoagulation throughout the procedure. A

baseline ACT was determined within 15 minutes after the administration of heparin or bivalirudin and prior to stenting. ACT and subsequent heparin or bivalirudin dosing was recorded throughout the procedure. Documentation of a final ACT level, before leaving the catheterization laboratory was also performed. All ACTs were recorded in the medical record for source documentation purposes.

iv. Following intracoronary injection of nitroglycerin, baseline angiography of the vessel was performed in at least 2 near-orthogonal views that show the target lesion free of foreshortening or vessel overlap, using a 6 French or larger guiding catheter.

Lesion/Vessel Pre-treatment

The target lesion was to have been pre-treated with standard percutaneous transluminal balloon angioplasty. The clinical protocol did not allow for direct stenting of the target vessel.

Meticulous attention must have been paid to the pre-dilatation technique in order to avoid balloon injury to ANY segment of the vessel that could not be entirely covered by the stent ("geographical miss"). Pre-dilatation should have been performed according to the Endeavor IFU and Taxus DFU provided with the assigned randomized stent.

Pre-dilatation must have been performed using a balloon with:

1. A diameter at least 0.5 mm smaller than the treatment stent, and
2. A length matching or shorter than the lesion length to be dilated (to avoid dilatation of the vessel wall adjacent to the stent), and
3. The length of the pre-dilatation balloon and the length of the pre-dilated vessel segment must be shorter than the stent to be implanted.

The use of other therapy (e.g., cutting balloons, directional coronary atherectomy (DCA), eximer laser, rotational atherectomy, thrombectomy, etc.) was not allowed in the target vessel.

IV. Post-procedure Phase

The Post-procedure Phase was the period immediately following implantation of the investigational device. At this time: Heparin was discontinued, ACT was monitored in accordance with hospital protocol, vascular sheaths were removed according to usual hospital practice, and approved vascular closure devices may have been used at the discretion of the investigator in accordance with the manufacturer's directions.

Antiplatelet/Anticoagulation Regimen

A loading dose of clopidogrel (≥300 mg) was administered immediately post-procedure (typically within 30 minutes after removal of the last catheter) if not administered prior to the procedure. Table 23 shows the reported compliance for this required medication regimen. If a patient developed a sensitivity or intolerance to clopidogrel subsequent to enrollment, the patient may have been given ticlopidine (250 mg BID); however, patients with a known hypersensitivity or contraindication to aspirin, clopidogrel, or ticlopidine were excluded from the study.

Clinical and Laboratory Procedures

ECG

An ECG was performed within 24 hours post-procedure. A 12 lead ECG was required to document any suspicious cardiac ischemic episode.

Cardiac Enzymes

CK and CK-MB were measured post-procedure following removal of the last catheter between:

- 6 - 8 hours
- 12 - 16 hours
- 20 - 24 hours

If a patient was discharged prior to 20 hours, the 20-24 hour blood draw may have not been performed. Other specified cardiac enzyme measurements must have been made within the specified time ranges. If total CK values were within normal ranges, CK-MB measurements may not have been performed (per hospital standards). However, it was strongly encouraged that CK-MB measurement was obtained with every total CK drawn, even if CK values were within normal limits.

If any CK elevation (CK above upper limit of normal) was noted post-procedure, CK and CK-MB measurements were performed every 8 hours for 24 hours, starting from when the first elevation was noted, and recorded on the CRF.

V. Discharge Phase

Prior to discharge, subjects had blood samples collected and ECGs performed (as described above in the post-procedure description). Information regarding concomitant medications and adverse events were recorded on the appropriate case report form.

All patients were to receive a minimum of 75 mg of aspirin daily indefinitely, and 75 mg daily of clopidogrel for at least 6 months.

VI. Follow-up Phase

Qualified study staff who conducted the follow-up imaging and clinical assessments were trained to the clinical protocol, listed on the Delegation of Authority, and were delegated responsibility to obtain follow-up information. Patients were instructed to return to the same research facility (including satellite campuses) during the 30 day and 9 month follow-up clinic visits.

Documentation of referring physicians, general practitioners, cardiologists, family members, and neighbors were solicited from study subjects. Any planned long absences from the area should have been recorded to facilitate continued ability to contact a study patient.

Follow-up contacts and procedures were/performed at the following time points:

30 days ± 5 days
6 months ± 14 days
8 months ± 14 days
9 months ± 14 days
12 months ± 30 days
Yearly to 5 years ± 30 days post-procedure

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Clinical assessments (e.g., angina status, blood draws, verifying adverse events, and capturing concomitant medications) must have been performed prior to any interventional procedure (e.g., angiography and IVUS) during 9 month follow-up period. Blood draws were performed according to hospital standard or as required for the needs of the patient's medication regimen. Subjects had two types of follow-up visits/assessments:

- Clinic visit: The patient must return to the same research facility (including satellite campuses).
- Follow-up assessments: These may be conducted by telephone, email, and/or office visits, unless stated otherwise.

All angiography cohort and multi-stent subsets patients were scheduled to have a protocol mandated repeat angiography performed at 8 months (±14 days) after the index procedure. These same angiographic cohort and multi-stent subset patients were also mandated to have an IVUS repeat evaluation during the 8 month follow-up angiogram (or earlier if a re-intervention was performed). Patients participating in the Angiographic/IVUS cohort and Multi-stent subset returned to the same research facility for the 8 month follow-up clinic visit.

Follow-up procedures for this study include:

6-8 hours, 12-16 hours, 20-24 hours post-procedure (post-procedure defined as removal of the last catheter)

- CK and CK-MB were measured within the specific time ranges to help determine the presence or absence of myocardial infarction post-procedure. If a patient was discharged prior to 20 hours, the 20-24 hour blood draw may not have been performed.
- An ECG was performed within 24 hours post-procedure.

Thirty days post-procedure (± 5 days) clinic visit

A clinical follow-up assessment during an office visit was scheduled at the investigational site 30 days post-procedure and consisted of:

- Angina status (according to the Canadian Cardiovascular Society Classification (CCSC) of angina)
- CBC with differential (including eosinophil counts)
- All adverse events (AEs)
- All concomitant medications
- Any interventional treatment that occurred since the previous contact (e.g., repeat revascularization)

Six months post-procedure (± 14 days) follow-up assessment

An assessment will be performed at 6 months post-procedure and consist of:

- Angina status (according to the CCSC of angina)
- All AEs
- All concomitant medications
- Any interventional treatment that occurred since the previous contact (e.g., repeat revascularization)

Eight months post-procedure (± 14 days) clinic visit (Angiographic/IVUS and Multi-stent subsets only)

A clinical follow-up assessment during an office visit was scheduled at the investigational site 8 months post-procedure and consisted of:

A clinical assessment (performed prior to angiographic and IVUS evaluation):

- Angina status (according to the CCSC of angina)
- All AEs
- All concomitant medications
- Any interventional treatment that occurred since the previous contact (e.g., repeat revascularization)
- Angiographic and IVUS evaluation:
- Study patients in the Angiography/IVUS subset underwent an angiogram and IVUS, respectively, at 8 months.
- Patients in the Multi-stent subset (patients receiving two or more stents at the target lesion) will undergo angiographic and IVUS evaluations at 8 months post-procedure at all sites.

Nine months post-procedure (± 14 days) clinic visit

A clinical follow-up assessment during an office visit was scheduled at the investigational site 9 months post-procedure and consisted of:

- Angina status assessment (according to the CCSC of angina)
- All AEs
- All concomitant medications
- Any interventional treatment that occurred since the previous contact (e.g., repeat revascularization)

Twelve months post-procedure (± 30 days) follow-up assessment

An assessment will be performed at 12 months post-procedure and consist of:

- Angina status (according to the CCSC of angina)
- Serious adverse events (SAEs) including MACE
- Concomitant antiplatelet/anticoagulant medications
- Any interventional treatment that occurred since the previous contact (e.g., repeat revascularization)

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Two years post-procedure (± 30 days) follow-up assessment

An assessment will be performed at 2 years post-procedure and consist of:

- Angina status (according to the CCSC of angina)
- SAEs including MACE
- Concomitant antiplatelet/anticoagulant medications
- Any interventional treatment that occurred since the previous contact (e.g., repeat revascularization)

Three years post-procedure (± 30 days) follow-up assessment

An assessment will be performed at 3 years post-procedure and consist of:

- Angina status (according to the CCSC of angina)
- SAEs including MACE
- Concomitant antiplatelet/anticoagulant medications
- Any interventional treatment that occurred since the previous contact (e.g., repeat revascularization)

Four years post-procedure (± 30 days) follow-up assessment

An assessment will be performed at 4 years post-procedure and consist of:

- Angina status (according to the CCSC of angina)
- SAEs including MACE
- Concomitant antiplatelet/anticoagulant medications
- Any interventional treatment that occurred since the previous contact (e.g., repeat revascularization)

Five years post-procedure (± 30 days) follow-up assessment

An assessment will be performed at 5 years post-procedure and consist of:

- Angina status (according to the CCSC of angina)
- SAEs including MACE
- Concomitant antiplatelet/anticoagulant medications
- Any interventional treatment that occurred since the previous contact (e.g., repeat revascularization)

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E. Clinical Events

Adverse Events

Adverse event information is collected throughout the study and documented in the patient's medical record. All AEs occurring through 9 months post-procedure, whether associated with the investigational product or not, were recorded on the CRFs by the Investigator or other appropriate site personnel.

Event, date of onset, severity, duration, and relationship to device were recorded on the appropriate CRF. AEs were followed until the event subsided or, in case of permanent impairment, until the event stabilized and the overall clinical outcome had been ascertained.

Serious Adverse Events and Death

For each adverse event observed, the Investigator decided whether it met the definition of a "serious" adverse event. The regulatory definition of a serious adverse event was an event that was fatal or life threatening, resulted in persistent or significant disability, required intervention to prevent permanent impairment/damage, or an event that resulted in congenital anomaly, hospital admission or prolongation of hospitalization.

Components of the composite secondary study endpoint, MACE (defined as death, QWMI or NQWMI, Emergent CABG, and TLR), were considered serious by this definition.

All SAEs occurring during the 9 month follow-up period, regardless of cause, was requested to be reported to the Data Coordinating Center (HCRI) within one 1 working day after the Investigator first learned of the event and to the IRB/EC within the required timeframe of each institution.

Unanticipated Adverse Device Effects

An unanticipated adverse device effect (UADE) was defined as any adverse effect on health or safety or any life-threatening problem or death that was caused by or associated with the investigational device. The effect must have not been previously identified in nature, severity or degree of incidence in the clinical protocol, informed consent or IFU. Other serious problems associated with the device that affects the rights or welfare of study patients was also considered UADEs.

UADEs were reported to HCRI within one (1) working day after the investigator first learned of the event and to the IRB/EC within the required timeframe of each institution.

Device Failures, Malfunctions and Near Incidents

All device failures, malfunctions and near incidents were documented on the Stent Tracking and Implant Information CRF, reported to Medtronic Clinical Customer Service and, if required, reported to the IRB/EC within one (1) working day after the investigator became aware of the event.

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In the case of an Endeavor device failure, malfunction or near incident related to the investigational device, the Endeavor stent was returned to the Medtronic Field Assurance Department.

All device failures and malfunctions were adjudicated by the CEC.

F. Statistical Methods of Analysis

This was a prospective, multi-center, single-blind, parallel, two-arm, randomized, controlled trial designed to assess the non-inferior effectiveness and safety of the Endeavor stent compared to the Taxus stent.

The final statistical analysis plan (version 6.0 dated January 24, 2007) was the source document for the analyses completed in this report.

The trial was conducted at 80 active sites in the US and enrolled 1,548 patients randomized to the Endeavor and Taxus stent in a 1:1 ratio. The number of patients in each group was 773 and 775 for Endeavor and Taxus, respectively.

Analysis and Reporting of Results

All statistical analyses were performed using Statistical Analysis System (SAS) for Windows (Version 8.02 or higher).

Analysis of Primary Endpoint

To test the non-inferiority of the primary clinical endpoint (9 month TVF), the Blackwelder (1982) approach was used. A statistical significance level of 0.05 was used.

Analysis of Baseline Variables

All clinically relevant baseline variables were tabulated and compared between subjects assigned the Endeavor stent and control arm of the trial. Categorical variables were tested using appropriate contingency table analyses (exact test), and continuous variables were tested using unpaired Student's t-test. Statistical significance on baseline variables were declared if the two-sided p-value was <0.05.

Analysis of Secondary Endpoints

<u>Pre-specified Secondary Endpoint of 8 Month In-segment Late Lumen Loss</u>

To test the inferiority hypothesis of the sufficiently powered secondary endpoint of 8-month in-segment late lumen loss, the unpaired Student's t-test was used at the statistical significance level of 0.05.

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Clinical Endpoints

Acute success, MACE rate at 30 days, 6, 9, and 12 months post-procedure, TLR rate and clinically-driven TLR rate at 9 months post-procedure, and TVR rate and clinically-driven TVR rate at 9 months post-procedure was calculated for the two arms. Categorical variables were tested using appropriate contingency table analyses (Fisher's exact test), and continuous variables were tested using unpaired Student's t-test. The time-sensitive nature of any response variable was displayed by using a Kaplan-Meier plot, with differences between groups for such variables tested by log rank tests.

Angiographic/IVUS Cohort

The first 328 consecutively enrolled patients were assigned to the Angiographic/IVUS cohort in an effort to evaluate in-stent and in-segment angiographic measures including: late lumen loss, late loss index, ABR rate, MLD and percent DS. These patients also received an IVUS assessment in an effort to evaluate IVUS parameters including neointimal hyperplasia and percent VO. ABR rate was tested using appropriate contingency table analyses (exact test). All other angiographic and IVUS measures were tested using unpaired Student's t-test.

Safety Analyses

Descriptive statistics were used to summarize and analyze the safety parameters. All safety analyses were performed on the ITT set.

Analysis Populations

The primary analysis sample was based on the principle of ITT. For this study, all patients who signed the written informed consent and were randomized were counted in the primary analysis.

In addition analyses, are presented on the per protocol population in this 9 month report.

Intent to Treat (ITT): For this study, all patients who met the study entry criteria, signed the written informed consent, and were randomized to a treatment arm, were counted in the primary analysis. Missing data for the primary endpoint were imputed via the multiple imputation technique, if applicable.

Per-Protocol (PP): The following table highlights the conditions that excluded subjects from the PP analysis. A count of the patients excluded from the ITT analysis based on these conditions is shown in the following discussion section.

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Endeavor	Taxus
During index procedure: 1. Did not receive any device 2. Received assigned study device, and another type of DES	During index procedure: 1. Did not receive any device 2. Received assigned study device, and another type of DES
Assigned Endeavor, but received Taxus	Assigned Taxus, but received Endeavor
The target lesion was a single de novo lesion in a native coronary artery.	The target lesion was a single de novo lesion in a native coronary artery.
Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave infarction having CK enzymes 2X the upper laboratory normal with the presence of a CK – MB elevated above the Institution's upper limit of normal).	Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave infarction having CK enzymes 2X the upper laboratory normal with the presence of a CK – MB elevated above the Institution's upper limit of normal).
Previous PCI of the target vessel within 9 months post-procedure..	Previous PCI of the target vessel within 9 months post-procedure..
During the index procedure, the target lesion required treatment with a device other than PTCA prior to stent placement (including but not limited to, cutting balloon, any atherectomy, any laser, thrombectomy, etc.).	During the index procedure, the target lesion required treatment with a device other than PTCA prior to stent placement (including but not limited to, cutting balloon, any atherectomy, any laser, thrombectomy, etc.).
Currently participating in an investigational drug or another device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints.[Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational trials.]	Currently participating in an investigational drug or another device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints.[Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational trials.]
Previous stenting (drug-eluting or bare metal) in the target vessel unless the following conditions were met: a) It had been at least 9 months since the previous stenting.	Previous stenting (drug-eluting or bare metal) in the target vessel unless the following conditions were met: a) It had been at least 9 months since the previous stenting.

Angiographic/IVUS Cohort: The Angiographic/IVUS cohort, consisted of the first 328 consecutively enrolled patients at all sites. All subset patients were to undergo angiography and IVUS immediately post-procedure and at 8 months post-procedure (or earlier if a re-intervention was performed).

Multi-Stent Subset: Patients who received two or more stents at the target lesion were to undergo angiographic and IVUS evaluations immediately post-procedure and at 8 months post-procedure at all sites. This subset is not analyzed in this report.

Principal safety and effectiveness analysis described below was performed on the ITT set. The analysis on the primary endpoint was repeated for the PP set at 9 months.

For the clinical outcomes of 30-day TVF, MACE, TLR, TVR, percentage rates were based on ITT patients with available 30-day follow-up (defined as patients with follow-up ≥25 days or

those that had an event within 30 days). For the clinical outcomes of 9-month TVF, MACE, TLR, TVR, percentage rates were based on ITT patients with available 9-month follow-up (defined as follow-up ≥256 days or have an event within 270 days). Kaplan-Meier estimates were presented for all ITT patients by treatment group, where patients without an event and without available 9-month follow-up will be censored at the last follow-up time point.

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Results Discussion

Summary of Protocol Deviations

Tables 17b and 18b display the most common site reported major and minor protocol deviations and the number of subjects with violations in each category. The most frequent site reported violation was:

	ENDEAVOR	TAXUS	All Patients
Target vessel has other lesions with greater than 40% diameter stenosis based on visual estimate or on-line QCA.	5	8	13

Violations of the study eligibility criteria leading to exclusion of subjects from the per protocol analyses are listed below.

	ENDEAVOR	TAXUS
The target lesion was a single de novo lesion in a native coronary artery.	2	2
Evidence of an acute myocardial infarction within 72 hours of the intended treatment (defined as: Q wave or non-Q wave infarction having CK enzymes 2X the upper laboratory normal with the presence of a CK – MB elevated above the Institution's upper limit of normal).	2	0
Previous PCI of the target vessel within 9 months post-procedure.	2	3
During the index procedure, the target lesion required treatment with a device other than PTCA prior to stent placement (including but not limited to, cutting balloon, any atherectomy, any laser, thrombectomy, etc.).	0	1
Currently participating in an investigational drug or another device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints.[Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational trials.]	1	0
Previous stenting (drug-eluting or bare metal) in the target vessel unless the following conditions were met: a) It had been at least 9 months since the previous stenting.	1	1

Baseline subject and lesion characteristics:

Baseline subject characteristics are summarized in Table 3. Randomized subjects had an overall mean age of 63.5 years, 67.7% were men, 30.8% had diabetes, 43.9% had multivessel coronary artery disease, 28.9% had prior PCI, 9.1% had prior CABG, and mean left ventricular ejection fraction was 57.38%. No statistical difference was observed between groups for any of the baseline characteristics summarized.

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Baseline lesion characteristics and quantitative angiographic data are shown in Tables 4 and 6a. No differences were observed for vessel or lesion location, lesion length, tortuosity, thrombus, calcification nor lesion class. The ACC/AHA lesion classification of B2 or C was met for 70.2% of lesions. As shown below from the data abstracted from Table 6a, no differences were observed in mean reference vessel diameter (RVD), MLD, and lesion length.

Lesion Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Pre-Procedure					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.73±0.47 (772)	2.70±0.46 (774)	2.72±0.47 (1546)	0.03 [-0.02, 0.08]	0.197
Range (Min,Max)	(1.64,4.34)	(1.49,4.02)	(1.49,4.34)		
MLD (mm)					
Mean±SD (n)	0.96±0.40 (772)	0.93±0.40 (774)	0.94±0.40 (1546)	0.03 [-0.01, 0.07]	0.149
Range (Min,Max)	(0.00,2.56)	(0.13,2.26)	(0.00,2.56)		
% Stenosis					
Mean±SD (n)	64.83±13.29 (772)	65.68±13.10 (774)	65.26±13.20 (1546)	-0.85 [-2.17, 0.46]	0.204
Range (Min,Max)	(20.34,100.00)	(26.73,95.30)	(20.34,100.00)		
Lesion Length (mm)					
Mean±SD (n)	13.41±5.67 (771)	13.80±6.09 (773)	13.60±5.88 (1544)	-0.38 [-0.97, 0.20]	0.199
Range (Min,Max)	(3.00,39.83)	(2.79,42.99)	(2.79,42.99)		

No statistically significant differences in baseline subject characteristics were observed between the treatment groups (clinical or lesion). The subjects enrolled in this study are representative of cardiac patients with moderate risk for development of restenosis and 9-month clinical events, based upon their baseline clinical characteristics. Compared with the published SIRIUS[1] and TAXUS IV[2] studies, the proportion of subjects with diabetes in this trial is slightly higher (24% in TAXUS IV and 26% in SIRIUS), and reference diameter (2.76 mm in TAXUS IV and 2.81 mm in SIRIUS) and lesion length are similar (13.4 mm in TAXUS IV and 14.4 mm in SIRIUS).

[1] Moses, JW; Leon, MB; Popma, JJ; Fitzgerald, PJ; Holmes, DR; O'Shaughnessy, C; Caputo, RP; Kereiakes, DJ; Williams, DO; Teirstein, PS, Jaeger, JL; Kuntz, RE. Sirolimus-Eluting Stents versus Standard Stents in Patients with Stenosis in a Native Coronary Artery. The New England Journal of Medicine 2003; 349:1315-1323.
[2] Stone, GW; Ellis, SG; Cox, DA; Hermiller, J; O'Shaughnessy, C; Mann, JT; Turco, M; Caputo, R; Bergin, P; Greenberg, J; Popma, JJ; Russell, ME. A Polymer-Based, Paclitaxel-Eluting Stent in Patients with Coronary Artery Disease. The New England Journal of Medicine 2004; 350:221-331.

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Study Procedures, Tests and Post-Procedure Implant Results

The compliance with pre and post procedure testing in this study was high. Deviations from the protocol required procedures are displayed in table 18b. For pre-procedure lab testing required within 7 days of randomization, 8 subjects reported protocol violations. These 8 deviations were reported for one or more component tests as shown in Table 18b. Table 18c lists the deviations classified as "other". All women who were not classified as post-menopausal/surgically sterile had a negative pregnancy test prior to procedure.

ECG:
All subjects had ECGs performed prior to enrollment except the 2 cases noted in Table 18b.

Pre- and post-procedure Baseline CK tests for all subjects
Three (3) subjects reported having pre-procedure CK enzyme testing completed outside the protocol-specified window, and 54 subjects did not have pre-procedure testing performed at all. Two hundred and sixty one additional patients had the post-procedure test taken outside of the protocol defined time window, and 101 patients did not have post-procedure testing performed at all. These and other post-procedure laboratory deviations are reported in Table 18b.

Medications
No statistically significant difference was observed for medication usage between study arms at any study timepoint. Prior to the procedure, subjects were to receive a minimum of 75 mg of aspirin and a loading dose of clopidogrel. Aspirin usage was reported in 96.2% (743/772) of Endeavor subjects and 96.1% (744/774) of Taxus subjects. Clopidogrel was reported in 64.2% (496/772) of Endeavor subjects and 64.9% (502/774) of Taxus subjects.

Following the procedure, subjects were to receive a minimum of 75 mg of aspirin daily indefinitely and 75 mg of clopidogrel daily for a minimum of 6 months. At post-procedure, data indicated that 28.8% (222/772) of Endeavor subjects and 27.9% (216/774) of Taxus subjects were receiving aspirin, 55.4% (428/772) of Endeavor subjects and 54.1% (419/774) of Taxus subjects were receiving clopidogrel, and 27.5% (212/772) of Endeavor subjects and 26.2% (203/774) of Taxus subjects were receiving both (or ticlopidine in place of clopidogrel).

At discharge, 99.2% (766/772) of Endeavor subjects and 99.2% (768/774) of Taxus subjects were receiving aspirin, 99.5% (768/772) of Endeavor subjects and 99.1% (767/774) of Taxus subjects were receiving clopidogrel, and 99.2% (766/772) of Endeavor subjects and 98.7% (764/774) of Taxus subjects were receiving both (or ticlopidine in place of clopidogrel).

Between discharge and 6 months post-procedure data shows that subjects retained the prescribed medication regimen at a rate of greater than 90% for each medication in each arm. Rates for aspirin usage continued to be high at 9 months post-procedure, but low compliance for clopidogrel usage reduces the rates for the combined aspirin and clopidogrel (or ticlopidine) administration (Table 23).

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A total of 22.7% of subjects (95/418) were reported as having been administered a GP IIb/IIIa receptor blocker pre-procedure, and the usage was divided evenly between the two groups (Table 5).

Randomization, Stent assignment and Actual Stent Implantation

The trial enrolled 1,548 subjects randomized to the Endeavor and Taxus stent in a 1:1 ratio. The number of subjects in each group was 773 and 775 for Endeavor and Taxus, respectively. There were 36 deviations related to stent implantation, as follows:

Deviation, n=36	Endeavor n=19	Taxus n=17
Assigned Stent Not Implanted/ Did Not Receive Assigned Stent	10	14
Received other study stent	3	1
Received Non-study DES	6*	1*
Unknown stent received	0	1

* Cypher was the non-study stent implanted.

The number of subjects with this deviation is small given the overall size of each study arm, evenly distributed between study groups, and the effect of these deviations are not believed to bias the current study results.

Acute procedural results and device performance:

There were no statistical differences between the study arms with respect to device, lesion and device-specific success. Device success was achieved in 97.3% and 97.9% of Endeavor and Taxus subjects respectively.

Procedural success was shown to be statistically significantly different (p=0.015), with an observed procedure success for Endeavor of 98.7% (760/770) and 96.8% (747/772). Differences for in-hospital MACE achieved statistical significance (p=0.018) as well and occurred in 0.9% of subjects in the Endeavor arm and 2.6% of subjects in Taxus arm.

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The acute quantitative angiographic results are reported in Table 6a. With respect to all parameters except proximal edge %DS (Endeavor = 2.44 ± 11.81 vs Taxus = 1.08 ± 11.68, p=0.027), no post-procedure results achieved statistical significance. The post-procedure angiographic results for each group are abstracted below from Table 6a for the main lesion and vessel characteristics.

Post-Procedure Lesion Characteristics	ENDEAVOR I(N=773 P atients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.79±0.47 (770)	2.76±0.47 (772)	2.78±0.47 (1542)	0.03 [-0.02, 0.08]	0.237
Range (Min,Max)	(1.56,4.48)	(1.63,4.13)	(1.56,4.48)		
In-Lesion					
MLD (mm)					
Mean±SD (n)	2.22±0.47 (770)	2.19±0.50 (772)	2.21±0.48 (1542)	0.03 [-0.02, 0.08]	0.196
Range (Min,Max)	(0.97,3.47)	(0.00,3.52)	(0.00,3.52)		
% Stenosis					
Mean±SD (n)	20.47±9.54 (770)	20.97±11.12 (772)	20.72±10.36 (1542)	-0.50 [-1.53, 0.54]	0.344
Range (Min,Max)	(-3.55,69.38)	(-1.65,100.00)	(-3.55,100.00)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	2.62±0.43 (763)	2.61±0.44 (763)	2.62±0.44 (1526)	0.01 [-0.04, 0.05]	0.703
Range (Min,Max)	(1.52,3.90)	(0.00,3.76)	(0.00,3.90)		
Mean Diameter (mm)					
Mean±SD (n)	2.96±0.44 (763)	2.97±0.45 (763)	2.96±0.44 (1526)	-0.01 [-0.05, 0.04]	0.727
Range (Min,Max)	(1.78,4.35)	(0.00,4.36)	(0.00,4.36)		
% Stenosis					
Mean±SD (n)	5.50±9.61 (763)	5.01±10.49 (763)	5.25±10.06 (1526)	0.48 [-0.53, 1.49]	0.348
Range (Min,Max)	(-31.25,35.70)	(-43.23,100.00)	(-43.23,100.00)		

Thirty-day MACE and early stent thrombosis (defined as occurring <30 days post-procedure):

By 30 days, MACE had occurred in 1.2% of subjects in the Endeavor arm and 3.0% of subjects in the Taxus arm. This difference in rates was statistically significant (p=0.019), and the observed rates for both arms are consistent with the results of DES devices for other contemporary stent trials. The difference in 30-day non-Q wave MI rate [0.5% (4/770) in Endeavor vs. 2.2% (17/771) in Taxus] was statistically significant (p=0.007) between groups, as was the 30-day percentage of TVF (p=0.010), in favor of the Endeavor group [1.0% (8/770)] compared with the Taxus group [3.0% (23/771)].

Early stent thrombosis occurred in 0.3% of subjects overall [0.4% (3/770) Endeavor vs. 0.3% (2/771) Taxus]. Early target vessel repeat revascularization was infrequent; occurring in 0.6% of subjects overall [0.4% (3/770) Endeavor vs. 0.9% (7/771) Taxus]. Statistical significance was not achieved for either event of early stent thrombosis nor TVR.

Refer to Table 11a for additional clinical results reported for subjects through day 30.

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Six-month MACE and late stent thrombosis:
By 180 days post-procedure, subjects experiencing MACE events occurred in 3.0% (23/766) of Endeavor subjects and 4.3% (33/759) of Taxus subjects, a result that did not achieve statistical significance. Between day 30 and 180 days, subjects in the Endeavor arm experienced the following new MACE events: 1 cardiac and 1 non-cardiac death, 4 non-Q wave MIs (NQWMI), and 10 new TLR events. For Taxus subjects, the new events were 4 deaths (2 cardiac and 2 non-cardiac) and 8 additional TLRs. There were no statistically significant differences in the component events of MACE between the two groups at 180 days. Three subjects experienced late stent thrombosis in the Endeavor group, but the difference between groups at 180 days did not achieve statistical significance. The rates for TVF at 180 days were 3.1% (24/766) and 5.1% (39/759), for the Endeavor and Taxus groups, respectively (p=0.054).

Refer to Table 11a for additional clinical results reported for subjects through Month 6.

Eight-month Follow-up Angiographic and IVUS Results:

Angiographic Cohort Analysis
Two subjects in the 8 Month Angio/IVUS subset were not required to return for the 8 Month angiographic follow-up due to a prior re-intervention (1) and subject death (1). Of the 326 remaining subjects, 210 had the follow-up within the protocol specified time window, 57 had their follow-up performed beyond the protocol specified window, 47 subjects had no follow-up angiography, and 12 subjects had an angiogram prior to the specified window.

IVUS Cohort Analysis
For the 8 Month Angio/IVUS subset, all subjects were required to have the 8 Month IVUS follow-up. Of the 328 subjects, 202 had the follow-up within the protocol specified time window, 5 subjects had their follow-up earlier than the protocol specified window, 50 subjects had their follow-up performed beyond the protocol specified window, and 70 subjects had no follow-up IVUS performed, and one subject died before having follow-up IVUS.

Angiographic and IVUS Results
Of the 328 subjects enrolled in the angiographic/IVUS cohort, 8 Month angiograms were available for 87.2% (286/328) of the subjects, of which 279 subjects had qualifying angiograms. With respect to IVUS, 73.8% (242/328) of the cohort had IVUS performed; only 46% (151/328) of subjects had evaluable data for the 8-months evaluation of the secondary endpoints of interest (neointimal hyperplastic volume and percent volume obstruction). All subjects in this cohort had one lesion treated during the index procedure. The number of subjects with evaluable angiographic/IVUS data is reported in parentheses in the table below for each parameter of interest.

The secondary objective of demonstrating non-inferiority of Endeavor to Taxus with respect to in-segment late loss was tested using a standard non-inferiority hypothesis test (Table 12). The p-value for testing the null hypothesis that Endeavor is inferior to Taxus with respect to in-segment late loss was 0.0890 and the upper limit of the 90% Confidence Interval for the difference was 0.22. Therefore the inferiority hypothesis could not be rejected and the secondary endpoint was not met.

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No statistically significant differences were observed in any of post-procedure angiographic and IVUS parameters, and in the 8-month result of in-stent and in-segment angiographic binary restenosis.

Statistically significant differences were observed in favor of the control device, Taxus, on several angiographic parameters. These data are reported in detail in Table 6a, and the findings were as follows:

8-Month Effectiveness Measure	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
In-Stent Minimal Lumen Diameter (mm)					
Mean±SD (n)	1.95±0.61 (143)	2.25±0.61 (135)	2.10±0.63 (278)	-0.30 [-0.45, -0.16]	<.001
Range (Min,Max)	(0.00,3.66)	(0.24,3.75)	(0.00,3.75)		
In-Stent Percent Diameter Stenosis (%)					
Mean±SD (n)	26.41±19.74 (143)	16.09±17.99 (135)	21.40±19.57 (278)	10.32 [5.85, 14.79]	<.001
Range (Min,Max)	(-9.60,100.00)	(-28.57,91.92)	(-28.57,100.00)		
In-Segment Minimal Lumen Diameter (mm)					
Mean±SD (n)	1.80±0.55 (144)	1.98±0.56 (135)	1.89±0.56 (279)	-0.18 [-0.31, -0.05]	0.008
Range (Min,Max)	(0.00,2.99)	(0.24,3.29)	(0.00,3.29)		
In-Segment Percent Diameter Stenosis (%)					
Mean±SD (n)	32.28±17.02 (144)	26.61±15.52 (135)	29.54±16.53 (279)	5.68 [1.83, 9.52]	0.004
Range (Min,Max)	(6.21,100.00)	(5.83,91.92)	(5.83,100.00)		
In-Stent Late Loss (mm)					
Mean±SD (n)	0.67±0.49 (142)	0.42±0.50 (135)	0.55±0.51 (277)	0.25 [0.13, 0.37]	<.001
Range (Min,Max)	(-0.42,2.31)	(-0.74,2.75)	(-0.74,2.75)		

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Results for the pre-specified secondary IVUS endpoints also demonstrate a statistically significant result, again in favor of the control device, Taxus.

8-Month Effectiveness Measure	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
Neointimal Hyperplastic Volume (mm^3)					
Mean±SD (n)	24.14±19.38 (74)	14.88±16.62 (77)	19.42±18.55 (151)	9.26 [3.46, 15.06]	0.002
Range (Min,Max)	(1.60,98.47)	(0.00,86.86)	(0.00,98.47)		
Volume Obstruction (%)					
Mean±SD (n)	15.72±10.40 (74)	9.88±9.24 (77)	12.74±10.22 (151)	5.84 [2.68, 9.00]	<.001
Range (Min,Max)	(2.05,41.02)	(0.00,35.00)	(0.00,41.02)		

Nine-month MACE and late stent thrombosis:
Nine-month clinical follow-up was available for 1,474 of the 1,548 total subjects (95.2%). The overall rate of 9-month MACE was 5.7% (42/740) for the Endeavor subjects vs. 5.7% (42/734) for the Taxus subjects (Table 1a). Between 180 and 270 days post-procedure in the Endeavor arm, 19 subjects experienced the following new MACE: 1 cardiac death, 1 NQWMI, and 17 TLRs. For Taxus, 9 subjects experienced new MACE events consisting of 2 non-cardiac deaths and 5 TLRs.

The TVR rate was 5.5% (41/740) in the Endeavor arm and 5.0% (37/734) in the Taxus arm. The Kaplan Meier estimate of the proportion of subjects free from TVF by month 9 was 93.3% for the Endeavor group compared with 92.8% for Taxus, a difference that did not reach statistical significance. The Kaplan Meier estimate of the proportion of subjects free from TLR by month 9 was 95.8% for Endeavor vs. 97.3% for Taxus, and the difference was not statistically significant. No additional late stent thrombosis events were reported by the 9-Month follow-up visit. The clinical narrative summaries for all of the MACE events that occurred through the 9 month follow-up visit are included in Table 26.

Refer to Table 11a for additional clinical results reported for subjects through Month 9.

Safety Results
Through 270 days, out of the 773 subjects randomized to the Endeavor stent, 606 (78.4%) experienced adverse events. Similarly, out of the 775 subjects randomized to the Taxus stent, 616 (79.5%) experienced adverse events through 270 days. A total of 270 subjects were reported to have had serious adverse events for each of the Endeavor and Taxus arms (34.9% and 34.8% respectively) through 270 days. No new safety concerns were identified during this study and the safety profile remains consistent between the two subject populations.

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Primary Clinical Endpoint Hypothesis Test:
The primary clinical endpoint evaluated in this non-inferiority study was TVF, defined as the rate of the composite of cardiac death, MI, or clinically-driven TVR at 9 months post-procedure. The inferiority null hypothesis for this study assumed that the Endeavor arm had a 9 month TVF rate that exceeded that of the control (Taxus) arm by the pre-specified margin of δ (delta) or greater. The alternative hypothesis was that the Endeavor arm had a 9 month TVF rate that was less than that of the Taxus arm, or exceeded that of the control but by less than δ.

Rejection of the null hypothesis signified that the Endeavor was non-inferior to Taxus with regard to 9 month TVF. The pre-specified non-inferiority margin for this trial was 3.8%.

Specifically, the null (H_o) and alternative (H_a) hypotheses were:

$$H_o: \pi_A \geq \pi_C + \delta$$
$$H_a: \pi_A < \pi_C + \delta$$

Where π_A was the true TVF rate for Endeavor and π_C was the true TVF rate for Taxus.

The results were as follows:

- The 9-month TVF rate for Endeavor was observed to be 6.8% (50/740).
- The 9-month TVF rate for Taxus was observed to be 7.4% (54/734).

The upper limit of the one-sided 95% Confidence Interval is below the protocol specified non-inferiority margin of 3.8% and the p-value of the test of the null hypothesis that the TVF rate in the Endeavor arm is greater than that in the Taxus arm plus delta was 0.0005. Therefore, the non-inferiority of Endeavor to Taxus with respect to the 9–Month TVF rate was demonstrated in this study.

Powered Secondary Endpoint
The study pre-specified to test the hypothesis of non-inferiority of in-segment late loss at 8 months as measured by QCA. The non-inferiority of 8 month in-segment late lumen loss was tested using a non-inferiority margin (delta) of 0.2 mm between the Endeavor arm compared to the Taxus arm. Therefore, the null hypothesis for the secondary endpoint was that the Endeavor stent had a secondary endpoint (in-segment late lumen loss) mean equal to or exceeding that of the control by 0.2 mm or more.

The alternative hypothesis was that the Endeavor stent had a mean in-segment late lumen loss less than the control Taxus stent mean plus 0.2 mm. Specifically,

$$H_o: \mu_{Endeavor} \geq \mu_{Taxus} + 0.2$$
$$H_a: \mu_{Endeavor} < \mu_{Taxus} + 0.2$$

Where $\mu_{Endeavor}$ was the mean late lumen loss for Endeavor and μ_{Taxus} was the mean late lumen loss for the control Taxus stent.

The results were as follows:

- The mean in-segment late lumen loss at 8 months in the Endeavor arm was 0.36 ± 0.47 mm (N=143).
- The mean in-segment late lumen loss at 8 months in the Taxus control arm was 0.23 mm ± 0.45 mm (N=135).

The p-value for testing the null hypothesis that Endeavor is inferior to Taxus with respect to in-segment late loss was 0.0890 and the upper limit of the 90% Confidence Interval for the difference was 0.22, which exceeded the 0.2 mm pre-specified non-inferiority margin. Therefore, the secondary objective of demonstrating non-inferiority of Endeavor to Taxus with respect to in-segment late loss was not met.

Subjects Excluded from the Per Protocol Analysis

A total of 48 ITT subjects were not included in the Per Protocol analysis for failing to meet eligibility (N=14) and stent implantation (N=36) requirements; two subjects (6445/3024 and 6451/3011) had both stent and inclusion/exclusion reasons that violated both sets of requirements. These subjects are not included in the per protocol analysis in Table 1b or Figure 4b. Fourteen subjects were omitted due to failed inclusion or exclusion criteria (7 Endeavor and 7 Taxus). Thirty-six total subjects were omitted due to stent related deviations (24 did not receive the assigned stent, 7 received a non-study stent, 4 received the stent opposite of their randomization assignment, and 1 stent type is not known the time of this date report).

Summary:
In summary, the 270-day results of ENDEAVOR IV show that the well balanced randomized groups performed fairly equally in most clinical measures and that some angiographic and IVUS measures that are significantly different between treatment groups still show that the Endeavor stent system is within acceptable clinical parameters and consistent with other clinical trial data for the product.

(1) The Endeavor Zotarolimus-Eluting Coronary Stent System demonstrates safety based on the following:
   A. Device success is greater than 97% and compares favorably with Taxus.
   B. The 30-day MACE rate is significantly lower than the rate in the Taxus arm.
   C. The long term MACE rates are consistent with the Taxus arm as well as other contemporary DES results.
   D. There were relatively few instances of early or late stent thrombosis.

(2) The Endeavor Zotarolimus-Eluting Coronary Stent System demonstrates efficacy with
   A. A significant non-inferior result with regard to the primary endpoint of 9 month TVF.
   B. Clinically acceptable angiographic result regarding late loss and %DS.
   C. Acceptably low rates of angiographic binary restenosis (in-stent and in-segment).

Conclusion:

Non-inferiority of the Endeavor Zotarolimus-Eluting Coronary Stent System to the Taxus Paclitaxel-Eluting Coronary Stent System was demonstrated on the primary clinical endpoint of Target Vessel Failure. Based on the totality of acute procedural results, 8-month angiographic and IVUS, and 9-month clinical follow-up the Endeavor Zotarolimus-Eluting Coronary Stent System has demonstrated similar clinical safety and efficacy outcomes and acceptable overall angiographic results compared with the Taxus Paclitaxel-Eluting Coronary Stent System.

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Section III. Tables

Table 2a. Number of Patients Treated by Investigator – All Enrolled Subjects

Site	Clinical Site, City, State	Principal Investigator		Number of Patients Enrolled
5006	Piedmont Hospital, Atlanta, GA	Charles	Brown	16
5023	Rush University Med. Center, Chicago. IL	Gary	Schaer	5
5038	Lehigh Valley Hospital, Allentown, PA	J. Patrick	Kleveland	18
5070	Huntsville Hospital, Huntsville, AL	Warren	Strickland	17
5091	Duke University Medical Center, Durham, NC	Michael	Sketch	28
5135	Penn State University, Hershey, PA	Steven	Ettinger	3
5166	St. Joseph Hospital of Atlanta, Atlanta, GA	Nicholas	Lembo	19
5186	Methodist Hospital Houston, Houston, TX	Stuart	Solomon	59
5216	Legacy Good Samaritan, Portland, OR	Brad	Titus	6
5251	Methodist Hospital, Indianapolis, IN	Jeffrey	Breall	2
5397	Emory Clinic, Atlanta, GA	John	Douglas	51
5434	Beth Israel Hospital, Boston, MA	Duane	Pinto	23
5451	Sinai Hospital, Baltimore, MD	Paul	Gurbel	14
5520	Oakwood Hospital, Dearborn, MI	Elias	Kassab	1
5545	ETMC Eastern Texas Medical Ctr, Tyler, TX	Jeffrey	Carr	19
5556	Wake Medical, Raleigh, NC	William	Newman	1
6001	Washington Hospital Ctr, Washington, DC	Lowell	Satler	14
6020	Henry Ford Hospital, Detroit, MI	Aaron	Kugelmass	11
6032	Abbott Northwestern Hospital, Minneapolis, MN	Michael	Mooney	14
6060	St. Mary's Rochester, Rochester, MN	Charanjit	Rihal	9
6143	Columbia Presbyterian Center NY, NY, NY	Leon	Moses	28
6160	Baptist Medical Center, Winston-Salem, NC	Robert	Applegate	11
6240	Riverside Methodist Hospital, Columbus, OH	Steven	Yakubov	16
6257	South Austin Hospital, Austin, TX	Samuel	DeMaio	14
6260	St. Luke's Hospital, Kansas City, MO	Barry	Rutherford	23
6261	St. Vincent Jacksonville, Jacksonville, FL	George	Pilcher	3
6419	UC Davis Medical Center, Sacramento, CA	Reginald	Low	4
6425	Anderson Medical Center, Anderson, SC	Brent	McLaurin	63
6426	Arkansas Heart Hospital, Little Rock, AK	David	Mego	12
6427	Barnes Jewish, St. Louis, MO	Jasvinder	Singh	23
6428	Baylor Heart & Vascular, Dallas, TX	Robert	Stoler	26
6429	Christ Hospital, Cincinnati, OH	Dean	Kereiakes	5
6430	Christus Spohn Shoreline, Corpus Chrisiti, TX	Doug	Pappas	13
6431	Carolinas Medical Center, Charlotte, NC	Hadley	Wilson	30
6433	Elyria Memorial Hospital, Elyria, OH	Charles	O'Shaughnessy	119
6434	Forsyth Medical Center, Winston-Salem, NC	John	Patterson	29
6435	Genesis Medical Center, Davenport, IA	Jon	Robken	3
6436	Indiana Heart, Indianapolis, IN	Woodrow	Corey	5
6437	Lakeland Regional Medical Center, Lakeland, FL	Douglas	Ebersole	16

(Table continued on following page)

Table 2a. (Continued) Number of Patients Treated by Investigator – All Enrolled Subjects

Site	Clinical Site, City, State	Principal Investigator		Number of Patients Enrolled
6438	Lubbock Heart Hospital, Lubbock, TX	Paul	Overlie	95
6439	Lutheran Hospital of IN, Fort Wayne, IN	Vijay	Chilakamarri	22
6440	Maine Medical Center, Portland, ME	Mirle	Kellet	1
6441	Mercy Hospital, Minneapolis, MN	Jeffrey	Chambers	15
6444	Mother Francis Health System, Tyler, TX	Thaddeus	Tolleson	45
6445	Nebraska Heart Institute, Lincoln, NE	Paul	Bajwa	29
6446	Ocala Regional Medical Center, Ocala, FL	Rakesh	Prashad	22
6448	Pitt County Memorial Hospital, Greenville, NC	Mike	Miller	11
6449	Presbyterian Hospital, Charlotte, NC	Bernard	Reen	44
6450	St. Vincent Health Center, Erie, PA	Mark	Izzo	9
6451	St. Cloud, St. Cloud, MN	Bernard	Erickson	4
6452	St. Joseph Hospital Health Center, Syracuse, NY	Ronald	Caputo	50
6453	St. Joseph Hospital, Lexington, KY	John	Sartini	14
6454	St. Joseph Medical Center, Towson, MD	Mark	Midei	4
6455	St. Thomas Hospital, Nashville, TN	Robert	Myers	13
6456	Heart Center of Indiana, Indianapolis, IN	Michael	Ball	51
6457	Strong Memorial Hospital, Rochester, NY	Fred	Ling	5
6458	Texsan Heart Hospital, San Antonio, TX	Christopher	Casey	2
6459	University of Florida, Jacksonville, FL	Ted	Bass	22
6461	Washington Hospital Healthcare, Fremont, CA	Ash	Jain	47
6462	Waukesha Memorial Hospital, Waukesha, WI	Terry	Zarling	7
6463	West Penn Hospital, Monroeville, PA	Aashish	Dua	18
6464	West Virginia University, Morgantown, WV	Robert	Beto	7
6574	Valley Hospital, Ridgewood, NJ	Janet	Strain	18
6575	Northern Michigan, Petosky, MI	Louis	Cannon	11
6576	Tacoma General Hospital, Tacoma, WA	Chad	Christopherson	8
6578	NY Hospital of Queens, Flushing, NY	Stylianos	Papadakos	26
6601	New York Presbyterian, NY, NY	S. Chiu	Wong	15
6620	St. Francis Hospital, Blue Island, IL	Joseph	Stella	12
6621	NY Methodist/Cornell Heart Center, Brooklyn, NY	Terrence	Sacchi	20
6624	Mercy General Hospital, Sacramento, CA	Joseph	Kozina	8
6625	Inova Fairfax, Falls Church, VA	Bryan	Raybuck	11
6626	Summa Health Akron City Hospital, Akron, OH	Ken	Berkovitz	19
6628	Emory Crawford Long, Atlanta, GA	Henry	Liberman	36
6634	Santa Rosa Memorial Hospital, Santa Rosa, CA	Sanjay	Dhar	4
6638	Sutter Medical Center, Santa Rosa, CA	Patrick	Coleman	27
6643	Geisinger Medical Center, Danville, PA	Thomas	Scott	4
6657	LDS Hospital, Salt Lake City, UT	J. Brent	Muhlestein	3
6663	MedCentral Mansfield Hospital, Mansfield, OH	Gregory	Eaton	2
6664	Welmont Holston Valley MC, Kingsport, TN	Herbert	Ladley	6
6670	Tufts - NEMC, Boston, MA	Carey	Kimmelstiel	8
			TOTAL	**1548**

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Table 2b. Clinical and Angiographic/IVUS Follow-Up Data Compliance - All Enrolled Subjects

Site	Index	30-Day Contact	6-Month Contact	9-Month Contact	Baseline QCA	8-Month QCA	Baseline IVUS	8-Month IVUS
5006	100.0% (16/16)	100.0% (16/16)	100.0% (16/16)	87.5% (14/16)	100.0% (16/16)	100.0% (5/5)	80.0% (4/5)	100.0% (5/5)
5023	100.0% (5/5)	100.0% (5/5)	80.0% (4/5)	60.0% (3/5)	100.0% (5/5)			
5038	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	88.9% (16/18)	100.0% (18/18)	85.7% (12/14)	78.6% (11/14)	71.4% (10/14)
5070	100.0% (17/17)	94.1% (16/17)	88.2% (15/17)	88.2% (15/17)	100.0% (17/17)			
5091	100.0% (28/28)	96.4% (27/28)	96.4% (27/28)	89.3% (25/28)	100.0% (28/28)	80.0% (8/10)	60.0% (6/10)	50.0% (5/10)
5135	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)			
5166	100.0% (19/19)	100.0% (19/19)	78.9% (15/19)	73.7% (14/19)	100.0% (19/19)	70.0% (7/10)	80.0% (8/10)	50.0% (5/10)
5186	100.0% (59/59)	96.6% (57/59)	93.2% (55/59)	84.7% (50/59)	100.0% (59/59)	90.5% (19/21)	76.2% (16/21)	76.2% (16/21)
5216	100.0% (6/6)	100.0% (6/6)	100.0% (6/6)	83.3% (5/6)	100.0% (6/6)			
5251	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)			
5397	100.0% (51/51)	98.0% (50/51)	90.2% (46/51)	90.2% (46/51)	100.0% (51/51)	75.0% (9/12)	58.3% (7/12)	50.0% (6/12)
5434	100.0% (23/23)	100.0% (23/23)	100.0% (23/23)	95.7% (22/23)	100.0% (23/23)	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)
5451	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	92.9% (13/14)	100.0% (14/14)	50.0% (2/4)	75.0% (3/4)	25.0% (1/4)
5520	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)			
5545	100.0% (19/19)	94.7% (18/19)	94.7% (18/19)	89.5% (17/19)	100.0% (19/19)			
5556	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)			
6001	100.0% (14/14)	100.0% (14/14)	92.9% (13/14)	92.9% (13/14)	100.0% (14/14)			
6020	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)	90.9% (10/11)	100.0% (11/11)			
6032	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	100.0% (4/4)	100.0% (4/4)	75.0% (3/4)
6060	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)			
6143	100.0% (28/28)	100.0% (28/28)	96.4% (27/28)	96.4% (27/28)	100.0% (28/28)	75.0% (6/8)	75.0% (6/8)	50.0% (4/8)
6160	100.0% (11/11)	100.0% (11/11)	81.8% (9/11)	81.8% (9/11)	100.0% (11/11)			
6240	100.0% (16/16)	100.0% (16/16)	93.8% (15/16)	93.8% (15/16)	100.0% (16/16)	88.9% (8/9)	77.8% (7/9)	66.7% (6/9)
6257	100.0% (14/14)	100.0% (14/14)	100.0% (14/14)	92.9% (13/14)	100.0% (14/14)	100.0% (6/6)	16.7% (1/6)	66.7% (4/6)
6260	100.0% (23/23)	100.0% (23/23)	100.0% (23/23)	95.7% (22/23)	100.0% (23/23)	87.5% (7/8)	87.5% (7/8)	62.5% (5/8)
6261	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)			
6419	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)			
6425	100.0% (63/63)	93.7% (59/63)	88.9% (56/63)	87.3% (55/63)	100.0% (63/63)	100.0% (7/7)	100.0% (7/7)	71.4% (5/7)
6426	100.0% (12/12)	91.7% (11/12)	91.7% (11/12)	91.7% (11/12)	91.7% (11/12)			
6427	100.0% (23/23)	100.0% (23/23)	100.0% (23/23)	100.0% (23/23)	100.0% (23/23)			
6428	100.0% (26/26)	100.0% (26/26)	96.2% (25/26)	92.3% (24/26)	100.0% (26/26)	84.6% (11/13)	76.9% (10/13)	61.5% (8/13)
6429	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
6430	100.0% (13/13)	100.0% (13/13)	100.0% (13/13)	76.9% (10/13)	100.0% (13/13)	62.5% (5/8)	75.0% (6/8)	12.5% (1/8)
6431	100.0% (30/30)	96.7% (29/30)	96.7% (29/30)	93.3% (28/30)	100.0% (30/30)	77.8% (7/9)	100.0% (9/9)	77.8% (7/9)
6433	100.0% (119/119)	99.2% (118/119)	98.3% (117/119)	100.0% (119/119)	100.0% (119/119)	97.1% (33/34)	88.2% (30/34)	97.1% (33/34)
6434	100.0% (29/29)	100.0% (29/29)	93.1% (27/29)	89.7% (26/29)	100.0% (29/29)	91.7% (11/12)	83.3% (10/12)	83.3% (10/12)
6435	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	33.3% (1/3)	66.7% (2/3)
6436	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	80.0% (4/5)	100.0% (5/5)	66.7% (2/3)	100.0% (3/3)	66.7% (2/3)
6437	100.0% (16/16)	93.8% (15/16)	87.5% (14/16)	81.3% (13/16)	100.0% (16/16)	33.3% (1/3)	100.0% (3/3)	33.3% (1/3)
6438	100.0% (95/95)	95.8% (91/95)	96.8% (92/95)	77.9% (74/95)	100.0% (95/95)	66.7% (8/12)	91.7% (11/12)	50.0% (6/12)

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Table 2b. (Continued) Clinical and Angiographic/IVUS Follow-Up Data Compliance - All Enrolled Subjects

Site	Index	30-Day Contact	6-Month Contact	9-Month Contact	Baseline QCA	8-Month QCA	Baseline IVUS	8-Month IVUS
6439	100.0% (22/22)	100.0% (22/22)	100.0% (22/22)	100.0% (22/22)	100.0% (22/22)	88.9% (8/9)	100.0% (9/9)	88.9% (8/9)
6440	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)			
6441	100.0% (15/15)	100.0% (15/15)	100.0% (15/15)	100.0% (15/15)	100.0% (15/15)	100.0% (5/5)	100.0% (5/5)	80.0% (4/5)
6444	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	100.0% (45/45)	81.8% (9/11)	81.8% (9/11)	72.7% (8/11)
6445	100.0% (29/29)	100.0% (29/29)	86.2% (25/29)	93.1% (27/29)	96.6% (28/29)	91.7% (11/12)	83.3% (10/12)	66.7% (8/12)
6446	100.0% (22/22)	100.0% (22/22)	100.0% (22/22)	100.0% (22/22)	100.0% (22/22)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)
6448	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)			
6449	100.0% (44/44)	100.0% (44/44)	100.0% (44/44)	100.0% (44/44)	100.0% (44/44)			
6450	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
6451	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (2/2)	50.0% (1/2)	50.0% (1/2)
6452	100.0% (50/50)	98.0% (49/50)	98.0% (49/50)	98.0% (49/50)	100.0% (50/50)			
6453	100.0% (14/14)	92.9% (13/14)	92.9% (13/14)	92.9% (13/14)	100.0% (14/14)			
6454	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (3/3)	66.7% (2/3)	100.0% (3/3)
6455	100.0% (13/13)	100.0% (13/13)	100.0% (13/13)	100.0% (13/13)	100.0% (13/13)			
6456	100.0% (51/51)	98.0% (50/51)	100.0% (51/51)	94.1% (48/51)	100.0% (51/51)	93.8% (15/16)	100.0% (16/16)	93.8% (15/16)
6457	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)			
6458	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)			
6459	100.0% (22/22)	100.0% (22/22)	81.8% (18/22)	77.3% (17/22)	100.0% (22/22)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)
6461	100.0% (47/47)	93.6% (44/47)	95.7% (45/47)	91.5% (43/47)	100.0% (47/47)	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)
6462	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)
6463	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)
6464	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	100.0% (7/7)	100.0% (1/1)	100.0% (1/1)	0.0% (0/1)
6574	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)
6575	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)	100.0% (11/11)			
6576	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (4/4)	75.0% (3/4)	100.0% (4/4)
6578	100.0% (26/26)	92.3% (24/26)	92.3% (24/26)	92.3% (24/26)	100.0% (26/26)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
6601	100.0% (15/15)	93.3% (14/15)	100.0% (15/15)	93.3% (14/15)	100.0% (15/15)	85.7% (6/7)	85.7% (6/7)	85.7% (6/7)
6620	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)			
6621	100.0% (20/20)	100.0% (20/20)	100.0% (20/20)	100.0% (20/20)	100.0% (20/20)	85.7% (6/7)	85.7% (6/7)	71.4% (5/7)
6624	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)			
6625	100.0% (11/11)	90.9% (10/11)	90.9% (10/11)	100.0% (11/11)	100.0% (11/11)			
6626	100.0% (19/19)	89.5% (17/19)	89.5% (17/19)	63.2% (12/19)	100.0% (19/19)			
6628	100.0% (36/36)	91.7% (33/36)	88.9% (32/36)	91.7% (33/36)	100.0% (36/36)			

Table 2b. (Continued) Clinical and Angiographic/IVUS Follow-Up Data Compliance - All Enrolled Subjects

Site	Index	30-Day Contact	6-Month Contact	9-Month Contact	Baseline QCA	8-Month QCA	Baseline IVUS	8-Month IVUS
6634	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)			
6638	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	88.9% (24/27)	100.0% (27/27)			
6643	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)			
6657	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	66.7% (2/3)	100.0% (3/3)			
6663	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)	100.0% (2/2)			
6664	100.0% (6/6)	100.0% (6/6)	100.0% (6/6)	100.0% (6/6)	100.0% (6/6)			
6670	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)			
	100.0% (1548/1548)	97.9% (1515/1548)	95.9% (1485/1548)	92.2% (1428/1548)	99.9% (1546/1548)	87.2% (286/328)	83.2% (273/328)	73.8% (242/328)

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Table 3. Baseline Demographics and Clinical Characteristics - ITT Set

Patient Characteristics	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Age (years)					
Mean±SD (n)	63.5±11.1 (773)	63.6±11.0 (775)	63.5±11.0 (1548)	-0.0 [-1.2, 1.1]	0.930
Range (Min,Max)	(27,92)	(31,89)	(27,92)		
Number of Men	66.9% (517/773)	68.5% (531/775)	67.7% (1048/1548)	-1.6% [-6.3%, 3.0%]	0.514
History of Smoking	62.6% (479/765)	60.4% (462/765)	61.5% (941/1530)	2.2% [-2.7%, 7.1%]	0.401
Prior Percutaneous Coronary Revascularization	28.2% (218/773)	29.5% (229/775)	28.9% (447/1548)	-1.3% [-5.9%, 3.2%]	0.575
Hyperlipidemia Requiring Treatment	81.4% (629/773)	84.8% (657/775)	83.1% (1286/1548)	-3.4% [-7.1%, 0.3%]	0.078
Diabetes Mellitus	31.2% (241/773)	30.5% (236/775)	30.8% (477/1548)	0.7% [-3.9%, 5.3%]	0.783
Insulin Dependent	10.3% (80/773)	8.3% (64/775)	9.3% (144/1548)	2.1% [-0.8%, 5.0%]	0.162
Hypertension Requiring Treatment	79.4% (614/773)	82.6% (640/775)	81.0% (1254/1548)	-3.1% [-7.1%, 0.8%]	0.120
Prior MI	21.1% (161/764)	23.2% (176/759)	22.1% (337/1523)	-2.1% [-6.3%, 2.1%]	0.324
Premature CAD in First Degree Relative	43.6% (267/612)	42.1% (257/611)	42.8% (524/1223)	1.6% [-4.0%, 7.1%]	0.603
Prior CABG	9.8% (76/773)	8.4% (65/775)	9.1% (141/1548)	1.4% [-1.4%, 4.3%]	0.332
Revascularization for Angina or MI	79.8% (617/773)	78.7% (610/775)	79.3% (1227/1548)	1.1% [-2.9%, 5.1%]	0.616
Worst Angina Category					0.367
Stable	45.6% (281/616)	47.9% (292/609)	46.8% (573/1225)		
Unstable	51.6% (318/616)	49.9% (304/609)	50.8% (622/1225)		
MI	2.8% (17/616)	2.1% (13/609)	2.4% (30/1225)		
CCS Class III or IV†	50.3% (309/614)	47.9% (292/610)	49.1% (601/1224)	2.5% [-3.1%, 8.1%]	0.392
Positive Stress Test	88.9% (447/503)	91.1% (460/505)	90.0% (907/1008)	-2.2% [-5.9%, 1.5%]	0.250
Ethnicity					
Hispanic/Latino	3.2% (24/759)	4.6% (35/762)	3.9% (59/1521)	-1.4% [-3.4%, 0.5%]	0.184
Race					0.211
White	90.4% (695/769)	88.7% (684/771)	89.5% (1379/1540)		
Black	5.2% (40/769)	5.4% (42/771)	5.3% (82/1540)		
Asian	1.7% (13/769)	1.2% (9/771)	1.4% (22/1540)		
Native Hawaiian or Other Pacific Islander	0.0% (0/769)	0.4% (3/771)	0.2% (3/1540)		
American Indian or Alaska Native	0.7% (5/769)	0.6% (5/771)	0.6% (10/1540)		
Other	2.1% (16/769)	3.6% (28/771)	2.9% (44/1540)		
Number of diseased, native, major epicardial coronary vessels (>50% Stenosed)					0.485
Single	54.9% (424/772)	57.2% (443/774)	56.1% (867/1546)		
Double	28.6% (221/772)	26.1% (202/774)	27.4% (423/1546)		
Triple	16.5% (127/772)	16.7% (129/774)	16.6% (256/1546)		
Ejection Fraction (%)					
Mean±SD (n)	57.30±9.92 (760)	57.46±10.30 (753)	57.38±10.11 (1513)	-0.17 [-1.19, 0.85]	0.745
Range (Min,Max)	(25.00,90.00)	(30.00,93.00)	(25.00,93.00)		

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.
Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value.
†CCS - Canadian Cardiovascular Society angina class.

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Table 4. Baseline Lesion Characteristics - ITT Set

Lesion Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Vessel Location					0.791
LAD	42.2% (326/772)	41.5% (321/774)	41.8% (647/1546)		
LCX	26.9% (208/772)	26.1% (202/774)	26.5% (410/1546)		
RCA	30.8% (238/772)	32.4% (251/774)	31.6% (489/1546)		
LCMA	0.0% (0/772)	0.0% (0/774)	0.0% (0/1546)		
Lesion Location					0.377
Ostial	1.9% (15/772)	2.8% (22/774)	2.4% (37/1546)		
Proximal	36.9% (285/772)	34.6% (268/774)	35.8% (553/1546)		
Mid	53.2% (411/772)	53.0% (410/774)	53.1% (821/1546)		
Distal	7.9% (61/772)	9.6% (74/774)	8.7% (135/1546)		
Lesion Length (mm)					0.199
Discrete (<10 mm)	31.3% (241/771)	30.1% (233/773)	30.7% (474/1544)		
Tubular (10-19.9 mm)	56.9% (439/771)	54.6% (422/773)	55.8% (861/1544)		
Diffuse (≥20 mm)	11.8% (91/771)	15.3% (118/773)	13.5% (209/1544)		
Eccentric	43.1% (332/771)	41.0% (317/774)	42.0% (649/1545)	2.1% [-2.8%, 7.0%]	0.410
Bend					0.384
<45 degrees	68.1% (526/772)	70.2% (543/774)	69.1% (1069/1546)		
≥45 degrees to <90 degrees	27.6% (213/772)	26.0% (201/774)	26.8% (414/1546)		
≥90 degrees	4.3% (33/772)	3.9% (30/774)	4.1% (63/1546)		
Thrombus	1.6% (12/772)	1.2% (9/774)	1.4% (21/1546)	0.4% [-0.8%, 1.5%]	0.520
Tortuosity					0.941
None	87.2% (673/772)	87.1% (674/774)	87.1% (1347/1546)		
Moderate	10.4% (80/772)	10.2% (79/774)	10.3% (159/1546)		
Severe	2.5% (19/772)	2.7% (21/774)	2.6% (40/1546)		
Calcification					0.932
Mild	66.7% (515/772)	66.9% (518/774)	66.8% (1033/1546)		
Moderate	26.8% (207/772)	26.6% (206/774)	26.7% (413/1546)		
Severe	6.5% (50/772)	6.5% (50/774)	6.5% (100/1546)		
Ulcerated	5.1% (39/772)	5.6% (43/774)	5.3% (82/1546)	-0.5% [-2.7%, 1.7%]	0.734
Aneurysm	2.7% (21/772)	3.9% (30/774)	3.3% (51/1546)	-1.2% [-2.9%, 0.6%]	0.254
Intimal Flap	0.6% (5/772)	0.1% (1/774)	0.4% (6/1546)	0.5% [-0.1%, 1.1%]	0.124
TIMI Flow					0.994
0	0.1% (1/772)	0.0% (0/774)	0.1% (1/1546)		
1	0.4% (3/772)	0.6% (5/774)	0.5% (8/1546)		
2	5.2% (40/772)	5.0% (39/774)	5.1% (79/1546)		
3	94.3% (728/772)	94.3% (730/774)	94.3% (1458/1546)		
Total Occlusion	0.5% (4/772)	0.6% (5/774)	0.6% (9/1546)	-0.1% [-0.9%, 0.6%]	1.000
Branch Vessel Disease	10.4% (80/772)	10.3% (80/774)	10.3% (160/1546)	0.0% [-3.0%, 3.1%]	1.000

Table 4. (Continued) Baseline Lesion Characteristics - ITT Set

Lesion Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Sidebranch Stenosis (%)					
Mean±SD (n)	25.01±29.54 (281)	25.88±31.07 (278)	25.44±30.29 (559)	-0.87 [-5.91, 4.17]	0.734
Range (Min,Max)	(0.00,90.00)	(0.00,100.00)	(0.00,100.00)		
Modified ACC/AHA Lesion Class					0.358
A	6.7% (52/772)	6.6% (51/774)	6.7% (103/1546)		
B1	23.7% (183/772)	22.5% (174/774)	23.1% (357/1546)		
B2	43.8% (338/772)	42.9% (332/774)	43.3% (670/1546)		
C	25.8% (199/772)	28.0% (217/774)	26.9% (416/1546)		

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.
Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value.

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Table 5. Procedural Characteristics - ITT Set

Lesion Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Pre-Stent Balloon Angioplasty					
Nominal Diameter (mm)					
Mean±SD (n)	2.53±0.37 (758)	2.51±0.37 (759)	2.52±0.37 (1517)	0.02 [-0.01, 0.06]	0.189
Range (Min,Max)	(2.00,4.00)	(1.50,3.70)	(1.50,4.00)		
Maximum Pressure (atm)					
Mean±SD (n)	10.30±3.29 (758)	10.22±3.17 (757)	10.26±3.23 (1515)	0.08 [-0.24, 0.41]	0.623
Range (Min,Max)	(1.00,26.00)	(3.00,26.00)	(1.00,26.00)		
Stenting Procedure					
Maximum Pressure (atm)					
Mean±SD (n)	13.28±2.61 (762)	13.96±2.79 (765)	13.62±2.72 (1527)	-0.68 [-0.95, -0.41]	<.001
Range (Min,Max)	(6.00,22.00)	(6.00,25.00)	(6.00,25.00)		
1st Stent Balloon Dilatation					
Nominal Diameter (mm)					
Mean±SD (n)	3.30±0.48 (272)	3.26±0.51 (267)	3.28±0.49 (539)	0.04 [-0.04, 0.12]	0.344
Range (Min,Max)	(2.00,4.50)	(1.50,4.50)	(1.50,4.50)		
Maximum Pressure (atm)					
Mean±SD (n)	15.41±3.70 (274)	15.32±3.57 (267)	15.37±3.64 (541)	0.09 [-0.52, 0.71]	0.764
Range (Min,Max)	(1.00,26.00)	(2.00,24.00)	(1.00,26.00)		
2nd Post-Stent Balloon Dilatation					
Nominal Diameter (mm)					
Mean±SD (n)	3.30±0.41 (23)	3.01±0.45 (36)	3.13±0.45 (59)	0.29 [0.06, 0.52]	0.014
Range (Min,Max)	(2.50,4.00)	(2.00,4.00)	(2.00,4.00)		
Maximum Pressure (atm)					
Mean±SD (n)	14.39±3.43 (23)	15.31±3.35 (35)	14.95±3.38 (58)	-0.92 [-2.74, 0.90]	0.314
Range (Min,Max)	(10.00,24.00)	(7.00,25.00)	(7.00,25.00)		
Maximum Post-Stent Balloon Diameter (mm)					
Mean±SD (n)	3.30±0.48 (281)	3.25±0.50 (283)	3.28±0.49 (564)	0.05 [-0.03, 0.13]	0.226
Range (Min,Max)	(2.00,4.50)	(1.50,4.50)	(1.50,4.50)		
Maximum Post-Stent Balloon Pressure (atm)					
Mean±SD (n)	15.43±3.70 (283)	15.45±3.53 (282)	15.44±3.61 (565)	-0.03 [-0.62, 0.57]	0.931
Range (Min,Max)	(1.00,26.00)	(6.00,25.00)	(1.00,26.00)		
GP IIb/IIIa Inhibitors					
Pre-procedure	23.9% (50/209)	21.5% (45/209)	22.7% (95/418)	2.4% [-5.6%, 10.4%]	0.641
During procedure	93.3% (195/209)	92.8% (194/209)	93.1% (389/418)	0.5% [-4.4%, 5.4%]	1.000
Post-procedure	73.7% (154/209)	76.1% (159/209)	74.9% (313/418)	-2.4% [-10.7%, 5.9%]	0.652

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.

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Table 6a. Quantitative Angiographic Analysis - ITT Set

Lesion Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Pre-Procedure					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.73±0.47 (772)	2.70±0.46 (774)	2.72±0.47 (1546)	0.03 [-0.02, 0.08]	0.197
Range (Min,Max)	(1.64,4.34)	(1.49,4.02)	(1.49,4.34)		
MLD (mm)					
Mean±SD (n)	0.96±0.40 (772)	0.93±0.40 (774)	0.94±0.40 (1546)	0.03 [-0.01, 0.07]	0.149
Range (Min,Max)	(0.00,2.56)	(0.13,2.26)	(0.00,2.56)		
% Stenosis					
Mean±SD (n)	64.83±13.29 (772)	65.68±13.10 (774)	65.26±13.20 (1546)	-0.85 [-2.17, 0.46]	0.204
Range (Min,Max)	(20.34,100.00)	(26.73,95.30)	(20.34,100.00)		
Lesion Length (mm)					
Mean±SD (n)	13.41±5.67 (771)	13.80±6.09 (773)	13.60±5.88 (1544)	-0.38 [-0.97, 0.20]	0.199
Range (Min,Max)	(3.00,39.83)	(2.79,42.99)	(2.79,42.99)		
Post-Procedure					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.79±0.47 (770)	2.76±0.47 (772)	2.78±0.47 (1542)	0.03 [-0.02, 0.08]	0.237
Range (Min,Max)	(1.56,4.48)	(1.63,4.13)	(1.56,4.48)		
In-Segment					
MLD (mm)					
Mean±SD (n)	2.22±0.47 (770)	2.19±0.50 (772)	2.21±0.48 (1542)	0.03 [-0.02, 0.08]	0.196
Range (Min,Max)	(0.97,3.47)	(0.00,3.52)	(0.00,3.52)		
% Stenosis					
Mean±SD (n)	20.47±9.54 (770)	20.97±11.12 (772)	20.72±10.36 (1542)	-0.50 [-1.53, 0.54]	0.344
Range (Min,Max)	(-3.55,69.38)	(-1.65,100.00)	(-3.55,100.00)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	2.62±0.43 (763)	2.61±0.44 (763)	2.62±0.44 (1526)	0.01 [-0.04, 0.05]	0.703
Range (Min,Max)	(1.52,3.90)	(0.00,3.76)	(0.00,3.90)		
Mean Diameter (mm)					
Mean±SD (n)	2.96±0.44 (763)	2.97±0.45 (763)	2.96±0.44 (1526)	-0.01 [-0.05, 0.04]	0.727
Range (Min,Max)	(1.78,4.35)	(0.00,4.36)	(0.00,4.36)		
% Stenosis					
Mean±SD (n)	5.50±9.61 (763)	5.01±10.49 (763)	5.25±10.06 (1526)	0.48 [-0.53, 1.49]	0.348
Range (Min,Max)	(-31.25,35.70)	(-43.23,100.00)	(-43.23,100.00)		

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Table 6a. (Continued) Quantitative Angiographic Analysis - ITT Set

Lesion Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Proximal Edge					
MLD (mm)					
Mean±SD (n)	2.73±0.57 (730)	2.74±0.56 (728)	2.73±0.57 (1458)	-0.01 [-0.07, 0.05]	0.705
Range (Min,Max)	(1.24,4.87)	(1.18,4.38)	(1.18,4.87)		
Mean Diameter (mm)					
Mean±SD (n)	2.94±0.56 (730)	2.94±0.54 (728)	2.94±0.55 (1458)	-0.01 [-0.06, 0.05]	0.797
Range (Min,Max)	(1.63,4.90)	(1.53,5.49)	(1.53,5.49)		
% Stenosis					
Mean±SD (n)	2.44±11.81 (730)	1.08±11.68 (728)	1.76±11.76 (1458)	1.36 [0.16, 2.57]	0.027
Range (Min,Max)	(-33.17,40.91)	(-33.73,42.01)	(-33.73,42.01)		
Distal Edge					
MLD (mm)					
Mean±SD (n)	2.36±0.54 (758)	2.35±0.53 (758)	2.36±0.53 (1516)	0.02 [-0.03, 0.07]	0.486
Range (Min,Max)	(1.08,4.70)	(0.42,4.29)	(0.42,4.70)		
Mean Diameter (mm)					
Mean±SD (n)	2.58±0.52 (758)	2.56±0.52 (758)	2.57±0.52 (1516)	0.02 [-0.03, 0.07]	0.449
Range (Min,Max)	(1.40,4.92)	(0.79,4.94)	(0.79,4.94)		
% Stenosis					
Mean±SD (n)	15.37±11.60 (758)	15.45±11.44 (758)	15.41±11.51 (1516)	-0.08 [-1.24, 1.08]	0.887
Range (Min,Max)	(-18.76,51.22)	(-26.61,79.51)	(-26.61,79.51)		

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Table 6a. (Continued) Quantitative Angiographic Analysis - Angiographic/IVUS Subset

Lesion Characteristic	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
8 Month Follow-up					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.65±0.47 (144)	2.68±0.45 (135)	2.67±0.46 (279)	-0.03 [-0.14, 0.08]	0.635
Range (Min,Max)	(1.67,3.76)	(1.69,3.86)	(1.67,3.86)		
In-Segment					
MLD (mm)					
Mean±SD (n)	1.80±0.55 (144)	1.98±0.56 (135)	1.89±0.56 (279)	-0.18 [-0.31, -0.05]	0.008
Range (Min,Max)	(0.00,2.99)	(0.24,3.29)	(0.00,3.29)		
% Stenosis					
Mean±SD (n)	32.28±17.02 (144)	26.61±15.52 (135)	29.54±16.53 (279)	5.68 [1.83, 9.52]	0.004
Range (Min,Max)	(6.21,100.00)	(5.83,91.92)	(5.83,100.00)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	1.95±0.61 (143)	2.25±0.61 (135)	2.10±0.63 (278)	-0.30 [-0.45, -0.16]	<.001
Range (Min,Max)	(0.00,3.66)	(0.24,3.75)	(0.00,3.75)		
Mean Diameter (mm)					
Mean±SD (n)	2.41±0.56 (143)	2.72±0.51 (135)	2.56±0.56 (278)	-0.31 [-0.44, -0.18]	<.001
Range (Min,Max)	(0.00,4.13)	(1.38,4.08)	(0.00,4.13)		
% Stenosis					
Mean±SD (n)	26.41±19.74 (143)	16.09±17.99 (135)	21.40±19.57 (278)	10.32 [5.85, 14.79]	<.001
Range (Min,Max)	(-9.60,100.00)	(-28.57,91.92)	(-28.57,100.00)		
Proximal Edge					
MLD (mm)					
Mean±SD (n)	2.45±0.60 (139)	2.50±0.69 (133)	2.47±0.65 (272)	-0.05 [-0.21, 0.10]	0.510
Range (Min,Max)	(0.29,3.95)	(0.28,4.12)	(0.28,4.12)		
Mean Diameter (mm)					
Mean±SD (n)	2.72±0.59 (139)	2.74±0.62 (133)	2.73±0.60 (272)	-0.02 [-0.16, 0.13]	0.808
Range (Min,Max)	(0.93,4.25)	(1.01,4.33)	(0.93,4.33)		
% Stenosis					
Mean±SD (n)	7.54±16.11 (139)	7.11±18.86 (133)	7.33±17.48 (272)	0.43 [-3.75, 4.61]	0.840
Range (Min,Max)	(-24.44,84.90)	(-35.57,90.57)	(-35.57,90.57)		

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Table 6a. (Continued) Quantitative Angiographic Analysis - Angiographic/IVUS Subset

Lesion Characteristic	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
Distal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.17±0.50 (143)	2.24±0.53 (135)	2.21±0.51 (278)	-0.06 [-0.18, 0.06]	0.300
Range (Min,Max)	(0.00,3.46)	(0.83,3.53)	(0.00,3.53)		
Mean Diameter (mm)					
Mean±SD (n)	2.38±0.51 (143)	2.45±0.52 (135)	2.41±0.52 (278)	-0.07 [-0.19, 0.05]	0.260
Range (Min,Max)	(0.00,3.64)	(1.33,3.66)	(0.00,3.66)		
% Stenosis					
Mean±SD (n)	17.82±12.59 (143)	16.83±12.13 (135)	17.34±12.36 (278)	0.99 [-1.93, 3.91]	0.505
Range (Min,Max)	(-3.61,100.00)	(-7.11,65.45)	(-7.11,100.00)		
Binary Restenosis					
In-Segment	15.3% (22/144)	10.4% (14/135)	12.9% (36/279)	4.9% [-2.9%, 12.7%]	0.284
Within the Stent	13.3% (19/143)	6.7% (9/135)	10.1% (28/278)	6.6% [-0.4%, 13.6%]	0.075
Proximal Edge	3.6% (5/139)	3.8% (5/133)	3.7% (10/272)	-0.2% [-4.6%, 4.3%]	1.000
Distal Edge	0.7% (1/143)	0.7% (1/135)	0.7% (2/278)	-0.0% [-2.0%, 1.9%]	1.000

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Table 6a. (Continued) Quantitative Angiographic Analysis - ITT Set and Angiographic/IVUS Subset

Lesion Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Acute Gain (mm)					
In-Segment					
Mean±SD (n)	1.26±0.50 (770)	1.26±0.51 (772)	1.26±0.50 (1542)	0.00 [-0.05, 0.05]	0.937
Range (Min,Max)	(0.00,2.81)	(-0.71,2.94)	(-0.71,2.94)		
Within the Stent					
Mean±SD (n)	1.66±0.48 (763)	1.68±0.47 (763)	1.67±0.48 (1526)	-0.02 [-0.07, 0.03]	0.425
Range (Min,Max)	(0.27,3.08)	(-0.64,3.16)	(-0.64,3.16)		

8-Month Late Loss (mm)	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
In-Segment					
Mean±SD (n)	0.36±0.47 (143)	0.23±0.45 (135)	0.30±0.46 (278)	0.13 [0.02, 0.23]	0.023
Range (Min,Max)	(-0.48,1.90)	(-0.78,2.45)	(-0.78,2.45)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	0.67±0.49 (142)	0.42±0.50 (135)	0.55±0.51 (277)	0.25 [0.13, 0.37]	<.001
Range (Min,Max)	(-0.42,2.31)	(-0.74,2.75)	(-0.74,2.75)		
Mean Diameter Late Loss					
Mean±SD (n)	0.55±0.42 (142)	0.29±0.34 (135)	0.42±0.40 (277)	0.27 [0.18, 0.36]	<.001
Range (Min,Max)	(-0.36,2.51)	(-0.74,1.15)	(-0.74,2.51)		
Within the Proximal Edge					
MLD (mm)					
Mean±SD (n)	0.24±0.46 (137)	0.27±0.45 (133)	0.25±0.45 (270)	-0.03 [-0.13, 0.08]	0.641
Range (Min,Max)	(-0.93,1.91)	(-0.59,3.06)	(-0.93,3.06)		
Mean Diameter Late Loss					
Mean±SD (n)	0.19±0.37 (137)	0.22±0.35 (133)	0.20±0.36 (270)	-0.02 [-0.11, 0.06]	0.595
Range (Min,Max)	(-0.83,1.48)	(-0.48,2.36)	(-0.83,2.36)		
Within the Distal Edge					
MLD (mm)					
Mean±SD (n)	0.13±0.40 (142)	0.10±0.35 (135)	0.11±0.38 (277)	0.03 [-0.06, 0.12]	0.532
Range (Min,Max)	(-0.72,2.36)	(-0.80,1.01)	(-0.80,2.36)		
Mean Diameter Late Loss					
Mean±SD (n)	0.15±0.37 (142)	0.13±0.42 (135)	0.14±0.40 (277)	0.02 [-0.07, 0.11]	0.680
Range (Min,Max)	(-0.49,2.54)	(-0.72,3.16)	(-0.72,3.16)		

The upper bound of one-sided 95% CI for in-segment late loss was 0.22, which exceeded 0.2 mm non-inferiority margin, the secondary endpoint was not met.

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Table 6a. (Continued) Quantitative Angiographic Analysis - ITT Set and Angiographic/IVUS Subset

Loss Index	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
In-Segment					
Arithmetic					
Mean±SD (n)	0.30±0.49 (143)	0.17±0.41 (135)	0.23±0.45 (278)	0.13 [0.02, 0.23]	0.018
Range (Min,Max)	(-1.39,2.44)	(-1.44,1.69)	(-1.44,2.44)		
Regression					
Coefficient ± SE	0.27±0.08	0.27±0.09	0.26±0.06	0.01[-0.22,0.23]	
Within the Stent					
Arithmetic					
Mean±SD (n)	0.43±0.34 (142)	0.24±0.31 (135)	0.34±0.34 (277)	0.18 [0.10, 0.26]	<.001
Range (Min,Max)	(-0.31,2.22)	(-0.28,1.49)	(-0.31,2.22)		
Regression					
Coefficient ± SE	0.14±0.09	0.19±0.10	0.15±0.07	-0.05[-0.30,0.21]	

N = the maximum number of eligible patients, n = number of patients with evaluable data.
All data assessed by the Angiographic Core Laboratory

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Table 6b. Interpolated Quantitative Angiographic Analysis - ITT Set

Lesion Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Pre-Procedure					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.66±0.50 (772)	2.64±0.48 (774)	2.65±0.49 (1546)	0.02 [-0.02, 0.07]	0.318
Range (Min,Max)	(0.55,4.53)	(1.36,4.24)	(0.55,4.53)		
MLD (mm)					
Mean±SD (n)	0.96±0.40 (772)	0.93±0.40 (774)	0.94±0.40 (1546)	0.03 [-0.01, 0.07]	0.149
Range (Min,Max)	(0.00,2.56)	(0.13,2.26)	(0.00,2.56)		
% Stenosis					
Mean±SD (n)	63.90±13.58 (772)	64.81±13.42 (774)	64.36±13.50 (1546)	-0.91 [-2.26, 0.44]	0.186
Range (Min,Max)	(20.74,100.00)	(24.00,96.35)	(20.74,100.00)		
Lesion Length (mm)					
Mean±SD (n)	13.41±5.67 (771)	13.80±6.09 (773)	13.60±5.88 (1544)	-0.38 [-0.97, 0.20]	0.199
Range (Min,Max)	(3.00,39.83)	(2.79,42.99)	(2.79,42.99)		
Post-Procedure					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.74±0.48 (770)	2.73±0.49 (772)	2.74±0.49 (1542)	0.01 [-0.04, 0.06]	0.685
Range (Min,Max)	(1.56,4.22)	(1.55,4.29)	(1.55,4.29)		
In-Segment					
MLD (mm)					
Mean±SD (n)	2.22±0.47 (770)	2.19±0.50 (772)	2.21±0.48 (1542)	0.03 [-0.02, 0.08]	0.196
Range (Min,Max)	(0.97,3.47)	(0.00,3.52)	(0.00,3.52)		
% Stenosis					
Mean±SD (n)	18.86±10.47 (770)	19.78±12.23 (772)	19.32±11.39 (1542)	-0.92 [-2.06, 0.22]	0.113
Range (Min,Max)	(-6.94,69.09)	(-2.69,100.00)	(-6.94,100.00)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	2.62±0.43 (763)	2.61±0.44 (763)	2.62±0.44 (1526)	0.01 [-0.04, 0.05]	0.703
Range (Min,Max)	(1.52,3.90)	(0.00,3.76)	(0.00,3.90)		
Mean Diameter (mm)					
Mean±SD (n)	2.96±0.44 (763)	2.97±0.45 (763)	2.96±0.44 (1526)	-0.01 [-0.05, 0.04]	0.727
Range (Min,Max)	(1.78,4.35)	(0.00,4.36)	(0.00,4.36)		
% Stenosis					
Mean±SD (n)	3.75±9.14 (763)	3.91±10.08 (763)	3.83±9.62 (1526)	-0.16 [-1.12, 0.81]	0.749
Range (Min,Max)	(-37.87,32.69)	(-26.21,100.00)	(-37.87,100.00)		

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Table 6b. (Continued) Interpolated Quantitative Angiographic Analysis - ITT Set

Lesion Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Proximal Edge					
MLD (mm)					
Mean±SD (n)	2.73±0.57 (730)	2.74±0.56 (728)	2.73±0.57 (1458)	-0.01 [-0.07, 0.05]	0.705
Range (Min,Max)	(1.24,4.87)	(1.18,4.38)	(1.18,4.87)		
Mean Diameter (mm)					
Mean±SD (n)	2.94±0.56 (730)	2.94±0.54 (728)	2.94±0.55 (1458)	-0.01 [-0.06, 0.05]	0.797
Range (Min,Max)	(1.63,4.90)	(1.53,5.49)	(1.53,5.49)		
% Stenosis					
Mean±SD (n)	-0.30±18.45 (730)	-1.06±18.74 (728)	-0.68±18.59 (1458)	0.76 [-1.15, 2.67]	0.436
Range (Min,Max)	(-82.32,47.48)	(-68.72,59.14)	(-82.32,59.14)		
Distal Edge					
MLD (mm)					
Mean±SD (n)	2.36±0.54 (758)	2.35±0.53 (758)	2.36±0.53 (1516)	0.02 [-0.03, 0.07]	0.486
Range (Min,Max)	(1.08,4.70)	(0.42,4.29)	(0.42,4.70)		
Mean Diameter (mm)					
Mean±SD (n)	2.58±0.52 (758)	2.56±0.52 (758)	2.57±0.52 (1516)	0.02 [-0.03, 0.07]	0.449
Range (Min,Max)	(1.40,4.92)	(0.79,4.94)	(0.79,4.94)		
% Stenosis					
Mean±SD (n)	13.76±11.71 (758)	14.31±12.27 (758)	14.04±11.99 (1516)	-0.55 [-1.76, 0.66]	0.372
Range (Min,Max)	(-20.06,48.64)	(-51.32,79.51)	(-51.32,79.51)		

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Table 6b. Interpolated Quantitative Angiographic Analysis - Angiographic/IVUS Subset

Lesion Characteristic	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
8 Month Follow-up					
Reference Vessel Diameter (mm)					
Mean±SD (n)	2.51±0.49 (144)	2.60±0.45 (135)	2.55±0.47 (279)	-0.09 [-0.20, 0.02]	0.103
Range (Min,Max)	(1.47,4.03)	(1.50,3.67)	(1.47,4.03)		
In-Segment					
MLD (mm)					
Mean±SD (n)	1.80±0.55 (144)	1.98±0.56 (135)	1.89±0.56 (279)	-0.18 [-0.31, -0.05]	0.008
Range (Min,Max)	(0.00,2.99)	(0.24,3.29)	(0.00,3.29)		
% Stenosis					
Mean±SD (n)	28.06±18.31 (144)	24.22±16.21 (135)	26.20±17.40 (279)	3.85 [-0.24, 7.93]	0.065
Range (Min,Max)	(-1.00,100.00)	(-4.11,90.66)	(-4.11,100.00)		
Within the Stent					
MLD (mm)					
Mean±SD (n)	1.95±0.61 (143)	2.25±0.61 (135)	2.10±0.63 (278)	-0.30 [-0.45, -0.16]	<.001
Range (Min,Max)	(0.00,3.66)	(0.24,3.75)	(0.00,3.75)		
Mean Diameter (mm)					
Mean±SD (n)	2.41±0.56 (143)	2.72±0.51 (135)	2.56±0.56 (278)	-0.31 [-0.44, -0.18]	<.001
Range (Min,Max)	(0.00,4.13)	(1.38,4.08)	(0.00,4.13)		
% Stenosis					
Mean±SD (n)	21.82±21.30 (143)	13.64±18.39 (135)	17.85±20.32 (278)	8.18 [3.47, 12.89]	<.001
Range (Min,Max)	(-17.23,100.00)	(-47.49,90.66)	(-47.49,100.00)		
Proximal Edge					
MLD (mm)					
Mean±SD (n)	2.45±0.60 (139)	2.50±0.69 (133)	2.47±0.65 (272)	-0.05 [-0.21, 0.10]	0.510
Range (Min,Max)	(0.29,3.95)	(0.28,4.12)	(0.28,4.12)		
Mean Diameter (mm)					
Mean±SD (n)	2.72±0.59 (139)	2.74±0.62 (133)	2.73±0.60 (272)	-0.02 [-0.16, 0.13]	0.808
Range (Min,Max)	(0.93,4.25)	(1.01,4.33)	(0.93,4.33)		
% Stenosis					
Mean±SD (n)	1.39±19.86 (139)	3.18±24.00 (133)	2.27±21.96 (272)	-1.79 [-7.04, 3.45]	0.503
Range (Min,Max)	(-62.00,85.54)	(-68.95,89.11)	(-68.95,89.11)		

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Table 6b. (Continued) Interpolated Quantitative Angiographic Analysis - Angiographic/IVUS Subset

Lesion Characteristic	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
Distal Edge (mm)					
MLD (mm)					
Mean±SD (n)	2.17±0.50 (143)	2.24±0.53 (135)	2.21±0.51 (278)	-0.06 [-0.18, 0.06]	0.300
Range (Min,Max)	(0.00,3.46)	(0.83,3.53)	(0.00,3.53)		
Mean Diameter (mm)					
Mean±SD (n)	2.38±0.51 (143)	2.45±0.52 (135)	2.41±0.52 (278)	-0.07 [-0.19, 0.05]	0.260
Range (Min,Max)	(0.00,3.64)	(1.33,3.66)	(0.00,3.66)		
% Stenosis					
Mean±SD (n)	12.82±13.10 (143)	14.08±12.98 (135)	13.43±13.03 (278)	-1.26 [-4.34, 1.82]	0.421
Range (Min,Max)	(-16.22,100.00)	(-14.29,65.34)	(-16.22,100.00)		
Binary Restenosis					
In-Segment	13.9% (20/144)	8.1% (11/135)	11.1% (31/279)	5.7% [-1.6%, 13.0%]	0.181
Within the Stent	12.6% (18/143)	4.4% (6/135)	8.6% (24/278)	8.1% [1.7%, 14.6%]	0.018
Proximal Edge	3.6% (5/139)	4.5% (6/133)	4.0% (11/272)	-0.9% [-5.6%, 3.8%]	0.765
Distal Edge	0.7% (1/143)	1.5% (2/135)	1.1% (3/278)	-0.8% [-3.2%, 1.7%]	0.613

N = the maximum number of eligible patients, n = number of patients with evaluable data.
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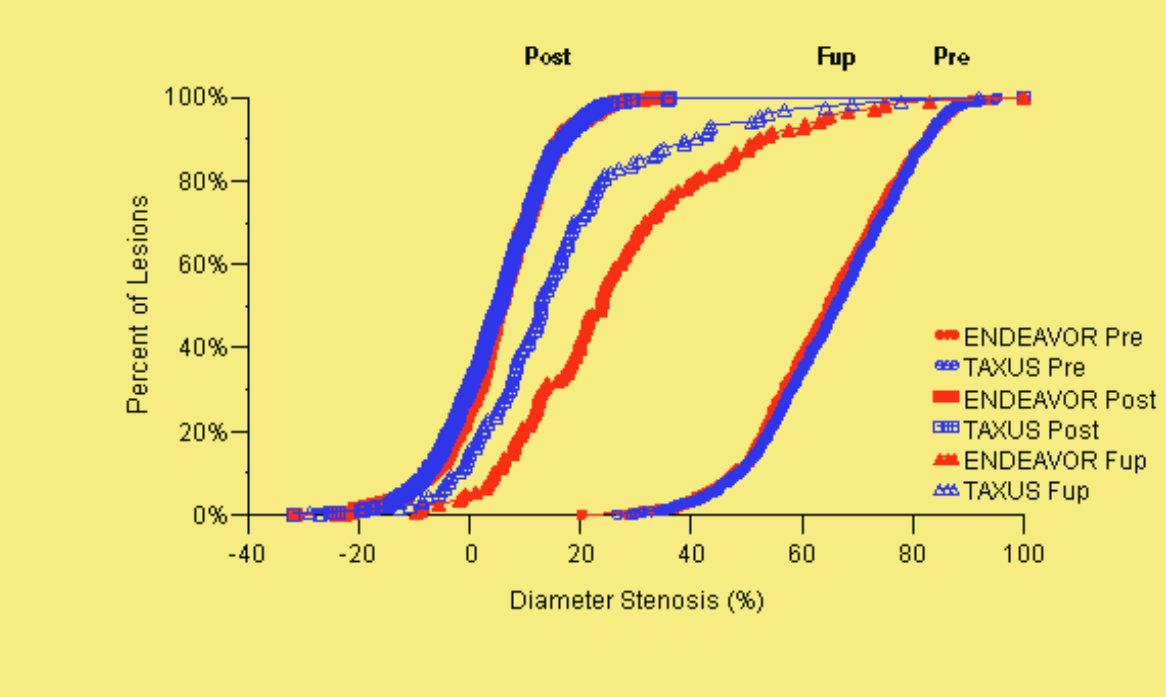
Figure 1. Cumulative Frequency Distribution of In-Stent Percent Diameter Stenosis - ITT Set, Angiographic/IVUS Subset

	Pre-Procedure			Post-Procedure In-Stent	
Measure	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)		ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)
Number	772	774		763	763
Median	64.9%	66.1%		5.7%	5.4%
Minimum	20.3%	26.7%		-31.3%	-43.2%
Maximum	100.0%	95.3%		35.7%	100.0%
Mean	64.8%	65.7%		5.5%	5.0%
SD	13.3%	13.1%		9.6%	10.5%
COV	20.5%	19.9%		174.8%	209.2%
Diff [CI]	-0.9%[-2.2%,0.5%]			0.5%[-0.5%,1.5%]	

All Lesion in Angiographic/IVUS Subset with QCA data						
	Pre-Procedure		Eight-Month Follow-up In-Stent		Post-Procedure In-Stent	
Measure	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)
Number	164	163	143	135	161	161
Median	65.1%	64.0%	23.9%	13.0%	4.1%	3.3%
Minimum	28.4%	30.9%	-9.6%	-28.6%	-31.3%	-43.2%
Maximum	90.4%	95.1%	100.0%	91.9%	25.6%	24.1%
Mean	64.7%	65.1%	26.4%	16.1%	3.6%	2.7%
SD	12.9%	12.5%	19.7%	18.0%	9.7%	10.8%
COV	19.9%	19.2%	74.7%	111.8%	267.0%	400.5%
Diff [CI]	-0.4% [-3.2%,2.4%]		10.3% [5.9%,14.8%]		0.9% [-1.3%,3.2%]	

Figure 1. (Continued) Cumulative Frequency Distribution of In-Stent Percent Diameter Stenosis - ITT Set, Angiographic/IVUS Subset



All data assessed by the Angiographic Core Laboratory.

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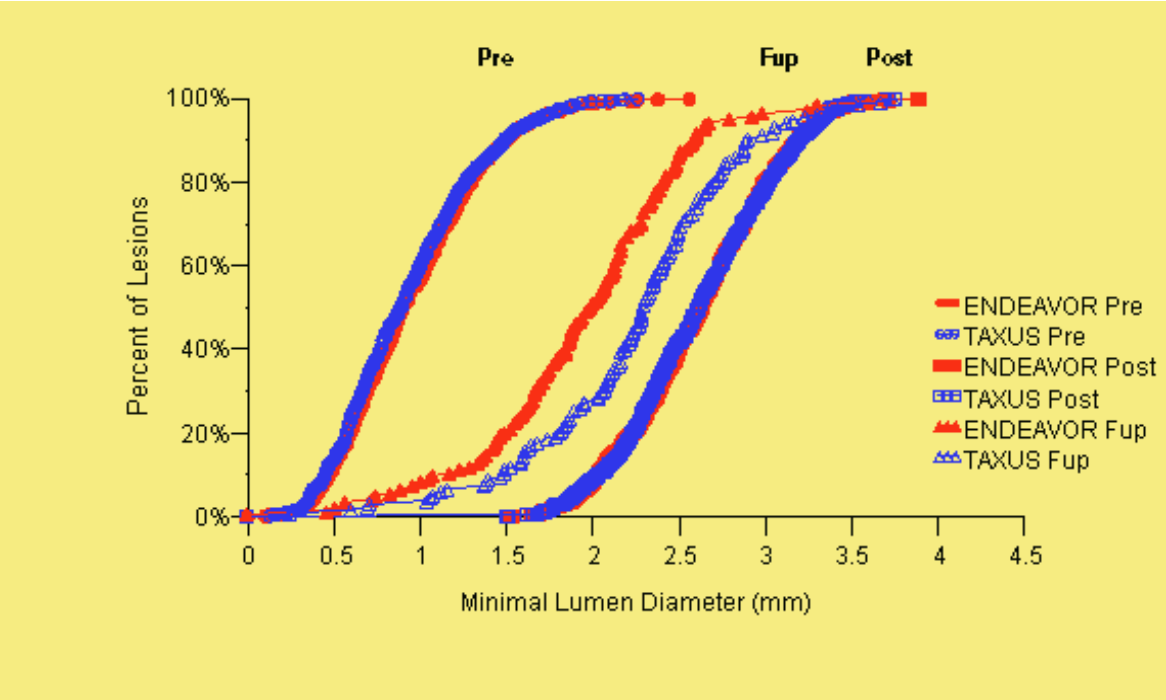
Figure 2. Cumulative Frequency Distribution of In-Stent Minimum Lumen Diameter - ITT Set, Angiographic/IVUS Subset

	Pre-Procedure			Post-Procedure In-Stent	
Measure	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)		ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)
Number	772	774		763	763
Median	0.91	0.89		2.64	2.62
Minimum	0.00	0.13		1.52	0.00
Maximum	2.56	2.26		3.90	3.76
Mean	0.96	0.93		2.62	2.61
SD	0.40	0.40		0.43	0.44
COV	42.2%	43.1%		16.4%	17.0%
Diff [CI]	0.03[-0.01,0.07]			0.01[-0.04,0.05]	

All Lesion in Angiographic/IVUS Subset with QCA data						
	Pre-Procedure		Eight-Month Follow-up In-Stent		Post-Procedure In-Stent	
Measure	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)
Number	164	163	143	135	161	161
Median	0.89	0.93	1.99	2.30	2.63	2.65
Minimum	0.22	0.15	0.00	0.24	1.69	1.71
Maximum	2.38	2.19	3.66	3.75	3.72	3.69
Mean	0.95	0.95	1.95	2.25	2.63	2.67
SD	0.39	0.40	0.61	0.61	0.42	0.44
COV	40.8%	42.7%	31.5%	27.2%	16.0%	16.7%
Diff [CI]	0.00[-0.08,0.09]		-0.30[-0.45,-0.16]		-0.04[-0.13,0.06]	

Figure 2. (Continued) Cumulative Frequency Distribution of In-Stent Minimum Lumen Diameter - ITT Set, Angiographic/IVUS Subset



All data assessed by the Angiographic Core Laboratory.

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Table 7. Acute Procedure Success - ITT Set

	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)
Lesions Evaluable for Lesion Success	770	772
Patients Evaluable for Procedure Success	770	772
Lesions Evaluable for Device Success	772	773
Patients Evaluable for Device Specific Procedure Success	772	773

Lesion Success	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	Difference	95% CI
Success	767	766		
% Successful	99.6%	99.2%	0.4%	[-0.4%, 1.1%]
Failure	3	6		
% Failed	0.4%	0.8%	-0.4%	[-1.1%, 0.4%]

Procedure Success	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	Difference	95% CI
Success	760	747		
% Successful	98.7%	96.8%	1.9%	[0.5%, 3.4%]
Failure	10	25		
% Failed	1.3%	3.2%	-1.9%	[-3.4%, -0.5%]

Device Success	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	Difference	95% CI
Success	751	757		
% Successful	97.3%	97.9%	-0.7%	[-2.2%, 0.9%]
Failure	21	16		
% Failed	2.7%	2.1%	0.7%	[-0.9%, 2.2%]

Device Specific Procedure Success	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	Difference	95% CI
Success	745	739		
% Successful	96.5%	95.6%	0.9%	[-1.0%, 2.8%]
Failure	27	34		
% Failed	3.5%	4.4%	-0.9%	[-2.8%, 1.0%]

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Table 8. Post-Procedure Morphology and Length of Stay - ITT Set

Patient Characteristic	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Post-Procedure Hospital Length of Stay (Days)					
Mean±SD (n)	1.2±0.8 (772)	1.1±0.8 (775)	1.2±0.8 (1547)	0.0 [-0.1, 0.1]	0.790
Range (Min,Max)	(0,10)	(0,12)	(0,12)		
Median (IQ Range)	1 (1 - 1)	1 (1 - 1)	1 (1 - 1)		
Pre-Stent Thrombus	1.6% (12/772)	1.2% (9/774)	1.4% (21/1546)	0.4% [-0.8%, 1.5%]	0.520
Post-Procedure Thrombus	0.3% (2/770)	0.1% (1/772)	0.2% (3/1542)	0.1% [-0.3%, 0.6%]	0.624
Post-Procedure Dissection					0.049
None	99.0% (762/770)	97.7% (754/772)	98.3% (1516/1542)		
Type A	0.3% (2/770)	0.6% (5/772)	0.5% (7/1542)		
Type B	0.4% (3/770)	0.8% (6/772)	0.6% (9/1542)		
Type C	0.4% (3/770)	0.5% (4/772)	0.5% (7/1542)		
Type D	0.0% (0/770)	0.0% (0/772)	0.0% (0/1542)		
Type E	0.0% (0/770)	0.0% (0/772)	0.0% (0/1542)		
Type F	0.0% (0/770)	0.4% (3/772)	0.2% (3/1542)		
Post-Procedure TIMI					0.998
0	0.0% (0/770)	0.4% (3/772)	0.2% (3/1542)		
1	0.0% (0/770)	0.0% (0/772)	0.0% (0/1542)		
2	0.9% (7/770)	0.5% (4/772)	0.7% (11/1542)		
3	99.1% (763/770)	99.1% (765/772)	99.1% (1528/1542)		

N = the maximum number of eligible patients, n = number of patients with evaluable data. Denominators indicate the total number of patients with available data for related parameter.
Cochran-Mantel-Haenszel Statistic (Modified Ridit Scores) used for calculating overall p-value.

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Table 9. Follow-up Morphology - Angiographic/IVUS and Multi-Stent Subset

Patient Characteristic	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
8 Month Follow-up					
Thrombus	0.0% (0/144)	0.0% (0/135)	0.0% (0/279)	0.00% [--, --]	--
TIMI Flow					0.761
0	0.7% (1/144)	0.0% (0/135)	0.4% (1/279)		
1	0.0% (0/144)	0.0% (0/135)	0.0% (0/279)		
2	2.1% (3/144)	2.2% (3/135)	2.2% (6/279)		
3	97.2% (140/144)	97.8% (132/135)	97.5% (272/279)		
Total Occlusion	0.7% (1/144)	0.0% (0/135)	0.4% (1/279)	0.7% [-0.7%, 2.1%]	1.000
In-Segment Restenosis Pattern					0.048
IA	0.0% (0/22)	0.0% (0/14)	0.0% (0/36)		
IB	13.6% (3/22)	57.1% (8/14)	30.6% (11/36)		
IC	31.8% (7/22)	14.3% (2/14)	25.0% (9/36)		
ID	0.0% (0/22)	7.1% (1/14)	2.8% (1/36)		
II	36.4% (8/22)	7.1% (1/14)	25.0% (9/36)		
III	13.6% (3/22)	14.3% (2/14)	13.9% (5/36)		
IV	4.5% (1/22)	0.0% (0/14)	2.8% (1/36)		
ISR Length (mm)					
Mean±SD (n)	12.67±6.44 (21)	9.99±4.69 (14)	11.60±5.88 (35)	2.68 [-1.40, 6.76]	0.190
Range (Min,Max)	(5.00,29.41)	(3.99,19.94)	(3.99,29.41)		

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Table 10. Major Adverse Events - In-Hospital and Out-of-Hospital (to 270 days) - ITT Set

In-Hospital Complications	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	0.9% (7/773)	2.6% (20/775)	1.7% (27/1548)	-1.7% [-3.0%, -0.4%]	0.018
Death	0.0% (0/773)	0.0% (0/775)	0.0% (0/1548)	0.00% [--, --]	--
Cardiac Death	0.0% (0/773)	0.0% (0/775)	0.0% (0/1548)	0.00% [--, --]	--
Myocardial Infarction (Q Wave or Non-Q Wave)	0.8% (6/773)	2.1% (16/775)	1.4% (22/1548)	-1.3% [-2.5%, -0.1%]	0.051
Q wave MI	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)	0.1% [-0.3%, 0.6%]	0.624
Non-Q wave MI	0.5% (4/773)	1.9% (15/775)	1.2% (19/1548)	-1.4% [-2.5%, -0.3%]	0.019
Emergent CABG	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)	-0.3% [-0.6%, 0.1%]	0.500
Target Lesion Revascularization	0.4% (3/773)	0.5% (4/775)	0.5% (7/1548)	-0.1% [-0.8%, 0.5%]	1.000
TL-CABG	0.1% (1/773)	0.4% (3/775)	0.3% (4/1548)	-0.3% [-0.8%, 0.2%]	0.625
TL-PTCA	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)	0.1% [-0.3%, 0.6%]	0.624
Target Vessel Revascularization not involving the Target Lesion	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)	-0.3% [-0.6%, 0.1%]	0.500
TV/Non-TL-CABG	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)	-0.3% [-0.6%, 0.1%]	0.500
TV/Non-TL-PTCA	0.0% (0/773)	0.0% (0/775)	0.0% (0/1548)	0.00% [--, --]	--
Target Vessel Revascularization	0.4% (3/773)	0.6% (5/775)	0.5% (8/1548)	-0.3% [-1.0%, 0.5%]	0.726
Target Vessel Failure	0.9% (7/773)	2.6% (20/775)	1.7% (27/1548)	-1.7% [-3.0%, -0.4%]	0.018
Perforation	0.1% (1/773)	0.4% (3/775)	0.3% (4/1548)	-0.3% [-0.8%, 0.2%]	0.625
Acute Stent Thrombosis	0.0% (0/773)	0.0% (0/775)	0.0% (0/1548)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)	0.3% [-0.1%, 0.6%]	0.249
Vascular Complications	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)	0.1% [-0.4%, 0.7%]	0.687
Cerebrovascular Accident (CVA)	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)	0.1% [-0.1%, 0.4%]	0.499
Bleeding Complications	1.2% (9/773)	1.4% (11/775)	1.3% (20/1548)	-0.3% [-1.4%, 0.9%]	0.823

N = the maximum number of eligible patients, denominators indicate the total number of patients with in-hospital information.

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Table 10. (Continued) Major Adverse Events - In-Hospital and Out-of-Hospital (to 270 days) - ITT Set

Out-of-Hospital Complications (to 30 Days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	0.3% (2/770)	0.4% (3/771)	0.3% (5/1541)	-0.1% [-0.7%, 0.4%]	1.000
Death	0.3% (2/770)	0.0% (0/771)	0.1% (2/1541)	0.3% [-0.1%, 0.6%]	0.250
Cardiac Death	0.1% (1/770)	0.0% (0/771)	0.1% (1/1541)	0.1% [-0.1%, 0.4%]	0.500
Myocardial Infarction (Q Wave or Non-Q Wave)	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500
Q wave MI	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
Non-Q wave MI	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500
Emergent CABG	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
Target Lesion Revascularization	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500
TL-CABG	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
TL-PTCA	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500
Target Vessel Revascularization not involving the Target Lesion	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
TV/Non-TL-CABG	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
TV/Non-TL-PTCA	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
Target Vessel Revascularization	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500
Target Vessel Failure	0.1% (1/770)	0.4% (3/771)	0.3% (4/1541)	-0.3% [-0.8%, 0.2%]	0.625
Perforation	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
Acute Stent Thrombosis	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.1% (1/770)	0.1% (1/771)	0.1% (2/1541)	0.0% [-0.4%, 0.4%]	1.000
Vascular Complications	0.0% (0/770)	0.5% (4/771)	0.3% (4/1541)	-0.5% [-1.0%, -0.0%]	0.125
Cerebrovascular Accident (CVA)	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
Bleeding Complications	0.1% (1/770)	0.4% (3/771)	0.3% (4/1541)	-0.3% [-0.8%, 0.2%]	0.625

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 25 days post index procedure or an event through 30 days.

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Table 10. (Continued) Major Adverse Events - In-Hospital and Out-of-Hospital (to 270 days) - ITT Set

Out-of-Hospital Complications (to 180 Days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	2.1% (16/766)	1.7% (13/759)	1.9% (29/1525)	0.4% [-1.0%, 1.7%]	0.708
Death	0.5% (4/766)	0.5% (4/759)	0.5% (8/1525)	-0.0% [-0.7%, 0.7%]	1.000
Cardiac Death	0.3% (2/766)	0.3% (2/759)	0.3% (4/1525)	-0.0% [-0.5%, 0.5%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	0.5% (4/766)	0.3% (2/759)	0.4% (6/1525)	0.3% [-0.4%, 0.9%]	0.687
Q wave MI	0.0% (0/766)	0.0% (0/759)	0.0% (0/1525)	0.00% [--, --]	--
Non-Q wave MI	0.5% (4/766)	0.3% (2/759)	0.4% (6/1525)	0.3% [-0.4%, 0.9%]	0.687
Emergent CABG	0.0% (0/766)	0.0% (0/759)	0.0% (0/1525)	0.00% [--, --]	--
Target Lesion Revascularization	1.3% (10/766)	1.1% (8/759)	1.2% (18/1525)	0.3% [-0.8%, 1.3%]	0.813
TL-CABG	0.3% (2/766)	0.1% (1/759)	0.2% (3/1525)	0.1% [-0.3%, 0.6%]	1.000
TL-PTCA	1.2% (9/766)	0.9% (7/759)	1.0% (16/1525)	0.3% [-0.8%, 1.3%]	0.803
Target Vessel Revascularization not involving the Target Lesion	0.7% (5/766)	1.3% (10/759)	1.0% (15/1525)	-0.7% [-1.7%, 0.3%]	0.206
TV/Non-TL-CABG	0.1% (1/766)	0.1% (1/759)	0.1% (2/1525)	-0.0% [-0.4%, 0.4%]	1.000
TV/Non-TL-PTCA	0.7% (5/766)	1.2% (9/759)	0.9% (14/1525)	-0.5% [-1.5%, 0.4%]	0.297
Target Vessel Revascularization	1.7% (13/766)	2.1% (16/759)	1.9% (29/1525)	-0.4% [-1.8%, 1.0%]	0.579
Target Vessel Failure	2.2% (17/766)	2.5% (19/759)	2.4% (36/1525)	-0.3% [-1.8%, 1.2%]	0.739
Perforation	0.0% (0/766)	0.0% (0/759)	0.0% (0/1525)	0.00% [--, --]	--
Acute Stent Thrombosis	0.0% (0/766)	0.0% (0/759)	0.0% (0/1525)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.1% (1/766)	0.1% (1/759)	0.1% (2/1525)	-0.0% [-0.4%, 0.4%]	1.000
Late Stent Thrombosis	0.4% (3/766)	0.0% (0/759)	0.2% (3/1525)	0.4% [-0.1%, 0.8%]	0.250
Vascular Complications	0.0% (0/766)	0.5% (4/759)	0.3% (4/1525)	-0.5% [-1.0%, -0.0%]	0.061
Cerebrovascular Accident (CVA)	0.5% (4/766)	0.3% (2/759)	0.4% (6/1525)	0.3% [-0.4%, 0.9%]	0.687
Bleeding Complications	0.4% (3/766)	1.3% (10/759)	0.9% (13/1525)	-0.9% [-1.8%, -0.0%]	0.055

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 166 days post index procedure or an event through 180 days.

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Table 10. (Continued) Major Adverse Events - In-Hospital and Out-of-Hospital (to 270 days) - ITT Set

Out-of-Hospital Complications (to 270 Days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	4.7% (35/740)	3.0% (22/734)	3.9% (57/1474)	1.7% [-0.2%, 3.7%]	0.104
Death	0.7% (5/740)	0.8% (6/734)	0.7% (11/1474)	-0.1% [-1.0%, 0.7%]	0.773
Cardiac Death	0.4% (3/740)	0.3% (2/734)	0.3% (5/1474)	0.1% [-0.5%, 0.7%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	0.7% (5/740)	0.3% (2/734)	0.5% (7/1474)	0.4% [-0.3%, 1.1%]	0.452
Q wave MI	0.0% (0/740)	0.0% (0/734)	0.0% (0/1474)	0.00% [--, --]	--
Non-Q wave MI	0.7% (5/740)	0.3% (2/734)	0.5% (7/1474)	0.4% [-0.3%, 1.1%]	0.452
Emergent CABG	0.0% (0/740)	0.0% (0/734)	0.0% (0/1474)	0.00% [--, --]	--
Target Lesion Revascularization	3.8% (28/740)	2.2% (16/734)	3.0% (44/1474)	1.6% [-0.1%, 3.3%]	0.091
TL-CABG	0.4% (3/740)	0.4% (3/734)	0.4% (6/1474)	-0.0% [-0.7%, 0.6%]	1.000
TL-PTCA	3.5% (26/740)	1.8% (13/734)	2.6% (39/1474)	1.7% [0.1%, 3.4%]	0.050
Target Vessel Revascularization not involving the Target Lesion	2.0% (15/740)	2.6% (19/734)	2.3% (34/1474)	-0.6% [-2.1%, 1.0%]	0.493
TV/Non-TL-CABG	0.4% (3/740)	0.1% (1/734)	0.3% (4/1474)	0.3% [-0.3%, 0.8%]	0.625
TV/Non-TL-PTCA	1.8% (13/740)	2.5% (18/734)	2.1% (31/1474)	-0.7% [-2.2%, 0.8%]	0.370
Target Vessel Revascularization	5.1% (38/740)	4.4% (32/734)	4.7% (70/1474)	0.8% [-1.4%, 2.9%]	0.541
Target Vessel Failure	5.8% (43/740)	4.8% (35/734)	5.3% (78/1474)	1.0% [-1.2%, 3.3%]	0.416
Perforation	0.0% (0/740)	0.0% (0/734)	0.0% (0/1474)	0.00% [--, --]	--
Acute Stent Thrombosis	0.0% (0/740)	0.0% (0/734)	0.0% (0/1474)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.1% (1/740)	0.1% (1/734)	0.1% (2/1474)	-0.0% [-0.4%, 0.4%]	1.000
Late Stent Thrombosis	0.4% (3/740)	0.0% (0/734)	0.2% (3/1474)	0.4% [-0.1%, 0.9%]	0.250
Vascular Complications	0.1% (1/740)	0.5% (4/734)	0.3% (5/1474)	-0.4% [-1.0%, 0.2%]	0.216
Cerebrovascular Accident (CVA)	0.5% (4/740)	0.5% (4/734)	0.5% (8/1474)	-0.0% [-0.8%, 0.7%]	1.000
Bleeding Complications	0.4% (3/740)	1.5% (11/734)	0.9% (14/1474)	-1.1% [-2.1%, -0.1%]	0.034

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 256 days post index procedure or an event through 270 days.

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Table 11a. Major Adverse Events (to 270 days) - ITT Set

Hierarchical Complications to 30 Days	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	1.2% (9/770)	3.0% (23/771)	2.1% (32/1541)	-1.8% [-3.2%, -0.4%]	0.019
Cardiac Death	0.1% (1/770)	0.0% (0/771)	0.1% (1/1541)	0.1% [-0.1%, 0.4%]	0.500
Non-cardiac Death	0.1% (1/770)	0.0% (0/771)	0.1% (1/1541)	0.1% [-0.1%, 0.4%]	0.500
Non-fatal Q wave MI	0.3% (2/770)	0.1% (1/771)	0.2% (3/1541)	0.1% [-0.3%, 0.6%]	0.625
Non-fatal Non-Q wave MI without Q wave MI	0.5% (4/770)	2.2% (17/771)	1.4% (21/1541)	-1.7% [-2.8%, -0.5%]	0.007
Emergent CABG without Death or MI	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500
Target Lesion CABG without Death, MI, or CABG	0.1% (1/770)	0.1% (1/771)	0.1% (2/1541)	0.0% [-0.4%, 0.4%]	1.000
Target Lesion PTCA without Death, MI, or CABG	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500

Non-Hierarchical Complications to 30 Days	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	1.2% (9/770)	3.0% (23/771)	2.1% (32/1541)	-1.8% [-3.2%, -0.4%]	0.019
Death	0.3% (2/770)	0.0% (0/771)	0.1% (2/1541)	0.3% [-0.1%, 0.6%]	0.250
Cardiac Death	0.1% (1/770)	0.0% (0/771)	0.1% (1/1541)	0.1% [-0.1%, 0.4%]	0.500
Myocardial Infarction (Q Wave or Non-Q Wave)	0.8% (6/770)	2.3% (18/771)	1.6% (24/1541)	-1.6% [-2.8%, -0.3%]	0.022
Q wave MI	0.3% (2/770)	0.1% (1/771)	0.2% (3/1541)	0.1% [-0.3%, 0.6%]	0.625
Non-Q wave MI	0.5% (4/770)	2.2% (17/771)	1.4% (21/1541)	-1.7% [-2.8%, -0.5%]	0.007
Emergent CABG	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500
Target Lesion Revascularization	0.4% (3/770)	0.8% (6/771)	0.6% (9/1541)	-0.4% [-1.1%, 0.4%]	0.507
TL-CABG	0.1% (1/770)	0.4% (3/771)	0.3% (4/1541)	-0.3% [-0.8%, 0.2%]	0.625
TL-PTCA	0.3% (2/770)	0.4% (3/771)	0.3% (5/1541)	-0.1% [-0.7%, 0.4%]	1.000
Target Vessel Revascularization not involving the Target Lesion	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500
TV/Non-TL-CABG	0.0% (0/770)	0.3% (2/771)	0.1% (2/1541)	-0.3% [-0.6%, 0.1%]	0.500
TV/Non-TL-PTCA	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
Target Vessel Revascularization	0.4% (3/770)	0.9% (7/771)	0.6% (10/1541)	-0.5% [-1.3%, 0.3%]	0.342
Target Vessel Failure	1.0% (8/770)	3.0% (23/771)	2.0% (31/1541)	-1.9% [-3.3%, -0.5%]	0.010
Perforation	0.1% (1/770)	0.4% (3/771)	0.3% (4/1541)	-0.3% [-0.8%, 0.2%]	0.625
Acute Stent Thrombosis	0.0% (0/770)	0.0% (0/771)	0.0% (0/1541)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/770)	0.1% (1/771)	0.3% (4/1541)	0.3% [-0.2%, 0.8%]	0.374
Vascular Complications	0.4% (3/770)	0.8% (6/771)	0.6% (9/1541)	-0.4% [-1.1%, 0.4%]	0.507
Cerebrovascular Accident (CVA)	0.1% (1/770)	0.0% (0/771)	0.1% (1/1541)	0.1% [-0.1%, 0.4%]	0.500
Bleeding Complications	1.3% (10/770)	1.8% (14/771)	1.6% (24/1541)	-0.5% [-1.8%, 0.7%]	0.538

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 25 days post index procedure or an event through 30 days.

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Table 11a. (Continued) Major Adverse Events (to 270 days) - ITT Set

Hierarchical Complications to 180 Days	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	3.0% (23/766)	4.3% (33/759)	3.7% (56/1525)	-1.3% [-3.2%, 0.5%]	0.175
Cardiac Death	0.3% (2/766)	0.3% (2/759)	0.3% (4/1525)	-0.0% [-0.5%, 0.5%]	1.000
Non-cardiac Death	0.3% (2/766)	0.3% (2/759)	0.3% (4/1525)	-0.0% [-0.5%, 0.5%]	1.000
Non-fatal Q wave MI	0.3% (2/766)	0.1% (1/759)	0.2% (3/1525)	0.1% [-0.3%, 0.6%]	1.000
Non-fatal Non-Q wave MI without Q wave MI	1.0% (8/766)	2.2% (17/759)	1.6% (25/1525)	-1.2% [-2.5%, 0.1%]	0.072
Emergent CABG without Death or MI	0.0% (0/766)	0.3% (2/759)	0.1% (2/1525)	-0.3% [-0.6%, 0.1%]	0.248
Target Lesion CABG without Death, MI, or CABG	0.4% (3/766)	0.3% (2/759)	0.3% (5/1525)	0.1% [-0.4%, 0.7%]	1.000
Target Lesion PTCA without Death, MI, or CABG	0.8% (6/766)	0.9% (7/759)	0.9% (13/1525)	-0.1% [-1.1%, 0.8%]	0.789

Non-Hierarchical Complications to 180 Days	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	3.0% (23/766)	4.3% (33/759)	3.7% (56/1525)	-1.3% [-3.2%, 0.5%]	0.175
Death	0.5% (4/766)	0.5% (4/759)	0.5% (8/1525)	-0.0% [-0.7%, 0.7%]	1.000
Cardiac Death	0.3% (2/766)	0.3% (2/759)	0.3% (4/1525)	-0.0% [-0.5%, 0.5%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	1.3% (10/766)	2.4% (18/759)	1.8% (28/1525)	-1.1% [-2.4%, 0.3%]	0.131
Q wave MI	0.3% (2/766)	0.1% (1/759)	0.2% (3/1525)	0.1% [-0.3%, 0.6%]	1.000
Non-Q wave MI	1.0% (8/766)	2.2% (17/759)	1.6% (25/1525)	-1.2% [-2.5%, 0.1%]	0.072
Emergent CABG	0.0% (0/766)	0.3% (2/759)	0.1% (2/1525)	-0.3% [-0.6%, 0.1%]	0.248
Target Lesion Revascularization	1.7% (13/766)	1.6% (12/759)	1.6% (25/1525)	0.1% [-1.2%, 1.4%]	1.000
TL-CABG	0.4% (3/766)	0.5% (4/759)	0.5% (7/1525)	-0.1% [-0.8%, 0.5%]	0.725
TL-PTCA	1.4% (11/766)	1.1% (8/759)	1.2% (19/1525)	0.4% [-0.7%, 1.5%]	0.646
Target Vessel Revascularization not involving the Target Lesion	0.7% (5/766)	1.6% (12/759)	1.1% (17/1525)	-0.9% [-2.0%, 0.1%]	0.093
TV/Non-TL-CABG	0.1% (1/766)	0.4% (3/759)	0.3% (4/1525)	-0.3% [-0.8%, 0.2%]	0.372
TV/Non-TL-PTCA	0.7% (5/766)	1.2% (9/759)	0.9% (14/1525)	-0.5% [-1.5%, 0.4%]	0.297
Target Vessel Revascularization	2.1% (16/766)	2.8% (21/759)	2.4% (37/1525)	-0.7% [-2.2%, 0.9%]	0.410
Target Vessel Failure	3.1% (24/766)	5.1% (39/759)	4.1% (63/1525)	-2.0% [-4.0%, -0.0%]	0.054
Perforation	0.1% (1/766)	0.4% (3/759)	0.3% (4/1525)	-0.3% [-0.8%, 0.2%]	0.372
Acute Stent Thrombosis	0.0% (0/766)	0.0% (0/759)	0.0% (0/1525)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/766)	0.1% (1/759)	0.3% (4/1525)	0.3% [-0.3%, 0.8%]	0.625
Late Stent Thrombosis	0.4% (3/766)	0.0% (0/759)	0.2% (3/1525)	0.4% [-0.1%, 0.8%]	0.250
Vascular Complications	0.4% (3/766)	0.8% (6/759)	0.6% (9/1525)	-0.4% [-1.2%, 0.4%]	0.340
Cerebrovascular Accident (CVA)	0.7% (5/766)	0.3% (2/759)	0.5% (7/1525)	0.4% [-0.3%, 1.1%]	0.452
Bleeding Complications	1.6% (12/766)	2.6% (20/759)	2.1% (32/1525)	-1.1% [-2.5%, 0.4%]	0.157

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 166 days post index procedure or an event through 180 days.

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Table 11a. (Continued) Major Adverse Events (to 270 days) - ITT Set

Hierarchical Complications to 270 Days	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	5.7% (42/740)	5.7% (42/734)	5.7% (84/1474)	-0.0% [-2.4%, 2.3%]	1.000
Cardiac Death	0.4% (3/740)	0.3% (2/734)	0.3% (5/1474)	0.1% [-0.5%, 0.7%]	1.000
Non-cardiac Death	0.3% (2/740)	0.5% (4/734)	0.4% (6/1474)	-0.3% [-0.9%, 0.4%]	0.450
Non-fatal Q wave MI	0.3% (2/740)	0.1% (1/734)	0.2% (3/1474)	0.1% [-0.3%, 0.6%]	1.000
Non-fatal Non-Q wave MI without Q wave MI	1.2% (9/740)	2.3% (17/734)	1.8% (26/1474)	-1.1% [-2.4%, 0.2%]	0.117
Emergent CABG without Death or MI	0.0% (0/740)	0.3% (2/734)	0.1% (2/1474)	-0.3% [-0.6%, 0.1%]	0.248
Target Lesion CABG without Death, MI, or CABG	0.5% (4/740)	0.5% (4/734)	0.5% (8/1474)	-0.0% [-0.8%, 0.7%]	1.000
Target Lesion PTCA without Death, MI, or CABG	3.0% (22/740)	1.6% (12/734)	2.3% (34/1474)	1.3% [-0.2%, 2.9%]	0.117

Non-Hierarchical Complications to 270 Days	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	5.7% (42/740)	5.7% (42/734)	5.7% (84/1474)	-0.0% [-2.4%, 2.3%]	1.000
Death	0.7% (5/740)	0.8% (6/734)	0.7% (11/1474)	-0.1% [-1.0%, 0.7%]	0.773
Cardiac Death	0.4% (3/740)	0.3% (2/734)	0.3% (5/1474)	0.1% [-0.5%, 0.7%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	1.5% (11/740)	2.5% (18/734)	2.0% (29/1474)	-1.0% [-2.4%, 0.5%]	0.194
Q wave MI	0.3% (2/740)	0.1% (1/734)	0.2% (3/1474)	0.1% [-0.3%, 0.6%]	1.000
Non-Q wave MI	1.2% (9/740)	2.3% (17/734)	1.8% (26/1474)	-1.1% [-2.4%, 0.2%]	0.117
Emergent CABG	0.0% (0/740)	0.3% (2/734)	0.1% (2/1474)	-0.3% [-0.6%, 0.1%]	0.248
Target Lesion Revascularization	4.2% (31/740)	2.7% (20/734)	3.5% (51/1474)	1.5% [-0.4%, 3.3%]	0.154
TL-CABG	0.5% (4/740)	0.8% (6/734)	0.7% (10/1474)	-0.3% [-1.1%, 0.6%]	0.546
TL-PTCA	3.8% (28/740)	1.9% (14/734)	2.8% (42/1474)	1.9% [0.2%, 3.6%]	0.041
Target Vessel Revascularization not involving the Target Lesion	2.0% (15/740)	2.9% (21/734)	2.4% (36/1474)	-0.8% [-2.4%, 0.7%]	0.316
TV/Non-TL-CABG	0.4% (3/740)	0.4% (3/734)	0.4% (6/1474)	-0.0% [-0.7%, 0.6%]	1.000
TV/Non-TL-PTCA	1.8% (13/740)	2.5% (18/734)	2.1% (31/1474)	-0.7% [-2.2%, 0.8%]	0.370
Target Vessel Revascularization	5.5% (41/740)	5.0% (37/734)	5.3% (78/1474)	0.5% [-1.8%, 2.8%]	0.727
Target Vessel Failure	6.8% (50/740)	7.4% (54/734)	7.1% (104/1474)	-0.6% [-3.2%, 2.0%]	0.685
Perforation	0.1% (1/740)	0.4% (3/734)	0.3% (4/1474)	-0.3% [-0.8%, 0.3%]	0.372
Acute Stent Thrombosis	0.0% (0/740)	0.0% (0/734)	0.0% (0/1474)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/740)	0.1% (1/734)	0.3% (4/1474)	0.3% [-0.3%, 0.8%]	0.625
Late Stent Thrombosis	0.4% (3/740)	0.0% (0/734)	0.2% (3/1474)	0.4% [-0.1%, 0.9%]	0.250
Vascular Complications	0.5% (4/740)	0.8% (6/734)	0.7% (10/1474)	-0.3% [-1.1%, 0.6%]	0.546
Cerebrovascular Accident (CVA)	0.7% (5/740)	0.5% (4/734)	0.6% (9/1474)	0.1% [-0.7%, 0.9%]	1.000
Bleeding Complications	1.6% (12/740)	2.9% (21/734)	2.2% (33/1474)	-1.2% [-2.8%, 0.3%]	0.116

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 256 days post index procedure or an event through 270 days.

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Table 11b. Major Adverse Events (to 270 days) - PP Set

Hierarchical Complications to 30 Days	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	1.1% (8/745)	2.5% (19/748)	1.8% (27/1493)	-1.5% [-2.8%, -0.1%]	0.050
Cardiac Death	0.1% (1/745)	0.0% (0/748)	0.1% (1/1493)	0.1% [-0.1%, 0.4%]	0.499
Non-cardiac Death	0.1% (1/745)	0.0% (0/748)	0.1% (1/1493)	0.1% [-0.1%, 0.4%]	0.499
Non-fatal Q wave MI	0.3% (2/745)	0.1% (1/748)	0.2% (3/1493)	0.1% [-0.3%, 0.6%]	0.624
Non-fatal Non-Q wave MI without Q wave MI	0.5% (4/745)	2.1% (16/748)	1.3% (20/1493)	-1.6% [-2.8%, -0.4%]	0.011
Emergent CABG without Death or MI	0.0% (0/745)	0.1% (1/748)	0.1% (1/1493)	-0.1% [-0.4%, 0.1%]	1.000
Target Lesion CABG without Death, MI, or CABG	0.0% (0/745)	0.0% (0/748)	0.0% (0/1493)	0.00% [--, --]	--
Target Lesion PTCA without Death, MI, or CABG	0.0% (0/745)	0.1% (1/748)	0.1% (1/1493)	-0.1% [-0.4%, 0.1%]	1.000

Non-Hierarchical Complications to 30 Days	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	1.1% (8/745)	2.5% (19/748)	1.8% (27/1493)	-1.5% [-2.8%, -0.1%]	0.050
Death	0.3% (2/745)	0.0% (0/748)	0.1% (2/1493)	0.3% [-0.1%, 0.6%]	0.249
Cardiac Death	0.1% (1/745)	0.0% (0/748)	0.1% (1/1493)	0.1% [-0.1%, 0.4%]	0.499
Myocardial Infarction (Q Wave or Non-Q Wave)	0.8% (6/745)	2.3% (17/748)	1.5% (23/1493)	-1.5% [-2.7%, -0.2%]	0.033
Q wave MI	0.3% (2/745)	0.1% (1/748)	0.2% (3/1493)	0.1% [-0.3%, 0.6%]	0.624
Non-Q wave MI	0.5% (4/745)	2.1% (16/748)	1.3% (20/1493)	-1.6% [-2.8%, -0.4%]	0.011
Emergent CABG	0.0% (0/745)	0.1% (1/748)	0.1% (1/1493)	-0.1% [-0.4%, 0.1%]	1.000
Target Lesion Revascularization	0.3% (2/745)	0.4% (3/748)	0.3% (5/1493)	-0.1% [-0.7%, 0.5%]	1.000
TL-CABG	0.0% (0/745)	0.1% (1/748)	0.1% (1/1493)	-0.1% [-0.4%, 0.1%]	1.000
TL-PTCA	0.3% (2/745)	0.3% (2/748)	0.3% (4/1493)	0.0% [-0.5%, 0.5%]	1.000
Target Vessel Revascularization not involving the Target Lesion	0.0% (0/745)	0.1% (1/748)	0.1% (1/1493)	-0.1% [-0.4%, 0.1%]	1.000
TV/Non-TL-CABG	0.0% (0/745)	0.1% (1/748)	0.1% (1/1493)	-0.1% [-0.4%, 0.1%]	1.000
TV/Non-TL-PTCA	0.0% (0/745)	0.0% (0/748)	0.0% (0/1493)	0.00% [--, --]	--
Target Vessel Revascularization	0.3% (2/745)	0.5% (4/748)	0.4% (6/1493)	-0.3% [-0.9%, 0.4%]	0.687
Target Vessel Failure	0.9% (7/745)	2.5% (19/748)	1.7% (26/1493)	-1.6% [-2.9%, -0.3%]	0.028
Perforation	0.1% (1/745)	0.3% (2/748)	0.2% (3/1493)	-0.1% [-0.6%, 0.3%]	1.000
Acute Stent Thrombosis	0.0% (0/745)	0.0% (0/748)	0.0% (0/1493)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/745)	0.1% (1/748)	0.3% (4/1493)	0.3% [-0.3%, 0.8%]	0.373
Vascular Complications	0.4% (3/745)	0.8% (6/748)	0.6% (9/1493)	-0.4% [-1.2%, 0.4%]	0.506
Cerebrovascular Accident (CVA)	0.1% (1/745)	0.0% (0/748)	0.1% (1/1493)	0.1% [-0.1%, 0.4%]	0.499
Bleeding Complications	1.3% (10/745)	1.7% (13/748)	1.5% (23/1493)	-0.4% [-1.6%, 0.9%]	0.675

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 25 days post index procedure or an event through 30 days.

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Table 11b. (Continued) Major Adverse Events (to 270 days) - PP Set

Hierarchical Complications to 180 Days	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	3.0% (22/741)	3.9% (29/736)	3.5% (51/1477)	-1.0% [-2.8%, 0.9%]	0.322
Cardiac Death	0.3% (2/741)	0.3% (2/736)	0.3% (4/1477)	-0.0% [-0.5%, 0.5%]	1.000
Non-cardiac Death	0.3% (2/741)	0.3% (2/736)	0.3% (4/1477)	-0.0% [-0.5%, 0.5%]	1.000
Non-fatal Q wave MI	0.3% (2/741)	0.1% (1/736)	0.2% (3/1477)	0.1% [-0.3%, 0.6%]	1.000
Non-fatal Non-Q wave MI without Q wave MI	1.1% (8/741)	2.2% (16/736)	1.6% (24/1477)	-1.1% [-2.4%, 0.2%]	0.104
Emergent CABG without Death or MI	0.0% (0/741)	0.1% (1/736)	0.1% (1/1477)	-0.1% [-0.4%, 0.1%]	0.498
Target Lesion CABG without Death, MI, or CABG	0.3% (2/741)	0.1% (1/736)	0.2% (3/1477)	0.1% [-0.3%, 0.6%]	1.000
Target Lesion PTCA without Death, MI, or CABG	0.8% (6/741)	0.8% (6/736)	0.8% (12/1477)	-0.0% [-0.9%, 0.9%]	1.000

Non-Hierarchical Complications to 180 Days	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	3.0% (22/741)	3.9% (29/736)	3.5% (51/1477)	-1.0% [-2.8%, 0.9%]	0.322
Death	0.5% (4/741)	0.5% (4/736)	0.5% (8/1477)	-0.0% [-0.8%, 0.7%]	1.000
Cardiac Death	0.3% (2/741)	0.3% (2/736)	0.3% (4/1477)	-0.0% [-0.5%, 0.5%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	1.3% (10/741)	2.3% (17/736)	1.8% (27/1477)	-1.0% [-2.3%, 0.4%]	0.180
Q wave MI	0.3% (2/741)	0.1% (1/736)	0.2% (3/1477)	0.1% [-0.3%, 0.6%]	1.000
Non-Q wave MI	1.1% (8/741)	2.2% (16/736)	1.6% (24/1477)	-1.1% [-2.4%, 0.2%]	0.104
Emergent CABG	0.0% (0/741)	0.1% (1/736)	0.1% (1/1477)	-0.1% [-0.4%, 0.1%]	0.498
Target Lesion Revascularization	1.6% (12/741)	1.2% (9/736)	1.4% (21/1477)	0.4% [-0.8%, 1.6%]	0.661
TL-CABG	0.3% (2/741)	0.3% (2/736)	0.3% (4/1477)	-0.0% [-0.5%, 0.5%]	1.000
TL-PTCA	1.5% (11/741)	1.0% (7/736)	1.2% (18/1477)	0.5% [-0.6%, 1.7%]	0.478
Target Vessel Revascularization not involving the Target Lesion	0.7% (5/741)	1.5% (11/736)	1.1% (16/1477)	-0.8% [-1.9%, 0.2%]	0.140
TV/Non-TL-CABG	0.1% (1/741)	0.3% (2/736)	0.2% (3/1477)	-0.1% [-0.6%, 0.3%]	0.623
TV/Non-TL-PTCA	0.7% (5/741)	1.2% (9/736)	0.9% (14/1477)	-0.5% [-1.5%, 0.4%]	0.298
Target Vessel Revascularization	2.0% (15/741)	2.4% (18/736)	2.2% (33/1477)	-0.4% [-1.9%, 1.1%]	0.602
Target Vessel Failure	3.1% (23/741)	4.8% (35/736)	3.9% (58/1477)	-1.7% [-3.6%, 0.3%]	0.109
Perforation	0.1% (1/741)	0.3% (2/736)	0.2% (3/1477)	-0.1% [-0.6%, 0.3%]	0.623
Acute Stent Thrombosis	0.0% (0/741)	0.0% (0/736)	0.0% (0/1477)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/741)	0.1% (1/736)	0.3% (4/1477)	0.3% [-0.3%, 0.8%]	0.624
Late Stent Thrombosis	0.4% (3/741)	0.0% (0/736)	0.2% (3/1477)	0.4% [-0.1%, 0.9%]	0.250
Vascular Complications	0.4% (3/741)	0.8% (6/736)	0.6% (9/1477)	-0.4% [-1.2%, 0.4%]	0.341
Cerebrovascular Accident (CVA)	0.7% (5/741)	0.1% (1/736)	0.4% (6/1477)	0.5% [-0.1%, 1.2%]	0.218
Bleeding Complications	1.6% (12/741)	2.6% (19/736)	2.1% (31/1477)	-1.0% [-2.4%, 0.5%]	0.209

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 166 days post index procedure or an event through 180 days.

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Table 11b. (Continued) Major Adverse Events (to 270 days) - PP Set

Hierarchical Complications to 270 Days	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	5.7% (41/716)	5.2% (37/711)	5.5% (78/1427)	0.5% [-1.8%, 2.9%]	0.727
Cardiac Death	0.4% (3/716)	0.3% (2/711)	0.4% (5/1427)	0.1% [-0.5%, 0.8%]	1.000
Non-cardiac Death	0.3% (2/716)	0.6% (4/711)	0.4% (6/1427)	-0.3% [-1.0%, 0.4%]	0.451
Non-fatal Q wave MI	0.3% (2/716)	0.1% (1/711)	0.2% (3/1427)	0.1% [-0.3%, 0.6%]	1.000
Non-fatal Non-Q wave MI without Q wave MI	1.3% (9/716)	2.3% (16/711)	1.8% (25/1427)	-1.0% [-2.4%, 0.4%]	0.164
Emergent CABG without Death or MI	0.0% (0/716)	0.1% (1/711)	0.1% (1/1427)	-0.1% [-0.4%, 0.1%]	0.498
Target Lesion CABG without Death, MI, or CABG	0.4% (3/716)	0.4% (3/711)	0.4% (6/1427)	-0.0% [-0.7%, 0.7%]	1.000
Target Lesion PTCA without Death, MI, or CABG	3.1% (22/716)	1.4% (10/711)	2.2% (32/1427)	1.7% [0.1%, 3.2%]	0.048

Non-Hierarchical Complications to 270 Days	ENDEAVOR (N=748 Patients)	TAXUS (N=752 Patients)	All Patients (N=1500 Patients)	Difference [95% CI]	P-Value
MACE (Death, MI, Emergent CABG, TLR)	5.7% (41/716)	5.2% (37/711)	5.5% (78/1427)	0.5% [-1.8%, 2.9%]	0.727
Death	0.7% (5/716)	0.8% (6/711)	0.8% (11/1427)	-0.1% [-1.1%, 0.8%]	0.773
Cardiac Death	0.4% (3/716)	0.3% (2/711)	0.4% (5/1427)	0.1% [-0.5%, 0.8%]	1.000
Myocardial Infarction (Q Wave or Non-Q Wave)	1.5% (11/716)	2.4% (17/711)	2.0% (28/1427)	-0.9% [-2.3%, 0.6%]	0.259
Q wave MI	0.3% (2/716)	0.1% (1/711)	0.2% (3/1427)	0.1% [-0.3%, 0.6%]	1.000
Non-Q wave MI	1.3% (9/716)	2.3% (16/711)	1.8% (25/1427)	-1.0% [-2.4%, 0.4%]	0.164
Emergent CABG	0.0% (0/716)	0.1% (1/711)	0.1% (1/1427)	-0.1% [-0.4%, 0.1%]	0.498
Target Lesion Revascularization	4.2% (30/716)	2.3% (16/711)	3.2% (46/1427)	1.9% [0.1%, 3.8%]	0.050
TL-CABG	0.4% (3/716)	0.6% (4/711)	0.5% (7/1427)	-0.1% [-0.9%, 0.6%]	0.725
TL-PTCA	3.9% (28/716)	1.7% (12/711)	2.8% (40/1427)	2.2% [0.5%, 3.9%]	0.015
Target Vessel Revascularization not involving the Target Lesion	2.1% (15/716)	2.7% (19/711)	2.4% (34/1427)	-0.6% [-2.2%, 1.0%]	0.493
TV/Non-TL-CABG	0.4% (3/716)	0.3% (2/711)	0.4% (5/1427)	0.1% [-0.5%, 0.8%]	1.000
TV/Non-TL-PTCA	1.8% (13/716)	2.4% (17/711)	2.1% (30/1427)	-0.6% [-2.1%, 0.9%]	0.467
Target Vessel Revascularization	5.6% (40/716)	4.6% (33/711)	5.1% (73/1427)	0.9% [-1.3%, 3.2%]	0.471
Target Vessel Failure	6.8% (49/716)	6.9% (49/711)	6.9% (98/1427)	-0.0% [-2.7%, 2.6%]	1.000
Perforation	0.1% (1/716)	0.3% (2/711)	0.2% (3/1427)	-0.1% [-0.6%, 0.3%]	0.623
Acute Stent Thrombosis	0.0% (0/716)	0.0% (0/711)	0.0% (0/1427)	0.00% [--, --]	--
Subacute Stent Thrombosis	0.4% (3/716)	0.1% (1/711)	0.3% (4/1427)	0.3% [-0.3%, 0.8%]	0.624
Late Stent Thrombosis	0.4% (3/716)	0.0% (0/711)	0.2% (3/1427)	0.4% [-0.1%, 0.9%]	0.249
Vascular Complications	0.6% (4/716)	0.8% (6/711)	0.7% (10/1427)	-0.3% [-1.2%, 0.6%]	0.546
Cerebrovascular Accident (CVA)	0.7% (5/716)	0.4% (3/711)	0.6% (8/1427)	0.3% [-0.5%, 1.1%]	0.726
Bleeding Complications	1.7% (12/716)	2.8% (20/711)	2.2% (32/1427)	-1.1% [-2.7%, 0.4%]	0.157

N = the maximum number of eligible patients, denominators indicate the total number of patients with information beyond 256 days post index procedure or an event through 270 days.

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Table 12. Endpoint Analysis – ITT Set

Primary Endpoint	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	One Sided 95% Upper CI	Delta	P-value
TVF	6.8% (50/740)	7.4% (54/734)	7.1% (104/1474)	1.6%	3.8%	0.0005

Secondary Endpoint	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	One Sided 95% Upper CI	Delta	P-value
8-Month In-Segment Late Loss						
Mean	0.36±0.47 (143)	0.23±0.45 (135)	0.30±0.46 (278)	0.22	0.2	0.0890
Range (min,max)	(-0.48,1.90)	(-0.78,2.45)	(-0.78,2.45)			

Hierarchical Complications to 270 Days	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)
TVF	6.8% (50/740)	7.4% (54/734)
Cardiac Death	0.4% (3/740)	0.3% (2/734)
QMI not CD	0.3% (2/740)	0.1% (1/734)
Non QMI but not CD or QMI	1.2% (9/740)	2.3% (17/734)
TV-CABG but not CD or MI	0.8% (6/740)	0.8% (6/734)
TV-PTCA but not CD or MI or TV-CABG	4.1% (30/740)	3.8% (28/734)

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Figure 3. Survival Free from Major Cardiac Adverse Events (at 270 days) - Event-free Survival ± 1.5SE - ITT Set

MACE	**0**	**7**	**14**	**21**	**30**	**60**	**90**	**120**	**150**	**180**	**210**	**240**	**270**
ENDEAVOR													
# Entered	773	769	760	760	760	756	750	746	745	739	731	721	708
# Censored	0	5	0	0	3	5	0	0	0	6	5	7	121
# Incomplete	0	0	0	0	0	0	0	0	0	0	0	0	0
# Events	4	4	0	0	1	1	4	1	6	2	5	6	8
% Survived	99.5%	99.0%	99.0%	99.0%	98.8%	98.7%	98.2%	98.0%	97.3%	97.0%	96.3%	95.5%	94.4%
SE	0.3%	0.4%	0.4%	0.4%	0.4%	0.4%	0.5%	0.5%	0.6%	0.6%	0.7%	0.8%	0.9%
TAXUS													
# Entered	775	755	748	748	747	744	736	734	728	724	718	703	696
# Censored	1	5	0	0	2	7	0	2	1	6	12	5	107
# Incomplete	0	0	0	0	0	0	0	0	0	0	0	0	0
# Events	19	2	0	1	1	1	2	4	3	0	3	2	4
% Survived	97.5%	97.3%	97.3%	97.2%	97.0%	96.9%	96.6%	96.1%	95.7%	95.7%	95.3%	95.0%	94.5%
SE	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.7%	0.7%	0.7%	0.7%	0.8%	0.8%	0.9%
Tests Between Groups													
	Test	Chi-Square	Deg Frdm	P-value									
	Log-Rank	0.00	1	0.952									
	Wilcoxon	0.04	1	0.850									

Figure 3. (Continued) Survival Free from Major Cardiac Adverse Events (at 270 days) - Event-free Survival ± 1.5SE - ITT Set

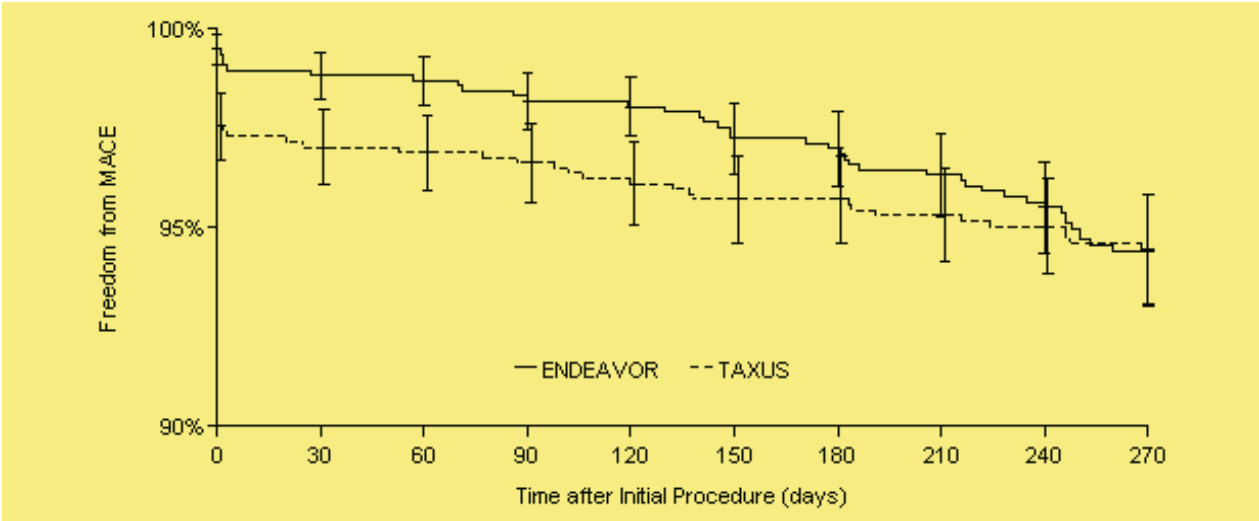

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Figure 4a. Survival Free from Target Vessel Failure (at 270 days) - Event-free Survival ± 1.5SE - ITT Set

TVF	0	7	14	21	30	60	90	120	150	180	210	240	270
ENDEAVOR													
# Entered	773	769	760	760	760	756	750	744	743	736	728	718	703
# Censored	0	5	0	0	4	5	0	0	1	6	5	7	118
# Incomplete	0	0	0	0	0	0	0	0	0	0	0	0	0
# Events	4	4	0	0	0	1	6	1	6	2	5	8	13
% Survived	99.5%	99.0%	99.0%	99.0%	99.0%	98.8%	98.0%	97.9%	97.1%	96.9%	96.2%	95.1%	93.3%
SE	0.3%	0.4%	0.4%	0.4%	0.4%	0.4%	0.5%	0.5%	0.6%	0.6%	0.7%	0.8%	1.0%
TAXUS													
# Entered	775	755	748	748	747	744	735	732	726	720	710	694	683
# Censored	1	5	0	0	2	7	1	2	2	6	13	5	105
# Incomplete	0	0	0	0	0	0	0	0	0	0	0	0	0
# Events	19	2	0	1	1	2	2	4	4	4	3	6	6
% Survived	97.5%	97.3%	97.3%	97.2%	97.0%	96.8%	96.5%	96.0%	95.4%	94.9%	94.5%	93.7%	92.8%
SE	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.7%	0.7%	0.8%	0.8%	0.8%	0.9%	1.0%
Tests Between Groups													
	Test	Chi-Square	Deg Frdm	P-value									
	Log-Rank	0.24	1	0.626									
	Wilcoxon	0.43	1	0.511									

Figure 4a. (Continued) Survival Free from Target Vessel Failure (at 270 days) - Event-free Survival ± 1.5SE - ITT Set

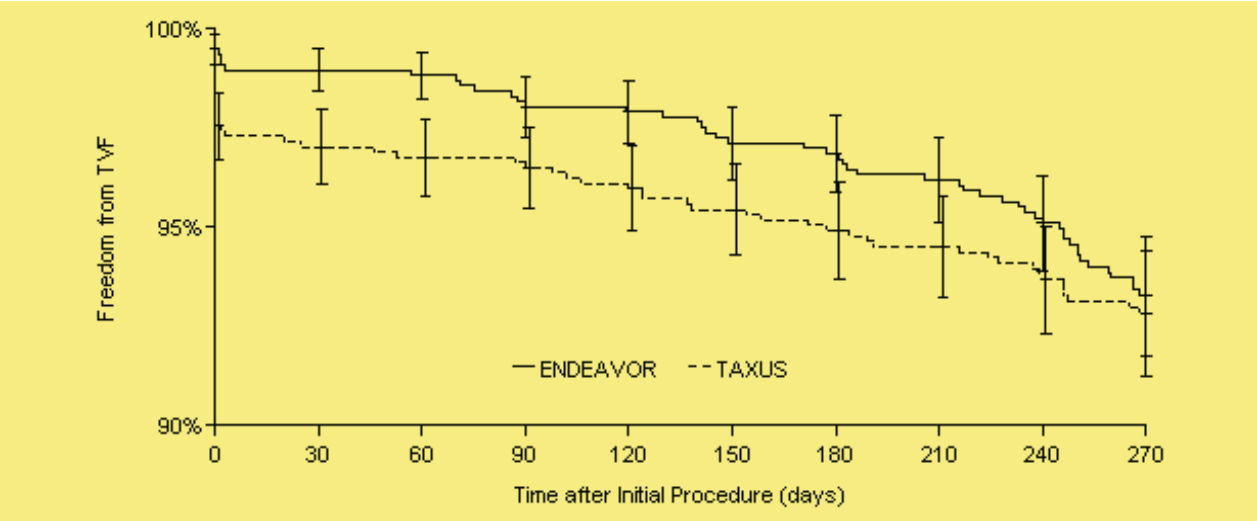

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Figure 4b. Survival Free from Target Vessel Failure (at 270 days) - Event-free Survival ± 1.5SE - PP Set

TVF	0	7	14	21	30	60	90	120	150	180	210	240	270
ENDEAVOR													
# Entered	748	744	737	737	737	734	729	723	722	715	707	698	683
# Censored	0	4	0	0	3	4	0	0	1	6	4	7	115
# Incomplete	0	0	0	0	0	0	0	0	0	0	0	0	0
# Events	4	3	0	0	0	1	6	1	6	2	5	8	13
% Survived	99.5%	99.1%	99.1%	99.1%	99.1%	98.9%	98.1%	98.0%	97.2%	96.9%	96.2%	95.1%	93.2%
SE	0.3%	0.4%	0.4%	0.4%	0.4%	0.4%	0.5%	0.5%	0.6%	0.6%	0.7%	0.8%	1.0%
TAXUS													
# Entered	752	735	730	730	729	728	719	716	710	704	695	679	669
# Censored	0	4	0	0	1	7	1	2	2	5	13	5	104
# Incomplete	0	0	0	0	0	0	0	0	0	0	0	0	0
# Events	17	1	0	1	0	2	2	4	4	4	3	5	6
% Survived	97.7%	97.6%	97.6%	97.5%	97.5%	97.2%	96.9%	96.4%	95.8%	95.3%	94.9%	94.2%	93.3%
SE	0.5%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.7%	0.7%	0.8%	0.8%	0.9%	1.0%
Tests Between Groups													
	Test	Chi-Square	Deg Frdm	P-value									
	Log-Rank	0.00	1	0.950									
	Wilcoxon	0.05	1	0.829									

Figure 4b. (Continued) Survival Free from Target Vessel Failure (at 270 days) - Event-free Survival ± 1.5SE - PP Set

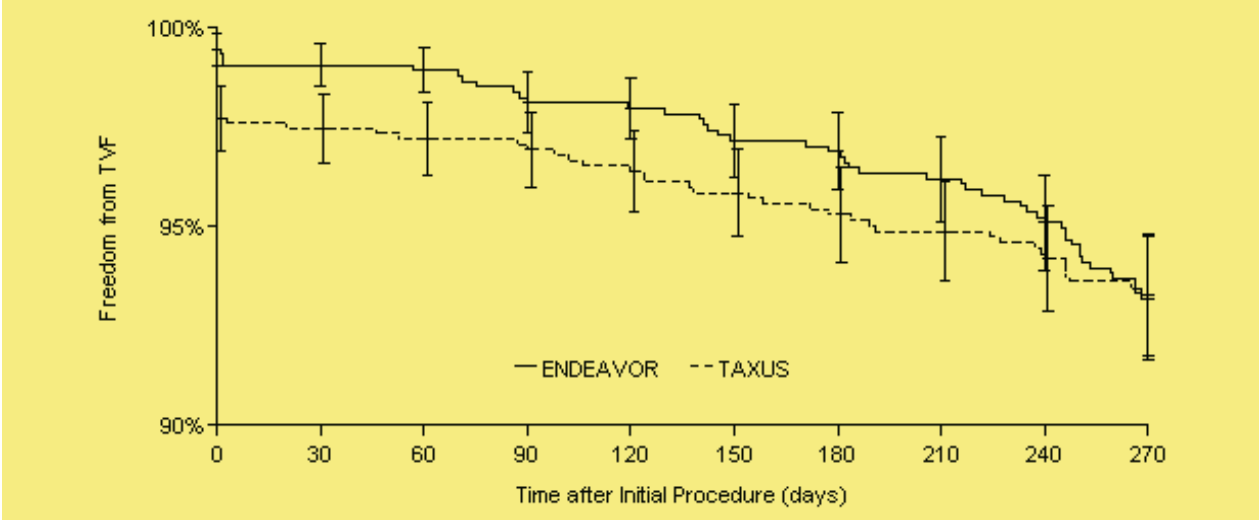

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Figure 5. Survival Free from Target Lesion Revascularization (at 270 days) - Event-free Survival ± 1.5SE - ITT Set

TLR	0	7	14	21	30	60	90	120	150	180	210	240	270
ENDEAVOR													
# Entered	773	773	763	763	763	759	753	750	749	744	736	725	710
# Censored	0	6	0	0	3	5	0	0	0	6	6	9	125
# Incomplete	0	1	0	0	1	1	0	0	1	0	0	1	0
# Events	0	3	0	0	0	0	3	1	4	2	5	5	8
% Survived	100.0%	99.6%	99.6%	99.6%	99.6%	99.6%	99.2%	99.1%	98.6%	98.3%	97.6%	96.9%	95.8%
SE	0.0%	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.4%	0.5%	0.6%	0.6%	0.8%
TAXUS													
# Entered	775	771	764	764	764	761	753	751	744	740	733	718	707
# Censored	1	5	0	0	2	7	0	3	1	7	12	9	118
# Incomplete	0	0	0	0	0	1	1	0	2	0	1	0	0
# Events	3	2	0	0	1	0	1	4	1	0	2	2	4
% Survived	99.6%	99.4%	99.4%	99.4%	99.2%	99.2%	99.1%	98.6%	98.4%	98.4%	98.2%	97.9%	97.3%
SE	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.4%	0.5%	0.5%	0.5%	0.5%	0.7%
Tests Between Groups													
	Test	Chi-Square	Deg Frdm	P-value									
	Log-Rank	2.33	1	0.127									
	Wilcoxon	2.18	1	0.139									

Figure 5. (Continued) Survival Free from Target Lesion Revascularization (at 270 days) - Event-free Survival ± 1.5SE - ITT Set

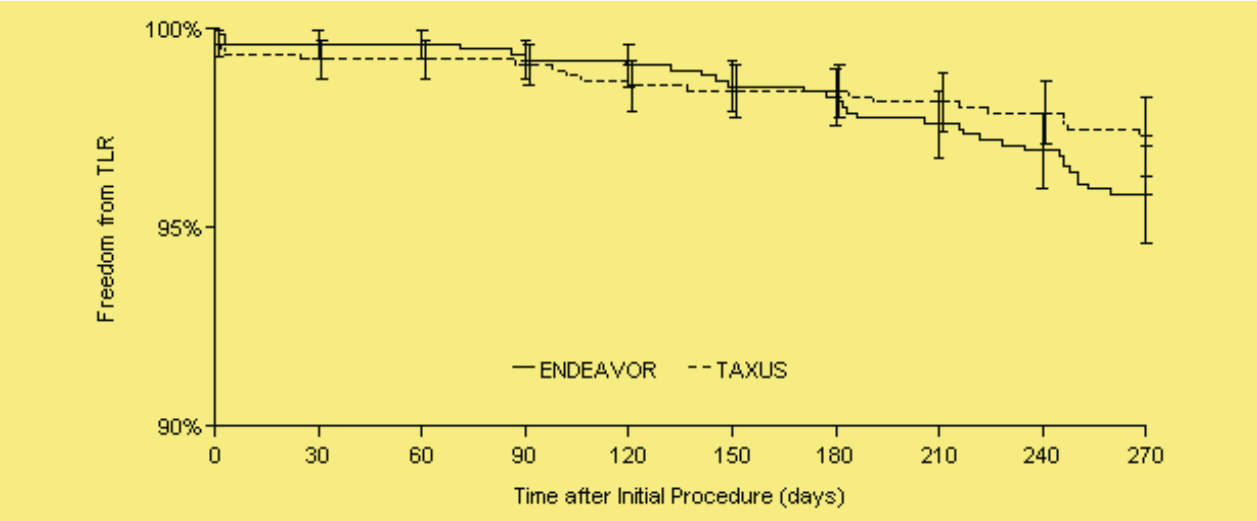

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Figure 6. Survival Free from Target Vessel Revascularization (at 270 days) - Event-free Survival ± 1.5SE - ITT Set

TVR	0	7	14	21	30	60	90	120	150	180	210	240	270
ENDEAVOR													
# Entered	773	773	764	764	764	760	754	749	748	742	734	724	709
# Censored	0	5	0	0	3	5	0	0	0	6	5	7	118
# Incomplete	0	1	0	0	1	1	0	0	1	0	0	1	0
# Events	0	3	0	0	0	0	5	1	5	2	5	7	13
% Survived	100.0%	99.6%	99.6%	99.6%	99.6%	99.6%	98.9%	98.8%	98.2%	97.9%	97.2%	96.3%	94.4%
SE	0.0%	0.2%	0.2%	0.2%	0.2%	0.2%	0.4%	0.4%	0.5%	0.5%	0.6%	0.7%	0.9%
TAXUS													
# Entered	775	771	763	763	763	760	751	748	742	736	726	710	699
# Censored	1	5	0	0	2	7	0	2	1	6	12	5	108
# Incomplete	0	0	0	0	0	1	1	0	2	0	1	0	0
# Events	3	3	0	0	1	1	2	4	3	4	3	6	7
% Survived	99.6%	99.2%	99.2%	99.2%	99.1%	99.0%	98.7%	98.2%	97.8%	97.2%	96.8%	96.0%	95.0%
SE	0.2%	0.3%	0.3%	0.3%	0.3%	0.4%	0.4%	0.5%	0.5%	0.6%	0.6%	0.7%	0.9%
Tests Between Groups													
	Test	Chi-Square	Deg Frdm	P-value									
	Log-Rank	0.17	1	0.682									
	Wilcoxon	0.11	1	0.740									

Figure 6. (Continued) Survival Free from Target Vessel Revascularization (at 270 days) - Event-free Survival ± 1.5SE - ITT Set

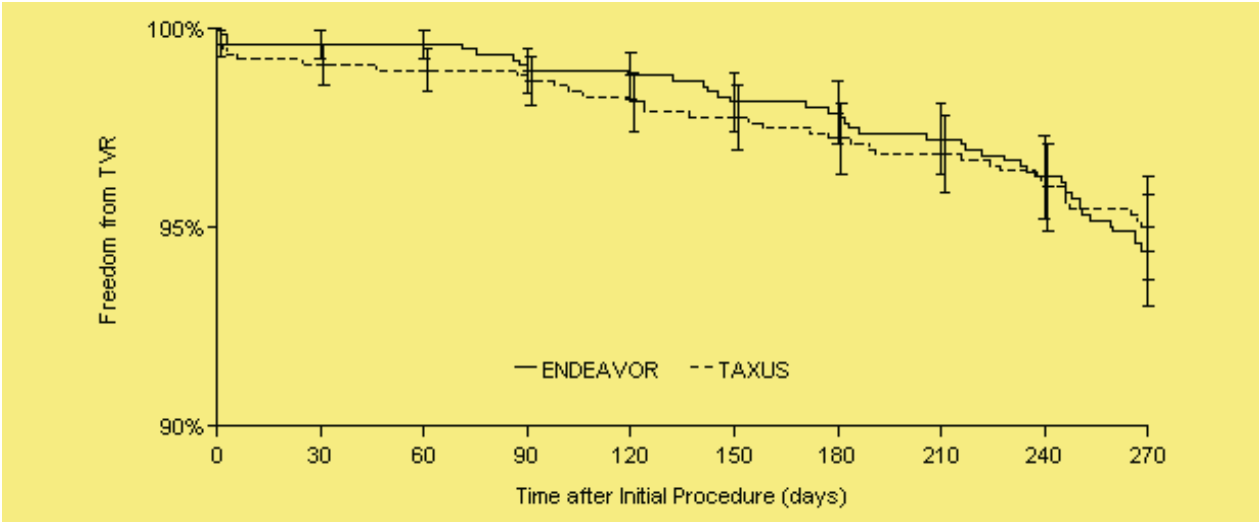

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Table 13. Quantitative Intravascular Ultrasound Analysis - Angiographic/IVUS Subset (Post-Stent Implantation)

Final Post-Stent	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
Measure					
EEM Area (mm^2)					
Mean±SD (n)	13.15±4.23 (79)	13.50±3.96 (65)	13.31±4.10 (144)	-0.35 [-1.71, 1.01]	0.611
Range (Min,Max)	(6.28,25.05)	(6.69,23.61)	(6.28,25.05)		
EEM Volume (mm^3)					
Mean±SD (n)	284.97±119.08 (79)	268.37±108.01 (64)	277.54±114.16 (143)	16.60 [-21.39, 54.59]	0.389
Range (Min,Max)	(91.88,592.94)	(105.91,589.42)	(91.88,592.94)		
Mean Stent Area (mm^2)					
Mean±SD (n)	6.67±2.00 (83)	7.31±2.01 (75)	6.97±2.02 (158)	-0.65 [-1.28, -0.02]	0.044
Range (Min,Max)	(3.49,12.47)	(2.92,11.14)	(2.92,12.47)		
Stent Volume (mm^3)					
Mean±SD (n)	145.21±58.97 (83)	146.40±61.47 (74)	145.77±59.97 (157)	-1.19 [-20.19, 17.81]	0.902
Range (Min,Max)	(45.79,310.44)	(46.21,308.48)	(45.79,310.44)		
Mean Lumen Area (mm^2)					
Mean±SD (n)	6.66±1.97 (83)	7.27±1.98 (75)	6.95±1.99 (158)	-0.61 [-1.23, 0.01]	0.054
Range (Min,Max)	(3.49,12.34)	(2.92,11.14)	(2.92,12.34)		
Minimal Lumen Area (mm^2)					
Mean±SD (n)	5.67±1.88 (122)	6.38±2.07 (110)	6.01±2.00 (232)	-0.71 [-1.22, -0.20]	0.006
Range (Min,Max)	(1.90,12.38)	(2.08,10.33)	(1.90,12.38)		
Lumen Volume (mm^3)					
Mean±SD (n)	144.89±58.82 (83)	146.01±61.34 (74)	145.42±59.83 (157)	-1.12 [-20.08, 17.83]	0.907
Range (Min,Max)	(45.79,310.44)	(46.21,307.98)	(45.79,310.44)		
Plaque Volume (mm^3)					
Mean±SD (n)	139.07±65.18 (79)	123.89±56.05 (64)	132.28±61.52 (143)	15.18 [-5.19, 35.55]	0.143
Range (Min,Max)	(30.94,311.34)	(36.31,281.43)	(30.94,311.34)		
Within Stent Volume (mm^3)					
Mean±SD (n)	0.32±1.20 (83)	0.38±1.06 (75)	0.35±1.13 (158)	-0.06 [-0.42, 0.30]	0.737
Range (Min,Max)	(0.00,8.04)	(0.00,5.39)	(0.00,8.04)		

N = the maximum number of eligible patients, n = number of patients with evaluable data.

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Table 14. Quantitative Intravascular Ultrasound Analysis (at 8 Months) - Angiographic/IVUS Subset

8-Month Follow-Up	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
Measure					
EEM Area (mm^2)					
Mean±SD (n)	13.43±3.78 (68)	14.80±4.78 (66)	14.10±4.34 (134)	-1.37 [-2.84, 0.11]	0.069
Range (Min,Max)	(6.24,21.95)	(6.40,27.17)	(6.24,27.17)		
EEM Volume (mm^3)					
Mean±SD (n)	288.25±99.12 (68)	294.71±129.08 (66)	291.43±114.47 (134)	-6.46 [-45.72, 32.79]	0.746
Range (Min,Max)	(99.99,559.59)	(106.95,846.53)	(99.99,846.53)		
Mean Stent Area (mm^2)					
Mean±SD (n)	6.82±1.96 (74)	7.47±2.19 (77)	7.16±2.10 (151)	-0.65 [-1.32, 0.02]	0.058
Range (Min,Max)	(3.45,11.35)	(3.00,11.92)	(3.00,11.92)		
Stent Volume (mm^3)					
Mean±SD (n)	146.94±53.03 (74)	151.14±61.38 (77)	149.08±57.29 (151)	-4.20 [-22.68, 14.27]	0.654
Range (Min,Max)	(41.79,303.14)	(50.19,393.72)	(41.79,393.72)		
Mean Lumen Area (mm^2)					
Mean±SD (n)	5.74±1.72 (74)	6.75±2.17 (77)	6.25±2.02 (151)	-1.01 [-1.64, -0.38]	0.002
Range (Min,Max)	(2.15,9.76)	(2.72,11.80)	(2.15,11.80)		
Minimal Lumen Area (mm^2)					
Mean±SD (n)	4.62±1.82 (113)	5.50±2.14 (109)	5.05±2.02 (222)	-0.87 [-1.39, -0.35]	0.001
Range (Min,Max)	(1.43,10.97)	(1.63,10.34)	(1.43,10.97)		
Lumen Volume (mm^3)					
Mean±SD (n)	122.79±43.01 (74)	136.26±57.58 (77)	129.66±51.24 (151)	-13.46 [-29.86, 2.93]	0.105
Range (Min,Max)	(36.86,248.12)	(45.51,391.92)	(36.86,391.92)		
Plaque Volume (mm^3)					
Mean±SD (n)	165.76±66.52 (68)	162.56±75.26 (66)	164.18±70.71 (134)	3.20 [-21.05, 27.46]	0.794
Range (Min,Max)	(60.84,354.91)	(60.14,454.60)	(60.14,454.60)		
Mean NIH Area (mm^2)					
Mean±SD (n)	1.09±0.76 (74)	0.72±0.73 (77)	0.90±0.77 (151)	0.36 [0.12, 0.60]	0.003
Range (Min,Max)	(0.09,3.27)	(0.00,2.95)	(0.00,3.27)		
Neointimal Hyperplastic Volume (mm^3)					
Mean±SD (n)	24.14±19.38 (74)	14.88±16.62 (77)	19.42±18.55 (151)	9.26 [3.46, 15.06]	0.002
Range (Min,Max)	(1.60,98.47)	(0.00,86.86)	(0.00,98.47)		
Volume Obstruction (%)					
Mean±SD (n)	15.72±10.40 (74)	9.88±9.24 (77)	12.74±10.22 (151)	5.84 [2.68, 9.00]	<.001
Range (Min,Max)	(2.05,41.02)	(0.00,35.00)	(0.00,41.02)		

N = the maximum number of eligible patients, n = number of patients with evaluable data.

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Table 15. Quantitative Intravascular Ultrasound Analysis - Angiographic/IVUS Subset (Difference Between Post-Stent Implantation and 8-Month Follow-Up)

Difference (8-Month Follow-up - Final Post-stent)	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
Measure					
EEM Area (mm^2)					
Mean±SD (n)	0.29±1.02 (48)	0.81±0.96 (38)	0.52±1.02 (86)	-0.52 [-0.95, -0.09]	0.019
Range (Min,Max)	(-2.69,2.26)	(-1.57,2.90)	(-2.69,2.90)		
EEM Volume (mm^3)					
Mean±SD (n)	1.30±28.71 (48)	14.93±31.38 (37)	7.23±30.49 (85)	-13.63 [-26.64, -0.62]	0.040
Range (Min,Max)	(-67.54,68.10)	(-49.82,82.10)	(-67.54,82.10)		
Mean Stent Area (mm^2)					
Mean±SD (n)	0.17±0.52 (50)	0.13±0.49 (45)	0.15±0.51 (95)	0.04 [-0.17, 0.24]	0.724
Range (Min,Max)	(-0.97,1.26)	(-1.03,1.40)	(-1.03,1.40)		
Stent Volume (mm^3)					
Mean±SD (n)	2.06±15.40 (50)	1.86±13.93 (45)	1.97±14.64 (95)	0.20 [-5.81, 6.21]	0.948
Range (Min,Max)	(-25.13,35.26)	(-24.00,33.03)	(-25.13,35.26)		
Mean Lumen Area (mm^2)					
Mean±SD (n)	-0.90±0.89 (50)	-0.67±0.90 (46)	-0.79±0.89 (96)	-0.24 [-0.60, 0.13]	0.198
Range (Min,Max)	(-3.14,0.96)	(-3.17,1.30)	(-3.17,1.30)		
Minimal Lumen Area (mm^2)					
Mean±SD (n)	-1.20±1.17 (94)	-0.95±1.18 (82)	-1.09±1.18 (176)	-0.25 [-0.60, 0.10]	0.157
Range (Min,Max)	(-6.27,0.53)	(-4.11,1.40)	(-6.27,1.40)		
Lumen Volume (mm^3)					
Mean±SD (n)	-22.52±25.91 (50)	-14.50±21.93 (45)	-18.72±24.32 (95)	-8.02 [-17.86, 1.82]	0.109
Range (Min,Max)	(-105.77,22.71)	(-68.00,25.62)	(-105.77,25.62)		
Plaque Volume (mm^3)					
Mean±SD (n)	24.53±25.30 (48)	29.85±30.55 (37)	26.84±27.66 (85)	-5.32 [-17.37, 6.73]	0.383
Range (Min,Max)	(-21.68,100.10)	(-26.86,145.38)	(-26.86,145.38)		
Neointimal Hyperplastic Volume (mm^3)					
Mean±SD (n)	24.58±21.84 (50)	16.36±18.53 (45)	20.68±20.65 (95)	8.22 [-0.08, 16.52]	0.052
Range (Min,Max)	(1.60,98.47)	(0.67,86.36)	(0.67,98.47)		

N = the maximum number of eligible patients, n = number of patients with evaluable data.

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Table 16. Quantitative Intravascular Ultrasound Analysis - Incomplete Stent Apposition Angiographic/IVUS Subset

Difference	ENDEAVOR (N=164 Patients)	TAXUS (N=164 Patients)	All Patients (N=328 Patients)	Difference [95% CI]	P-Value
Incomplete Stent Apposition at Post-Procedure	12.5% (17/136)	11.8% (15/127)	12.2% (32/263)	0.7% [-7.2%, 8.6%]	1.000
Incomplete Stent Apposition at 8 Month Follow-up	10.0% (12/120)	14.7% (17/116)	12.3% (29/236)	-4.7% [-13.0%, 3.7%]	0.324
Resolved	3.8% (4/106)	2.1% (2/95)	3.0% (6/201)	1.7% [-3.0%, 6.3%]	0.686
Persistent	8.5% (9/106)	10.5% (10/95)	9.5% (19/201)	-2.0% [-10.2%, 6.1%]	0.638
Late Acquired	0.9% (1/106)	3.2% (3/95)	2.0% (4/201)	-2.2% [-6.2%, 1.8%]	0.346

N = the maximum number of eligible patients. Denominators indicate the total number of patients with available data for related parameter.

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Table 17a. Major Protocol Deviation by Site - ITT Set

Site	ENDEAVOR	TAXUS	All Patients
5091	1	0	1
5166	2	0	2
5434	0	1	1
5451	1	0	1
6001	1	0	1
6060	2	0	2
6143	1	3	4
6160	0	1	1
6260	1	0	1
6430	0	1	1
6431	5	2	7
6434	0	2	2
6435	0	1	1
6438	1	1	2
6441	1	0	1
6444	1	1	2
6445	0	3	3
6448	1	1	2
6451	1	2	3
6453	0	1	1
6456	1	0	1
6461	0	1	1
6463	3	1	4
6464	0	1	1
6575	2	0	2
6601	0	1	1
6620	1	0	1
6621	0	1	1
6626	0	1	1
6670	0	2	2
Total	26	28	54

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Table 17b. Major Protocol Deviation by Type - ITT Set

Type	ENDEAVOR	TAXUS	All Patients
The target vessel reference diameter is 2.5 mm and <3.5 mm.	0	1	1
A known hypersensitivity or contraindication to aspirin, heparin or bivalirudin ticlopidine or clopidogrel, cobalt, nickel, chromium, molybdenum, polymer coatings (e.g., Phosphorylcholine or Translute), or a sensitivity to contrast media, which cannot be adequately pre-medicated.	2	0	2
A platelet count < 100,000 cells/mm³ or > 700,000 cells/mm³, or a WBC < 3,000 cells/mm³.	3	1	4
A serum creatinine level > 2.0 mg/dl within seven days prior to index procedure.	2	0	2
Evidence of an acute myocardial infarction within 72 hours of the intended index procedure (defined as: Q wave or non-Q wave myocardial infarction having creatine kinase (CK) enzymes >2X the upper laboratory normal with the presence of a creatine kinase myocardial-band isoenzyme (CK-MB) elevated above the Institution's upper limit of normal).	3	1	4
Previous percutaneous coronary intervention of the target vessel within 9 months pre-procedure.	0	1	1
Planned percutaneous coronary intervention of any vessel within 30 days post-procedure.	1	0	1
Currently participating in an investigational drug or another device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints, or requires coronary angiography, intravascular ultrasound (IVUS) or other coronary artery imaging procedures. Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, arenot considered investigational trials.	1	0	1
Documented left ventricular ejection fraction (LVEF) < 30% at most recent evaluation.	0	1	1
Previous stenting (drug-eluting or bare metal) in the target vessel: A stent has been implanted in the target vessel within the last 9 months.	0	2	2
Target vessel has other lesions with greater than 40% diameter stenosis based on visual estimate or on-line QCA.	5	8	13
Lesion location is aorto-ostial, an unprotected left main lesion, or within 5 mm of the origin of the LAD, LCX, or RCA	0	3	3

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Table 17b. (Continued) Major Protocol Deviation by Type - ITT Set

Type	ENDEAVOR	TAXUS	All Patients
Is severely calcified.	0	1	1
Incorrect version of consent provided to the patient	8	3	11
Consent not dated by the patient	0	1	1
The target lesion must be a single de novo lesion in a native coronary artery.	1	4	5
The target lesion is < 27 mm in length.	0	1	1
Total	26	28	54

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Table 18a. Minor Protocol Deviation by Site - ITT Set

Site	ENDEAVOR	TAXUS	All Patients
5006	7	12	19
5023	3	6	9
5038	22	43	65
5070	13	10	23
5091	43	25	68
5135	1	3	4
5166	36	36	72
5186	65	42	107
5216	1	7	8
5251	1	2	3
5397	33	47	80
5434	23	42	65
5451	29	11	40
5520	0	4	4
5545	19	26	45
5556	0	7	7
6001	13	13	26
6020	12	7	19
6032	6	11	17
6060	3	0	3
6143	57	49	106
6160	13	1	14
6240	22	30	52
6257	15	20	35
6260	22	20	42
6261	1	3	4
6419	0	5	5
6425	42	54	96
6426	11	9	20
6427	31	26	57
6428	20	16	36
6429	1	2	3
6430	2	8	10
6431	30	24	54
6433	152	107	259
6434	29	63	92
6435	0	19	19
6436	1	6	7
6437	17	7	24
6438	129	135	264

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Table 18a. (Continued) Minor Protocol Deviation by Site - ITT Set

Site	ENDEAVOR	TAXUS	All Patients
6439	24	15	39
6441	6	13	19
6444	35	23	58
6445	16	27	43
6446	7	5	12
6448	26	21	47
6449	23	17	40
6450	3	1	4
6451	0	7	7
6452	42	73	115
6453	16	4	20
6454	2	0	2
6455	12	16	28
6456	52	30	82
6457	3	3	6
6458	1	0	1
6459	25	21	46
6461	42	37	79
6462	3	7	10
6463	20	18	38
6464	6	14	20
6574	4	14	18
6575	3	6	9
6576	2	13	15
6578	31	17	48
6601	10	6	16
6620	5	9	14
6621	6	20	26
6624	7	4	11
6625	4	1	5
6626	14	11	25
6628	26	26	52
6634	2	0	2
6638	10	8	18
6643	4	4	8
6657	0	21	21
6663	7	0	7
6664	4	5	9
6670	3	5	8
Total	1431	1480	2911

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Table 18b. Minor Protocol Deviation by Type - ITT Set

Type	ENDEAVOR	TAXUS	All Patients
Medications not given per protocol	12	11	23
Patient discharged on incorrect ASA dose	1	2	3
Patient discharged on incorrect Ticlid/Plavix dose	2	0	2
ASA not given	5	7	12
Plavix/Ticlid not given	1	0	1
NTG not given pre-stent	1	1	2
NTG not given post-stent	27	26	53
Patient did not take required ASA	90	86	176
Patient did not take required Ticlid/Plavix	10	16	26
Plavix /Ticlid not taken for 6 Months post-procedure	1	4	5
ACT did not reach therapeutic level	9	11	20
ACT done outside protocol time frame	2	1	3
Pre-procedure CBC not done	0	1	1
Pre-procedure Liver Function Tests not done	2	2	4
Pre-procedure Chemistry panel not done	0	3	3
Pre-procedure CK/CK-MB not done	23	31	54
Pre-procedure CK/CK-MB taken outside protocol time frame	1	2	3
Post-procedure CK/CK-MB not done	47	54	101
Post-procedure CK/CK-MB taken outside protocol time frame	125	136	261
Pre-procedure ECG done outside protocol time frame	1	1	2
30 Day CBC not done	0	2	2
30 Day CBC done outside protocol time frame	132	124	256
30 Day differential not done	0	1	1
30 Day differential done outside protocol time frame	130	124	254
Stent deployed above nominal pressure	14	10	24
Treatment performed outside protocol	21	31	52
Patient randomized/enrolled but no study stent was attempted/tried to implant	3	4	7
More than allowable study stent length implanted in single vessel.	0	1	1
Other stent implanted than randomized	0	3	3
Follow-up health status information not obtained per protocol.	8	23	31
Follow-up phone call/visit outside protocol time frame	421	413	834
Follow-up 6 month not done	2	1	3
Follow-up 8 month not done	0	4	4
Follow-up 9 month not done	0	1	1
Follow-up 12 month not done	0	1	1
Follow-up angiogram not done	10	10	20
Follow-up angiogram done outside protocol time frame	32	35	67
Follow-up IVUS not done	12	12	24
Follow-up IVUS done outside protocol time frame	28	31	59
Physician not trained to protocol or on delegation of authority saw patient	33	33	66

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Table 18b. (Continued) Minor Protocol Deviation by Type - ITT Set

Type	ENDEAVOR	TAXUS	All Patients
Blinding noncompliance	7	7	14
Other	218	214	432
Total	1431	1480	2911

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Table 18c. Listing of Protocol Deviation - Other

Site	----------	Specify
5006	-----	SAE NOTIFICATION OUT OF WINDOW
5023	-----	SAE REPORTED GREATER THAN 24 HRS.
5038	---	CHEMISTRY RESULTS OUT OF WINDOW
5038	---	BASELINE CREATININE PERFORMED OUT OF WINDOW
5038	---	DIFFERENTIAL, LFT AND CKMB (PRE-PROCEDURE) DRAWN AFTER GUIDE CATHETER PLACED.
5038	---	HCRI NOT INFORM WITHIN 24 HR.
5038	---	PRE-DILATATION BALLOON NOT 0.5 MM LESS THAN STENT
5038	-----	SAE NOT REPORTED TO SPONSOR WITHIN 1 WORKING DAY
5038	------	CBC PERFORMED OUTSIDE OF 7 DAY WINDOW AND DIFFERENTIAL
5038	------	GGT NOT DONE AS PART OF LIVER FUNCTION PANEL AT THIS SITE
5038	------	IVUS NOT DONE
5038	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME
5038	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME
5038	------	SAE NOT REPORTED WITHIN WINDOW
5038	------	PRE-PROCEDURE LABS DRAWN POST PROCEDURE START
5038	------	POST STENT DILATATION PERFORMED WITH STENT BALLOON
5038	------	HOSPITAL DOES NOT RUN GGT AS PART OF LIVER FUNCTION PANEL.
5070	-----	PRE-DILATATION BALLOON WAS SAME SIZE AS STENT.
5070	------	CBC COLLECTED OUT OF WINDOW - TO EARLY
5070	------	SAE NOT REPORTED WITH-IN WINDOW.
5070	------	WBC DIFF DONE OUTSIDE OF WINDOW
5091	---	POST-INDEX PROCEDURE IVUS NOT COMPLETED
5091	-----	POST DIL WITH STENT BALLOON
5091	-----	RANDOMIZATION ERROR
5091	------	NOT REPORTED WITHIN 24 HOURS (SAE)
5091	------	SAE NOT REPORTED WITHIN 24; OF ACCNOWLEDGMENT (8 MTH)
5091	------	PRE DIL BALLOON NOT <=0.5 MM THAN STENT
5091	------	SAE NOT REPORTED IN 24 HOURS
5135	-----	SAE NOTIFICATION FOR NOT FAXED IN W/I 24 HOURS. PHONE CALL WAS GIVEN TO SPONSOR, BUT DID NOT FAX IN NOTIFICATION SHEET.
5166	---	LATE SAE NOTIFICATION
5166	-----	RANDOMIZATION ERROR.
5166	------	VISIT ALSO COMPLETED VIA TELEPHONE
5186	---	SAE NOT REPORTED WITHIN APPROPRIATE TIME FRAME.
5186	-----	FAILURE TO REPORT SAE TO IRB WITHIN IRB'S GUIDELINES
5186	------	PRE-TREATMENT BALLOON NOT 0.5 MM SMALLER THAN TARGET VESSEL

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	----------	Specify
5186	------	SAE NOT REPORTED WITHIN PROTOCOL WINDOW
5186	------	ON SAE 9/22/05, SPONSOR WAS NOTIFIED WITHIN 24 HOURS BUT
5186	------	FAILURE TO REPORT SAE TO SPONSOR WITHIN 24 HRS.
5216	-----	DATE OF NOTIFICATION OF SAE IS OUTSIDE THE 24 HOUR TIME FRAME REQUIRED IN REPORTING THE SAE FOR UNKNOWN REASONS.
5216	------	PRE-PROCEDURE LIPID PANEL DONE OUTSIDE PROTOCOL SPECIFIED TIMEFRAME.
5251	-----	DATE OF SAE NOTIFICATION IS OUTSIDE THE 24 HR. TIME FRAME IN REPORTING THE SAE.
5251	-----	DATE OF SAE NOTIFICATION IS OUTSIDE THE 24 HR. TIME FRAME IN REPORTING THE SAE.
5397	---	DID NOT DO POST-STENT IVUS
5397	---	IRB NOT NOTIFIED WITHIN 10 DAYS
5397	---	NO POST STENT IVUS
5397	-----	LATE NOTICE OF SAE TO HCRI > 24 HOURS
5397	-----	REPORTING OF SAE > 24 HOURS TO HCRI
5397	-----	LATE NOTIFICATION OF SAE
5397	------	IRB NOT NOTIFIED WITHIN 10 DAYS OF KNOWLEDGE
5397	------	LATE NOTIFICATION OF SAE
5397	------	9 MO VISIT BY TELEPHONE CALL
5397	------	LATE NOTIFICATION OF SAE TO HCRI
5397	------	LATE NOTICE OF SAE TO HCRI > 24 HOURS
5434	------	PRE PROCEDURE CBC/DIFF DRAWN OUTSIDE OF WINDOW
5434	------	SAE NOT REPORTED TO HCRI WITH 24 HOURS
5434	------	STAGING CRITERIA NO FOLLOWED
5434	------	IVUS NOT DONE DURING MULTISTENT SUBSET
5434	------	IVUS NOT DONE AFTER ADDITIONAL STENT PLACED
5451	---	PRE CBC DONE AT OUTSIDE LAB; OUT OF PROTOCOL TIME FRAME
5451	---	PRE-PROCEDURE CHEMISTRY DONE AT OUTSIDE LAB; OUT OF
5451	---	WBC OUTSIDE OF PROTOCOL TIME DUE TO ERROR
5451	-----	PRE-DIL BALLOON WAS LESS THAN 0.5 MM SMALLER THAN STENT
5451	-----	PRE-DIL BALLOON WAS NOT .5 SMALLER THAN STENT
5451	-----	DID NOT NOTIFY SPONSOR WITHIN 25 HOURS KNOWLEDGE OF SAE
5451	------	OPERATOR PREFERENCE
5451	------	CBC OUT OF WINDOW
5451	------	CHEMISTY DONE OUT OF WINDOW
5451	------	LIPID PANEL OUT OF WINDOW
5451	------	PRE-DIL BALLOON WAS NOT < 0.5 MM SMALLER THAN THE STENT
5451	------	TAXUS STENT PLACED IN NON-TARGET VESSEL WITHIN 30 DAYS OF INDEX PROC.

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	----------	Specify
5451	------	PRE-DIL BALLOON SIZE NOT LESS THAN STENT BALLOON SIZE
5545	-----	PREDILATION BALLOON NET 0.5 MM SMALLER THAN STENT
5545	-----	SAE NOT REPORTED IN 24 HOURS OF KNOWLEDGE
5545	------	PREDILATION BALLOON NOT 0.5 MM SMALLER THAN STENT
5545	------	SAE NOT REPORTED TO SPONSOR WITHIN TIMEFRAME
5545	------	PREDILATION BALLOON NOT 0.5 MM SMALLER THAN STENT
5545	------	TUMOR (CANCER) AND REMOVAL SAE NOT REPORTED IN 24 HOURS
5545	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME.
5545	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME
5545	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME.
5556	-----	POST DILATION WITH STENT BALLOON
5556	-----	PREDILATATION BALLOON NOT <= 0.5 MM SMALLER THAN STENT DIAMETER
5556	-----	SAES NOT REPORTED WITHIN 24 HOURS OF EVENT KNOWLEDGE
6001	------	SAE NOT REPORTED PER PROTOCOL.
6020	-----	REPORTING DATE OF SAE IS OUTSIDE 24 HOURS WINDOW OF KNOWLEDGE OF EVENT 11/28/05 - COORDINATOR NOT AWARE THIS WAS REPORTABLE SAE - SAE REPORTING CRITERIA REVIEWED.
6060	------	REPORT OF SAE GREATER THAN 24 HOURS
6143	---	PRE PROCEDURE CBC, DIFFERENTIAL, CHEMISTRY, LIPID PANEL
6143	---	RE PROCEDURE LFT OUT OF WINDOW
6143	---	SAE NOT REPORTED TO HCRI WITHIN 24 HOURS.
6143	-----	PRE-PROCEDURAL LIPID PANEL PERFORMED OUT OF WINDOW
6143	-----	LIPID PANEL DRAWN OUT OF WINDOW.
6143	------	LIPID PANEL DRAWN OUT OF WINDOW
6143	------	PRE PROCEDURAL DIFFERENTIAL OUT OF WINDOW
6143	------	PRE PROCEDURE CBC W/DIFFERENTIAL, LFT AND CHEMISTRY PANEL OUT OF WINDOW DUE TO STAFF OVERSITE, SITE REEDUCATED.
6143	------	PRE PROCEDURE LIPID PANEL OUT OF WINDOW
6143	------	PRE-DILITATION BALLOON WAS NOT < 0.5 MM THAN STENT
6143	------	IVUS WAS NOT PERFORMED IN MULTISTENT COHORT PATIENT
6143	------	RESEARCH COORDINATOR CONSENTED PATIENT PRIOR TO "GO" LETTER RECEIPT
6160	------	HCRI NOT NOTIFIED OF EVENT WITHIN 24 HOURS
6160	------	PATIENT WANTED HIS CARDIOLOGIST TO DO CLINICALLY DRIVEN CATH
6160	------	PRE-DIL NOT <= 0.5 MM SMALLER THAN STENT
6240	---	DIFFERENTIAL LFT'S AND CHEMISTRY DRAWN OUTSIDE OF EXCEPTABLE WINDOW
6240	------	PRE-PROCEDURE CBC, WBC, LIPIDS OUTSIDE PROTOCOL TIME FRAME
6240	------	PRE GGT NOT DONE
6240	------	RANDOMIZATION ERROR.

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	----------	Specify
6240	------	SAE NOTIFICATION REPORTED OUTSIDE OF 24 HOUR TIME FRAME
6240	------	SAE 09/13/05 - 09/15/05 NOT REPORTED W/IN 24 HRS OF DISCOVERY
6240	------	DRAWN OUT-OF-WINDOW
6240	------	SAE NOT REPORTED TO SPONSOR WITH IN 24 HOURS OF KNOWLEGDE OF EVENT
6240	------	RANDOMIZATION ERROR.
6257	---	IVUS NOT DONE, UNABLE TO CROSS LESION
6257	---	STENT BALLOON USED FOR POST-DILATION
6257	---	BLANK
6257	---	SAE ON 9/13/05 REPORTED OUTSIDE 24 HR WINDOW
6257	---	USED STENT BALLOON FOR POST DILATION
6257	---	SAE ON 10/18/05 REPORTED OUTSIDE OF 24 HR WINDOW
6257	-----	PRE-DILATION BALLOON NOT 0.5 MM SMALLER THAN STENT
6257	-----	SAE NOT REPORTED WITHIN ONE DAY OF KNOWLEDGE.
6257	------	PREDIL BALLOON
6257	------	RANDOMIZATION PROCESS NOT PROPERLY COMPLETED
6257	------	SAE ON 8/17/05 REPORTED OUTSIDE OF 24 HOUR TIME FRAME
6257	------	BLANK
6257	------	SAE NOT REPORTED TO SPONSOR W/IN TIME FRAME
6260	-----	PREDILATED WITH BALLOON DIAMETER SAME AS STENT DIAMETER.
6260	-----	PREDILATATION BALLOON SAME SIZE AS STENT.
6260	-----	HCRI NOTIFIED OF EVENT > 1 DAY.
6260	------	SAE NOTIFICATION GREATER THAN 24 HOURS.
6260	------	PRE-DILATION DONE WITH BALLOON DIAMETER SAME AS
6260	------	SAE REPORTED LATE TO SPONSOR.
6261	------	SAE NOTIFICATION OUTSIDE 24 HR. WINDOW.
6261	------	SAE NOTIFICATION OUTSIDE 24 HR. WINDOW.
6419	-----	TELEPHONE CONTACT ONLY INSTEAD OF OFFICE VISIT. PT NO SHOWED TO APPT WITH MD.
6425	---	IVUS DONE BEFORE POST DILITATION BUT NOT POST FINAL BALLOON
6425	---	SAE REPORTED GREATER THAN 24 HOURS
6425	------	RANDOMIZATION ERROR
6425	------	SUBJECT INADVERTENTLY RANDOMIZED TO NON-DIABETIC STATUS IN ERROR IN ICON (CRF CORRECT)
6425	------	PATIENT RETURNED FOR 8 MONTH FOLLOW-UP UNNECCESSARILY DUE TO AN ICON ERROR
6425	------	PT. RECEIVED TAXUS STENT 31D PRIOR
6425	------	POST DILATATION WITH STENT BALLOON
6425	------	STENT DIAMETER < PREDIL BALLOON

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	Patient	Specify
6425	------	ENZYMES NOT CONTINUED UNTIL DECREASE TREND OBSERVED
6425	------	ENZYMES NOT CONTINUED UNTIL DECREASED TREND OBSERVED
6426	-----	NOTIFICATION OF SAE
6427	-----	BLANK
6427	-----	BLANK
6427	------	RANDOMIZATION ERROR
6428	-----	PRE DILATATION BALLOON NOT SMALLER THAN STENT
6428	-----	PRE DILATION BALLOON NOT 0.5 MM SMALLER THAN STENT
6428	-----	RANDOMIZATION ERROR
6428	-----	RANDOMIZATION PROCESS NOT PROPERLY COMPLETED
6428	------	PRE-DILATATION BALLOON NOT <= 0.5 MM THAN STENT
6428	------	NO AUTOMATIC IVUS PULLBACK
6428	------	RANDOMIZATION ERROR
6428	------	RANDOMIZATION PROCESS NOT PROPERLY COMPLETED
6428	------	SAE NOT REPORTED. TO SPONSOR WITHIN TIME FRAME
6428	------	PREDIL BALLOON NOT 0.5 MM SMALLER THAN STENT
6428	------	PRE-DILATION BALLOON NOT <= 0.5 MM THAN STENT
6428	------	PRE-DIL BALLOON NOT <= 0.5 MM SMALLER THAN STENT.
6428	------	PRE DIL BALLOON NOT SMALLER THAN STENT
6428	------	PRE DIL BALLOON NOT 0.5 SMALLER THAN STENT
6428	------	PRE-DILATION BALLOON NOT 0.5 MM SMALLER THAN STENT
6429	------	POST DILATATION WITH STENT BALLOON
6430	------	HIPAA WAS NOT SIGNED
6431	---	PRE PROCEDURE GGT OUTSIDE TIME FRAME
6431	---	PREDIL BALLOON NOT <= 5 MM SMALLER THAN STENT DIAMETER
6431	---	RANDOMIZATION ERROR
6431	-----	SAE NOT REPORTED IN 24 HOURS
6431	------	BASELINE LIPIDS OOW
6431	------	PRE DIL BALLOON NOT <= 0.5 MM SMALLER THAN STENT
6431	------	RANDOMIZATION ERROR.
6431	------	PRE-DIL BALLOON LONGER THAN STENT
6431	------	PRE-DILATION BALLOON NOT <= 0.5 MM THEN STENT DIAMETER.
6431	------	NONE
6431	------	LFT'S
6431	------	RANDOMIZED TO NON-DIABETIC WHEN PT IS DIABETIC

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	Patient	Specify
6433	---	SGOT, SGPT, ALP DONE OUTSIDE OF WINDOW
6433	------	RAMDOMIZATION ERROR
6433	------	SAE NOT REPORTED WITHIN 24 HOURS TO HCRI
6433	------	PRE PROCEDURE LIPID PROFILE DONE 1 DAY TOO EARLY
6433	------	BLANK
6433	------	RANDOMIZATION ERROR
6433	------	RANDOMIZATION ERROR
6433	------	SAE OF NON-Q MI WAS NOT REPORTED WITHIN 24 HRS. TO HCRI
6433	------	FINAL ACT DRAWN BUT RESULTS COULD NOT BE OBTAINED ON MACHINE
6433	------	LIPID PROFILE DONE OUT OF WINDOW. 11 DAYS EARLY
6433	------	30 DAY CONTACT DONE BY PHONE INSTEAD OF CLINICAL VISIT
6433	------	SAE NOT REPORTED WITHIN 1 DAY
6433	------	PRE-PROCEDURE CBC DONE OUT OF WINDOW
6433	------	PRE PROCEDURE DIFF DONE OUT OF WINDOW
6434	-	BLANK
6434	-	SAE NOTIFICATION OUTSIDE 24 HOUR WINDOW
6434	-	SAE NOTIFICATION OUTSIDE 24 HOUR WINDOW
6434	---	PRE-DIL BALLOON IS GREATER THAN STATED LESION LENGTH.
6434	------	SAE NOTIFICATION OUT OF 24 HOUR WINDOW
6434	------	PRE DIL BALLOON LONGER THAN STATED TL
6434	------	STENT PLACED NOT >3 M LONGER THAN STATED TL
6434	------	IVUS NOT DONE UNABLE TO PASS CATHETER
6434	------	SAE NOTIFICATION OUTSIDE OF 24 HOUR WINDOW
6434	------	SAE NOTIFICATION OUTSIDE 24 HOUR WINDOW
6434	------	SAE NOTIFICATION OUTSIDE 24 HOUR WINDOW
6435	------	POST STENT IVUS NOT DONE
6435	------	AUTOMATIC PULLBACK NOT DONE
6435	------	DIFFERENT IVUS MACHINE USED FOR 8 MO ANGIO
6435	------	IVUS NOT DONE AT ALL DURING INDEX PROCEDURE
6435	------	DIFFERENT IVUS MACHINE USED
6435	------	AUTOMATIC PULLBACK NOT DONE
6436	---	LIPID PROFILE DONE OUTSIDE OF WINDOW
6436	---	BASELINE LIPIDS DONE OUTSIDE OF WINDOW
6438	---	PREDILATION BALLOON NOT EQUAL OR LESS THAN 0.5 MM SMALLER THAN STENT.
6438	---	SAE NOT REPORTED TO HCRI/SPONSOR WITHIN 24 HOURS.

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	Patient	Specify
6438	-----	PRE DILATION BALLOON NOT <= 0.5 MM THAN STENT
6438	-----	SAE NOT REPORTED TO SPONSOR WITHIN
6438	-----	IRB NOT NOTIFIED PER POLICY
6438	-----	SAE - HOSPITALIZATION NOT REPORTED IN TIMELY MANNER
6438	-----	SAE NOT REPORTED WITHIN TIMEFRAME
6438	-----	SAE NOT REPORTED TO SPONSOR WITHIN APPROPRIATE
6438	-----	PRE DILATION BALLOON NOT SHORTER THAN STENT
6438	-----	LIPID PANEL OUT OF PROTOCOL TIME FRAME
6438	-----	LFT PANEL OUT OF PROTOCOL TIME FRAME
6438	-----	NOT REPORTED IN TIMELY FASHION
6438	-----	PRE-PROCEDURE LIVER FUNCTION TESTS COLLECTED OUTSIDE OF PROTOCOL TIME FRAME
6438	-----	BLANK
6438	-----	LFTS PRE-OUT OF WINDOW
6438	-----	CHEM-PANEL PRE-OUT OF WINDOW
6438	-----	CBC, DIFF PRE-OUT OF WINDOW
6438	-----	LIPIDS PRE-OUT OF WINDOW
6438	------	PRE-DILATION BALLOON NOT EQUAL OR LESS THAN 0.5 MM SMALLER
6438	------	INCORRECT RANDOMIZATION
6438	------	PREDILATION BALLOON NOT .5 MM SMALELR THAN STENT
6438	------	INCORRECT RANDOMIZATION
6438	------	INCORRECT RANDOMIZATION
6438	------	SAE NOT REPORTED WITHIN TIME FRAME
6438	------	PRE-DILATION BALLOON NOT 0.5 MM SMALLER THAN STENT
6438	------	PRE DIL BALLOON NOT <= 0.5 MM SMALLER THAN STENT.
6438	------	RANDOMIZED IN ERROR
6438	------	SAE NOT REPORTED WITHIN TIME FRAME
6438	------	SAE NOT REPORTED WITHIN PROTOCOL WINDOW
6438	------	RANDOMIZATION ERROR
6438	------	PRE DELATION BALLOON NOT SMALLER THAN STENT
6438	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME
6438	------	SAE NOT REPORTED WITHIN TIME FRAME
6438	------	SAE NOT REPORTED WITHIN TIME FRAME
6438	------	RANDOMIZATION ERROR
6438	------	SAE NOT REPORTED WITHIN TIME FRAME
6438	------	RANDOMIZATION ERROR

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	----------	Specify
6438	------	SAE NOT REPORTED TO SPONSOR WITHIN TIMEFRAME
6438	------	RANDOMIZATION ERROR
6438	------	CBC (DONE OUT OF WINDOW)
6438	------	LIPID PANEL DONE OUT OF WINDOW
6438	------	DIFFERENTIAL (DONE OUT OF WINDOW)
6438	------	CHEMISTRY PRE PRO (DONE OUT WINDOW)
6438	------	LFT DONE OUT OF WINDOW
6438	------	PRE-PROCEDURE LABS DONE OUT OF WINDOW
6438	------	CBC OUT OF WINDOW
6438	------	CHEM PANEL OUT OF WINDOW
6438	------	DIFF OUT OF WINDOW
6438	------	LIPID PANEL DONE OUT OF WINDOW
6438	------	LFT DONE OUT OF WINDOW
6438	------	LIPID PANEL OUT OF WINDOW
6438	------	LFT PANEL OUT OF WINDOW
6438	------	LFT DONE OUT OF WINDOW
6438	------	PRE-PROCEDURE LIPID PANEL COLLECTED OUTSIDE OF PROTOCOL TIME FRAME
6438	------	LFT'S OUT OF WINDOW
6438	------	LIPID PANEL OUT OF WINDOW
6439	---	DATE OF NOTIFICATION OUTSIDE 24 HOUR TIME FRAME
6439	---	DATE OF NOTIFICATION OUTSIDE 24 HOUR TIME FRAME
6439	------	SAE NOT REPORTED TO IRB WITHIN PROTOCOL REQUIRED TIME FRAME
6439	------	SAE NOT REPORTED TO IRB WITHIN PROTOCOL REQUIRED TIME FRAME
6439	------	IVUS NOT DONE AT BASELINE - MULTI-STENT
6439	------	DATE OF SAE NOTIFICATION OUTSIDE 24 HOURS TIME FRAME
6441	---	REPORT OF SAE >24 HOURS AFTER KNOWLEDGE OF EVENT.
6441	------	HCRI WAS NOT NOTIFIED WITHIN 24 HRS OF KNOWLEDGE OF EVENT
6441	------	SAE REPORTED AFTER 24 HOUR TIME PERIOD.
6441	------	SAE REPORTED AFTER 24 HOUR TIME PERIOD
6441	------	SAE REPORTED GREATER THAN 24 HOURS AFTER KNOWLEDGE.
6444	---	USED STENT BALLOON FOR POST DILATION
6444	---	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME
6444	---	PRE-DILATION BALLOON NOT <= 0.5 MM THAN STENT
6444	---	NOTIFIED SAE OUTSIDE 24 HOUR TIME FRAME
6444	-----	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME DUE TO TIME RESTRAINTS, UNABLE TO REPORT.

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	Patient	Specify
6444	-----	SAE NOT REPORTED WITHIN 24 HRS OF KNOWLEDGE OF EVENT
6444	-----	REPORTING SAE OUTSIDE 24 HR. TIME FRAME
6444	------	PRE-DILATION BALLOON SAME SIZE AS STUDY STENT 2.5 MM.
6444	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME. SITE
6444	------	SAE NOT REPORTED WITHIN SPECIFIED TIME FRAME
6444	------	EVENT REPORTED OUTSIDE 24 HR TIME FRAME
6444	------	PRE-DILATION BALLOON NOT <= 0.5 MM
6444	------	PRE-DILATION BALLON NOT <= 0.5 MM THAN STENT
6444	------	USED STENT BALLOON AS POST DILATION BALLOON
6444	------	NOT REPORTED WITHIN TIME FRAME
6444	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME
6444	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME
6444	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME
6444	------	SAE NOT REPORTED TO SPONSOR WITHIN TIME FRAME
6445	---	PRE-DIL BALLOON WAS SAME SIZE AS RVD
6445	-----	PRE-DILATION BALLOON WAS 0.25 MM SMALLER THAN THE REFERENCE VESSEL DIAMETER
6445	-----	PREDIL BALLOON NOT <.5 MM SMALLER THAN STENT.
6445	------	SAE REPORTED OUTSIDE 24 HOUR TIME FRAME REQUIRED FOR REPORTING EVENT
6445	------	INADVERTENTLY RANDOMIZED AS NON DIABETIC
6445	------	SAE. NOT REPORTED WITHIN 5 DAYS PER SOP'S
6445	------	PRE-DIL BALLOON WAS SAME SIZE AS RVD
6445	------	SAE REPORTED OUTSIDE 24 HOUR TIME FRAME REQUIRED FOR REPORTING.
6445	------	NON-DIABETIC INADVERTENTLY CHOSEN AT RANDOMIZATION
6446	------	SERUM LDL NOT PERFORMED
6446	------	SAE REPORTING > 24 HOUR OF EVENT KNOWLEDGE
6448	-----	CBC NOT ORDERED - VALUES TAKEN FROM MOST RECENT LAB DRAW
6448	-----	CHEMISTRY PANEL NOT ORDERED - VALUES TAKEN FROM MOST RECENT LAB DRAW
6448	-----	WBC DONE OUT OF PROTOCOL TIME FRAME
6448	-----	PRE PROCEDURE LAB (CHEM) DONE OUT OF WINDOW
6448	------	SAE NOT REPORTED TO HCRI WITHIN 24 HRS
6448	------	LFT'S NOT DONE WITHIN TIME FRAME.
6448	------	PRE PROCEDURE LIPID PANEL OUTSIDE OF PROTOCOL FRAME
6448	------	SAE NOT REPORTED TO HCRI WITHIN 24 HRS
6448	------	PRE PROCEDURE LABS OUT OF WINDOW.
6449	-----	SAE REPORTED TO SPONSOR OUT OF WINDOW

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	----------	Specify
6449	-----	SAE REPORTED TO SPONSOR ONE DAY LATE
6449	-----	DATE OF NOTIFICATION ON MDT 111 IS OUT OF WINDOW
6449	-----	SAE REPORTED TO SPONSOR ONE DAY LATE
6449	------	DRAWN AFTER PROCEDURE STARTED - LIPID PANEL
6449	------	LFTS DRAWN AFTER PROCEDURE STARTED
6449	------	BLANK
6449	------	RANDOMIZATION PROCESS NOT PROPERLY COMPLETED.DIABETIC STATUS INCORRECTLY MARKED.
6449	------	LFT DRAWN AFTER PROCEDURE STARTED
6449	------	LIPID PANEL DRAWN AFTER PROCEDURE STARTED
6449	------	RANDOMIZATION NOT PROPERLY COMPLETED. DIABETIC STATUS IMPROPERLY MARKED.
6452	-----	PRE PROCEDURE CKMB NOT DONE
6452	-----	POST DILATATION WITH STENT CATHETER BALLOON
6452	-----	SAE NOTIFICATION OUT OF PROTOCOL WINDOW
6452	------	PRE PROCEDURE CKMB NOT DONE
6452	------	IVUS IMAGING NOT DONE
6452	------	RANDOMIZATION ERROR
6452	------	RANDOMIZATION ERROR
6452	------	CBC WITH DIFFERENTIAL DONE OUTSIDE OF PROTOCOL WINDOW
6452	------	RANDOMIZATION ERROR
6453	------	IVUS NOT PERFORMED DURING INDEX PROCEDURE
6455	------	SAE NOT REPORTED WITHIN 24 HRS
6455	------	SAE NOT REPORTED WITHIN 24 HRS
6455	------	POST DILATED 2ND STENT WITH STENT BALLOON
6455	------	PLEURAL EFFUSION
6456	---	RANDOMIZATION ERROR
6456	------	SAE NOT REPORTED WTIHIN 24 WINDOW
6456	------	RANDOMIZATION ERROR
6456	------	CHEMISTRY ONE DAY EARLY
6456	------	SAE NOT REPORTED WITHIN TIME FRAME TO SPONSOR
6456	------	LATE SPONSOR NOTIFICATION OF SAE
6456	------	LATE SPONSOR NOTIFICATION OF SAE
6459	---	POST. DIL DONE WITH STUDY STENT
6459	------	POST-DIL DONE WITH STENT BALLOON
6459	------	POST-DILATION DONE WITH STENT BALLOON
6459	------	PATIENT HAD REVASC DONE DUE TO CPAIN.

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	Patient	Specify
6459	------	TIME FRAME 24 HRS. FOR REPORTING SAE
6459	------	SAE - NOTED @ 6 MOS. NOT REPORTED TO HCRI WITHIN 24 HOURS KNOWLEDGE OF EVENT.
6459	------	SAE NOTED @ 6 MO. TIME POINT, WAS
6461	------	PRE PROCEDURAL CBC DRAWN AFTER RAMDOMIZATION
6461	------	PRE PROCEDURAL CK, CK-MB DRAWN AFTER RANDOMIZATION
6461	------	PRE PROCEDURAL WBC DRAWN AFTER RANDOMIZATION
6461	------	PRE PROCEDURAL LFT DRAWN AFTER RANDOMIZATION
6461	------	PRE PROCEDURAL CHEM DRAWN AFTER RANDOMIZATION
6461	------	DATE OF NOTIFICATION 02/27/2006 WAS OUTSIDE 24-HOUR TIME FRAME
6462	------	SAE REPORTED > 24 HOURS
6462	------	SAE REPORTED > 24 HOURS
6462	------	SAE REPORTED > 24 HRS TO HCRI
6463	-----	SAE REPORTED > 24 HR TO SPONSOR
6463	-----	SAE REPORTED > 24 HRS TO SPONSOR
6463	-----	SAE REPORTED > 24 HRS TO SPONSOR
6463	------	SAE REPORTED > 24 HRS TO SPONSOR
6464	------	REPORTED OUTSIDE PROTOCOL TIME FRAME
6464	------	REPORTED OUTSIDE PROTOCOL TIME FRAME
6464	------	REPORTED OUTSIDE PROTOCOL TIME FRAME
6574	-	CRF COMPLETING CRF'S HAD NOT RECEIVED "GO" LETTER
6574	-	PRE-DIL BALLOON NOT <.5 MM SMALLER THAN STENT
6574	-----	INDEX PROCEDURE IVUS NOT PERFORMED.
6574	------	HCRI NOTIFIED OF SAE > 24 HRS.
6574	------	HCRI NOTIFIED OF SAE > 24 HRS
6576	------	SCHEDULED PCI NOT REPORTED AS SAE IN 24 HOURS
6576	------	SAE NOT REPORTED TO HCRI IN 24 HOURS AFTER NOTIFICATION
6576	------	SAE NOT REPORTED IN PROTOCOL TIMEFRAME
6576	------	SCHEDULED PCI NOT REPORTED AS SAE IN 24 HOURS
6576	------	SAE NOT REPORTED IN PROTOCOL TIMEFRAME
6578	-----	PRE DILATATION BALLOON DOES NOT CONFORM TO THE PROTOCOL REQUIREMENT.
6578	------	PRE DILATION DIAMETER WAS NOT DONE WITH BALLOON LESS THAN 0.5 REFERENCE
6578	------	BLANK
6578	------	IT WAS NOT REPORTED TO HCRI WITHIN 24 HOURS.
6578	------	SAE NOT REPORTED WITHIN 24 HOURS.
6578	------	PATIENT DID NOT MEET STAGING CRITERIA

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	Patient	Specify
6578	------	SAE NOT REPORTED WITHIN 24 HOURS.
6578	------	RANDOMIZATION ERROR.
6578	------	BALLOON USED WAS NOT .5 MM SMALLER THAN LESION
6578	------	BALLOON LENGTH NOT SHORTER THAN LESION
6578	------	BALLOON USED BY MD IS LONGER THAN LESION
6578	------	PRE DIL. BALLOON DID NOT NEET CRITERIA
6578	------	PRE DIL BALLOON NOT SHORTER THAN LESION LENGTH
6578	------	PRE DIL BALLOON NOT SHORTER.
6578	------	PRE DIL BALLOON NOT SHORTER THAN LESION
6620	------	SAE NOTIFICATION FORM OUTSIDE 24 HOUR TIME FRAME
6620	------	SAE NOTIFICATION FORM OUTSIDE 24 HOUR TIME FRAME
6620	------	RANDOMIZATION ERROR
6620	------	DELAYED SAE REPORTING
6620	------	SAE NOTIFICATION FORM OUTSIDE 24 HOUR TIME FRAME
6621	---	CONSENT CONDUCTED BY CRC PRIOR TO GO LETTER.
6621	---	COORDINATOR CONSENTING PT. DID NOT HAVE GO LETTER.
6621	---	CRC CONSENTING PT. DID NOT HAVE GO LETTER
6621	---	CRC CONSULTING PT. PRIOR TO GO LETTER
6624	-----	SAE SUBMITTED OUTSIDE 24 HR. REQUIRED TIME FRAME
6624	------	PATIENT TAKING 150 MG CLOPIDOGREL DAILY
6624	------	PATIENT TAKING 150 MG CLOPIDOGREL DAILY
6624	------	PRE-PROCEDURE CBC OUTSIDE 7 DAY WINDOW BY 1 DAY
6624	------	PRE-PROCEDURE DIFFERENTIAL OUTSIDE 7 DAY WINDOW BY 1 DAY
6625	------	PRE-DILATATION BALLOON LONGER THEN LESION LENGTH
6628	-----	SAE NOT REPORTED WITHIN 24 HOURS.
6628	-----	SAE NOT REPORTED TO HCRI WITHIN ONE DAY
6628	-----	SAE NOT REPORTED TO HCRI WITHIN ONE DAY
6628	-----	SAE NOT REPORTED WITHIN ONE DAY
6628	-----	SAE NOT REPORTED WITHIN 24 HOURS
6628	------	20-24 HOUR CARDIAC ENZYMES OUT OF WINDOW
6628	------	LIVER FUNCTION TEST OUT OF WINDOW
6628	------	SAE NOT REPORTED WITHIN 24 HRS.
6628	------	SAE NOT REPORTED WITHIN 24 HOURS
6628	------	UNKNOWN
6628	------	SAE NOT REPORTED WITHIN 24 HOURS.

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Table 18c. (Continued) Listing of Protocol Deviation - Other

Site	Patient	Specify
6628	------	SAE NOT REPORTED WITHIN 24 HOURS.
6638	------	LABS DRAWN 8 DAYS PRIOR TO PCI (OUTSIDE WINDOW OF 7 DAYS) CHEMISTRY PANEL
6638	------	LABS DRAWN OUTSIDE OF PROTOCOL TIME FRAME
6638	------	LABS DONE OUTSIDE OF TIME FRAME (8 DAYS NOT 7)
6643	------	LATE SAE NOTIFICATION TO HCRI
6657	------	IVUS NOT DONE RELATIVE TO COMPLICATION
6657	------	FOLLOW UP BY NON-STUDY PHYSICIAN
6657	------	SAE REPORTED OUTSIDE 24 HOUR WINDOW
6657	------	INDEX IVUS NOT DONE
6664	------	USED 3.0 BALLOON USED FOR PRE DIL.
6664	------	STENT DEPLOYED AT 18 ATM.
6664	------	COORDINATOR WHO COMPLETED 9 MO VISIT NOT TRAINED ON PROTOCOL

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Table 19a. Adverse Events (to 270 Days) - ITT Patients

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
Any Adverse Event	78.4% (606/773)	79.5% (616/775)	78.9% (1222/1548)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2.3% (18/773)	3.1% (24/775)	2.7% (42/1548)
ANAEMIA	1.8% (14/773)	2.6% (20/775)	2.2% (34/1548)
ANAEMIA VITAMIN B12 DEFICIENCY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
COAGULOPATHY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HILAR LYMPHADENOPATHY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
LEUKOCYTOSIS	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
LYMPHADENOPATHY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
THROMBOCYTOPENIA	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
CARDIAC DISORDERS	40.1% (310/773)	40.0% (310/775)	40.1% (620/1548)
ACUTE CORONARY SYNDROME	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
ACUTE MYOCARDIAL INFARCTION	0.5% (4/773)	0.0% (0/775)	0.3% (4/1548)
ANGINA PECTORIS	29.1% (225/773)	27.6% (214/775)	28.4% (439/1548)
ANGINA UNSTABLE	0.6% (5/773)	0.9% (7/775)	0.8% (12/1548)
ARRHYTHMIA	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
ARTERIOSPASM CORONARY	0.6% (5/773)	0.3% (2/775)	0.5% (7/1548)
ATRIAL FIBRILLATION	1.9% (15/773)	1.8% (14/775)	1.9% (29/1548)
ATRIAL FLUTTER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ATRIAL TACHYCARDIA	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
ATRIAL THROMBOSIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ATRIOVENTRICULAR BLOCK	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ATRIOVENTRICULAR BLOCK COMPLETE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ATRIOVENTRICULAR BLOCK SECOND DEGREE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BRADYARRHYTHMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BRADYCARDIA	2.1% (16/773)	1.5% (12/775)	1.8% (28/1548)
CARDIAC DISORDER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CARDIAC FAILURE CONGESTIVE	1.6% (12/773)	1.7% (13/775)	1.6% (25/1548)
CARDIAC FLUTTER	0.3% (2/773)	0.8% (6/775)	0.5% (8/1548)
CARDIO-RESPIRATORY ARREST	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CARDIOGENIC SHOCK	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CHEST DISCOMFORT	0.1% (1/773)	0.5% (4/775)	0.3% (5/1548)
CHEST PAIN	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CORONARY ARTERY ATHEROSCLEROSIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CORONARY ARTERY DISEASE	1.0% (8/773)	1.0% (8/775)	1.0% (16/1548)
CORONARY ARTERY DISSECTION	1.8% (14/773)	3.9% (30/775)	2.8% (44/1548)
CORONARY ARTERY EMBOLISM	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
CORONARY ARTERY OCCLUSION	0.0% (0/773)	0.6% (5/775)	0.3% (5/1548)
CORONARY ARTERY STENOSIS	0.6% (5/773)	1.2% (9/775)	0.9% (14/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
CORONARY ARTERY THROMBOSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CYANOSIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
EXTRASYSTOLES	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HEART INJURY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYPERTENSIVE CARDIOMYOPATHY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HYPERTROPHIC CARDIOMYOPATHY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ISCHAEMIC CARDIOMYOPATHY	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
MITRAL VALVE INCOMPETENCE	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
MYOCARDIAL INFARCTION	2.3% (18/773)	3.2% (25/775)	2.8% (43/1548)
MYOCARDIAL ISCHAEMIA	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
MYOCARDIAL REPERFUSION INJURY	0.1% (1/773)	0.5% (4/775)	0.3% (5/1548)
NODAL RHYTHM	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PALPITATIONS	2.3% (18/773)	1.8% (14/775)	2.1% (32/1548)
PERICARDIAL EFFUSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
REPERFUSION ARRHYTHMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SICK SINUS SYNDROME	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
SINUS BRADYCARDIA	0.1% (1/773)	0.4% (3/775)	0.3% (4/1548)
SINUS TACHYCARDIA	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
SUPRAVENTRICULAR EXTRASYSTOLES	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SUPRAVENTRICULAR TACHYCARDIA	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)
TACHYCARDIA	0.8% (6/773)	0.3% (2/775)	0.5% (8/1548)
VENTRICULAR EXTRASYSTOLES	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
VENTRICULAR FIBRILLATION	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
VENTRICULAR TACHYCARDIA	1.3% (10/773)	0.5% (4/775)	0.9% (14/1548)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ARTERIOVENOUS MALFORMATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GASTROINTESTINAL ARTERIOVENOUS MALFORMATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
EAR AND LABYRINTH DISORDERS	1.0% (8/773)	1.0% (8/775)	1.0% (16/1548)
DEAFNESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
EAR CONGESTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
EAR HAEMORRHAGE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
EAR PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
TINNITUS	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
VERTIGO	0.6% (5/773)	0.5% (4/775)	0.6% (9/1548)
ENDOCRINE DISORDERS	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
ADRENAL MASS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GOITRE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HYPOGONADISM	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
EYE DISORDERS	1.2% (9/773)	1.3% (10/775)	1.2% (19/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
AMAUROSIS FUGAX	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BLINDNESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CATARACT	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CORNEAL OEDEMA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
EYE HAEMORRHAGE	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
IRITIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
OCULAR HYPERAEMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
RETINAL DETACHMENT	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
RETINAL INFARCTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VISION BLURRED	0.4% (3/773)	0.5% (4/775)	0.5% (7/1548)
VISUAL ACUITY REDUCED	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
VISUAL DISTURBANCE	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
GASTROINTESTINAL DISORDERS	17.3% (134/773)	15.0% (116/775)	16.1% (250/1548)
ABDOMINAL DISCOMFORT	0.5% (4/773)	0.1% (1/775)	0.3% (5/1548)
ABDOMINAL DISTENSION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ABDOMINAL HERNIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ABDOMINAL PAIN	1.7% (13/773)	1.3% (10/775)	1.5% (23/1548)
ABDOMINAL PAIN LOWER	0.4% (3/773)	0.4% (3/775)	0.4% (6/1548)
ABDOMINAL PAIN UPPER	1.3% (10/773)	1.5% (12/775)	1.4% (22/1548)
ABDOMINAL TENDERNESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BARRETT'S OESOPHAGUS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CAECITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
COLONIC POLYP	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CONSTIPATION	1.0% (8/773)	0.9% (7/775)	1.0% (15/1548)
DIARRHOEA	1.8% (14/773)	0.8% (6/775)	1.3% (20/1548)
DIVERTICULUM	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
DIVERTICULUM INTESTINAL	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DRY MOUTH	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
DUODENAL ULCER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DYSPEPSIA	2.2% (17/773)	2.1% (16/775)	2.1% (33/1548)
DYSPHAGIA	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
EPIGASTRIC DISCOMFORT	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
ERUCTATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
FAECALOMA	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
FAECES DISCOLOURED	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)
FLATULENCE	0.0% (0/773)	0.6% (5/775)	0.3% (5/1548)
FOOD POISONING	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GASTRIC ULCER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GASTRITIS	0.1% (1/773)	0.6% (5/775)	0.4% (6/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
GASTRITIS EROSIVE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GASTROINTESTINAL DISORDER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GASTROINTESTINAL HAEMORRHAGE	0.5% (4/773)	0.9% (7/775)	0.7% (11/1548)
GASTROINTESTINAL MUCOSAL NECROSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GASTROOESOPHAGEAL REFLUX DISEASE	0.4% (3/773)	0.8% (6/775)	0.6% (9/1548)
GINGIVAL BLEEDING	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
GLOSSODYNIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HAEMATEMESIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
HAEMATOCHEZIA	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
HAEMORRHOIDAL HAEMORRHAGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HAEMORRHOIDS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HIATUS HERNIA	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
ILEUS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
INGUINAL HERNIA	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
INTESTINAL OBSTRUCTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INTESTINAL PERFORATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
IRRITABLE BOWEL SYNDROME	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
LIP DISCOLOURATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
MELAENA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MOUTH HAEMORRHAGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
MOUTH ULCERATION	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
NAUSEA	7.0% (54/773)	5.2% (40/775)	6.1% (94/1548)
OESOPHAGEAL PAIN	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
OESOPHAGEAL SPASM	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
OESOPHAGITIS	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
PANCREATITIS	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
PEPTIC ULCER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RECTAL HAEMORRHAGE	1.0% (8/773)	0.5% (4/775)	0.8% (12/1548)
RECTAL POLYP	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
REFLUX GASTRITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RETROPERITONEAL HAEMORRHAGE	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
SMALL INTESTINAL OBSTRUCTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
STOMACH DISCOMFORT	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)
TOOTHACHE	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
UPPER GASTROINTESTINAL HAEMORRHAGE	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
VOMITING	2.5% (19/773)	1.7% (13/775)	2.1% (32/1548)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	33.5% (259/773)	31.4% (243/775)	32.4% (502/1548)
ADVERSE DRUG REACTION	0.1% (1/773)	0.4% (3/775)	0.3% (4/1548)
ASTHENIA	1.4% (11/773)	2.1% (16/775)	1.7% (27/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
AXILLARY PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CATHETER SITE HAEMORRHAGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CHEST DISCOMFORT	5.2% (40/773)	4.8% (37/775)	5.0% (77/1548)
CHEST PAIN	8.7% (67/773)	7.2% (56/775)	7.9% (123/1548)
CHILLS	0.0% (0/773)	0.5% (4/775)	0.3% (4/1548)
CREPITATIONS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CYST	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
DEATH	0.3% (2/773)	0.8% (6/775)	0.5% (8/1548)
DISCOMFORT	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
FATIGUE	6.3% (49/773)	4.6% (36/775)	5.5% (85/1548)
FEELING ABNORMAL	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
FEELING JITTERY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GAIT DISTURBANCE	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
GRAVITATIONAL OEDEMA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HERNIA	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
IMPAIRED HEALING	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INFLUENZA LIKE ILLNESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INFUSION SITE PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INFUSION SITE REACTION	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
INJECTION SITE ANAESTHESIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INJECTION SITE DISCOMFORT	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
INJECTION SITE ERYTHEMA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INJECTION SITE EXTRAVASATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INJECTION SITE HAEMORRHAGE	6.3% (49/773)	6.2% (48/775)	6.3% (97/1548)
INJECTION SITE IRRITATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INJECTION SITE NECROSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INJECTION SITE PAIN	3.5% (27/773)	2.5% (19/775)	3.0% (46/1548)
INJECTION SITE SWELLING	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
MALAISE	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
MIGRATION OF IMPLANT	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NON-CARDIAC CHEST PAIN	4.1% (32/773)	3.0% (23/775)	3.6% (55/1548)
OEDEMA	1.7% (13/773)	1.4% (11/775)	1.6% (24/1548)
OEDEMA PERIPHERAL	2.8% (22/773)	2.7% (21/775)	2.8% (43/1548)
PAIN	1.4% (11/773)	1.4% (11/775)	1.4% (22/1548)
PITTING OEDEMA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
POLYP	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PYREXIA	1.6% (12/773)	1.8% (14/775)	1.7% (26/1548)
SUDDEN CARDIAC DEATH	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SWELLING	0.5% (4/773)	0.4% (3/775)	0.5% (7/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
TERMINAL STATE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
WOUND NECROSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HEPATOBILIARY DISORDERS	1.6% (12/773)	0.4% (3/775)	1.0% (15/1548)
BILIARY CIRRHOSIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CHOLECYSTITIS	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
CHOLECYSTITIS ACUTE	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
CHOLECYSTITIS CHRONIC	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CHOLELITHIASIS	0.6% (5/773)	0.1% (1/775)	0.4% (6/1548)
HEPATOMEGALY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
IMMUNE SYSTEM DISORDERS	0.6% (5/773)	0.5% (4/775)	0.6% (9/1548)
DRUG HYPERSENSITIVITY	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
HYPERSENSITIVITY	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
SARCOIDOSIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INFECTIONS AND INFESTATIONS	10.9% (84/773)	10.3% (80/775)	10.6% (164/1548)
ABDOMINAL ABSCESS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ABSCESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ABSCESS LIMB	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ACUTE SINUSITIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
APPENDICITIS	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)
BACTERAEMIA	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
BRONCHITIS	1.3% (10/773)	0.6% (5/775)	1.0% (15/1548)
BRONCHITIS ACUTE	0.5% (4/773)	0.1% (1/775)	0.3% (5/1548)
CANDIDIASIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CELLULITIS	0.5% (4/773)	0.9% (7/775)	0.7% (11/1548)
CLOSTRIDIAL INFECTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CLOSTRIDIUM COLITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CYSTITIS	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
DIVERTICULITIS	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
EAR INFECTION	0.1% (1/773)	0.4% (3/775)	0.3% (4/1548)
EPSTEIN-BARR VIRUS INFECTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
EYE INFECTION	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
FOLLICULITIS	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
FUNGAL SKIN INFECTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GANGRENE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GASTROENTERITIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GASTROENTERITIS VIRAL	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GASTROINTESTINAL INFECTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HERPES ZOSTER	0.5% (4/773)	0.6% (5/775)	0.6% (9/1548)
INFECTION	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
INFLUENZA	0.6% (5/773)	0.5% (4/775)	0.6% (9/1548)
INJECTION SITE ABSCESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INJECTION SITE CELLULITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INJECTION SITE INFECTION	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
LARYNGITIS	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
LOBAR PNEUMONIA	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
LOCALISED INFECTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NASOPHARYNGITIS	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
ORAL CANDIDIASIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
OTITIS EXTERNA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
OTITIS MEDIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PAROTITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PNEUMONIA	1.2% (9/773)	1.4% (11/775)	1.3% (20/1548)
PNEUMONIA KLEBSIELLA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PYELONEPHRITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RESPIRATORY TRACT INFECTION	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
SEPSIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
SINUSITIS	0.6% (5/773)	0.8% (6/775)	0.7% (11/1548)
STAPHYLOCOCCAL INFECTION	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
STREPTOCOCCAL INFECTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SUBCUTANEOUS ABSCESS	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
TOOTH ABSCESS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
TRACHEITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
UPPER RESPIRATORY TRACT INFECTION	0.6% (5/773)	0.6% (5/775)	0.6% (10/1548)
URINARY TRACT INFECTION	2.6% (20/773)	1.3% (10/775)	1.9% (30/1548)
UROSEPSIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
VAGINAL CANDIDIASIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
VARICELLA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VIRAL INFECTION	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
WOUND INFECTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8.0% (62/773)	7.5% (58/775)	7.8% (120/1548)
ANAEMIA POSTOPERATIVE	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
ANIMAL BITE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ANKLE FRACTURE	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)
BACK INJURY	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
CARDIAC PACEMAKER MALFUNCTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CONTUSION	2.8% (22/773)	3.2% (25/775)	3.0% (47/1548)
CORONARY ARTERY PERFORATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CORONARY ARTERY RESTENOSIS	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
EXCORIATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
EYE INJURY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
FACIAL BONES FRACTURE	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
FALL	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
FIBULA FRACTURE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
FRACTURE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HEAD INJURY	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
HIP FRACTURE	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
IMPLANTABLE DEFIBRILLATOR MALFUNCTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INCISION SITE COMPLICATION	0.6% (5/773)	0.4% (3/775)	0.5% (8/1548)
INCISION SITE HAEMORRHAGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INCISIONAL HERNIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
JAW FRACTURE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
JOINT DISLOCATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
JOINT SPRAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
LACERATION	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
LIGAMENT SPRAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
LIMB INJURY	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
MEDICAL DEVICE COMPLICATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MENISCUS LESION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MUSCLE INJURY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
MUSCLE STRAIN	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
NECK INJURY	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
NERVE INJURY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NERVE ROOT INJURY LUMBAR	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
POISONING	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
POST PROCEDURAL HAEMORRHAGE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
POST PROCEDURAL PAIN	0.1% (1/773)	0.4% (3/775)	0.3% (4/1548)
PROCEDURAL HYPERTENSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PROCEDURAL HYPOTENSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RIB FRACTURE	0.0% (0/773)	0.5% (4/775)	0.3% (4/1548)
SKIN LACERATION	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
SPLINTER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
STENT OCCLUSION	0.6% (5/773)	0.3% (2/775)	0.5% (7/1548)
SUBDURAL HAEMATOMA	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
SUNBURN	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SURGICAL SKIN TEAR	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
TENDON RUPTURE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
THROMBOSIS IN DEVICE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
TOOTH INJURY	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
TRANSPLANT FAILURE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
UPPER LIMB FRACTURE	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
WOUND	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
WRIST FRACTURE	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
INVESTIGATIONS	7.5% (58/773)	8.0% (62/775)	7.8% (120/1548)
ACTIVATED PARTIAL THROMBOPLASTIN TIME ABNORMAL	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ALANINE AMINOTRANSFERASE INCREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ANGIOGRAM	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
ARTERIOGRAM CORONARY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BIOPSY CHEST WALL	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BIOPSY LUNG	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
BLOOD CALCIUM DECREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BLOOD CHLORIDE DECREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BLOOD CHOLESTEROL INCREASED	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
BLOOD CREATINE INCREASED	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
BLOOD CREATINE PHOSPHOKINASE INCREASED	0.0% (0/773)	0.6% (5/775)	0.3% (5/1548)
BLOOD CREATINE PHOSPHOKINASE MB INCREASED	0.8% (6/773)	1.0% (8/775)	0.9% (14/1548)
BLOOD CREATININE INCREASED	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
BLOOD GLUCOSE DECREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BLOOD GLUCOSE INCREASED	0.3% (2/773)	0.6% (5/775)	0.5% (7/1548)
BLOOD MAGNESIUM DECREASED	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
BLOOD POTASSIUM DECREASED	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
BLOOD PRESSURE DECREASED	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
BLOOD PRESSURE INCREASED	0.6% (5/773)	0.1% (1/775)	0.4% (6/1548)
BLOOD SODIUM DECREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BLOOD THYROID STIMULATING HORMONE DECREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BLOOD TRIGLYCERIDES INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BLOOD UREA INCREASED	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
BLOOD URINE PRESENT	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
BODY TEMPERATURE INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BRONCHOSCOPY	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
CARBON DIOXIDE DECREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CARDIAC ENZYMES INCREASED	0.6% (5/773)	0.9% (7/775)	0.8% (12/1548)
CARDIAC IMAGING PROCEDURE ABNORMAL	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CARDIAC STRESS TEST ABNORMAL	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
CHEST X-RAY ABNORMAL	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
COLONOSCOPY	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
EJECTION FRACTION DECREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ELECTROCARDIOGRAM ST SEGMENT ELEVATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ELECTROCARDIOGRAM ST-T CHANGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ENDOSCOPY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
FAECAL OCCULT BLOOD POSITIVE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
FEMORAL BRUIT	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
GLOMERULAR FILTRATION RATE INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GLUCOSE URINE PRESENT	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GLYCOSYLATED HAEMOGLOBIN INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HAEMATOCRIT	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HAEMATOCRIT DECREASED	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
HAEMATOCRIT INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HAEMOGLOBIN DECREASED	0.6% (5/773)	0.3% (2/775)	0.5% (7/1548)
HEART RATE INCREASED	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
HEART RATE IRREGULAR	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)
HEART SOUNDS ABNORMAL	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HEPATIC ENZYME INCREASED	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
INTERNATIONAL NORMALISED RATIO INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
LIVER FUNCTION TEST ABNORMAL	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
LOW DENSITY LIPOPROTEIN INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
OXYGEN SATURATION DECREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PCO2 INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PROSTATIC SPECIFIC ANTIGEN INCREASED	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
PROTHROMBIN TIME PROLONGED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PULSE ABNORMAL	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
RED BLOOD CELL COUNT DECREASED	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
RED CELL DISTRIBUTION WIDTH INCREASED	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
SCAN MYOCARDIAL PERFUSION ABNORMAL	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
SWEAT CHLORIDE TEST ELEVATED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
THYROXINE FREE DECREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
TROPONIN I INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
TROPONIN INCREASED	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)
WEIGHT DECREASED	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
WHITE BLOOD CELL COUNT DECREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
WHITE BLOOD CELL COUNT INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
METABOLISM AND NUTRITION DISORDERS	3.9% (30/773)	4.4% (34/775)	4.1% (64/1548)
ANOREXIA	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
DEHYDRATION	0.5% (4/773)	0.4% (3/775)	0.5% (7/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
DIABETES MELLITUS	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
DIABETES MELLITUS INADEQUATE CONTROL	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
DIABETES MELLITUS NON-INSULIN-DEPENDENT	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)
GOUT	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
HYPERCALCAEMIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HYPERCHOLESTEROLAEMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYPERGLYCAEMIA	0.4% (3/773)	0.4% (3/775)	0.4% (6/1548)
HYPERKALAEMIA	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
HYPOCALCAEMIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HYPOGLYCAEMIA	0.4% (3/773)	0.4% (3/775)	0.4% (6/1548)
HYPOKALAEMIA	1.8% (14/773)	1.7% (13/775)	1.7% (27/1548)
HYPONATRAEMIA	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
HYPOVOLAEMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INSULIN RESISTANCE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
IRON DEFICIENCY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
METABOLIC ACIDOSIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
OBESITY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
POLYDIPSIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	20.8% (161/773)	23.0% (178/775)	21.9% (339/1548)
ARTHRALGIA	2.5% (19/773)	4.0% (31/775)	3.2% (50/1548)
ARTHRITIS	0.4% (3/773)	0.4% (3/775)	0.4% (6/1548)
BACK PAIN	7.9% (61/773)	9.4% (73/775)	8.7% (134/1548)
BONE PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BURSITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CHEST WALL PAIN	0.5% (4/773)	0.6% (5/775)	0.6% (9/1548)
EXOSTOSIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
FLANK PAIN	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
GROIN PAIN	1.3% (10/773)	1.0% (8/775)	1.2% (18/1548)
INTERVERTEBRAL DISC DEGENERATION	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
JOINT SWELLING	0.1% (1/773)	0.8% (6/775)	0.5% (7/1548)
LIMB DISCOMFORT	0.1% (1/773)	0.8% (6/775)	0.5% (7/1548)
MUSCLE SPASMS	0.4% (3/773)	1.0% (8/775)	0.7% (11/1548)
MUSCLE TIGHTNESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
MUSCULAR WEAKNESS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MUSCULOSKELETAL CHEST PAIN	0.5% (4/773)	0.3% (2/775)	0.4% (6/1548)
MUSCULOSKELETAL DISCOMFORT	0.6% (5/773)	0.3% (2/775)	0.5% (7/1548)
MUSCULOSKELETAL PAIN	0.8% (6/773)	0.5% (4/775)	0.6% (10/1548)
MUSCULOSKELETAL STIFFNESS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MYALGIA	1.2% (9/773)	1.9% (15/775)	1.6% (24/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
NECK MASS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NECK PAIN	0.9% (7/773)	1.0% (8/775)	1.0% (15/1548)
NODULE ON EXTREMITY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
OSTEOARTHRITIS	0.5% (4/773)	0.6% (5/775)	0.6% (9/1548)
PAIN IN EXTREMITY	3.9% (30/773)	5.3% (41/775)	4.6% (71/1548)
PERIARTHRITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PLANTAR FASCIITIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
RHEUMATOID ARTHRITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ROTATOR CUFF SYNDROME	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
SENSATION OF HEAVINESS	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
SHOULDER PAIN	1.3% (10/773)	1.4% (11/775)	1.4% (21/1548)
SPINAL OSTEOARTHRITIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
TORTICOLLIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1.7% (13/773)	1.7% (13/775)	1.7% (26/1548)
BLADDER CANCER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BREAST CANCER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
COLON CANCER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
COLON CANCER METASTATIC	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GASTRIC CANCER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
LEUKAEMIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
LIPOMA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
LUNG NEOPLASM	0.0% (0/773)	0.5% (4/775)	0.3% (4/1548)
LUNG NEOPLASM MALIGNANT	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
MEDULLARY THYROID CANCER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NEOPLASM MALIGNANT	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NEOPLASM PROSTATE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PAPILLARY THYROID CANCER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PITUITARY TUMOUR	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
RECURRENT CANCER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RENAL CELL CARCINOMA STAGE UNSPECIFIED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SKIN CANCER	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
SQUAMOUS CELL CARCINOMA OF THE CERVIX	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
TERATOMA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
THYROID NEOPLASM	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
TRANSITIONAL CELL CARCINOMA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NERVOUS SYSTEM DISORDERS	17.1% (132/773)	16.0% (124/775)	16.5% (256/1548)
AGEUSIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
AMNESIA	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
ANOSMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
APHASIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BALANCE DISORDER	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
BURNING SENSATION	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
CAROTID ARTERY STENOSIS	0.6% (5/773)	0.1% (1/775)	0.4% (6/1548)
CEREBRAL INFARCTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CEREBROVASCULAR ACCIDENT	0.4% (3/773)	0.4% (3/775)	0.4% (6/1548)
CERVICAL CORD COMPRESSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
COMPLEX PARTIAL SEIZURES	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CONVULSION	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
COORDINATION ABNORMAL	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DEPRESSED LEVEL OF CONSCIOUSNESS	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
DIABETIC NEUROPATHY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
DIZZINESS	6.5% (50/773)	6.3% (49/775)	6.4% (99/1548)
DIZZINESS POSTURAL	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
DYSARTHRIA	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
DYSGEUSIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
FACIAL PALSY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HAEMORRHAGE INTRACRANIAL	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HEADACHE	6.0% (46/773)	3.6% (28/775)	4.8% (74/1548)
HEMIPARESIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HYPOAESTHESIA	1.2% (9/773)	1.9% (15/775)	1.6% (24/1548)
LETHARGY	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
LOSS OF CONSCIOUSNESS	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
MEMORY IMPAIRMENT	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
METABOLIC ENCEPHALOPATHY	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
MIGRAINE	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
NERVE ROOT COMPRESSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NEURALGIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NEUROLOGICAL SYMPTOM	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NEUROPATHY PERIPHERAL	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
PARAESTHESIA	0.9% (7/773)	1.2% (9/775)	1.0% (16/1548)
PARKINSON'S DISEASE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RADICULOPATHY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RESTLESS LEGS SYNDROME	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
SCIATICA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SENSORY DISTURBANCE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SINUS HEADACHE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SOMNOLENCE	0.1% (1/773)	0.4% (3/775)	0.3% (4/1548)
SPINAL CORD COMPRESSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
SUBARACHNOID HAEMORRHAGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SYNCOPE	1.7% (13/773)	1.4% (11/775)	1.6% (24/1548)
SYNCOPE VASOVAGAL	0.9% (7/773)	0.9% (7/775)	0.9% (14/1548)
TRANSIENT ISCHAEMIC ATTACK	0.5% (4/773)	0.1% (1/775)	0.3% (5/1548)
TREMOR	0.3% (2/773)	0.6% (5/775)	0.5% (7/1548)
TRIGEMINAL NEURALGIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PSYCHIATRIC DISORDERS	4.4% (34/773)	3.1% (24/775)	3.7% (58/1548)
AFFECT LABILITY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
AGITATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ANXIETY	2.5% (19/773)	1.0% (8/775)	1.7% (27/1548)
CONFUSIONAL STATE	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
DEPRESSION	0.6% (5/773)	0.6% (5/775)	0.6% (10/1548)
DISORIENTATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INSOMNIA	0.8% (6/773)	0.9% (7/775)	0.8% (13/1548)
MENTAL DISORDER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MENTAL STATUS CHANGES	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
NERVOUSNESS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
PANIC ATTACK	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
RESTLESSNESS	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
SCHIZOAFFECTIVE DISORDER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SLEEP DISORDER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SUICIDAL IDEATION	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
RENAL AND URINARY DISORDERS	5.2% (40/773)	4.6% (36/775)	4.9% (76/1548)
ACUTE PRERENAL FAILURE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CALCULUS URETERIC	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
DYSURIA	0.8% (6/773)	0.3% (2/775)	0.5% (8/1548)
HAEMATURIA	1.0% (8/773)	1.5% (12/775)	1.3% (20/1548)
HAEMORRHAGE URINARY TRACT	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYDRONEPHROSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INCONTINENCE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NEPHROLITHIASIS	0.6% (5/773)	0.3% (2/775)	0.5% (7/1548)
NEPHROPATHY TOXIC	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
POLLAKIURIA	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
POLYURIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RENAL ARTERY STENOSIS	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
RENAL CYST	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RENAL FAILURE	1.0% (8/773)	0.8% (6/775)	0.9% (14/1548)
RENAL FAILURE ACUTE	0.5% (4/773)	0.1% (1/775)	0.3% (5/1548)
RENAL IMPAIRMENT	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
RENAL MASS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
URINARY BLADDER HAEMORRHAGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
URINARY BLADDER POLYP	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
URINARY INCONTINENCE	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
URINARY RETENTION	0.5% (4/773)	0.6% (5/775)	0.6% (9/1548)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0.9% (7/773)	1.4% (11/775)	1.2% (18/1548)
BREAST MASS	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
BREAST PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BREAST TENDERNESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ERECTILE DYSFUNCTION	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
PENIS DISORDER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
POSTMENOPAUSAL HAEMORRHAGE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PROSTATITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SEXUAL DYSFUNCTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
TESTICULAR PAIN	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
TESTICULAR SWELLING	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
VAGINAL HAEMORRHAGE	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	17.2% (133/773)	15.9% (123/775)	16.5% (256/1548)
ACUTE RESPIRATORY DISTRESS SYNDROME	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ALLERGIC SINUSITIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
APNOEA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ASTHMA	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
ATELECTASIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE EXACERBATED	0.1% (1/773)	0.5% (4/775)	0.3% (5/1548)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
COUGH	3.0% (23/773)	3.2% (25/775)	3.1% (48/1548)
DRY THROAT	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DYSPNOEA	10.5% (81/773)	9.5% (74/775)	10.0% (155/1548)
DYSPNOEA EXACERBATED	0.1% (1/773)	0.4% (3/775)	0.3% (4/1548)
DYSPNOEA EXERTIONAL	1.0% (8/773)	0.9% (7/775)	1.0% (15/1548)
EPISTAXIS	1.8% (14/773)	1.2% (9/775)	1.5% (23/1548)
HAEMOPTYSIS	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
HYPOXIA	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
MEDIASTINAL HAEMATOMA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NASAL CONGESTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PARANASAL SINUS HYPERSECRETION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PHARYNGOLARYNGEAL PAIN	0.6% (5/773)	0.3% (2/775)	0.5% (7/1548)
PLEURAL EFFUSION	0.0% (0/773)	0.5% (4/775)	0.3% (4/1548)
PRODUCTIVE COUGH	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
PULMONARY CONGESTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PULMONARY EMBOLISM	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
PULMONARY FIBROSIS	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
PULMONARY HYPERTENSION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PULMONARY MASS	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
PULMONARY OEDEMA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
RESPIRATORY DISTRESS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
RESPIRATORY FAILURE	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
RESPIRATORY TRACT CONGESTION	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
RHINORRHOEA	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
SINUS CONGESTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SLEEP APNOEA SYNDROME	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SNEEZING	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
THROAT TIGHTNESS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
UPPER RESPIRATORY TRACT CONGESTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
WHEEZING	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	5.2% (40/773)	7.0% (54/775)	6.1% (94/1548)
ALOPECIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ANGIONEUROTIC OEDEMA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BLISTER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
DECUBITUS ULCER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DERMATITIS BULLOUS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DIABETIC ULCER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DRUG ERUPTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ECCHYMOSIS	0.6% (5/773)	1.0% (8/775)	0.8% (13/1548)
ERYTHEMA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HAND DERMATITIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYPERHIDROSIS	0.5% (4/773)	1.2% (9/775)	0.8% (13/1548)
INCREASED TENDENCY TO BRUISE	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
INGROWING NAIL	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PHOTOSENSITIVITY REACTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PRURITUS	1.3% (10/773)	0.8% (6/775)	1.0% (16/1548)
RASH	2.6% (20/773)	2.5% (19/775)	2.5% (39/1548)
RASH GENERALISED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SKIN DISORDER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SKIN EXFOLIATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SKIN FISSURES	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SKIN IRRITATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SKIN ULCER	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
SWELLING FACE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
URTICARIA	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
SURGICAL AND MEDICAL PROCEDURES	10.6% (82/773)	13.2% (102/775)	11.9% (184/1548)
AORTIC BYPASS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
AORTIC SURGERY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ARTERIAL BYPASS OPERATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ARTERIAL STENT INSERTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ARTERIOVENOUS FISTULA OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ATHERECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BLOOD PRODUCT TRANSFUSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CARDIAC PACEMAKER INSERTION	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
CARDIAC PACEMAKER REVISION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CAROTID ENDARTERECTOMY	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
CATARACT OPERATION	0.4% (3/773)	0.4% (3/775)	0.4% (6/1548)
COLON POLYPECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CORONARY ANGIOPLASTY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CORONARY ARTERY SURGERY	1.2% (9/773)	1.3% (10/775)	1.2% (19/1548)
CORONARY REVASCULARISATION	6.0% (46/773)	7.6% (59/775)	6.8% (105/1548)
DETACHED RETINA REPAIR	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
EYE OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
FOOT OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GASTRIC BANDING	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HERNIA REPAIR	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HIP ARTHROPLASTY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HIP SURGERY	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
HOSPITALISATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYSTERECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
IMPLANTABLE DEFIBRILLATOR INSERTION	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
INGUINAL HERNIA REPAIR	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INTERVERTEBRAL DISC OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
KNEE ARTHROPLASTY	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
KNEE OPERATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
LAPAROTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
LIMB OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NECK EXPLORATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NEPHROURETERECTOMY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
OESOPHAGEAL LESION EXCISION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PARTIAL MASTECTOMY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PERIPHERAL ARTERY ANGIOPLASTY	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
PERIPHERAL REVASCULARISATION	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
PROSTATIC OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SHOULDER OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SPINAL FUSION SURGERY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SPINAL LAMINECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
STENT PLACEMENT	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
STERNOTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
STRANGULATED HERNIA REPAIR	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SURGERY	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
TENDON REPAIR	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
THORACOTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
THYROIDECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
TOE AMPUTATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
TOOTH EXTRACTION	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
TUMOUR EXCISION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VARICOSE VEINS STRIPPING	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
VASCULAR STENT INSERTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
VITRECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
WHOLE BLOOD TRANSFUSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VASCULAR DISORDERS	10.1% (78/773)	11.2% (87/775)	10.7% (165/1548)
AORTIC ANEURYSM	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
AORTIC STENOSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ARTERIAL HAEMORRHAGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ARTERIAL STENOSIS LIMB	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ARTERIAL THROMBOSIS LIMB	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BLOOD PRESSURE INADEQUATELY CONTROLLED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
DEEP VEIN THROMBOSIS	0.4% (3/773)	0.5% (4/775)	0.5% (7/1548)
EMBOLISM	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
FLUSHING	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
HAEMATOMA	1.6% (12/773)	2.8% (22/775)	2.2% (34/1548)
HAEMODYNAMIC INSTABILITY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HAEMORRHAGE	0.3% (2/773)	0.6% (5/775)	0.5% (7/1548)
HOT FLUSH	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYPERTENSION	1.6% (12/773)	2.2% (17/775)	1.9% (29/1548)
HYPOTENSION	3.6% (28/773)	3.6% (28/775)	3.6% (56/1548)
HYPOVOLAEMIC SHOCK	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ILIAC ARTERY STENOSIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INTERMITTENT CLAUDICATION	0.1% (1/773)	0.5% (4/775)	0.3% (5/1548)
LABILE HYPERTENSION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)

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Table 19a. (Continued) Adverse Events (to 270 Days) - ITT Set

Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
LYMPHANGITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ORTHOSTATIC HYPOTENSION	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
PERIPHERAL ARTERY DISSECTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PERIPHERAL VASCULAR DISORDER	0.5% (4/773)	0.4% (3/775)	0.5% (7/1548)
PHLEBITIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
THROMBOPHLEBITIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
THROMBOSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VASCULAR PSEUDOANEURYSM	1.2% (9/773)	0.9% (7/775)	1.0% (16/1548)

N = the maximum number of eligible patients.
NOS - Not Otherwise Specified.
NOTE: AEs missing event dates were included in this listing.

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Table 19b. Adverse Events (to 270 Days) by Site - ITT Set

Site	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients
5006	1.1% (34/3160)	2.0% (63/3175)	1.5% (97/6335)
5023	0.0% (0/3160)	0.7% (21/3175)	0.3% (21/6335)
5038	0.9% (27/3160)	1.0% (32/3175)	0.9% (59/6335)
5070	0.9% (27/3160)	0.8% (26/3175)	0.8% (53/6335)
5091	4.5% (143/3160)	1.4% (46/3175)	3.0% (189/6335)
5135	0.2% (5/3160)	0.1% (4/3175)	0.1% (9/6335)
5166	1.1% (36/3160)	0.6% (20/3175)	0.9% (56/6335)
5186	4.9% (156/3160)	7.6% (241/3175)	6.3% (397/6335)
5216	0.2% (6/3160)	0.6% (18/3175)	0.4% (24/6335)
5251	0.9% (30/3160)	3.8% (122/3175)	2.4% (152/6335)
5397	2.2% (71/3160)	2.6% (81/3175)	2.4% (152/6335)
5434	1.3% (41/3160)	1.1% (34/3175)	1.2% (75/6335)
5451	0.7% (21/3160)	0.1% (4/3175)	0.4% (25/6335)
5520	0.0% (0/3160)	0.1% (2/3175)	0.0% (2/6335)
5545	0.7% (21/3160)	0.4% (14/3175)	0.6% (35/6335)
5556	0.0% (0/3160)	0.3% (10/3175)	0.2% (10/6335)
6001	0.7% (21/3160)	0.1% (3/3175)	0.4% (24/6335)
6020	0.2% (7/3160)	0.3% (9/3175)	0.3% (16/6335)
6032	0.5% (15/3160)	0.7% (22/3175)	0.6% (37/6335)
6060	0.2% (7/3160)	0.1% (2/3175)	0.1% (9/6335)
6143	0.7% (22/3160)	1.1% (34/3175)	0.9% (56/6335)
6160	0.7% (22/3160)	0.0% (1/3175)	0.4% (23/6335)
6240	0.5% (16/3160)	0.9% (28/3175)	0.7% (44/6335)
6257	0.4% (14/3160)	1.3% (42/3175)	0.9% (56/6335)
6260	1.4% (44/3160)	1.1% (34/3175)	1.2% (78/6335)
6261	0.1% (2/3160)	0.5% (16/3175)	0.3% (18/6335)
6419	0.0% (0/3160)	0.2% (7/3175)	0.1% (7/6335)
6425	2.5% (79/3160)	2.1% (66/3175)	2.3% (145/6335)
6426	0.2% (5/3160)	0.0% (0/3175)	0.1% (5/6335)
6427	1.0% (33/3160)	1.4% (43/3175)	1.2% (76/6335)
6428	0.2% (7/3160)	0.5% (17/3175)	0.4% (24/6335)
6429	0.2% (7/3160)	0.2% (6/3175)	0.2% (13/6335)
6430	0.5% (16/3160)	0.9% (27/3175)	0.7% (43/6335)
6431	2.9% (91/3160)	2.9% (93/3175)	2.9% (184/6335)
6433	13.8% (435/3160)	15.2% (484/3175)	14.5% (919/6335)
6434	1.5% (46/3160)	2.2% (70/3175)	1.8% (116/6335)
6435	0.0% (0/3160)	0.1% (3/3175)	0.0% (3/6335)
6436	0.0% (0/3160)	0.1% (3/3175)	0.0% (3/6335)
6437	0.8% (25/3160)	1.2% (39/3175)	1.0% (64/6335)
6438	11.3% (358/3160)	12.3% (390/3175)	11.8% (748/6335)

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Table 19b. (Continued) Adverse Events (to 270 Days) by Site - ITT Set

Site	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients
6439	1.8% (57/3160)	0.3% (9/3175)	1.0% (66/6335)
6440	0.1% (3/3160)	0.0% (0/3175)	0.0% (3/6335)
6441	0.8% (26/3160)	1.1% (36/3175)	1.0% (62/6335)
6444	1.6% (50/3160)	2.2% (71/3175)	1.9% (121/6335)
6445	0.9% (28/3160)	0.9% (29/3175)	0.9% (57/6335)
6446	4.1% (129/3160)	1.6% (51/3175)	2.8% (180/6335)
6448	0.7% (22/3160)	0.6% (19/3175)	0.6% (41/6335)
6449	3.4% (109/3160)	1.9% (60/3175)	2.7% (169/6335)
6450	0.3% (8/3160)	0.3% (10/3175)	0.3% (18/6335)
6451	0.1% (4/3160)	0.4% (13/3175)	0.3% (17/6335)
6452	1.7% (55/3160)	2.7% (87/3175)	2.2% (142/6335)
6453	1.7% (54/3160)	0.8% (24/3175)	1.2% (78/6335)
6454	0.5% (15/3160)	0.0% (0/3175)	0.2% (15/6335)
6455	0.3% (8/3160)	0.4% (13/3175)	0.3% (21/6335)
6456	3.2% (100/3160)	2.6% (84/3175)	2.9% (184/6335)
6457	0.3% (8/3160)	0.3% (8/3175)	0.3% (16/6335)
6458	0.5% (16/3160)	0.1% (3/3175)	0.3% (19/6335)
6459	1.7% (55/3160)	2.3% (73/3175)	2.0% (128/6335)
6461	3.6% (113/3160)	2.8% (88/3175)	3.2% (201/6335)
6462	0.1% (3/3160)	0.4% (14/3175)	0.3% (17/6335)
6463	1.1% (34/3160)	0.6% (20/3175)	0.9% (54/6335)
6464	0.1% (4/3160)	0.4% (13/3175)	0.3% (17/6335)
6574	1.9% (60/3160)	1.0% (31/3175)	1.4% (91/6335)
6575	0.3% (10/3160)	0.3% (10/3175)	0.3% (20/6335)
6576	0.1% (4/3160)	0.7% (22/3175)	0.4% (26/6335)
6578	0.3% (9/3160)	0.1% (3/3175)	0.2% (12/6335)
6601	0.3% (11/3160)	0.7% (21/3175)	0.5% (32/6335)
6620	0.6% (19/3160)	0.4% (14/3175)	0.5% (33/6335)
6621	0.4% (13/3160)	0.6% (18/3175)	0.5% (31/6335)
6624	0.2% (7/3160)	0.4% (14/3175)	0.3% (21/6335)
6625	1.1% (34/3160)	0.2% (7/3175)	0.6% (41/6335)
6626	0.3% (9/3160)	0.3% (9/3175)	0.3% (18/6335)
6628	2.6% (81/3160)	1.7% (54/3175)	2.1% (135/6335)
6634	0.0% (0/3160)	0.2% (6/3175)	0.1% (6/6335)
6638	2.4% (76/3160)	1.0% (31/3175)	1.7% (107/6335)
6643	0.4% (13/3160)	0.3% (9/3175)	0.3% (22/6335)
6657	0.0% (0/3160)	0.3% (9/3175)	0.1% (9/6335)
6663	0.1% (4/3160)	0.0% (0/3175)	0.1% (4/6335)
6664	0.4% (12/3160)	0.2% (7/3175)	0.3% (19/6335)
6670	0.2% (7/3160)	0.3% (8/3175)	0.2% (15/6335)

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Table 20a. Serious Adverse Events (to 270 Days) - ITT Patients

Serious Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
Any Serious Adverse Event	34.9% (270/773)	34.8% (270/775)	34.9% (540/1548)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
ANAEMIA	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
THROMBOCYTOPENIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CARDIAC DISORDERS	15.5% (120/773)	16.8% (130/775)	16.1% (250/1548)
ACUTE CORONARY SYNDROME	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
ACUTE MYOCARDIAL INFARCTION	0.5% (4/773)	0.0% (0/775)	0.3% (4/1548)
ANGINA PECTORIS	8.5% (66/773)	8.3% (64/775)	8.4% (130/1548)
ANGINA UNSTABLE	0.6% (5/773)	0.6% (5/775)	0.6% (10/1548)
ARRHYTHMIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ATRIAL FIBRILLATION	1.3% (10/773)	1.4% (11/775)	1.4% (21/1548)
ATRIAL FLUTTER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ATRIAL THROMBOSIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ATRIOVENTRICULAR BLOCK	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ATRIOVENTRICULAR BLOCK SECOND DEGREE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BRADYCARDIA	0.4% (3/773)	0.5% (4/775)	0.5% (7/1548)
CARDIAC FAILURE CONGESTIVE	1.2% (9/773)	1.4% (11/775)	1.3% (20/1548)
CARDIO-RESPIRATORY ARREST	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CHEST PAIN	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CORONARY ARTERY DISEASE	1.0% (8/773)	1.0% (8/775)	1.0% (16/1548)
CORONARY ARTERY DISSECTION	0.3% (2/773)	0.9% (7/775)	0.6% (9/1548)
CORONARY ARTERY OCCLUSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CORONARY ARTERY STENOSIS	0.6% (5/773)	1.2% (9/775)	0.9% (14/1548)
HYPERTENSIVE CARDIOMYOPATHY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HYPERTROPHIC CARDIOMYOPATHY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ISCHAEMIC CARDIOMYOPATHY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
MYOCARDIAL INFARCTION	2.3% (18/773)	3.2% (25/775)	2.8% (43/1548)
MYOCARDIAL ISCHAEMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PALPITATIONS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PERICARDIAL EFFUSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SICK SINUS SYNDROME	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
SUPRAVENTRICULAR TACHYCARDIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
TACHYCARDIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VENTRICULAR FIBRILLATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VENTRICULAR TACHYCARDIA	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
EAR AND LABYRINTH DISORDERS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
VERTIGO	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ENDOCRINE DISORDERS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)

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Table 20a. (Continued) Serious Adverse Events (to 270 Days) - ITT Set

Serious Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
GOITRE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
EYE DISORDERS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
CORNEAL OEDEMA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
EYE HAEMORRHAGE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RETINAL DETACHMENT	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GASTROINTESTINAL DISORDERS	3.1% (24/773)	3.0% (23/775)	3.0% (47/1548)
ABDOMINAL HERNIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ABDOMINAL PAIN	0.6% (5/773)	0.4% (3/775)	0.5% (8/1548)
ABDOMINAL PAIN LOWER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ABDOMINAL PAIN UPPER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ABDOMINAL TENDERNESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CAECITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DIARRHOEA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GASTRITIS	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
GASTRITIS EROSIVE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GASTROINTESTINAL HAEMORRHAGE	0.4% (3/773)	0.9% (7/775)	0.6% (10/1548)
GASTROINTESTINAL MUCOSAL NECROSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
GASTROOESOPHAGEAL REFLUX DISEASE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ILEUS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
INGUINAL HERNIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INTESTINAL OBSTRUCTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INTESTINAL PERFORATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NAUSEA	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
OESOPHAGITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PANCREATITIS	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
RECTAL HAEMORRHAGE	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
RETROPERITONEAL HAEMORRHAGE	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
SMALL INTESTINAL OBSTRUCTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
UPPER GASTROINTESTINAL HAEMORRHAGE	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
VOMITING	0.4% (3/773)	0.4% (3/775)	0.4% (6/1548)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4.1% (32/773)	4.3% (33/775)	4.2% (65/1548)
CHEST DISCOMFORT	0.3% (2/773)	0.5% (4/775)	0.4% (6/1548)
CHEST PAIN	1.8% (14/773)	1.4% (11/775)	1.6% (25/1548)
CHILLS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DEATH	0.3% (2/773)	0.8% (6/775)	0.5% (8/1548)
FATIGUE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HERNIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INJECTION SITE HAEMORRHAGE	0.5% (4/773)	0.3% (2/775)	0.4% (6/1548)
INJECTION SITE NECROSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)

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Table 20a. (Continued) Serious Adverse Events (to 270 Days) - ITT Set

Serious Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
NON-CARDIAC CHEST PAIN	0.8% (6/773)	0.6% (5/775)	0.7% (11/1548)
OEDEMA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PYREXIA	0.3% (2/773)	0.4% (3/775)	0.3% (5/1548)
SUDDEN CARDIAC DEATH	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
TERMINAL STATE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
WOUND NECROSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HEPATOBILIARY DISORDERS	0.9% (7/773)	0.3% (2/775)	0.6% (9/1548)
CHOLECYSTITIS	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
CHOLECYSTITIS ACUTE	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
CHOLECYSTITIS CHRONIC	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CHOLELITHIASIS	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
IMMUNE SYSTEM DISORDERS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SARCOIDOSIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INFECTIONS AND INFESTATIONS	3.4% (26/773)	2.8% (22/775)	3.1% (48/1548)
ABDOMINAL ABSCESS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ABSCESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
APPENDICITIS	0.0% (0/773)	0.4% (3/775)	0.2% (3/1548)
BACTERAEMIA	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
BRONCHITIS	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
BRONCHITIS ACUTE	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
CELLULITIS	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
CLOSTRIDIAL INFECTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
DIVERTICULITIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
GASTROENTERITIS VIRAL	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HERPES ZOSTER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INFECTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INJECTION SITE INFECTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
LOBAR PNEUMONIA	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
PNEUMONIA	0.5% (4/773)	1.0% (8/775)	0.8% (12/1548)
PNEUMONIA KLEBSIELLA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SEPSIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
STAPHYLOCOCCAL INFECTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SUBCUTANEOUS ABSCESS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
URINARY TRACT INFECTION	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
UROSEPSIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
VARICELLA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
WOUND INFECTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2.1% (16/773)	1.5% (12/775)	1.8% (28/1548)
ANKLE FRACTURE	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)

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Table 20a. (Continued) Serious Adverse Events (to 270 Days) - ITT Set

Serious Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
BACK INJURY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CORONARY ARTERY RESTENOSIS	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
FALL	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HIP FRACTURE	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
IMPLANTABLE DEFIBRILLATOR MALFUNCTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
JOINT DISLOCATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
LIMB INJURY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NERVE ROOT INJURY LUMBAR	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SKIN LACERATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
STENT OCCLUSION	0.5% (4/773)	0.3% (2/775)	0.4% (6/1548)
SUBDURAL HAEMATOMA	0.1% (1/773)	0.3% (2/775)	0.2% (3/1548)
THROMBOSIS IN DEVICE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
TRANSPLANT FAILURE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
WRIST FRACTURE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INVESTIGATIONS	1.3% (10/773)	1.4% (11/775)	1.4% (21/1548)
ANGIOGRAM	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ARTERIOGRAM CORONARY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BIOPSY LUNG	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
BLOOD CREATINE INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BLOOD CREATINE PHOSPHOKINASE MB INCREASED	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
BLOOD CREATININE INCREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BLOOD GLUCOSE DECREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BLOOD PRESSURE DECREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
BODY TEMPERATURE INCREASED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
BRONCHOSCOPY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CARDIAC ENZYMES INCREASED	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
COLONOSCOPY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
EJECTION FRACTION DECREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HEART RATE INCREASED	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HEART RATE IRREGULAR	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SCAN MYOCARDIAL PERFUSION ABNORMAL	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
TROPONIN INCREASED	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
METABOLISM AND NUTRITION DISORDERS	0.6% (5/773)	0.3% (2/775)	0.5% (7/1548)
DEHYDRATION	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
HYPERGLYCAEMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYPOGLYCAEMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYPOKALAEMIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYPONATRAEMIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
OBESITY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)

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Table 20a. (Continued) Serious Adverse Events (to 270 Days) - ITT Set

Serious Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1.0% (8/773)	0.9% (7/775)	1.0% (15/1548)
ARTHRALGIA	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
BACK PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
FLANK PAIN	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INTERVERTEBRAL DISC DEGENERATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
MUSCULOSKELETAL CHEST PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MUSCULOSKELETAL PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NECK MASS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NECK PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
OSTEOARTHRITIS	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
PAIN IN EXTREMITY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SHOULDER PAIN	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0.9% (7/773)	0.5% (4/775)	0.7% (11/1548)
COLON CANCER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
COLON CANCER METASTATIC	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
GASTRIC CANCER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
LEUKAEMIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
LUNG NEOPLASM MALIGNANT	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
MEDULLARY THYROID CANCER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PAPILLARY THYROID CANCER	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PITUITARY TUMOUR	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
RENAL CELL CARCINOMA STAGE UNSPECIFIED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
TERATOMA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
TRANSITIONAL CELL CARCINOMA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NERVOUS SYSTEM DISORDERS	3.1% (24/773)	1.9% (15/775)	2.5% (39/1548)
APHASIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CAROTID ARTERY STENOSIS	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
CEREBRAL INFARCTION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CEREBROVASCULAR ACCIDENT	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
CONVULSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DEPRESSED LEVEL OF CONSCIOUSNESS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DIZZINESS	0.3% (2/773)	0.3% (2/775)	0.3% (4/1548)
DYSARTHRIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HAEMORRHAGE INTRACRANIAL	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HEMIPARESIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HYPOAESTHESIA	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
METABOLIC ENCEPHALOPATHY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MIGRAINE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
NEURALGIA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)

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Table 20a. (Continued) Serious Adverse Events (to 270 Days) - ITT Set

Serious Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
SUBARACHNOID HAEMORRHAGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SYNCOPE	0.6% (5/773)	0.6% (5/775)	0.6% (10/1548)
SYNCOPE VASOVAGAL	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
TRANSIENT ISCHAEMIC ATTACK	0.4% (3/773)	0.0% (0/775)	0.2% (3/1548)
PSYCHIATRIC DISORDERS	0.3% (2/773)	0.5% (4/775)	0.4% (6/1548)
ANXIETY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
DISORIENTATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
INSOMNIA	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MENTAL DISORDER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
MENTAL STATUS CHANGES	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SCHIZOAFFECTIVE DISORDER	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RENAL AND URINARY DISORDERS	1.7% (13/773)	1.2% (9/775)	1.4% (22/1548)
ACUTE PRERENAL FAILURE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HAEMATURIA	0.1% (1/773)	0.4% (3/775)	0.3% (4/1548)
NEPHROLITHIASIS	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
NEPHROPATHY TOXIC	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
RENAL ARTERY STENOSIS	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
RENAL FAILURE	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
RENAL FAILURE ACUTE	0.5% (4/773)	0.1% (1/775)	0.3% (5/1548)
RENAL MASS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
URINARY BLADDER HAEMORRHAGE	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
URINARY RETENTION	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1.7% (13/773)	2.3% (18/775)	2.0% (31/1548)
ACUTE RESPIRATORY DISTRESS SYNDROME	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE EXACERBATED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DYSPNOEA	0.6% (5/773)	1.2% (9/775)	0.9% (14/1548)
DYSPNOEA EXACERBATED	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
EPISTAXIS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HAEMOPTYSIS	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
HYPOXIA	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
PHARYNGOLARYNGEAL PAIN	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PLEURAL EFFUSION	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
PRODUCTIVE COUGH	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
PULMONARY EMBOLISM	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
PULMONARY FIBROSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PULMONARY OEDEMA	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
RESPIRATORY DISTRESS	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
RESPIRATORY FAILURE	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)

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Table 20a. (Continued) Serious Adverse Events (to 270 Days) - ITT Set

Serious Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
RASH	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
SURGICAL AND MEDICAL PROCEDURES	9.3% (72/773)	11.1% (86/775)	10.2% (158/1548)
AORTIC BYPASS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
AORTIC SURGERY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ARTERIAL BYPASS OPERATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ARTERIAL STENT INSERTION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
ATHERECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CARDIAC PACEMAKER INSERTION	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
CARDIAC PACEMAKER REVISION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
CAROTID ENDARTERECTOMY	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
CORONARY ANGIOPLASTY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
CORONARY ARTERY SURGERY	1.2% (9/773)	1.3% (10/775)	1.2% (19/1548)
CORONARY REVASCULARISATION	6.0% (46/773)	7.5% (58/775)	6.7% (104/1548)
HIP ARTHROPLASTY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HIP SURGERY	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
HOSPITALISATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYSTERECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
IMPLANTABLE DEFIBRILLATOR INSERTION	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
INTERVERTEBRAL DISC OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
KNEE ARTHROPLASTY	0.4% (3/773)	0.1% (1/775)	0.3% (4/1548)
KNEE OPERATION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
LIMB OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NECK EXPLORATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
NEPHROURETERECTOMY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
OESOPHAGEAL LESION EXCISION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PERIPHERAL ARTERY ANGIOPLASTY	0.0% (0/773)	0.3% (2/775)	0.1% (2/1548)
PERIPHERAL REVASCULARISATION	0.3% (2/773)	0.1% (1/775)	0.2% (3/1548)
PROSTATIC OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SHOULDER OPERATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SPINAL FUSION SURGERY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
SPINAL LAMINECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
STENT PLACEMENT	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
STERNOTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
STRANGULATED HERNIA REPAIR	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
SURGERY	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
TUMOUR EXCISION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VITRECTOMY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VASCULAR DISORDERS	2.5% (19/773)	2.1% (16/775)	2.3% (35/1548)
AORTIC ANEURYSM	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)

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Table 20a. (Continued) Serious Adverse Events (to 270 Days) - ITT Set

Serious Adverse Events (to 270 days)	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)
ARTERIAL STENOSIS LIMB	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
ARTERIAL THROMBOSIS LIMB	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
DEEP VEIN THROMBOSIS	0.4% (3/773)	0.3% (2/775)	0.3% (5/1548)
HAEMATOMA	0.1% (1/773)	0.1% (1/775)	0.1% (2/1548)
HAEMODYNAMIC INSTABILITY	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
HAEMORRHAGE	0.3% (2/773)	0.0% (0/775)	0.1% (2/1548)
HYPERTENSION	0.1% (1/773)	0.0% (0/775)	0.1% (1/1548)
HYPOTENSION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
INTERMITTENT CLAUDICATION	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
LYMPHANGITIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
PERIPHERAL VASCULAR DISORDER	0.5% (4/773)	0.4% (3/775)	0.5% (7/1548)
THROMBOSIS	0.0% (0/773)	0.1% (1/775)	0.1% (1/1548)
VASCULAR PSEUDOANEURYSM	0.9% (7/773)	0.5% (4/775)	0.7% (11/1548)

N = the maximum number of eligible patients.
NOS - Not Otherwise Specified.
NOTE: AEs missing event dates were included in this listing.

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Table 20b. Serious Adverse Events (to 270 Days) by Site - ITT Patients

Site	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients
5006	0.0% (0/483)	0.2% (1/502)	0.1% (1/985)
5023	0.0% (0/483)	0.6% (3/502)	0.3% (3/985)
5038	0.6% (3/483)	1.2% (6/502)	0.9% (9/985)
5070	1.2% (6/483)	1.6% (8/502)	1.4% (14/985)
5091	2.9% (14/483)	2.4% (12/502)	2.6% (26/985)
5135	0.0% (0/483)	0.4% (2/502)	0.2% (2/985)
5166	0.6% (3/483)	0.0% (0/502)	0.3% (3/985)
5186	2.3% (11/483)	3.6% (18/502)	2.9% (29/985)
5216	0.0% (0/483)	1.2% (6/502)	0.6% (6/985)
5251	0.0% (0/483)	2.8% (14/502)	1.4% (14/985)
5397	1.9% (9/483)	3.6% (18/502)	2.7% (27/985)
5434	0.8% (4/483)	0.4% (2/502)	0.6% (6/985)
5451	1.2% (6/483)	0.0% (0/502)	0.6% (6/985)
5520	0.0% (0/483)	0.2% (1/502)	0.1% (1/985)
5545	1.0% (5/483)	0.8% (4/502)	0.9% (9/985)
5556	0.0% (0/483)	1.0% (5/502)	0.5% (5/985)
6001	1.9% (9/483)	0.0% (0/502)	0.9% (9/985)
6020	0.8% (4/483)	0.6% (3/502)	0.7% (7/985)
6032	0.6% (3/483)	1.2% (6/502)	0.9% (9/985)
6060	0.2% (1/483)	0.4% (2/502)	0.3% (3/985)
6143	1.9% (9/483)	3.4% (17/502)	2.6% (26/985)
6160	0.8% (4/483)	0.0% (0/502)	0.4% (4/985)
6240	0.8% (4/483)	1.4% (7/502)	1.1% (11/985)
6257	0.6% (3/483)	2.4% (12/502)	1.5% (15/985)
6260	1.0% (5/483)	1.8% (9/502)	1.4% (14/985)
6261	0.2% (1/483)	0.2% (1/502)	0.2% (2/985)
6419	0.0% (0/483)	0.2% (1/502)	0.1% (1/985)
6425	4.3% (21/483)	2.8% (14/502)	3.6% (35/985)
6426	0.2% (1/483)	0.0% (0/502)	0.1% (1/985)
6427	0.6% (3/483)	1.8% (9/502)	1.2% (12/985)
6428	0.2% (1/483)	0.8% (4/502)	0.5% (5/985)
6429	0.2% (1/483)	0.2% (1/502)	0.2% (2/985)
6430	0.6% (3/483)	1.0% (5/502)	0.8% (8/985)
6431	2.5% (12/483)	0.8% (4/502)	1.6% (16/985)
6433	8.1% (39/483)	9.2% (46/502)	8.6% (85/985)
6434	1.0% (5/483)	0.8% (4/502)	0.9% (9/985)
6435	0.0% (0/483)	0.2% (1/502)	0.1% (1/985)
6436	0.0% (0/483)	0.2% (1/502)	0.1% (1/985)
6437	0.4% (2/483)	0.4% (2/502)	0.4% (4/985)
6438	12.0% (58/483)	9.4% (47/502)	10.7% (105/985)

Table 20b. (Continued) Serious Adverse Events (to 270 Days) by Site - ITT Patients

Site	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients
6439	2.7% (13/483)	0.4% (2/502)	1.5% (15/985)
6441	1.9% (9/483)	2.0% (10/502)	1.9% (19/985)
6444	3.7% (18/483)	3.8% (19/502)	3.8% (37/985)
6445	1.7% (8/483)	1.4% (7/502)	1.5% (15/985)
6446	1.7% (8/483)	0.4% (2/502)	1.0% (10/985)
6448	1.2% (6/483)	0.2% (1/502)	0.7% (7/985)
6449	2.3% (11/483)	1.6% (8/502)	1.9% (19/985)
6450	0.0% (0/483)	0.6% (3/502)	0.3% (3/985)
6451	0.2% (1/483)	0.0% (0/502)	0.1% (1/985)
6452	2.7% (13/483)	3.6% (18/502)	3.1% (31/985)
6453	1.7% (8/483)	0.8% (4/502)	1.2% (12/985)
6454	0.2% (1/483)	0.0% (0/502)	0.1% (1/985)
6455	0.2% (1/483)	0.2% (1/502)	0.2% (2/985)
6456	4.3% (21/483)	2.4% (12/502)	3.4% (33/985)
6458	0.2% (1/483)	0.0% (0/502)	0.1% (1/985)
6459	1.9% (9/483)	1.0% (5/502)	1.4% (14/985)
6461	4.3% (21/483)	1.8% (9/502)	3.0% (30/985)
6462	0.0% (0/483)	0.6% (3/502)	0.3% (3/985)
6463	1.4% (7/483)	0.8% (4/502)	1.1% (11/985)
6464	0.4% (2/483)	1.6% (8/502)	1.0% (10/985)
6574	1.0% (5/483)	1.4% (7/502)	1.2% (12/985)
6575	0.2% (1/483)	0.0% (0/502)	0.1% (1/985)
6576	0.4% (2/483)	1.4% (7/502)	0.9% (9/985)
6578	0.8% (4/483)	0.4% (2/502)	0.6% (6/985)
6601	0.8% (4/483)	2.8% (14/502)	1.8% (18/985)
6620	1.7% (8/483)	1.6% (8/502)	1.6% (16/985)
6621	1.2% (6/483)	2.2% (11/502)	1.7% (17/985)
6624	0.6% (3/483)	0.6% (3/502)	0.6% (6/985)
6625	1.0% (5/483)	0.2% (1/502)	0.6% (6/985)
6626	1.0% (5/483)	1.4% (7/502)	1.2% (12/985)
6628	3.5% (17/483)	3.6% (18/502)	3.6% (35/985)
6638	2.3% (11/483)	0.4% (2/502)	1.3% (13/985)
6643	0.4% (2/483)	0.8% (4/502)	0.6% (6/985)
6657	0.0% (0/483)	1.2% (6/502)	0.6% (6/985)
6670	0.4% (2/483)	0.0% (0/502)	0.2% (2/985)

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Table 21. Site Reported Major Adverse Events to 270 Days - ITT Set

Complications	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
MACE (Death, Emergent CABG, MI, TLR)	7.2% (56/773)	6.6% (51/775)	6.9% (107/1548)	0.7% [-1.9%, 3.2%]	0.618
Death	0.6% (5/773)	0.8% (6/775)	0.7% (11/1548)	-0.1% [-1.0%, 0.7%]	1.000
Emergent CABG	0.1% (1/773)	0.5% (4/775)	0.3% (5/1548)	-0.4% [-1.0%, 0.2%]	0.374
MI	2.8% (22/773)	3.4% (26/775)	3.1% (48/1548)	-0.5% [-2.2%, 1.2%]	0.660
Q-Wave	0.3% (2/773)	0.6% (5/775)	0.5% (7/1548)	-0.4% [-1.1%, 0.3%]	0.452
Non Q-Wave	2.6% (20/773)	2.7% (21/775)	2.6% (41/1548)	-0.1% [-1.7%, 1.5%]	1.000
TLR	4.8% (37/773)	3.1% (24/775)	3.9% (61/1548)	1.7% [-0.2%, 3.6%]	0.091
TVR not involving the Target Lesion	2.8% (22/773)	4.0% (31/775)	3.4% (53/1548)	-1.2% [-3.0%, 0.7%]	0.263
Major Vascular Events	2.5% (19/773)	1.9% (15/775)	2.2% (34/1548)	0.5% [-0.9%, 2.0%]	0.494
CVA	0.5% (4/773)	0.3% (2/775)	0.4% (6/1548)	0.3% [-0.4%, 0.9%]	0.452

N = the maximum number of eligible patients. Denominators indicate the total number of patients with available data for related parameter.
Among the 107 MACEs that were reported by sites, 75 of them were adjudicated as MACE by the CEC.

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Table 22. Laboratory - Cardiac Enzymes Findings - ITT Set

Laboratory - CK, CKMB	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
CK					
Pre-Procedure Peak >2 ULN	1.1% (8/745)	0.7% (5/752)	0.9% (13/1497)	0.4% [-0.5%, 1.3%]	0.420
Post-Procedure Peak >2 ULN	0.9% (7/758)	2.2% (17/767)	1.6% (24/1525)	-1.3% [-2.5%, -	0.062
Post-Procedure Peak >3 ULN	0.7% (5/758)	1.2% (9/767)	0.9% (14/1525)	-0.5% [-1.5%, 0.4%]	0.422
Post-Procedure Peak >4 ULN	0.5% (4/758)	0.8% (6/767)	0.7% (10/1525)	-0.3% [-1.1%, 0.6%]	0.753
Post-Procedure Peak >5 ULN	0.5% (4/758)	0.5% (4/767)	0.5% (8/1525)	0.0% [-0.7%, 0.7%]	1.000
CKMB					
Pre-Procedure Peak >1 ULN	5.0% (34/680)	4.4% (30/681)	4.7% (64/1361)	0.6% [-1.7%, 2.8%]	0.611
Post-Procedure Peak >1 ULN	14.4% (102/707)	19.6% (140/713)	17.0% (242/1420)	-5.2% [-9.1%, -	0.011
Post-Procedure Peak >2 ULN	5.2% (37/707)	10.1% (72/713)	7.7% (109/1420)	-4.9% [-7.6%, -	<.001
Post-Procedure Peak >3 ULN	2.7% (19/707)	6.0% (43/713)	4.4% (62/1420)	-3.3% [-5.5%, -	0.003
Post-Procedure Peak >4 ULN	1.4% (10/707)	4.2% (30/713)	2.8% (40/1420)	-2.8% [-4.5%, -	0.002
Pre-Procedure CK >2 ULN and CKMB >1 ULN	0.3% (2/672)	0.3% (2/677)	0.3% (4/1349)	0.0% [-0.6%, 0.6%]	1.000
Post-Procedure CK >2 ULN and CKMB >1 ULN	0.6% (4/700)	2.2% (16/712)	1.4% (20/1412)	-1.7% [-2.9%, -	0.011
Pre- and Post-Procedure CK >2 ULN and CKMB >1 ULN	0.2% (1/637)	0.2% (1/653)	0.2% (2/1290)	0.0% [-0.4%, 0.4%]	1.000

N = the maximum number of eligible patients. Denominators indicate the total number of patients with available data for related parameter.

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Table 23. Medication - Anti-Coagulants Use - ITT Set

Anti-Coagulant	ENDEAVOR (N=773 Patients)	TAXUS (N=775 Patients)	All Patients (N=1548 Patients)	Difference [95% CI]	P-Value
Pre-Procedure					
Aspirin	96.2% (743/772)	96.1% (744/774)	96.2% (1487/1546)	0.1% [-1.8%, 2.0%]	1.000
Clopidogrel	64.2% (496/772)	64.9% (502/774)	64.6% (998/1546)	-0.6% [-5.4%, 4.2%]	0.832
GP IIb/IIIa	23.9% (50/209)	21.5% (45/209)	22.7% (95/418)	2.4% [-5.6%, 10.4%]	0.641
During-Procedure					
Aspirin	6.3% (49/772)	7.4% (57/774)	6.9% (106/1546)	-1.0% [-3.5%, 1.5%]	0.481
GP IIb/IIIa	93.3% (195/209)	92.8% (194/209)	93.1% (389/418)	0.5% [-4.4%, 5.4%]	1.000
Post-Procedure					
Aspirin	28.8% (222/772)	27.9% (216/774)	28.3% (438/1546)	0.8% [-3.6%, 5.3%]	0.735
Clopidogrel	55.4% (428/772)	54.1% (419/774)	54.8% (847/1546)	1.3% [-3.7%, 6.3%]	0.610
Ticlopidine	0.0% (0/769)	0.4% (3/770)	0.2% (3/1539)	-0.4% [-0.8%, 0.1%]	0.250
GP IIb/IIIa	73.7% (154/209)	76.1% (159/209)	74.9% (313/418)	-2.4% [-10.7%, 5.9%]	0.652
Aspirin and (Clopidogrel or Ticlopidine)	27.5% (212/772)	26.2% (203/774)	26.8% (415/1546)	1.2% [-3.2%, 5.7%]	0.606
At Discharge					
Aspirin	99.2% (766/772)	99.2% (768/774)	99.2% (1534/1546)	-0.0% [-0.9%, 0.9%]	1.000
Clopidogrel	99.5% (768/772)	99.1% (767/774)	99.3% (1535/1546)	0.4% [-0.5%, 1.2%]	0.547
Ticlopidine	0.3% (2/772)	0.4% (3/774)	0.3% (5/1546)	-0.1% [-0.7%, 0.4%]	1.000
Aspirin and (Clopidogrel or Ticlopidine)	99.2% (766/772)	98.7% (764/774)	99.0% (1530/1546)	0.5% [-0.5%, 1.5%]	0.452
At 30-Day					
Aspirin	98.2% (743/757)	97.3% (731/751)	97.7% (1474/1508)	0.8% [-0.7%, 2.3%]	0.303
Clopidogrel	97.7% (738/755)	98.1% (732/746)	97.9% (1470/1501)	-0.4% [-1.8%, 1.1%]	0.717
Ticlopidine	25.8% (8/31)	22.2% (10/45)	23.7% (18/76)	3.6% [-16.0%, 23.2%]	0.787
Aspirin and (Clopidogrel or Ticlopidine)	96.4% (730/757)	95.7% (719/751)	96.1% (1449/1508)	0.7% [-1.3%, 2.7%]	0.509
At 6-Month					
Aspirin	95.8% (713/744)	95.7% (708/740)	95.8% (1421/1484)	0.2% [-1.9%, 2.2%]	0.898
Clopidogrel	94.8% (697/735)	94.8% (692/730)	94.8% (1389/1465)	0.0% [-2.2%, 2.3%]	1.000
Ticlopidine	29.4% (5/17)	21.7% (5/23)	25.0% (10/40)	7.7% [-19.8%, 35.1%]	0.717
Aspirin and (Clopidogrel or Ticlopidine)	92.3% (687/744)	91.6% (678/740)	92.0% (1365/1484)	0.7% [-2.0%, 3.5%]	0.634
At 9-Month					
Aspirin	96.0% (675/703)	96.0% (668/696)	96.0% (1343/1399)	0.0% [-2.0%, 2.1%]	1.000
Clopidogrel	95.4% (391/410)	96.8% (393/406)	96.1% (784/816)	-1.4% [-4.1%, 1.2%]	0.368
Ticlopidine	36.4% (4/11)	33.3% (6/18)	34.5% (10/29)	3.0% [-32.8%, 38.8%]	1.000
Aspirin and (Clopidogrel or Ticlopidine)	54.6% (384/703)	54.6% (380/696)	54.6% (764/1399)	0.0% [-5.2%, 5.2%]	1.000

N = the maximum number of eligible patients. Denominators indicate the total number of patients with available data for related parameter.

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Table 24. Device Performance*

	Endeavor	Taxus
Stent delivery issues	**6**	**9**
Never Delivered	4	5
Subsequent Success	1	0
Other Delivery issue	1	4
Treatment	**6**	**9**
Failure-CABG	0	1
Failed Procedure	1	0
PTCA only	2	2
Non-study Stent	1	2
QCA <50%	2	4

* 21 patients did not receive the assigned strategy and 6 patients did not receive the assigned stent

Table 25. Device Performance Narratives

Site	Patient	Treatment Group	Narrative
----------		Taxus	Device Performance–Non-Success, Stent Delivery On 01/03/2006 at 09:59 the patient underwent the index procedure with pre-treatment balloon angioplasty. The site reported an unsuccessful attempt to cross the target lesion in the 2nd OM with the assigned stent due to excessive proximal tortuousity and calcification according to the Cardiac Catheterization Report. Balloon angioplasty was repeated and there was a failed attempt to deliver a bare-metal stent to the target lesion. The site reported a grade C dissection, a worst stenosis of 20%, and TIMI 3 flow with associated angina during pre-dilation. The Angiographic Core Lab confirmed the study stent was not deployed and noted a 50.3% final residual in-lesion stenosis with a grade C dissection, staining and TIMI 3 flow with the notation "abrupt closure seen before wire was passed down ostial lesion." It further noted the presence of calcifications and significant tortuosities.
----------		Taxus	Device Performance–Non-Success, Stent Delivery On 11/10/2005 at 15:01 the patient underwent the index procedure with pre-treatment balloon angioplasty in the mid RCA. The site noted despite multiple attempts with balloon angioplasty, the Investigator reported the vessel was too tortuous and was therefore attempts to deliver the assigned stent in the mid RCA were unsuccessful. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 27% final residual in-lesion stenosis with a no dissection and TIMI 3 flow.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Device Performance–Non-Success, Stent Delivery, Subsequent Success
			On 08/18/2005 at 16:12 the patient underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 2nd OM, noted by the site as a "de novo lesion" at time of enrollment. Bivalirudin was administered. The site reported the device "stent wires were frayed in the middle with struts sticking out;" therefore delivery was difficult. The Cardiac Catheterization Report noted that the first stent was damaged and withdrawn. A second assigned stent was advanced to the OM; however this was not deployed. The assigned stent was subsequently delivered to the 2nd OM with the use of a buddy wire and successfully deployed. The post-stent IVUS catheter was not able to cross the target lesion; therefore IVUS was not performed. There were no clinical sequelae. The Angiographic Core Lab reported a 55% final residual in-lesion stenosis with no dissection and TIMI 3 flow.
----------		Taxus	Device Performance–Non-Success, Use of Non-study Stent
			On 06/26/2006 at 16:08 the patient underwent the index procedure with pre-treatment balloon angioplasty with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal CX. The Cardiac Catheterization Report noted this stent was felt to be too small for the reference diameter and during post-dilation there was balloon rupture causing a proximal dissection. This was treated with a non-study stent. IVUS showed the stent was partially under deployed and it was post-dilated. There were no clinical sequelae. In a query response the site indicated the balloon which ruptured was the non-study stent balloon. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Device Performance–Non-Success, Stent Delivery On 04/27/2006 at 08:16 the patient underwent the index procedure with pre-treatment balloon angioplasty. Eptifibatide was administered. The site reported a grade B dissection following pre-treatment. An Interventional Catheterization Report revealed there was a balloon rupture at 16 atmospheres in the distal portion of the mid RCA at the acute margin. This area was then re-dilated to 18 atmospheres with a non-compliant balloon. There was an unsuccessful attempt to cross the target lesion with the assigned stent and the lesion was again re-dilated. Another attempt to place the assigned stent was made; however the stent could not "access the lesion in its entirety." After removal of the guide catheter, there was embolization of the assigned stent to the right femoral artery and vascular surgery was consulted. Right common iliac arteriography revealed the stent was residing halfway outside the femoral artery and half inside the femoral artery. The stent was successfully extracted using a stent extraction device. Additional coronary angiography revealed a site reported "stable angiographic result with normal flow" and the patient's vital signs remained stable during the procedure. The site reported a 30% final residual stenosis with a grade B dissection and TIMI 3 flow. The Angiographic Core Lab reported a 53% final residual in-lesion stenosis with grade C dissection and TIMI 3 flow with the notation "plain old balloon angioplasty to mid RCA; coronary stent dislodged in RFA, successfully retrieved, unable to deliver stent to coronary artery."

Site	Patient	Treatment Group	Narrative
----------		Taxus	Device Performance–Non-Success, Stent Balloon Malfunction On 05/03/2006 at 15:35 the patient underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. Bivalirudin was administered. The Cardiac Catheterization Report noted that the stent balloon became lodged inside the stent and could not be retrieved. After multiple manipulations with the guide catheter in the aorta the stent balloon was successfully removed and balloon angioplasty was performed; however a distal grade A dissection was noted with incomplete filling of the LAD apex. The site reported an abrupt closure or threatened abrupt closure with a 0% worst stenosis and TIMI 3 flow and further reported a 0% final residual stenosis with a grade A dissection and TIMI 3 flow. In response to a query, the Angiographic Core Lab reported a worst TIMI 3 flow in-stent and a worst TIMI 0 flow in the distal LAD and a 26% final residual in-lesion stenosis with abrupt closure, a grade F dissection, staining and TIMI 3 flow.
----------		Endeavor	Device Performance–Non-Success, Stent Delivery On 12/08/2005 at 10:46 the patient underwent the index procedure with pre-treatment balloon angioplasty. Abciximab was administered. The Cardiac Catheterization Report noted during delivery of the assigned stent in the target lesion in the proximal CX; the stent became lodged at an area of a second stenosis on a curve. A Mailman wire could not be positioned past the distal tip of the stent and the wire was removed. An attempt was made to remove the stent; however the stent became dislodged from the stent balloon. An attempt to snare the stent was unsuccessful and the stent migrated to the left main coronary artery/proximal CX. A consultation determined due to significant calcification an emergent bypass graft would be difficult; therefore additional attempts were made to snare the stent and it was subsequently successfully removed. The site reported the stent was misshaped upon removal. There were no clinical sequelae. The Angiographic Core Lab reported a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "PCI, severe calcifications, tortuosities present; study stent was not delivered, significant residual lesion present in final."

Site	Patient	Treatment Group	Narrative
----------		Taxus	Device Performance–Non-Success, Stent Delivery On 02/28/2006 the patient underwent an outpatient diagnostic angiography, which revealed a severe LAD disease with a discrete 90% lesion in the mid segment. On 02/28/2006 at 15:43 she underwent the index procedure with pre-treatment balloon angioplasty. Bivalirudin was administered. In a query responses the site confirmed there were no attempts to deliver the assigned stent; however a subsequent query response confirmed "only the randomized stent was used multiple times." All attempts to deliver the assigned stent to the target lesion in the mid LAD were unsuccessful. The Interventional Catheterization Report noted that the patient was randomized and the stent could not cross a more proximal area of calcification. Wires were changed and the lesion was re-dilated and this left a residual dissection. During the procedure the site reported a grade D dissection and a 90% diameter stenosis which improved to a final 50% stenosis with a final grade C dissection and TIMI 3 flow. The Angiographic Core Lab reported a 45% final residual in-lesion stenosis with a final grade B dissection and TIMI 3 flow.
----------		Endeavor	Device Performance–Non-Success, Stent Migration On 09/13/2005 at 12:15 the patient underwent the index procedure with pre-treatment balloon angioplasty; however attempts to deliver the assigned stent to target lesion in the mid RCA were unsuccessful. The Cardiac Catheterization Report noted the stent "moved forward" and the site reported deployment of the 1st assigned stent in the distal RCA. A second assigned stent was placed proximal to and overlapping the 1st stent; the stents were post-dilated, and IVUS was performed. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow.
----------		Taxus	Device Performance–Non-Success, Stent Delivery On 06/15/2005 at 10:23 the patient underwent the index procedure with pre-treatment balloon angioplasty; however all attempts to deliver the assigned stent to target lesion in the mid RCA were unsuccessful. Bivalirudin was administered. The Cardiac Catheterization Report noted there was also an unsuccessful attempt to deliver a non-study VISION™ stent to the target lesion. All stents were withdrawn and balloon angioplasty was performed. There were no clinical sequelae. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with a grade A dissection and TIMI 3 flow.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Device Performance–Non-Success, Stent Delivery, Use of Non-study Stent
			On 03/27/2006 at 09:46 the patient underwent the index procedure with pre-treatment balloon angioplasty; however multiple attempts to deliver the assigned stent to the target lesion in the mid LAD were unsuccessful. Subsequently a non-study stent was implanted in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow with a notation of "foreshortened projection."
----------		Endeavor	Device Performance–Non-Success, Stent Delivery
			On 06/16/2006 at 09:44 the patient underwent the index procedure with pre-treatment balloon angioplasty. According to the Cardiac Catheterization Log the assigned stent was delivered to target lesion in then 1st OM; however there was failure to deploy the assigned stent and it was withdrawn. The site confirmed the assigned stent was not deployed due to heavy calcification and tortuosity. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 54% final residual in-lesion stenosis with no dissection and TIMI 3 flow.
----------		Taxus	Device Performance–Non-Success, Stent Delivery
			On 11/07/2005 at 09:36 the patient underwent the index procedure with pre-treatment balloon angioplasty and placement of one assigned stent in the mid LAD. The stent was post-dilated and IVUS was attempted but was unable to cross the distal portion of the stent. The site reported despite successful multiple balloon dilations, two additional assigned stents could not cross the first stent placed in the distal portion of the mid LAD and were withdrawn. The Angiographic Core Lab reported a 47% final residual in-lesion stenosis with a grade B dissection, TIMI 3 flow and a notation of a B dissection in mid LAD distal to stent at site of POBA-unable to be covered by a stent. The CEC ruled the event met the criteria for a Protocol Non-Success due to an inability to deliver additional stents to treat a dissection.

Site Patient	Treatment Group	Narrative
----------	Taxus	Device Performance–Non-Success, Stent Delivery On 06/14/2006 at 13:05 the patient underwent the index procedure with pre-treatment balloon angioplasty in the proximal RCA. Eptifibatide was administered. The site reported a grade A dissection after pre-treatment. An Interventional Catheterization Report revealed the following information. The RCA "demonstrated a prominent shepherd's crook deformity in the proximal vessel." After placement of the guide, a wire was advanced across the area of disease, which resulted in a marked straightening of the vessel with a "resulting pseudolesion and near occlusion of the vessel." The area of stenosis was pre-dilated with a balloon. An attempt was made to advance an assigned stent. This stent, however, would not pass through the pre-dilated area and could not be retracted into the guiding catheter. The guiding catheter was withdrawn into the ilio-femoral region. A "buddy wire" was then advanced into the common iliac and the study stent was retrieved with difficulty, due to a deformity of the proximal portion of the stent, which was noted to have "some elevation of one of the stent struts." A "section flap" was then noted in the RCA at the point of balloon dilatation. One assigned stent was placed to seal the dissection. However, the dissection appeared to propagate proximally, which required placement of a second assigned stent that was telescoped into the first stent and then deployed. A buddy wire was used to position the second stent. The Catheterization Report noted the second stent "appeared to have advanced somewhat into the RCA" with stent deployment, and the ostium was not completely covered; this was confirmed with IVUS evaluation. A third assigned stent was then positioned in the two prior stents and successfully deployed in the right coronary ostium. The Angiographic Core Lab reported an 1.6% final residual in-lesion stenosis with no dissection, no thrombus and TIMI 2 flow with the notation "dissection with abrupt closure and no reflow, covered by 2nd and 3rd stent (large overlap); acceptable end result with reduced flow TIMI 2.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Device Performance–Non-Success, Stent Delivery, Use of Non-study Stent On 05/25/2006 at 10:43 the patient underwent the index procedure with pre-treatment balloon angioplasty; however the Cardiac Catheterization Report noted the assigned stent could not be delivered to the distal LAD target lesion due to disease in the mid segment of the vessel. The site reported after pre-dilation there was a grade C dissection with a 90% worst diameter stenosis. Attempts to deliver the assigned stent in the distal vessel failed. There was subsequent successful delivery of two mini VISION™ stents in the distal LAD, two mini VISION™ stents in the mid LAD and one assigned stent in the proximal LAD. The Angiographic Core Lab reported a 42% final residual in-lesion stenosis with a proximal grade C dissection and TIMI 3 flow with the notation of some apositioning of the proximal stent.

Table 26. Narrative Summaries of Major Adverse Events

The narratives presented below are sorted by patient ID not in hierarchical order of MACE (Cardiac Death, Non-Cardiac Death, Q wave MI, Non-Q wave MI, Emergent CABG, Target Lesion Revascularization). All deaths regardless of time from procedure are reported. Deaths beyond 270 days are presented at the end of this section.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-CABG 1 day post-procedure, Stroke 134 days post-procedure The patient is a 66 year-old woman with a history of former smoking, diabetes, dyslipidemia, CVA in 1995 and hypertension who presented with CCS Class III angina. On 01/03/2006 at 09:59 she underwent the index procedure with pre-treatment balloon angioplasty. The site reported an unsuccessful attempt to cross the target lesion in the 2nd OM with the assigned stent due to excessive proximal tortuousity and calcification according to the Cardiac Catheterization Report. Balloon angioplasty was repeated and there was a failed attempt to deliver a bare-metal stent to the target lesion. The site reported a grade C dissection, a worst stenosis of 20%, and TIMI 3 flow with associated angina during pre-dilation. The Angiographic Core Lab confirmed the study stent was not deployed and noted a 50.3% final residual in-lesion stenosis with a grade C dissection, staining and TIMI 3 flow with the notation "abrupt closure seen before wire was passed down ostial lesion." It further noted the presence of calcifications and significant tortuosities. IABP was inserted and a surgical consult was performed due to the residual stenosis after angioplasty of the 2nd OM. The pre-procedure CK and CKMB drawn at a non-study site on 01/01/2006 at 06:45 were 111 (nl 232, ratio <1) and 2.4 (nl 23.6, ratio <1) respectively. Only one post-procedure CK and CKMB was recorded on the CRF. The CK drawn at the study site on 01/03/2006 at 20:00 was 217 (nl 200, ratio 1.1) with a CKMB of 35.5 (nl 5.3, ratio 6.7). In a query response the site submitted all admission laboratory results and two additional cardiac enzymes were noted. The CK and CKMB on 01/04/2006 at 01:15 was 267 (ratio 1.3) and 38.2 (ratio 7.2) respectively. The final CK drawn on 01/04/2006 at 06:00 peaked at 314 (ratio 1.6) with a CKMB of 34.3 (ratio 6.5). The site reported a Q wave MI. The ECG Core Lab reported persistent RBBB, incomplete with no new major ST-T abnormalities and no new Q waves. On 01/04/2006 the patient underwent emergent CABG surgery with a SVG to the 2nd OM, a LIMA to the mid LAD and a SVG to the distal RCA. The OR Report noted a post-operative diagnosis of acute MI. The CEC ruled the event did not meet criteria for a Q wave MI. The patient was discharged on 01/10/2006 on ASA. An ER note indicates the patient was rehospitalized on 05/18/2006 with an acute onset one day prior to admission of slurred speech and facial numbness. The Discharge Summary reported the patient's left sided weakness was unchanged since a previous CVA. There was a negative brain CT; however the patient was evaluated by neurology and diagnosed with an acute CVA, felt to be a small brainstem infarct. The patient was discharged on 05/23/2006.

Site	Patient	Treatment Group	Narrative
----------	----------	Taxus	Emergent Target Lesion Revascularization-CABG, Target Vessel Revascularization-CABG day of procedure The patient is a 58 year-old man with a history of former smoking, dyslipidemia, hypertension, premature CAD in a 1st degree relative, a MI on 05/21/2005, and PCI in a non-target vessel in 05/2005 who presented with CCS Class I angina. On 06/29/2005 at 14:03 he underwent the index procedure with pre-treatment balloon angioplasty of the proximal LAD; however following pre-treatment there was a site reported grade D dissection, a spiral shaped filing defect with dye extravasation. The site reported associated angina and further noted a 75% final residual stenosis and TIMI 2 flow. Bivalirudin was administered. The Angiographic Core Lab reported a 38% final residual in-lesion stenosis with a grade C dissection, a perforation with staining and TIMI 3 flow with the notation "possible distal wire perforation, dissection after pre-dilation in the proximal LAD and the Left Main, patient went for surgery, the study stent wasn't deployed." The site confirmed that the delivery of the assigned stent was never attempted. The patient underwent insertion of an intra-aortic balloon pump and was transferred to the OR for emergent CABG surgery of the proximal LAD, the 1st diagonal and the 1st OM. The pre-procedure CK was not recorded and the CKMB drawn on 06/29/2005 at 14:05 was 3 (nl 5, ratio <1). The post-procedure CK and CKMB were not done. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The post-surgical course was complicated with rapid atrial fibrillation which subsequently converted to normal sinus rhythm and he was discharged on 07/05/2005 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Non-Q wave MI 186 days post-procedure, Target Lesion Revascularization-PTCA 186 days post-procedure The patient is a 76 year-old man with a history of former smoking who presented with CCS Class IV angina. On 06/09/2006 at 08:40 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD and eptifibatide was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 28% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/10/2006 on ASA and clopidogrel. The patient was rehospitalized for sudden onset of chest pain on 12/12/2006. On 12/12/2006 at 11:16 the CK was 294 (nl 170, ratio 1.7) with a CKMB of 30.1 (nl 5, ratio 6). On 12/12/2006 at 18:10 the CK was 410 (ratio 2.4) with a peak CKMB of 31.7 (ratio 6.3). The CK peaked at 536 (ratio 3.2) on 12/13/2006 at 04:16 and the CKMB was 19.4 (ratio 3.9). The final set of enzymes reported on 12/13/2006 at 12:20 was a CK of 400 (ratio 2.4) with a CKMB of 10.9 (ratio 2.2). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. Repeat angiography on 12/12/2006 for recurrent chest pain and without a functional ischemia study revealed an 84% proliferative in-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. A faxed Interventional Catheterization Report noted a 99% in-stent restenosis. The patient underwent repeat revascularization with balloon angioplasty and placement of a drug-eluting stent in the mid LAD.

Site Patient	Treatment Group	Narrative
----------	Endeavor	Target Lesion Revascularization-CABG 3 days post-procedure The patient is a 57 year-old man with a history of dyslipidemia, hypertension and former smoking who presented with CCS Class II angina and a positive functional ischemia study. On 02/14/2006 at 15:14 the patient underwent the index procedure with pre-treatment balloon angioplasty in the mid LAD which resulted in plaque rupture. A narrative reported the target vessel was severely calcified and after attempts with multiple wires and devices the procedure was unsuccessful and further noted there was no attempt to deliver the assigned stent. A faxed Cardiac Catheterization Report indicates there was an unsuccessful attempt to deliver a non-study stent [OTW VISION™]. This was followed by balloon angioplasty. There were no clinical sequelae. The Angiographic Core Lab reported a 42% final residual in-lesion stenosis with a grade C dissection and TIMI 3 flow with the notation "mid LAD, no stent deployed, two balloons used, residual 'C' on final." The site reported a 50% final residual stenosis with no dissection and TIMI 3 flow and noted the procedure was aborted at this time. The Operative Report dated 02/17/2006 noted that on 02/14/2006 a PTCA procedure could not be completed due to a fracture of a densely calcified plaque. The patient was maintained in CCU on eptifibatide and intravenous heparin and had no difficulty after the catheterization. On 02/17/2006 the patient underwent CABG surgery with a LIMA to the LAD. The Report further noted a subendocardial hemorrhage around the proximal to mid LAD over several centimeters and also noted a "modest serosanguinous pericardial effusion" approximately 50 to 70 mls. In a narrative the site reported the patient withdrew from the study on 02/21/2006. The patient was discharged on 02/23/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-CABG 235 days post-procedure The patient is a 56 year-old woman with a history of current smoking, dyslipidemia, hypertension, and premature CAD in a first degree relative who presented with CCS Class IV angina and a positive functional ischemia study. On 07/01/2005 at 16:14 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal LAD. A second stent was placed proximal to the first stent for insufficient lesion coverage. Eptifibatide was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The patient was discharged on 07/02/2005 on ASA and clopidogrel. A narrative reported the patient complained of shortness of breath and shoulder pain since the index procedure. A protocol re-study on 02/17/2006 in the absences of recurrent angina without a functional ischemia study revealed a 75% proliferative in-stent restenosis reported by the Angiographic Core Lab. The Cardiac Catheterization Report noted a 95% restenosis of the target lesion extending into the mid LAD and reported additional disease in non-target vessels. On 02/21/2006 the patient underwent CABG surgery with a LIMA to the LAD, a SVG to the 1st diagonal, a SVG to the 1st OM and a SVG to the R-PDA. The site reported a target vessel revascularization and a non-target vessel revascularization; however the CEC determined the event met the criteria for a clinically driven target lesion revascularization.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Cardiac Death 57 days post-procedure The patient was a 52 year-old man with a history of current smoking, dyslipidemia, hypertension, and a MI on 11/04/2005 who presented with CCS Class IV angina. On 11/08/2005 at 12:32 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the R-PDA. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated (not confirmed) and the patient was discharged on 11/10/2005 on ASA and clopidogrel. The site reported on 01/04/2006 the patient had a witnessed cardiac arrest at home after experiencing nausea and was transported by EMS to the Emergency Department. The ER Report noted the patient was vomiting and stopped breathing approximately 30 minutes prior to the arrival of EMS personnel. According to the Ambulance report the patient was found pulseless with CPR being performed by a bystander. On 01/04/2006 at 06:36 he was admitted to the ER with ALS protocol in progress. In query response the site reported that ECG tracings and cardiac enzyme reporting are not available. Resuscitative efforts were unsuccessful and the patient subsequently expired on 01/04/2006 at 06:46. No autopsy was performed and the Death Certificate reported the cause of death as acute MI, CAD.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-PTCA 246 days post-procedure The patient is a 59 year-old woman with a history of diabetes, dyslipidemia, and hypertension who presented with CCS Class IV angina. On 05/24/2006 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. The site reports following stent placement in the index lesion, additional lesions in the mid and distal LAD were discovered and two stents were placed to treat these lesions. Eptifibatide was administered and the additional two stents were post-dilated. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/25/2006 on ASA and clopidogrel. Protocol re-study on 01/25/2007 in the presence of recurrent exertional angina and without a functional ischemia study revealed a 57% intra-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. An Interventional Catheterization Report noted the distal and proximal LAD stents had no significant in-stent restenosis and the medial stent had 70% restenosis. The patient underwent repeat revascularization with balloon angioplasty and placement of a CYPHER® stent in the mid LAD, reported by the site as a target lesion revascularization.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Vessel Revascularization-PTCA 142 days post-procedure The patient is a 69 year-old man with a history of former smoking, diabetes, dyslipidemia, hypertension, and PCI of the mid RCA on 06/07/2004 who presented with CCS Class III angina. On 01/16/2006 at 10:34 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 35% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 01/17/2006 on ASA and clopidogrel. On 06/07/2006 the patient complained of angina. An unscheduled repeat angiography on 06/07/2006 for recurrent clinical symptoms and a positive functional ischemia study on 05/19/2006 revealed a 28% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent and a remote target vessel revascularization. The site reported a 70% restenosis of the target lesion and an 80% stenosis of the proximal RCA. The patient underwent repeat revascularization with stent placement in the proximal RCA and was discharged on 06/08/2006.
----------	----------	Taxus	Stroke 198 days post-procedure The patient is a 73 year-old man with a history of former smoking, dyslipidemia, hypertension, and PCI and stenting of the proximal LAD in 05/2003 who presented with CCS Class IV angina and a positive functional ischemia study. On 10/05/2005 at 12:15 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. A second stent was placed distal to the first stent for insufficient lesion coverage. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/06/2005 on ASA and clopidogrel. On 04/21/2006 the patient was rehospitalized for complaints of slurred speech, left arm heaviness, an unsteady gait, and a left facial droop, which persisted for longer than 24 hours. A brain CT revealed a 2.9 cm subdural hematoma according to the site and on 04/26/2006 he underwent surgical decompression. The deficits slowly improved following the surgical intervention and he was discharged on 05/01/2006 with no change of his medical regimen.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-Q wave MI, Target Lesion Revascularization-PTCA, Subacute Closure/Stent Thrombosis 2 days post-procedure, Target Vessel Revascularization-CABG 47 days post-procedure The patient is a 64 year-old woman with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class II angina and a positive functional ischemia study. On 11/10/2005 at 13:16 she underwent the index procedure with direct stenting of the mid LAD using the assigned stent. The site confirmed that the investigator inadvertently omitted pre-dilation prior to stent placement. There were no clinical sequelae. The Angiographic Core Lab reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/11/2005 on ASA and clopidogrel. On 11/12/2005 at approximately 20:00 the patient developed an acute onset of severe chest pain. She was taken to the Emergency Room and the site reported presence of acute anterior ST elevations on her ECG. The History and Physical Report noted that a dose of clopidogrel was taken on the day of admission and the site confirmed the patient took all post-index doses of clopidogrel. She was transferred urgently to the Catheterization Lab and at 23:33 underwent repeat angiography which revealed an in-stent total occlusion of the target site with presence of thrombus and TIMI 0 flow reported by the Angiographic Core Lab. Eptifibatide was administered. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. The initial CK and CKMB drawn on 11/12/2005 at 21:27 were 33 (nl 232, ratio <1) and 1 (nl 6, ratio <1) respectively. The CK peaked on 11/13/2005 at 09:35 at 1743 (ratio 8) with a CKMB of 105 (ratio 18). There was subsequent decline in both CK and CKMB levels. The site reported a Q wave MI. The ECG Core Lab reading of the ischemic event ECG tracings dated 11/12/2005 to 11/13/2005 reported new intermittent anterior T wave changes with new persistent ST-T changes of an evolving acute anterolateral/apical myocardial injury or infarction and no new Q waves. It further noted inadequate tracing quality due to severe artifact and variation in precordial lead placement. The ECG Core Lab reading of the ischemic event ECG tracings dated 11/13/2005 through 11/18/2005 reported new intermittent anterolateral/apical ST depressions and no new Q waves. It further noted inadequate tracing quality due to variation in precordial lead placement. The CEC ruled the event met the criteria for a non-Q wave MI after a review of the clinical data and the ECGs. A Discharge Summary noted that the post-revascularization course was complicated by hypotension, tachycardia and anemia. An echocardiogram revealed an EF of 45-50% with anterolateral hypokinesis. The patient was treated with beta-blockers and was transfused with 2 units of PRBCs for a hematocrit of 24.9% on 11/17/2005. She was subsequently discharged on 11/18/2005. Repeat angiography on 12/09/2005 for recurrent clinical symptoms without a functional ischemia study revealed a 31% in-lesion restenosis reported by the Angiographic Core Lab with the notation a patent study stent. In a narrative the site reported a 50% ostial narrowing of the LA, a diffusely diseased distal LAD and a 60% eccentric plaque in the mid-portion. The patient's medical regimen was intensified at this time and CABG surgery was planned. On 12/27/2005 the patient underwent CABG surgery with a LIMA to the mid LAD, and a pedicle graft to the 2nd OM, reported by the site as a target lesion/target vessel and a non-target vessel revascularization. The OR Report notes the LAD was grafted in its mid to distal segment where it was moderately diseased.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA 246 days post-procedure The patient is a 55 year-old man with a history of diabetes, hypertension, dyslipidemia, current smoking, and prior PCI in the 2nd OM in 2002 who presented with CCS Class IV angina. On 08/18/2005 at 16:12 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 2nd OM, noted by the site as a "de novo lesion" at time of enrollment. Bivalirudin was administered. The site reported the device "stent wires were frayed in the middle with struts sticking out;" therefore delivery was difficult. The Cardiac Catheterization Report noted that the first stent was damaged and withdrawn. A second assigned stent was advanced to the OM; however this was not deployed. The assigned stent was subsequently delivered to the 2nd OM with the use of a buddy wire and successfully deployed. The post-stent IVUS catheter was not able to cross the target lesion; therefore IVUS was not performed. There were no clinical sequelae. The Angiographic Core Lab reported a 55% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 08/19/2005 on ASA and clopidogrel. Protocol re-study on 04/21/2006 in the absence of recurrent angina or a functional ischemia study revealed a 75% focal body in-stent restenosis reported by the Angiographic Core Lab with the notation of a focal body in-stent restenosis, target lesion revascularization. The patient underwent repeat revascularization with balloon angioplasty of the 2nd OM.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA, Target Vessel Revascularization-PTCA 222 days post-procedure The patient is a 47 year-old man with a history of diabetes, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class IV angina. On 09/08/2005 at 13:50 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 28% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/09/2005 on ASA and clopidogrel. Protocol re-study on 04/18/2006 for recurrent clinical symptoms and a positive functional ischemia study on 03/27/2006 revealed a 68% proliferative in-stent restenosis reported by the Angiographic Core Lab. IVUS was performed. The patient underwent repeat revascularization with balloon angioplasty and placement of a CYPHER® stent in the mid LAD and balloon angioplasty of the 2nd diagonal according to the Cardiac Catheterization Flow Sheet.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-PTCA day of the procedure The patient is a 55 year-old man with a history of a MI on unk/unk/1999, PCI of a non-target vessel, dyslipidemia, hypertension, current smoking, and premature CAD in a first degree relative who presented with CCS Class IV angina. On 02/03/2006 at 11:15 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. The site reported a grade B dissection after pre-treatment. Bivalirudin was administered. (The last catheter was removed at 11:44.) There were no clinical sequelae. The Angiographic Core Lab reported a 41% final residual in-lesion stenosis with a grade C dissection, the presence of staining and TIMI 3 flow. The site reported the patient had a distal edge dissection and was returned to the Catheterization Lab for placement of a second stent according to the Interventional Catheterization Report. Upon arrival in the Lab at 12:31 the patient was experiencing chest pain, rated as a 4 on a scale of 1 to 10. Repeat angiography on 02/03/2006 at 12:38 for recurrent clinical symptoms without a functional ischemia study revealed a site reported 93% renarrowing of the target lesion. The Interventional Catheterization Report noted the mid LAD lesion is a branch point; flow through the vessel was reduced (TIMI 1); and confirmed a 93% pre-PTCA stenosis. The Angiographic Core Lab reported an 83% marginal in-stent renarrowing with no thrombus formation and TIMI 2 flow and noted residual dissection seen in the baseline final; significant lesion present in the distal edge of the stent; PCI and target lesion revascularization. The site reported the patient underwent balloon angioplasty of the proximal LAD, reported as a target vessel revascularization. The Interventional Catheterization Report however noted the patient underwent balloon angioplasty and stent placement in the mid LAD. In response to a query for further clarification concerning the location of the revascularization, the site reported the following information: repeat revascularization involved a distal edge dissection of the target lesion stent (CASS 12) and that the stent placed during the revascularization at the distal end of the target lesion stent, involved the mid territory of LAD as well as the proximal territory (CASS 12). The post-procedure course was uncomplicated and the patient was discharged on 02/04/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Vessel Revascularization-CABG 266 days post-procedure The patient is a 52 year-old man with a history of hypertension who presented with CCS Class IV angina. On 11/18/2005 at 08:36 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 45% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/19/2005 on ASA and clopidogrel. The site reported on 07/30/2006 the patient complained of a choking sensation, "recognized as an angina equivalent in this particular case." Repeat angiography on 08/08/2006 for recurrent clinical symptoms without a functional ischemia study revealed a 21% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent. A Cardiac Catheterization Report also noted a patent mid LAD stent, and reported an ostial 50%-60% stenosis of the left main, and a 40% lesion of the proximal CX. The Report further noted that IVUS reading in the LMT demonstrated a MLA <6 which indicates significant LMT narrowing. No revascularization was performed at this time and a surgical intervention was scheduled. On 08/11/2006 he underwent non-emergent CABG surgery with a LIMA to the LMCA and an SVG to the 1st OM.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-PTCA 97 days post-procedure The patient is a 77 year-old man with a history of dyslipidemia, hypertension, and former smoking who presented with CCS Class III angina. On 01/03/2006 at 14:03 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD and the stent was post-dilated with the stent balloon. The site reported a second assigned stent was placed for incomplete coverage of the lesion and noted the second stent jailed the diagonal which required balloon angioplasty. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "diffusely diseased LAD, regional plaques present proximal and distal to the segment of analysis." The post-procedure course was uncomplicated and the patient was discharged on 01/04/2006 on ASA and clopidogrel. On 04/07/2006 the patient was rehospitalized through the ER for recurrent angina and the site reported cardiac enzymes and ECG tracings were negative. Repeat angiography on 04/10/2006 for recurrent angina in the absence of a functional ischemia study revealed a 62% diffuse proliferative in-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization. An Interventional Catheterization Report noted an 80-90% in-stent restenosis with a patent stent in the 2nd diagonal. The patient underwent cutting balloon angioplasty with placement of one CYPHER® stent to the mid LAD and balloon angioplasty with placement of two overlapping CYPHER® stents in the proximal LAD.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Vessel Revascularization-PTCA 123 days post-procedure The patient is a 74 year-old man with a history of MI in 1992, CABG surgery in 1998 involving the target vessel, dyslipidemia, and hypertension who presented with CCS Class IV angina. On 06/26/2006 at 18:30 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal RCA. The Angiographic Core Lab reported on a lesion in the mid RCA with an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The patient developed a pseudoaneurysm at the right femoral artery puncture sight following the procedure requiring surgical repair, transfusion of 8 units PRBCs, and prolonged hospitalization. The patient was discharged on 07/02/2006 on ASA and clopidogrel and coumadin was continued for a history of atrial fibrillation. The site reported the patient was admitted on 10/20/2006 to a non-study site for chest pain. A stress test performed at that site was negative. Repeat angiography on 10/27/2006 for recurrent clinical symptoms and a negative functional ischemia study revealed a 14% in-lesion restenosis reported by the Angiographic Core Lab with the notation remote target vessel revascularization of the distal RCA. A Procedure Report noted an 80% stenosis of the mid RCA. The patient underwent repeat revascularization with balloon angioplasty and placement of a drug-eluting stent in the mid RCA.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Emergent Target Lesion Revascularization-CABG day of procedure The patient is a 70 year-old man with a history of diabetes, dyslipidemia, hypertension, former smoking and a MI on 05/16/2006 who presented with CCS Class II angina and a positive stress test. On 06/07/2006 at 09:02 he underwent the index procedure with pre-treatment balloon angioplasty of the mid RCA; however there was a site reported grade F dissection with abrupt closure, a total occlusion, TIMI 0 flow, recurrent angina, and ischemic ECG changes after pre-treatment. Three assigned stents were placed to cover the dissection. The site reported a final residual total occlusion with a grade D dissection and TIMI 0 flow. An Interventional Catheterization Report noted an attempt to re-open the RCA, "but acute occlusion developed requiring emergent CABG." The Angiographic Core Lab reported a final residual total occlusion with a grade F dissection, staining, TIMI 0 flow and no thrombus with the notation "mid RCA high grade ulcerative stenosis, long "F" dissection with abrupt closure, 4 stents, not successful with occlusion of RCA distal, diffuse dye, urgent CABG." The patient was transported to the OR for emergent CABG with placement of a SVG to the diagonal and CX margins as a bridge graft and SVG to the distal RCA and PDA as a bridge graft. An Operative Report noted the RCA had acutely occluded beyond the PDA branch and the patient had ongoing ST segment elevation chest pain in the catheterization lab. A severe coagulopathy in the OR was treated was fresh frozen plasma, platelets, PRBCs and cryoprecipitate. The pre-procedure CK drawn on 06/07/2006 at 06:05 was 99 (nl 397, ratio <1) with a CKMB of 2.3 (nl 6.3, ratio <1). No additional cardiac enzymes were measured. The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. On 06/09/2006 the patient returned to the OR for an urgent exploratory sternal surgery after developing chest tube drainage of 900 cc over 60-90 minutes. The discharge summary noted a large amount of clot along the anterior and inferior walls of the heart was evacuated, but no exact bleeding sites were found. He then developed hypoxia and respiratory failure, probably related to fluid overload, and was eventually extubated on 06/10/2006. On 06/10/2006, the patient also experienced altered mentation and agitation which worsened into sleepiness and a metabolic encephalopathy. A head CT scan was negative. A discharge summary reported the metabolic encephalopathy was due to vitamin B-12 deficiency and two surgical procedures with anesthesia. The mental status changes were resolved by the time of transfer to a general unit on 06/14/2006. The post-procedure course was also complicated by atrial fibrillation, which was converted to sinus rhythm after IV amiodarone treatment. The patient was discharged on 06/19/2006 on ASA.

Site	Patient	Treatment Group	Narrative
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Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-CABG 90 days post-procedure The patient is a 48 year-old man with a history of current smoking, diabetes, dyslipidemia and hypertension who presented with CCS Class II angina. On 11/01/2005 at 13:23 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. Eptifibatide was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/02/2005 on ASA and clopidogrel. Repeat angiography on 01/24/2006 at a non-study hospital for recurrent clinical symptoms without a positive functional ischemia study revealed a 57% intra-stent restenosis reported by the Angiographic Core Lab. The site reported an 80% restenosis of the target lesion with the notation of progressive cardiac disease. No revascularization was performed at this time. In a query response the site reported a Discharge Summary for this admission is not available. On 01/30/2006 he underwent non-emergent CABG surgery with bypass grafts to the proximal LAD, the R-PDA and the distal CX. The patient was discharged on 02/07/2006.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA 181 days post-procedure The patient is a 75 year-old woman with a history of prior PCI with stenting of the R-PDA in January 2002, diabetes, dyslipidemia and hypertension who presented with CCS Class III angina. On 04/26/2006 at 14:15 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. Bivalirudin was administered and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/27/2006 on ASA and clopidogrel. Repeat angiography on 10/24/2006 for recurrent angina without a functional ischemia study revealed a 62% intra-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. An Interventional Catheterization Report summary noted a 70% focal area of in-stent restenosis that appeared to involve the distal end of the stent placed on 04/26/2006 with some extension into the previously placed stent in the R-PDA. The patient underwent balloon angioplasty with placement of a CYPHER® stent to the mid RCA, reported by the site as a target lesion revascularization.
----------		Taxus	Non-Q wave MI day of procedure The patient is a 68 year-old man with a history of hypertension who presented with a positive functional ischemia study. On 05/31/2006 at 13:29 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK drawn on 05/31/2006 at 09:24 was elevated at 226 (nl 174, ratio 1.3) with a CKMB of 7 (nl 7, ratio 1). The CK peaked post-procedure on 06/01/2006 at 07:10 at 402 (ratio 2.3) with a CKMB 32 (ratio 4.6). The site reported a non-Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 06/01/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non Q-wave MI day of procedure The patient is a 66 year-old man with a history of current smoking, dyslipidemia, hypertension, a MI in 05/1993, and CABG surgery of the target vessel on 05/19/1993 who presented with a positive functional ischemia study. On 11/02/2005 the patient underwent the index procedure with pre-treatment balloon angioplasty and delivery of one assigned stent in the proximal CX. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis, a total occlusion of a side branch, with no dissection and TIMI 3 flow. The pre-procedure CK was not performed; however the CKMB drawn on 11/02/2005 at 09:00 was 3 (nl 5.5, ratio <1). The CK and CKMB drawn on 11/02/2005 at 17:59 were 480 (nl 294, ratio 1.6) and 42.9 (ratio 8). The CK peaked on 11/02/2005 at 21:00 at 912 (nl 294, ratio 3.1) with a CKMB of 78.6 (ratio, 14.3). The CK drawn on 11/03/2005 at 06:05 was 756 (ratio 2.6) and the CKMB was not done. Repeat angiography on 11/03/2005 at 14:40 for a site reported sudden elevation of CK without a functional ischemia study revealed a 23% in-lesion renarrowing reported by the Angiographic Core Lab with the notation of a patent study stent. No repeat revascularization was performed at this time. The patient was discharged on 11/04/2005 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Q wave MI day of procedure The patient is a 59 year-old man with a history of former smoking, dyslipidemia, and hypertension who presented with a positive functional ischemia study. On 04/19/2006 at 11:00 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal CX. According to the Cardiac Catheterization Report there was a large grade D spiral dissection following pre-treatment and noted abrupt closure. The site further reported a side branch occlusion, no/slow reflow, a 25% stenosis, and TIMI 2 flow with ischemic ECG changes following stenting. Abciximab was administered. The second assigned stent was successfully placed distal to the first assigned stent. The third assigned stent was unable to cross the lesion and was withdrawn. Subsequently, two additional assigned stents were placed distal to the 1st stent in the 3rd OM, which successfully sealed the dissection. The stents were post-dilated. The Angiographic Core Lab reported abrupt closure and a 32% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK drawn on 04/19/2006 at 07:30 was elevated at 246 (nl 180, ratio 1.4) with a CKMB of 5.8 (nl 15, ratio <1). The CK peaked post-procedure on 04/20/2006 at 21:00 at 2445 (ratio 14) with a non-concurrent CKMB peak on 04/20/2006 at 10:00 of 483.5 (ratio 32). The site reported a non-Q wave MI and noted the patient experienced post-procedure right shoulder pain. A bedside ECHO showed no pericardial effusion and "no evidence of stent thrombosis." The ECG Core Lab reported a new posterior Q wave MI with new major intermittent inferoposterolateral ST elevations. The patient was discharged on 04/21/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Lesion Revascularization-PTCA, Target Vessel Revascularization-PTCA 119 days post-procedure The patient is a 78 year-old man with a history of dyslipidemia, hypertension, and former smoking who presented with CCS Class III angina. On 04/24/2006 at 12:52 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. An Interventional Catheterization Report noted a significant plaque shift into the ostium of the 2nd diagonal resulting severe stenosis following placement of the first stent. Balloon angioplasty of the lesion resulted in a dissection. The site reported abrupt closure or threatened abrupt closure with ischemic ECG changes, a grade E dissection, an 80% worst stenosis, no/slow reflow, and a side branch occlusion. The Angiographic Core Lab noted a significant residual diagonal lesion following stent placement and reported a grade C dissection was treated with placement of a second assigned stent, which overlapped the first stent by <2mm. The Core Lab further reported a 40% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/25/2006 on ASA and clopidogrel. Repeat angiography on 08/21/2006 for recurrent angina without a functional ischemia study revealed a 69% intra-stent restenosis reported by the Angiographic Core Lab with the notation that the stenosis was at the site of a bifurcation and ostium of the 1st diagonal. It further reported a target lesion revascularization with kissing balloon angioplasty and placement of one new stent in the mid LAD. The site reported a 30% in-stent stenosis of the mid LAD. A Cardiac Catheterization Report noted an 80% in-stent stenosis of the 2nd diagonal. The patient underwent balloon angioplasty with placement of a CYPHER® stent in the mid LAD just distal to the baseline stent and balloon angioplasty to the 2nd diagonal.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-PTCA, Target Vessel Revascularization-PTCA 101 days post-procedure The patient is a 64 year-old man with a history of dyslipidemia, current smoking, CAD in a 1st degree relative, and a MI in 1998 who presented with CCS Class IV angina and a recent positive functional ischemia study. On 02/28/2006 at 09:26 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/01/2006 on ASA and clopidogrel. The patient presented to the ER on 06/08/2006 with chest pain and was rehospitalized according to a Discharge Summary. Repeat angiography on 06/09/2006 for recurrent angina without a functional ischemia study revealed an 84% marginal in-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization with placement of one CYPHER® stent from the distal CX to the 2nd OM and PTCA in the L-PDA. A Catheterization Procedure Log dated 06/09/2006 noted balloon angioplasty with drug-eluting stent placement in the distal CX and balloon PDA of CX. The patient was discharged on 06/10/2006 according to the Summary.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-CABG 190 days post-procedure The patient is a 60 year-old woman with a history of dyslipidemia and hypertension who presented with CCS Class III angina. On 09/13/2005 at 09:12 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal CX and the stent was post-dilated. Post-stenting was a site reported grade B dissection and further noted that the proximal portion of the CX appeared torn with an intraluminal flap. A second assigned stent was placed proximal to the first stent and post-dilated with the stent balloon. There were no clinical sequelae. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/14/2005 on ASA and clopidogrel. On 03/20/2006 the patient was rehospitalized for recurrent angina. Repeat angiography on 03/20/2006 for recurrent clinical symptoms without a positive functional ischemia study revealed a 92% marginal in-stent restenosis reported by the Angiographic Core Lab. The Discharge Summary noted a "highly critical" ostial stenosis of the CX. No revascularization was performed at this time according the Cardiac Catheterization Report. On 03/22/2006 she underwent non-emergent CABG surgery with a SVG to the OM, a LIMA to the LAD and a SVG to the RCA.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Vessel Revascularization-PTCA 238 days post-procedure The patient is a 53 year-old man with a history of former smoking, dyslipidemia, hypertension, premature CAD in a first degree relative, PCI of a non-target vessel on an unknown date, and CABG surgery of the target vessel in 03/1995 who presented with CCS Class II stable angina. On 08/09/2005 at 09:40 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. Abciximab was administered. After stenting there was a site reported grade F dissection, an intimal flap, no/slow reflow, a 100% worst stenosis and TIMI 0 flow. Angina was also present at this time. The Cardiac Catheterization report noted there was a 0% stenosis after stenting but upon balloon pullback no flow was present distally. Balloon angioplasty restored the flow; however a "minimal opening" was noted in the LIMA, possibly related to a post-stenting plaque shift. This required the administration of intracoronary nitroglycerin and placement of two additional assigned stents in the LIMA to the proximal LAD. The Angiographic Core Lab reported a 7% final residual in-lesion stenosis with no dissection and TIMI 3 flow. It also reported a 24% final residual in-lesion stenosis with no dissection and TIMI 3 flow of a lesion in the LIMA to the mid LAD with the notation of wire dissection of LIMA, bailout with study stent with good final result. The post-procedure course was uncomplicated and the patient was discharged on 08/10/2005 on ASA and clopidogrel. Protocol re-study on 04/04/2006 without recurrent clinical symptoms and with a negative functional ischemia study (09/28/2005) revealed a 33% in-lesion restenosis reported by the Angiographic Core Lab with the notation of moderate neointimal hyperplasia. The Cardiac Catheterization Report noted a 60-70% narrowing and haziness within the exit portion of the left main coronary artery, a patent LIMA to the LAD, a 50% mid-LIMA in-stent stenosis and a patent study sent within the LAD. It also noted a critical 95-99% lesion in the CX and additional chronic occlusive disease in the RCA and ostial LAD. The patient underwent repeat revascularization with direct stenting using a CYPHER® stent in the left main coronary artery and balloon angioplasty and placement of a CYPHER® stent in the proximal CX, reported by the site as a non-target vessel revascularization.

Site	Patient	Treatment Group	Narrative
		Endeavor	Target Vessel Revascularization-PTCA 88 days post-procedure The patient is a 71 year-old man with a history of former smoking, diabetes, and dyslipidemia who presented with CCS Class IV angina and a positive functional ischemia study. On 08/18/2005 at 09:06 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st diagonal. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the ramus (confirmed) with a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 08/19/2005 on ASA and clopidogrel. Repeat angiography on 11/14/2005 for recurrent clinical symptoms without a functional ischemia study revealed a 19% in-lesion restenosis reported on a lesion in the ramus by the Angiographic Core Lab with the notation of a patent study stent and an ostial lesion of a side branch, PCI of the ostium, remote target lesion revascularization. The Cardiac Catheterization Report noted just at the proximal edge of a widely patent stent there was a diagonal side branch with a 90% eccentric lesion at the ostium. The patient underwent repeat revascularization with balloon angioplasty of the 1st diagonal.
		Taxus	Target Lesion Revascularization-PTCA 105 days post-procedure The patient is a 68 year-old woman with a history of diabetes, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class II angina and a positive functional ischemia study. On 12/07/2005 at 09:38 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 5% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/08/2005 on ASA and clopidogrel. Repeat angiography on 03/22/2006 for recurrent clinical symptoms with a positive functional ischemia study revealed a 52% intra-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD.

Site	Patient	Treatment Group	Narrative
----------	----------	Taxus	Target Lesion Revascularization-PTCA 86 days post-procedure The patient is a 64 year-old woman with a history of diabetes, dyslipidemia, hypertension, and premature CAD in a 1st degree relative who presented with CCS Class I angina and a positive functional ischemia study. On 04/24/2006 at 16:12 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD and the stent was post-dilated. The site reported a side branch occlusion at the ostium of the diagonal during the procedure that was treated with balloon angioplasty. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/25/2006 on ASA and clopidogrel. Repeat angiography on 07/19/2006 for recurrent angina and without a functional ischemia study revealed a site reported 98% stenosis of the target lesion. The Angiographic Core Lab reported a 72% proliferative in-stent restenosis and noted a target lesion revascularization. The patient underwent repeat revascularization of the mid LAD with placement of a CYPHER® stent.
----------	----------	Endeavor	Target Lesion Revascularization-PTCA 245 days post-procedure The patient is a 45 year-old man with a history of dyslipidemia and hypertension who presented with a recent positive functional ischemia study. On 08/03/2005 at 10:14 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 08/04/2005 on ASA and clopidogrel. Protocol re-study on 04/05/2006 for recurrent clinical symptoms without a functional ischemia study revealed a 52% margin in-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization. The Cardiac Catheterization Report noted a 60 to 70% stenosis just proximal to the previously placed stent in the mid LAD, and a 30 to 40% in-stent restenosis approximately 5 mm into the stent. The report further noted intravascular ultrasound guided stenting of the LAD with a CYPHER® stent which overlapped the initial stent by 5 mm and then went more proximal into the LAD.

Site Patient	Treatment Group	Narrative
----------	Taxus	Target Vessel Revascularization-PTCA 123 days post-procedure The patient is a 58 year-old man with a history of MI on 11/10/2004, non-target vessel PCI, dyslipidemia, hypertension, current smoking, and premature CAD in a first degree relative who presented with CCS Class II angina and a recent positive functional ischemia study. On 09/19/2005 at 08:55 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st diagonal. There were no clinical sequelae. The Angiographic Core Lab reported a 30% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/20/2005 on ASA and ticlopidine. Repeat angiography on 01/20/2006 for recurrent clinical symptoms without a functional ischemia study revealed a 39% marginal in-stent restenosis reported by the Angiographic Core Lab with the notation a target lesion revascularization. The Cardiac Catheterization Report dated 01/20/2006 noted a patent stent in the diagonal branch and reported a 75% eccentric ostial lesion narrowing just proximal to the target stent. According to a query response the IVUS reading was positive. The patient underwent repeat revascularization with balloon angioplasty and placement of a CYPHER® stent in the 1st diagonal.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Vessel Revascularization-PTCA 233 days post-procedure The patient is a 63 year-old woman with a history of an MI on an unknown date, prior PCI to a non target vessel, diabetes, dyslipidemia, hypertension and premature CAD in a 1st degree relative who presented with CCS Class IV angina. On 01/17/2006 at 15:09 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 01/18/2006 on ASA and clopidogrel. Repeat angiography on 09/07/2006 for recurrent angina with a positive functional ischemia study revealed a 25% in-lesion restenosis reported by the Angiographic Core Lab with the notation of moderate neointimal hyperplasia. A Cardiac Catheterization Report noted 50 to 70% stenosis in the proximal LAD followed by more mid vessel stented segment and a more distal vessel 50% stenosis. The Report further noted placement of a stent in the proximal LAD and the distal LAD. The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Lesion Revascularization-PTCA 250 days post-procedure The patient is a 74 year-old woman with a history of dyslipidemia, hypertension, and PCI of a non-target vessel who presented with CCS Class III stable angina. On 10/06/2005 at 12:31 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal CX. Bivalirudin was administered. The stent was post-dilated and there were no clinical sequelae. The Angiographic Core Lab reported a 30% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/07/2005 on ASA and clopidogrel. Protocol re-study on 06/13/2006 in the absence of recurrent clinical symptoms or a functional ischemia study revealed a 76% marginal in-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization (procedure not shown). The Cardiac Catheterization Report noted a 95% to 99% severe in-stent restenosis involving the CX stent margin first several millimeters of the stent. The site confirmed the IVUS reading was clinically significant. The patient underwent successful repeat revascularization with balloon angioplasty of the proximal CX.
----------	----------	Taxus	Non-Q wave MI day of procedure The patient is a 66 year-old man with a history of former smoking, dyslipidemia, and hypertension who presented with CCS Class II angina and a positive functional ischemia study. On 02/27/2006 at 14:09 the patient underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. There were no clinical sequelae. The site reported a 0% final residual stenosis with no dissection and TIMI 3 flow. The Angiographic Core Lab reported on a lesion in the mid LAD, revealing a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 02/27/2006 at 08:35 were 188 (nl 230, ratio <1) with an elevated CKMB of 5.6 (nl 5, ratio 1.1). Only two sets of post-procedure cardiac enzymes were drawn. The highest CK was drawn on 02/28/2006 at 04:00 at 2478 (ratio 11) with a CKMB of 347.9 (ratio 70). The site reported a non-Q wave MI and confirmed that the post-procedure ECG was not performed. Therefore, an ECG Core Lab reading will not be forthcoming. The patient was discharged on 02/28/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Cardiac Death 137 days post-procedure The patient was a 61 year-old man with a history of an MI in 1999, dyslipidemia, and current smoking who presented with CCS Class II angina. On 04/13/2006 at 11:15 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal RCA. Bivalirudin, enoxaparin, and eptifibatide were administered. The site narrative reported after pre-dilatation there was a grade A dissection and transient no-reflow that was reversed with intracoronary nitroglycerin and adenosine. The Angiographic Core Lab reported on a lesion in the mid RCA with an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/14/2006 on ASA and clopidogrel. An Emergency Department Treatment Record stated the patient collapsed at home after complaints of not feeling well on 08/28/2006 at around 07:30. His wife attempted resuscitation until EMS arrived and found him in a fine atrial fibrillation pattern. EMS intubated and shocked the patient who went into asystole and was treated with atropine, epinephrine, and sodium bicarbonate. He briefly had an organized rhythm with a faint pulse; however he arrived in the Emergency Department with no pulse or spontaneous respirations. Treatment efforts in the Emergency Department resulted in pulseless ventricular tachycardia and medical treatment failed with the patient becoming asystolic. He was pronounced dead at 11:48 and the cause of death was listed as cardiac arrest. The site reported the categorical cause of death was cardiac and no autopsy was performed.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Vessel Revascularization-PTCA 264 days post-procedure The patient is a 57 year-old man with a history of prior MI in 02/2005, prior PCI in a non-target vessel, diabetes, dyslipidemia, and hypertension who presented with CCS Class IV stable angina. On 11/30/2005 at 13:08 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 3rd OM. There were no clinical sequelae. The Angiographic Core Lab reported a 30% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/01/2005 on ASA and clopidogrel. Repeat angiography on 08/21/2006 for recurrent angina without a functional ischemia study revealed a 33% in-lesion restenosis reported by the Angiographic Core Lab with a notation of a patent study stent and an unchanged proximal edge narrowing; remote TVR of mid CX with gap approximately 5 mm to study stent. An Interventional Catheterization Report noted a widely patent target lesion and a 70% lesion in the proximal CX that was analyzed with a RADI wire that resulted in a 0.79 FFR. The patient underwent successful balloon angioplasty and CYPHER® stent placement in the proximal CX.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-Q wave MI day of procedure The patient is a 72 year-old woman with a history of dyslipidemia, hypertension, premature CAD in a first degree relative, and PCI in a non-target vessel in 09/2000 who presented with CCS Class II stable angina. On 05/03/2006 at 15:35 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. Bivalirudin was administered. The Cardiac Catheterization Report noted that the stent balloon became lodged inside the stent and could not be retrieved. After multiple manipulations with the guide catheter in the aorta the stent balloon was successfully removed and balloon angioplasty was performed; however a distal grade A dissection was noted with incomplete filling of the LAD apex. The site reported an abrupt closure or threatened abrupt closure with a 0% worst stenosis and TIMI 3 flow and further reported a 0% final residual stenosis with a grade A dissection and TIMI 3 flow. In response to a query, the Angiographic Core Lab reported a worst TIMI 3 flow in-stent and a worst TIMI 0 flow in the distal LAD and a 26% final residual in-lesion stenosis with abrupt closure, a grade F dissection, staining and TIMI 3 flow. Post-procedure, the patient experienced angina and was started on abciximab and nitroglycerin infusions. The pre-procedure CK and CKMB drawn on 05/03/2006 at 15:24 were 38 (nl 170, ratio <1) and 2 (nl 7, ratio <1) respectively. The CK peaked on 05/04/2006 at 04:30 at 341 (ratio 2.01) with a CKMB of 38 (ratio 5.4). The site reported a non-Q wave MI. The ECG Core Lab reported the ECG tracings were not interpretable due to severe artifact. The site was unable to provide another pre-procedure ECG. The patient was discharged on 05/05/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Vessel Revascularization – PTCA 238 days post-procedure The patient is a 63 year-old man with a history of PCI of a non-target vessel, dyslipidemia, hypertension, and premature CAD in a 1st degree relative who presented with CCS Class III angina. On 06/12/2006 at 14:18 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. Eptifibatide and enoxaparin were administered and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/13/2006 on ASA and clopidogrel. Repeat angiography on 02/05/2007 for recurrent exertional angina and dyspnea and without a functional ischemia study revealed a 50-60% narrowing in the mid RCA stent and an 80% lesion in the R-PDA according to a faxed Interventional Catheterization Report. The Angiographic Core Lab report is not available at this time. The patient underwent repeat revascularization with balloon angioplasty and placement of a CYPHER® stent in the R-PDA.
----------		Endeavor	Non-cardiac Death, Stroke 149 days post-procedure The patient was a 78 year-old woman with a history of PCI and stenting of the proximal LAD in 1998 and CABG surgery on an unknown date who presented with CCS Class III angina. On 10/24/2005 at 12:41 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/25/2005 on ASA and clopidogrel. The site reported the patient was rehospitalized on 03/22/2006 for extreme hypertension with atrial fibrillation and was diagnosed with a stroke. The patient never regained consciousness and the family withdrew care. She subsequently died later in the day on 03/22/2006. The death certificate reported the cause of death as hemorrhagic CVA with chronic anti-coagulation. The site confirmed that no additional information is forthcoming.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-Q wave MI day of procedure The patient is a 50 year-old woman with a history of former smoking, dyslipidemia, hypertension, premature CAD in a first degree relative, a MI in 1997, and PCI of a non-target vessel who presented with CCS Class IV angina and a negative functional ischemia study. On 05/17/2006 at 14:30 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA and the stent was post-dilated. There was a site reported grade B dissection after stent placement which was covered with one additional assigned stent place proximal to the first stent and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were not done. Only two sets of post-procedure cardiac enzymes were drawn. The CK and CKMB drawn on 05/17/2006 at 21:45 were 103 (nl 130, ratio <1) and 2.6 (nl 4, ratio <1). On 05/18/2006 at 05:50 the CK and CKMB were 299 (ratio 2.3) and 13.3 (ratio 3.3) respectively. The site reported an asymptomatic non-Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 05/18/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-CABG 245 days post-procedure The patient is a 60 year-old woman with a history of diabetes, dyslipidemia, hypertension, premature CAD in a first degree relative, and PCI of a non-target vessel on an unknown date who presented with CCS Class III angina. On 05/31/2005 at 13:06 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 05/31/2005 at 12:09 were 56 (nl 204, ratio <1) and 1.9 (nl 3.3, ratio <1) respectively. The CK peaked on 06/01/2005 at 14:30 at 94 (ratio <1) with a CKMB of 13.5 (ratio 4.1). The site reported the patient's hospitalization was prolonged due to an elevation of cardiac enzymes. The ECG Core Lab reported on ECG tracings with inadequate tracing quality and noted no new major ST-T abnormalities and no new Q waves with the notation of apparent poor R wave progression, attributable to lead placement. The patient was discharged on 06/01/2005 on ASA and clopidogrel. Protocol re-study on 01/31/2006 for recurrent clinical symptoms without a positive functional ischemia study revealed a 70% marginal in-stent restenosis reported by the Angiographic Core Lab with the notation of left main disease noted during the procedure, LAD- CD analyzed, type 1B in-stent restenosis in the proximal edge. The Cardiac Catheterization Report noted significant 60-80% stenosis of the left main coronary artery, a 20% in-stent restenosis of the distal CX, and a "widely patent" stent in the LAD. On 01/31/2006 she underwent CABG surgery with a LIMA to the LAD and a SVG to the OM of the CX. The site reported CABG surgery of the left main coronary artery, identified as a non-target vessel; however the CEC determined the event met the criteria for a clinically driven target lesion revascularization.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Lesion Revascularization-PTCA 149 days post-procedure
			The patient is a 67 year-old man with a history of former smoking, dyslipidemia, and hypertension and who presented with CCS Class II stable angina and a positive functional ischemia study. On 07/05/2005 at 14:16 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of two assigned study stents in the proximal RCA; the second stent was placed distal to the first stent and the stents were post-dilated. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure was uncomplicated and the patient was discharged on 07/06/2005 on ASA and clopidogrel. Repeat angiography on 12/01/2005 for recurrent angina with a positive functional ischemia study revealed an 83% intra-stent restenosis reported by the Angiographic Core Lab. IVUS was performed. The patient underwent repeat revascularization with balloon angioplasty of the proximal RCA.
----------	----------	Taxus	Non-cardiac Death 182 days post-procedure
			The patient was a 69 year-old man with a history of smoking and CCS Class III angina. On 08/04/2005 the patient underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. Post-stenting balloon angioplasty was performed. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow in the mid LAD. The patient was discharged on 08/08/2005 on ASA and clopidogrel. On 10/08/2005 the patient was hospitalized and diagnosed with pulmonary fibrosis then transferred to a nursing home on 10/19/2005 with a guarded to poor prognosis. According to a nursing home's Progress Notes, on 02/02/2006 about 07:15 the patient was found unresponsive without vital signs by the nursing home staff and a 911 was called. CPR was initiated and the paramedics were called; however despite medical efforts the patient expired at 07:39. The site reported the official cause of death is unknown and listed the categorical cause of death as non-cardiac. No autopsy was performed and a death certificate is not available.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Lesion Revascularization-PTCA 246 days post-procedure The patient is a 70 year-old man with a history of diabetes, dyslipidemia, hypertension, and former smoking who presented with a recent positive functional ischemia study. On 05/24/2006 at 11:08 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. The site reported a grade A edge dissection during the procedure that was treated with a second assigned stent placed proximal to the target lesion. The stents were post-dilated. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/26/2006 on ASA and clopidogrel. Protocol re-study on 01/25/2007 in the absence of recurrent angina or a functional ischemia study revealed a 66% intra-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. A Coronary Intervention Report from the site noted an 80% lesion in the proximal LAD. The FFR pre-revascularization average was 0.65. The patient underwent repeat revascularization with placement of a CYPHER® stent in the proximal LAD.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Non-cardiac Death 27 days post-procedure The patient was an 85 year-old woman with a history of dyslipidemia, hypertension and former smoking who presented with CCS Class III angina and a positive functional ischemia study. On 04/28/2006 at 10:04 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. During evaluation for the procedure, an abnormal chest x-ray noted a soft tissue mass in the left paratracheal upper lobe region, which was probably anterior mediastinal in origin. A CT scan was performed, but the results were not available. The post-procedure course was uncomplicated and the patient was discharged on 04/29/02006 on ASA and clopidogrel. On 05/21/2006 the patient was admitted to the ICU in the enrolling facility with sudden onset of massive hemoptysis status post lung biopsy. A History and Physical noted the patient was recently diagnosed with non-small cell lung carcinoma on the basis of a bronchoscopy with endobronchial biopsy a week prior to admission. The patient had not begun any cancer treatment. Her hematocrit was 22.7% and she was transfused with one unit of PRBCs on 05/21/2006. The site was unable to provide a discharge summary for this admission. The patient expired on 05/25/2006. The site reported the official cause of death was respiratory failure and the categorical cause of death was non-cardiac. An autopsy was not performed. A Death Certificate reported the immediate causes of death were pulmonary hemorrhage and non-small cell lung cancer.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA, Target Vessel Revascularization-PTCA 216 days post-procedure The patient is a 54 year-old man with a history of former smoking, dyslipidemia, hypertension, a MI in 2002, and CABG surgery of the target vessel in 01/04/2002 who presented with CCS Class II stable angina and a positive functional ischemia study. On 06/21/2005 at 10:55 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/22/2005 on ASA and clopidogrel. Repeat angiography on 01/18/2006 for recurrent clinical symptoms without a functional ischemia study revealed a 47% in-lesion restenosis reported by the Angiographic Core Lab with the notation moderate neointimal hyperplasia. IVUS was performed; however the site was unable to provide an IVUS interpretation. No revascularization was performed at this time. The patient was rehospitalized on 01/23/2006 and a re-study that day revealed a 53% focal body in-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization. On 01/23/2006 he underwent repeat revascularization with balloon angioplasty and placement of one CYPHER® stent in the mid LAD and one CYPHER® in the protected ostial left main, reported by the site as a target lesion revascularization and a target vessel revascularization.

Site Patient	Treatment Group	Narrative
----------	Taxus	Non-Q wave MI day of procedure, Target Vessel Revascularization-PTCA 266 days post-procedure The patient is a 69 year-old man with a history of former smoking, dyslipidemia, hypertension, and PCI in the distal LAD on 10/29/1998 who presented with CCS Class IV angina. On 08/31/2005 at 12:13 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. Bivalirudin was administered and there were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 08/31/2005 at 10:05 were 71 (nl 232, ratio <1) and 1 (nl 6, ratio <1) respectively. The CK peaked on 09/01/2005 at 09:12 at 977 (ratio 4.2) with a CKMB of 7 (ratio 1.2). The site reported a non-Q wave MI without ECG changes and confirmed there were no episodes of chest pain post-procedure. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 09/01/2005 on ASA and clopidogrel. Protocol re-study on 05/18/2006 in the absence of recurrent angina or a functional ischemia study revealed a 19% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent. No revascularization was performed at that time. A re-study on 05/24/2006 for an unknown clinical status without a functional ischemia study revealed a 16% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent and remote target vessel revascularization, mid LAD and non-target lesion revascularization, distal RCA. IVUS was performed; however the site was unable to provide an IVUS interpretation. The site reported a 75% mid LAD lesion and a 90% lesion of the distal RCA. The patient underwent repeat revascularization with balloon angioplasty and placement of one CYPHER® stent in both the mid LAD and the distal RCA.

Site Patient	Treatment Group	Narrative
----------	Taxus	Target Vessel Revascularization-PTCA 240 days post-procedure The patient is a 52 year-old man with a history of current smoking and hypertension who presented without angina or a functional ischemia study. On 09/12/2005 at 12:23 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 6% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/13/2005 on ASA and clopidogrel. Protocol re-study on 05/05/2006 for an unknown clinical status without a functional ischemia study revealed a 10% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent. IVUS was performed; however the site was unable to provide an IVUS interpretation. No revascularization was performed at that time. Repeat angiography on 05/10/2006 for an unknown clinical status revealed an 11% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent and non-target lesion revascularization of 1st OM. The site reported an 80% lesion just proximal to target site. An Interventional Catheterization Report noted an 80% de novo lesion in the R-PDA and an 80% de novo lesion in the 1st OM. The patient underwent repeat revascularization with balloon angioplasty and placement of one drug-eluting stent in both the R-PDA and the 1st OM.

Site Patient	Treatment Group	Narrative
----------	Taxus	Target Vessel Revascularization-PTCA 188 days post-procedure The patient is a 51 year-old man with a history of current smoking, dyslipidemia, hypertension, PCI and stenting of the 1st OM on 12/14/2000, and CABG surgery of the target vessel on 08/10/2001 who presented with CCS Class IV angina and a positive functional ischemia study. On 10/12/2005 at 10:17 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the L-PDA. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/13/2005 on ASA and clopidogrel. At the 6 month contact the patient complained of worsening chest pain. Repeat angiography on 04/18/2006 for recurrent clinical symptoms without a functional ischemia study revealed an 18% in-lesion restenosis reported by the Angiographic Core Lab with the notation intervention non-target lesion of the 1st OM through a SVG. The site reported a 90% lesion of the 1st OM and the patient underwent repeat revascularization with balloon angioplasty and placement of a drug-eluting stent in the 1st OM. The CEC ruled the event met the criteria for a clinically driven target vessel revascularization.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Non-Q wave MI 70 days post-procedure The patient is an 80 year-old man with a history of prior PCI of the target vessel on 04/04/2001, dyslipidemia, hypertension, and former smoking who presented with CCS Class II angina and a positive functional ischemia study. On 03/20/2006 at 13:33 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/21/2006 on ASA and clopidogrel. The patient presented in the ER of a non-study site on 05/29/2006 for a site reported non-Q wave MI. The initial CK on 05/29/2006 at 10:36 was 50 (nl 261, ratio <1) with a CKMB of 2.2 (nl 4.9, ratio<1). On 05/29/2006 at 13:42 the CK was 252 (ratio <1) with a CKMB of 31.7 (ratio 6.5). A final set of enzymes was drawn after the patient transferred to the study site on 05/30/2006 at 08:23 with a CK of 548 (nl 232, ratio 2.4) with a CKMB of 64 (nl 6, ratio 10.7). The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. Repeat angiography on 05/30/2006 for recurrent angina in the absence of a functional ischemia study revealed a 38% in-lesion restenosis reported by the Angiographic Core Lab with the notation unchanged closure of 1st diagonal. No intervention was performed.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Non-Q wave MI, Target Lesion Revascularization-PTCA, Late Stent Thrombosis 171 days post-procedure The patient is a 54 year-old woman with a history of dyslipidemia, hypertension, and current smoking who presented with CCS Class II angina. On 05/05/2006 at 12:39 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/06/2006 on ASA and clopidogrel. On 10/23/2006 the patient was admitted for a site reported non-Q wave MI. The patient experienced acute onset chest pressure and was found to be in complete heart block. She went into cardiogenic shock and required intubation and a temporary pacemaker. The initial CK on 10/23/2006 at 12:50 was 1640 (nl 215, ratio 7.6) with a CKMB of 181 (nl 6, ratio 30.2). The CK peaked on 10/23/2006 at 21:10 at 2882 (ratio 13.4) with a concurrent CKMB peak of 291 (ratio 48.5). The final CK reported on 10/24/2006 at 05:10 was 2346 (ratio 10.9) with a CKMB of 217 (ratio 36.2). The ECG Core Lab reported new major intermittent inferior and posterior hyperacute T waves, intermittent infero-posterolateral ST elevations, and no new Q waves and noted inadequate tracing quality with severe artifact. Repeat angiography on 10/23/2006 for recurrent angina in the absence of a functional ischemia study revealed a total occlusion at the proximal stent site and TIMI 0 flow reported by the Angiographic Core Lab with the notation of target lesion revascularization. A Cardiac Catheterization Report noted evidence of severe thrombus in the mid portion of the proximal CX with 100% occlusion and TIMI 0 flow. The patient underwent repeat revascularization with placement of a VISION® stent in the proximal CX.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Vessel Revascularization – PTCA 266 days post-procedure The patient is a 65 year-old man with a history of hypertension who presented with CCS Class I angina. On 05/08/2006 at 10:18 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. There were no clinical sequelae. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/09/2006 on ASA and clopidogrel. Repeat angiography on 01/29/2007 for recurrent chest pain and without a functional ischemia study revealed a 25% in-lesion restenosis reported by the Angiographic Core Lab with the notation revascularization of the distal CX/ 3rd OM. The site reported a 90% lesion in the distal CX. The patient underwent repeat revascularization with placement of a CYPHER® stent placed in the distal CX.
----------		Taxus	Stroke 196 days post-procedure The patient is a 67 year-old woman with a history of prior PCI of the target vessel on 11/12/1996, dyslipidemia, hypertension, and current smoking who presented with CCS Class III angina. On 05/24/2006 at 12:55 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. A second assigned stent was placed distal to the target lesion for a site reported grade A dissection. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/25/2006 on ASA and clopidogrel. The patient was admitted on 12/06/2006 for complaints of left sided weakness, numbness, slurred speech, drooping of right side of the face, and a severe headache. A head CT showed no acute findings and a MRI showed a small recent ischemic focus in the right superior parietal region and old lacunar infarcts in the basal ganglia. The site reported neurological deficits lasted greater than 24 hours but were resolved by the time of discharge on 12/09/2006.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Cardiac Death 240 days post-procedure The patient was an 86 year-old woman with a history of dyslipidemia and premature CAD in a 1st degree relative who presented with CCS Class II angina. On 05/31/2006 at 10:38 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 43% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/01/2006 on ASA and clopidogrel. On 6/17/2006 the patient fell at home and developed a subdural hematoma. A craniotomy was performed to evacuate the hematoma on 06/18/2006. The site reported clopidogrel and ASA were stopped temporarily due to this event and then resumed on an unknown date in June 2006. Over the course of recovery the patient had episodes of confusion and was also treated for bone flap osteomyelitis. On 01/21/2007 the patient was rehospitalized for an episode of severe chest pain radiating to the left arm that was unrelieved by nitroglycerin. The site reported a MI was ruled out by EKGs and cardiac enzymes and the patient was discharged in stable condition and scheduled for an outpatient stress test. On 01/26/2007 the patient became unresponsive at home and stopped breathing. Emergency services were called and determined the patient was asystolic. CPR was initiated and the patient was intubated. She arrived in the Emergency Room in full cardiopulmonary arrest; however despite resuscitative efforts she was subsequently pronounced dead. No autopsy was performed. The site reported the categorical cause of death as cardiac with an official cause of death listed as cardiopulmonary arrest secondary to MI.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Non-Q wave MI 140 and 228 days post-procedure The patient is a 33 year-old man with a history of current smoking, dyslipidemia, premature CAD in a first degree relative, and a MI in 09/2004 who presented with CCS Class II stable angina and a negative functional ischemia study. On 05/12/2005 at 11:59 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. Abciximab was administered. The stent was post-dilated and there were no clinical sequelae. The Angiographic Core Lab reported a 17% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/13/2005 on ASA and clopidogrel. On 09/29/2005 the patient presented to the ER with chest pain and was rehospitalized. The CK peaked on 09/29/2005 at 19:45 at 393 (nl 195, ratio 2.02) with a CKMB peak of 6.4 (nl 5, ratio 1.3). The site reported a non-Q wave MI. The ECG Core Lab reported no new ST-T abnormalities and no new Q waves on tracings of inadequate quality with the notation of small isoelectric R waves preceding S waves in leads III and AVF, simulating inferior Q wave MI. On 12/26/2005 the patient presented to the ER with recurrent angina and was rehospitalized. Repeat angiography on 12/27/2005 for recurrent angina without a functional ischemia study revealed a 32% in-lesion restenosis reported by the Angiographic Core Lab. IVUS was performed and there was no revascularization at this time. The CK peaked on 12/26/2005 at 16:35 at 398 (nl 195, ratio 2.04) with a CKMB peak of 8.3 (nl 5, ratio 1.7). The site reported a non-Q wave MI. The ECG Core Lab reported no new ST-T abnormalities and no new Q waves.

Site	Patient	Treatment Group	Narrative
----------	----------	Taxus	Non-Q wave MI day of procedure The patient is a 76 year-old man with a history of former smoking, dyslipidemia, hypertension, and PCI of the target vessel in 06/1998 who presented with CCS Class III angina. On 09/29/2005 at 12:20 he underwent the index procedure with pre-treatment balloon angioplasty. Abciximab was administered. Following pre-treatment there was a site reported grade B dissection. The assigned stent was successfully delivered in the mid RCA; however the site reported a plaque shift. Subsequently a second assigned stent was placed distally to treat the plaque shift and the dissection. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The patient developed chest pain post-procedure and the site reported a non-Q wave MI with the notation that repeat cath was deemed not necessary. The pre-procedure CK and CKMB drawn on 09/29/2005 at 09:12 were 74 (nl 195, ratio <1) and 0.9 (nl 5, ratio <1) respectively. The CK peaked on 09/30/2005 at 09:31 at 898 (ratio 5) with a CKMB peak of 74.3 (ratio 15). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves on ECG tracings of inadequate tracing quality due to severe artifact. The patient was discharged on 09/30/2005 on ASA and clopidogrel.
----------	----------	Taxus	Target Lesion Revascularization-PTCA, Target Vessel Revascularization-PTCA 215 days post-procedure The patient is a 61 year-old man with a history of PCI of a target vessel, diabetes, dyslipidemia, hypertension, and current smoking who presented with CCS Class I angina and a positive functional ischemia study. On 08/04/2005 at 16:20 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 08/05/2005 on ASA and clopidogrel. Protocol re-study on 03/07/2006 in the absence of recurrent angina or a functional ischemia study revealed a 78% focal body in-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization and a remote vessel target vessel revascularization of proximal LAD. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD and proximal LAD.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-Q wave MI day of procedure The patient is a 70 year-old woman with a history of former smoking, dyslipidemia, and hypertension who presented with a positive functional ischemia study. On 02/24/2006 at 14:16 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. The site reported a grade D dissection following pretreatment was successfully sealed with the assigned stent. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 23% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 02/24/2006 at 07:45 were 82 (nl 135, ratio <1) and 0.9 (nl 5, ratio <1). The CK peaked post-procedure on 02/25/2006 at 12:08 at 1354 (ratio 10) with a non-concurrent CKMB peak at 07:30 of 145.1 (ratio 29). The site reported a non-Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q wave on tracings of inadequate quality due to a missing lead V3 in the pre-procedure ECG. The patient was discharged on 02/26/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Non-Q wave MI day of procedure The patient is a 70 year-old man with a history of dyslipidemia, hypertension and current smoking who presented with a positive functional ischemia study. On 11/03/2005 at 11:06 the patient underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 11/03/2005 at 08:00 were 53 (nl 170, ratio <1) and 1 (nl 5, ratio <1) respectively. The CK and CKMB drawn on 11/03/2005 at 19:30 were 84 (ratio <1) and 5.7 (ratio 1.1) respectively. The CK and CKMB drawn on 11/04/2005 at 03:30 were 270 (ratio 1.6) and 32.7 (ratio 6.5) respectively. The CK peaked on 11/04/2005 at 10:56 at 338 (ratio 1.99) with a CKMB peak of 39.9 (ratio 7.98). The site confirmed no additional cardiac enzyme testing was done. A narrative reported that the physician felt the abnormal labs were due to the length of the procedure; however the site reported a non-Q wave MI without chest pain or ECG changes. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The CEC ruled the event met the criteria for a non-Q wave MI in the absence of additional cardiac enzyme data. The patient was discharged on 11/04/2005 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA 248 days post-procedure The patient is a 66 year-old man with a history of diabetes, dyslipidemia, hypertension, and CABG surgery of a non-target vessel on 06/25/2002 who presented with a positive functional ischemia study. On 09/13/2005 at 08:48 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 27% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/14/2005 on ASA and clopidogrel. Protocol re-study on 05/19/2006 with recurrent clinical symptoms in the absence of a functional ischemia study revealed a 64% focal body in-stent restenosis reported by the Angiographic Core Lab with the notation status post-CABG with graft to distal RCA. The Cardiac Catheterization Report noted a 99% in-stent restenosis of the target lesion and a query response reported that IVUS results were positive. The patient underwent repeat revascularization with balloon angioplasty and placement of a drug-eluting stent in the mid RCA.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-PTCA 183 days post-procedure The patient is a 67 year-old woman with a history of PCI of a non-target vessel, diabetes, dyslipidemia, and hypertension who presented with CCS Class II angina and a positive functional ischemia study. On 11/09/2005 at 07:54 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. There were no clinical sequelae. The Angiographic Core Lab reported a 27% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation of moderate disease proximal to stent left untreated. The post-procedure course was uncomplicated and the patient was discharged on 11/10/2005 on ASA and clopidogrel. Repeat angiography on 05/11/2006 with recurrent clinical symptoms and with a positive functional ischemia study on 05/08/2006 revealed a 64% focal body in-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization. The Cardiac Catheterization Report noted a 95% in-stent restenosis of the 1st OM with additional disease in non-target vessels. The patient underwent repeat revascularization with balloon angioplasty with placement of a drug-eluting stent in the 1st OM; reported by the site on the event form as the proximal CX, a non-target vessel revascularization. The CEC ruled the event met the criteria for a clinically driven target lesion revascularization.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Stroke 82 days post-procedure The patient is a 73 year-old man with a history of MI on 05/08/2002, diabetes, hypertension, and former smoking who presented with a positive functional ischemia study. On 02/22/2006 at 08:33 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 02/23/2006 on ASA and clopidogrel. The site reported on 05/15/2006 the patient was diagnosed with a light stroke of the left eye. A query for an event form and additional information regarding this event yielded a Radiology Consultation Report dated 07/05/2006 which noted the patient had a history of visual changes in both eyes. A Progress Note dated 10/09/2006 reported the patient was informed by the VA Hospital on an unknown date that he had suffered a stroke in the left eye. The CEC ruled the event met the criteria for a stroke on 05/15/2006.

Site	Patient	Treatment Group	Narrative
	----------	Endeavor	Non-Q wave MI 130 days post-procedure, Target Lesion Revascularization-PTCA 132 days post-procedure, Stroke 109 days post-procedure The patient is a 78 year-old woman with a history of MI on 01/16/2004, prior PCI and CABG surgery on 1/16/2004 involving the target vessel, diabetes, dyslipidemia, and hypertension who presented with CCS Class II angina. On 03/02/2006 at 07:45 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/03/2006 on ASA and clopidogrel. The patient was rehospitalized on 06/19/2006 with sudden onset left facial weakness, left hemiparesis, and slurred speech according to a Discharge Summary; however the SAE reported an event date of 06/20/2006. A Neurological Consultation Report dated 06/19/2006 reported CT testing revealed a right lacunar CVA and further noted that a rehabilitation plan included physical, occupational, and speech therapy. The site confirmed the symptoms lasted less than 24 hours although the Discharge Summary listed a final diagnosis of cerebral vascular accident with a history of right ventricular clot. The patient was discharged on 06/22/2006 with physical therapy and occupational therapy as needed. A SAE reported the patient was rehospitalized on 07/12/2006 for an abnormal functional ischemia study and dyspnea; however the Cumulative Lab Report noted an admission date of 07/10/2006 with the initial CK drawn on 07/10/2006 at 07:10 at 156 (nl 140, ratio 1.1) with a CKMB of 4.2 (nl 6.3, ratio<1). On 7/10/2006 at 16:41 the CK peaked at 450 (ratio 3.2) with a concurrent CKMB peak of 56.6 (ratio 9). On 07/10/2006 at 23:26 the CK was 394 (ratio 2.8) and the CKMB was 46.1 (ratio 7.3). The final CK reported on 07/13/2006 was 78 (ratio <1) and no CKMB was performed. The site reported Q wave MI on 07/12/2006. According to the Investigator the patient was non-compliant with her medications and noted a "conflicting history" of clopidogrel compliance. The ECG Core Lab reported on tracings dated 07/10/2006 to 07/13/2006 and noted no new major ST-T abnormalities and no new Q waves. It further reported an inadequate tracing quality with dramatically different precordial lead placement. The CEC ruled the event met criteria for a non-Q wave MI on 07/10/2006. Repeat angiography on 07/12/2006 for recurrent clinical symptoms and a positive functional ischemia study revealed a 54% intra-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. The patient underwent repeat revascularization with cutting balloon angioplasty of the distal RCA.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Vessel Revascularization-PTCA 245 days post-procedure The patient is an 82 year-old woman with a history of hypertension who presented with CCS Class III angina and a positive functional ischemia study. On 09/20/2005 at 09:38 she underwent the index procedure with pre-treatment angioplasty and delivery of the assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn 09/20/2005 at 07:45 were 72 (nl 174, ratio <1) and 2.2 (nl 6.3, ratio <1) respectively. The CK peaked on 09/20/2005 at 22:49 at 194 (ratio 1.1) with a non-concurrent peaked CKMB at 05:20 of 29 (ratio 4.6). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves with the notation of variation in precordial lead placement. The patient was discharged on 09/21/2005 on ASA and clopidogrel. Protocol re-study on 05/23/2006 in the absence of recurrent angina or a functional ischemia study revealed a 22% in-lesion restenosis reported by the Angiographic Core Lab. The site reported a 0% restenosis of the target lesion and a negative IVUS result. The patient underwent revascularization with balloon angioplasty of the mid LAD. The CEC determined the event met the criteria for a clinically driven target vessel revascularization based on the available information.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Q wave MI day of procedure The patient is 55 year-old man with a history of former smoking, dyslipidemia, hypertension, premature CAD in a first degree relative, a MI on unknown date in 1997 and PCI in a non-target vessel who presented with a CCS Class I angina and a positive functional ischemia study. On 12/13/2005 at 09:35 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. The Cardiac Catheterization Report noted when injecting the RCA the patient went into ventricular fibrillation which was successfully treated with a single defibrillation of 200 joules. The site reported during stenting there was a small side branch occlusion which was unable to be resolved despite multiple attempts to reopen the diagonal artery according to the Cardiac Catheterization Report. The Angiographic Core Lab noted abrupt occlusion of the 1st diagonal and a failed attempt to re-open. Post-stenting balloon angioplasty was performed. The Angiographic Core Lab reported a 28% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 12/13/2005 at 07:55 were 84 (nl 174, ratio <1) and 0.7 (nl 6.3, ratio <1) respectively. The CK peaked on 12/14/2005 at 09:20 at 1411 (ratio 8.1) with a CKMB peak of 125.6 (ratio 20). The site reported a Q wave MI with elevated CK and CKMB levels due to jailing of a small side branch >2 mm during deployment of the stent. The ECG Core Lab reported the post-procedure ECG tracing on 12/13/2005 at 11:41 showed persistent high lateral ST elevations and no new Q waves. It further reported ischemic ECG tracings on 12/15/2005 at 04:31 showed a lateral Q wave MI and high lateral ST elevations of an evolving acute myocardial injury or infarction with the notation apparent loss of R waves in leads V1-V3, attributable to lead placement. The patient was discharged on 12/15/2005 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------	----------	Taxus	Non-Q wave MI day of procedure The patient is an 85 year-old woman with a history of hypertension who presented with a positive functional ischemia study. On 12/15/2005 at 10:20 the patient underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal LAD. A Cardiac Catheterization Report noted a perforation after stenting which was successfully treated with administration of protamine and prolonged balloon inflation. The Angiographic Core Lab reported on a lesion in the mid LAD with a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The Core Lab further reported the following: perforation after balloon post-dilatation of the study stent; hemostasis achieved with balloon; good final result. The pre-procedure CK and CKMB drawn on 12/15/2005 at 07:00 were 27 (nl 140, ratio <1) and 1.9 (nl 6.3, ratio <1) respectively. The CK peaked on 12/15/2005 at 23:20 at 366 (ratio 2.6) with a CKMB peak of 129.1 (ratio 20.5). The ECG Core Lab reported persistent anterior ST elevations and no new Q waves with the notation of slope ST elevations, new since pre-procedure ECG. The patient was discharged on 12/16/2005 on ASA and clopidogrel.
----------	----------	Taxus	Target Vessel Revascularization-PTCA 176 days post-procedure The patient is a 63 year-old man with a history of MI on an unknown date, PCI of a target vessel, dyslipidemia and smoking who presented with CCS Class IV angina and a positive functional ischemia study. On 01/03/2006 at 09:52 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow and noted the presence of an aneurysm on the baseline and final report. The post-procedure course was uncomplicated and the patient was discharged on 01/04/2006 on ASA and clopidogrel. Repeat angiography on 06/28/2006 for recurrent clinical symptoms without a functional ischemia study revealed a 17% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent, target vessel revascularization of distal RCA." The patient underwent repeat revascularization with balloon angioplasty of the distal RCA.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-Q wave MI day of procedure The patient is a 72 year-old woman with a history of former smoking, dyslipidemia, hypertension, premature CAD in a first degree relative, and PCI with stenting of the mid LAD on 10/11/1999 who presented with CCS Class II angina. On 03/28/2006 at 10:04 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 37% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 03/28/2006 at 08:21 were 42 (nl 140, ratio <1) and 3.1 (nl 6.3, ratio <1) respectively. The CK drawn on 03/28/2006 at 17:30 was 65 (ratio <1) with a CKMB of 15.1 (ratio 2.4). On 03/28/2006 at 23:21 the CK was 207 (ratio 1.5) with a CKMB of 64.8 (ratio 10). The CK on 03/29/2006 at 08:29 was 245 (ratio 1.8) with a CKMB of 72.7 (ratio 11.5). The CKMB peaked on 03/29/2006 at 05:47 at 82 (ratio 13). The CK was not performed and a query response confirmed the reason for the omission was unknown. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves on tracings of inadequate quality due to severe artifact and a variation in precordial lead placement. The CEC ruled the event met the criteria for a non-Q wave MI based on clinical judgment, secondary to the missed CK draw on 03/29/2006 at 05:47. The site reported prolonged hospitalization due to chest pain and she was discharged on 03/30/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA 250 days post-procedure The patient is a 92 year-old woman with a history of prior PCI of the target vessel in 1992, dyslipidemia and hypertension who presented with CCS Class I angina and a positive functional ischemia study. On 05/25/2006 at 08:25 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 29% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/26/2006 on ASA and clopidogrel. Repeat angiography on 01/30/2007 in the absence of recurrent angina and with a positive functional ischemia study revealed a 72% intra-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. A Coronary Intervention Report noted a focal lesion of 95-99% in the mid RCA stent. The patient underwent repeat revascularization with cutting balloon angioplasty of the mid RCA.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Stroke 121 days post-procedure (estimated) The patient is an 85 year-old man with a history of CABG surgery involving the target vessel in 1993, dyslipidemia, and former smoking who presented with a recent positive functional ischemia study. On 06/16/2006 at 10:18 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 9% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/17/2006 on ASA and clopidogrel. On 06/29/2006 the patient was hospitalized for left carotid endarterectomy surgery. On 11/02/2006 the patient was seen for an office visit at which the patient's wife reported the patient might have recently had a little stroke and experienced symptoms of numbness and tingling on the right side of his face, slurred speech, and generalized weakness that was greater on his right side. A Progress Note from that visit reports no deficits on physical examination and reported a possible small stroke and/or TIA and an 80% blockage in the left internal carotid artery. No CT scan or MRI was performed according to the Progress Note. A query response reported the onset of symptoms was an unknown date in October 2006. A Neurological Event Form reported the onset of symptoms as 11/02/2006 and that the deficits lasted greater that 24 hours but resolved.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA, Late Stent Thrombosis 145 days post-procedure The patient is a 37 year-old man with a history of current smoking, dyslipidemia and hypertension who presented with CCS Class III angina. On 03/20/2006 at 11:51 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. There were no clinical sequelae. The Angiographic Core Lab reported a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/22/2006 on ASA and clopidogrel. On 8/12/2006 the patient presented to the Emergency Room of a non-study hospital with chest pain. A narrative reported the ECG tracings showed ST elevations consistent with an acute inferior wall MI. Intravenous morphine, a nitroglycerin drip and enoxaparin were initiated. The patient was subsequently transferred to the investigational hospital. A Narrative reported the patient stopped taking clopidogrel and ASA in June due to financial difficulties. Repeat angiography on 08/12/2006 at 17:30 for recurrent clinical symptoms in the absence of a functional ischemia study revealed presence of a thrombus and a 71% intra-stent restenosis with TIMI 3 flow reported by the Angiographic Core Lab with the notation of thrombus in proximal part of stent extracted with Cougar wire. An Interventional Catheterization Report noted a subtotal occlusion of stent with thrombus, which appeared very soft, secondary to medication non-adherence; removal of thrombus with an export catheter; and IVUS evaluation revealed good apposition of the stent, minimal residual thrombus with a proximal 40-50% stenosis before the stent. The patient underwent thrombus extraction of the 1st OM. No further intervention was reported. The initial CK drawn at the non-study site on 08/12/2006 at 17:02 was 184 (nl 237, ratio <1) with a CKMB of 1.7 (nl 5, ratio <1). On 8/12/2006 at 23:10 at the study site the CK was 178 (nl 255, ratio <1) with an elevated CKMB of 6.6 (nl 5, ratio 1.3). The CK drawn on 08/13/2006 at 04:45 was 170 (ratio <1) with a CKMB peak of 7.5 (ratio 1.5). Subsequent CKs and CKMBs decreased. The site reported a Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The CEC ruled the event did not meet the criteria for a Protocol-defined MI. The patient was discharged on 08/14/2006.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Stroke day of procedure The patient is a 64 year-old man with a history of dyslipidemia who presented with CCS Class II angina and a positive functional ischemia study. On 09/16/2005 at 10:07 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was complicated. A consultation dated 09/17/2005 reported that on 09/16/2005 the patient was noted to be somewhat confused with speech difficulties; however he was known to be sedated. The following day his speech difficulties persisted and a brain MRI revealed "acute/subacute ischemic change left centrum semiovale/left frontal lobe deep white matter with no significant mass effect." The site reported a CVA with >24 hours of unresolved speech deficit. The patient was discharged on 09/18/2005 on ASA and clopidogrel.
----------		Endeavor	Target Lesion Revascularization-PTCA 260 days post-procedure The patient is a 62 year-old woman with a history of diabetes, dyslipidemia and hypertension who presented with CCS Class III angina. On 07/06/2005 at 12:49 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. Enoxaparin was administered and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported an 8% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 07/07/2005 on ASA and clopidogrel. The site confirmed the patient was experiencing CCS Class IV angina at the time of the re-study on 03/23/2006. Protocol re-study on 03/23/2006 in the presence of recurrent clinical symptoms in the absence of a functional ischemia study revealed a 60% intra-stent restenosis reported by the Angiographic Core Lab. The site reported a 72% restenosis of the target lesion and indicated in-stent restenosis was discovered on IVUS and determined the result was clinically significant. The patient underwent successful repeat revascularization with balloon angioplasty and placement of a stent in the proximal LAD.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-PTCA 267 days post-procedure The patient is an 87 year-old woman with a history of diabetes, dyslipidemia, hypertension and CABG surgery in November 2001 who presented with CCS Class III angina. On 07/14/2005 at 15:03 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal RCA. The site reported that post-stent angiography revealed an "ostial lesion was in fact more occluded than previously thought" and the Investigator felt "it was in the patient's best interest" to treat the lesion and a second assigned stent was placed proximal to the target lesion in the ostial RCA according to a query response. There were no clinical sequelae. The Angiographic Core Lab reported an 18% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation: "target lesion is the proximal RCA" after deployment of the study stent there was a significant residual ostial lesion; a second study stent was deployed over the ostial lesion with gap in between the two stents, "only study stent analyzed." The post-procedure course was uncomplicated and the patient was discharged on 07/15/2005 on ASA and clopidogrel. Protocol re-study on 04/07/2006 in the presence of recurrent clinical symptoms in the absence of a positive functional ischemia study revealed a 3% in-lesion restenosis reported by the Angiographic Core Lab with the notation remote target vessel revascularization. The site reported a 0% restenosis of the target lesion and an 80% ostial lesion at the proximal end of the stent per IVUS. The Interventional Catheterization Report noted an 80% lesion in the ostial RCA. The patient underwent repeat revascularization with balloon angioplasty of the proximal RCA. After a discussion the CEC ruled the event met the criteria of a clinically driven target lesion revascularization due to the use of a second stent "within the same lesion" during the index procedure.

Site Patient	Treatment Group	Narrative
----------	Taxus	Target Vessel Revascularization-PTCA 226 days post-procedure The patient is a 70 year-old woman with a history of a previous MI in 1995, prior PCI of the distal RCA on 03/14/2005, dyslipidemia, hypertension, and former smoking who presented with CCS Class IV angina. On 12/12/2005 at 13:31 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal RCA. Eptifibatide was administered and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 27% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 12/13/2005 on ASA and clopidogrel. Repeat angiography on 07/26/2006 for recurrent angina without a functional ischemia study revealed a 23% restenosis of the target lesion reported by the Angiographic Core Lab with the notation study stent patent, remote target lesion revascularization of the mid and distal RCA with stenting, some overlap of mid RCA stent with the study stent. An Interventional Catheterization Report noted a widely patent stent in the proximal RCA, a 70% stenosis of the mid RCA, and a 90% stenosis of the distal RCA. The patient underwent balloon angioplasty with drug-eluting stents placed in the mid RCA and the distal RCA.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Lesion Revascularization-CABG, Target Vessel Revascularization-CABG 158 days post-procedure, Target Lesion Revascularization-PTCA, Target Vessel Revascularization-PTCA 71 days post-procedure The patient is an 81 year-old man with a history of dyslipidemia who presented with a positive functional ischemia study. On 02/23/2006 at 12:17 he underwent the index procedure with successful delivery of the assigned stent in the mid LAD. The Angiographic Core Lab reported a 19% final residual stenosis with no dissection and TIMI 3 flow with the notation: "residual disease ballooned, but not stented proximal to the study stent; proximal geographic miss." The post-procedure course was uncomplicated and the patient was discharged on 02/24/2006 on ASA and clopidogrel. Repeat angiography on 05/05/2006 for recurrent angina with a positive functional ischemia study revealed an 85% margin in-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization. A Cardiac Catheterization Report revealed the LAD had "mid level 90% disease which is a long segment" and "this disease segment is just proximal to the previously deployed stent of 02/23/2006." In addition, the origin of the diagonal artery was also involved in this disease process. The patient underwent primary stenting of the mid LAD with a drug-eluting stent and PTCA of the 1st diagonal artery. The same report also noted the first diagonal artery was jailed; however, after NTG injection, the artery "was noted to be recanalized partially" and repeat attempts to cross into the diagonal artery with a pilot wire were unsuccessful. The site reported the patient was rehospitalized for a second time with recurrent chest pain. Repeat angiography on 07/28/2006 revealed a 66% proliferative, diffuse in-stent restenosis reported by the Angiographic Core Lab with the notation that no TLR was shown. The Cardiac Catheterization Report revealed a 90% stenosis of the left main coronary artery followed by an 80% focal stenosis within the prior stent. The Report also noted additional disease in non-target vessels. On 07/31/2006 the patient underwent non-emergent CABG surgery with placement of bypass grafts to the proximal LAD, the mid LAD, the 1st OM and the 2nd OM.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Lesion Revascularization-PTCA 228 days post-procedure The patient is a 51 year-old woman with a history of diabetes, dyslipidemia, and hypertension who presented with CCS Class II angina and a positive functional ischemia study. On 01/30/2006 at 14:27 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. Enoxaparin was administered and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 01/31/2006 on ASA and clopidogrel. Repeat angiography on 09/15/2006 in the presence of recurrent angina and in the absence of a functional ischemia study revealed a 62% intra-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. An Interventional Catheterization Report noted a 90% stenosis of the mid RCA. The patient underwent repeat revascularization with balloon angioplasty in the mid RCA stent.
----------	----------	Taxus	Target Vessel Revascularization-PTCA 236 days post-procedure The patient is an 84 year-old woman with a history of diabetes, dyslipidemia, and hypertension who presented with CCS Class IV angina. On 02/01/2006 at 15:29 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 02/02/2006 on ASA and clopidogrel. Repeat angiography on 09/25/2006 in the presence of recurrent angina and in the absence of a functional ischemia study revealed an 80% restenosis of the target lesion as reported by the site. The Angiographic Core Lab reported an 8% in-lesion restenosis with the notation "remote target vessel revascularization of ostial RCA, one stent, no overlap with study stent." The patient underwent repeat revascularization with a drug-eluting stent placed in the distal RCA.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Non-Q wave MI, Subacute Closure/Stent Thrombosis 2 days post-procedure, Target Lesion Revascularization-PTCA 3 days post-procedure The patient is a 54 year-old woman with a history of diabetes, dyslipidemia, hypertension, and premature CAD in a first degree relative who presented with CCS Class IV angina. On 04/21/2006 at 17:45 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. Eptifibatide was administered. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the mid LAD with a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB were 21 (nl 173, ratio <1) and 0.5 (nl 3.6, ratio <1) respectively. The 20-24 hour CK and CKMB drawn on 04/22/2006 at 16:20 were 57 (ratio <1) and 1.6 (ratio <1) respectively. The ECG Core Lab reported no new ST-T abnormalities and no new Q waves. The site reported, after the index procedure, the patient developed nausea, vomiting and a vagal response requiring atropine and I.V. fluids. The gastrointestinal service was consulted and diagnostic testing on 04/22/2006 revealed acute cholecystitis and she underwent a laparoscopic cholecystectomy on 04/23/2006. The site confirmed that clopidogrel was not discontinued for the surgical period. A Discharge Summary reported the patient was asymptomatic post-operatively on 04/23/2006 with ST elevations in leads 1 and AVL. The administration of intravenous nitroglycerin seemed to improve the ST elevation. On the morning of 04/24/2006 the patient experienced recurrent chest pain and hypertension. The initial CK and CKMB drawn on 04/23/2006 at 20:20 were elevated at 400 (ratio 2.3) and 45.8 (ratio 12.7). On 04/24/2006 at 00:33 the CK and CKMB were 1318 (ratio 7.6) and 150 (ratio 41.7). On 04/24/2006 at 11:30 the CK peaked at 2190 (ratio 12.6) with a CKMB peak of 179.1 (ratio 49.7). Follow-up CK and CKMB drawn on 04/24/2006 at 19:00 were 966 (ratio 5.6) and 81.8 (ratio 22.3). The site reported a non-Q wave MI. The ECG Core Lab reported on ECG tracings dated 04/23/2006 an acute anterior MI with a loss of R waves and poor R wave progression with persistent anterior and high lateral hyperacute T waves, persistent anterior and high lateral ST elevations. Repeat angiography on 04/24/2006 at 08:36 for recurrent clinical symptoms without a functional ischemia study revealed an in-stent total occlusion and TIMI 0 flow with the presence of new thrombus (not present on index final) reported by the Angiographic Core Lab. The Discharge Summary further reported a total occlusion of the LAD stent (mid segment). Bivalirudin was administered and a "fairly good size red thrombus" was extracted with an Export catheter. Balloon angioplasty and IVUS were performed. The patient was discharged on 05/01/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Vessel Revascularization-PTCA 75 days post-procedure The patient is a 58 year-old man with a history of former smoking, dyslipidemia, hypertension, PCI of a non-target vessel, a MI in 2002 and CABG surgery of a non-target vessel in 2002 who presented with CCS Class III stable angina and a positive functional ischemia study. On 05/05/2006 at 08:43 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. The stent was post-dilated. Eptifibatide was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/06/2006 on ASA and clopidogrel. On 07/19/2006 the patient presented to the Emergency Room with chest pain. Repeat angiography on 07/19/2006 for recurrent clinical symptoms in the absence of a functional ischemia study revealed a 10% in-lesion restenosis reported by the Angiographic Core Lab with the notation study stent patent. The site reported a 90% restenosis of the target lesion and a target lesion revascularization. The site further reported the patient underwent repeat revascularization with balloon angioplasty and placement of a stent in the mid RCA; however the Cardiac Catheterization Report noted stenting of the proximal RCA and the Angiographic Core Lab reported remote target vessel revascularization of proximal RCA with minimal overlap of new stent with study stent.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-Q wave MI day of procedure, Target Vessel Revascularization-CABG 5 days post-procedure The patient is a 69 year-old man with a history of non-target vessel PCI, dyslipidemia, hypertension, and former smoking who presented with CCS Class II angina. On 03/15/2006 at 11:41 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. The stent was post-dilated. The site reported a grade C dissection following pre-treatment and stent placement. A second assigned stent was delivered distal to the first stent in an attempt to cover the dissection; however the site reported a 30% final residual stenosis with a grade D dissection and TIMI 2 flow. The Angiographic Core Lab reported a grade F spiral dissection in the distal vessel with TIMI 0 flow and abrupt closure. It further reported a 0% final residual in-stent stenosis. The pre-procedure CK and CKMB drawn on 03/15/2006 at 09:05 were 53 (nl 207, ratio <1) and 0.8 (nl 5, ratio <1) respectively. The CK peaked on 03/16/2006 at 10:34 at 648 (ratio 3.1) with a CKMB peak of 93.8 (ratio 18.8). The site reported a non-Q wave MI. The ECG Core Lab reported intermittent atrial flutter and persistent atrial fibrillation on tracings that were uninterpretable for MI due to left bundle branch block and variation in precordial lead placement. Repeat angiography on 03/17/2006 at 08:19 for an elevation of CK in the absence of a functional ischemia study revealed a site reported 50% renarrowing of the target lesion. The Angiographic Core Lab reported a 14% in-lesion renarrowing and TIMI 0 flow with the notation of a patent study stent with residual dissection and distal occlusion. No revascularization was performed at this time. On 03/20/2006 the patient underwent non-emergent CABG surgery with placement of a SVG to the 1st OM, a SVG to the 1st diagonal, a LIMA to the mid LAD, and a SVG to the R-PDA according to the Operation Report. The patient was subsequently discharged on 03/24/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Vessel Revascularization-PTCA 171 days post-procedure The patient is a 52 year-old man with a history of an MI on 09/03/2005, prior PCI of a non-target vessel, diabetes, dyslipidemia, hypertension, and current smoking who presented with CCS Class IV angina and a positive functional ischemia study. On 04/28/2006 at 10:39 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 48% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/29/2006 on ASA and clopidogrel. Repeat angiography on 10/16/2006 for recurrent clinical symptoms in the absence of a functional ischemia study revealed a 41% in-lesion restenosis reported by the Angiographic Core Lab with the notation study stent patent, remote target vessel revascularization, and overlap of the study stent with the new stent. A Cardiac Catheterization Report noted a 75% lesion in the proximal CX extending into a large 1st marginal branch with placement of a stent. The patient underwent repeat revascularization in the proximal CX and the 1st OM.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA 177 days post-procedure The patient is a 62 year-old man with a history of CABG surgery to the target vessel in 09/2003, dyslipidemia, hypertension, former smoking, and premature CAD in a 1st degree relative who presented with CCS Class II angina and a positive functional ischemia study. On 05/22/2006 at 11:03 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal CX. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the 1st OM (confirmed) with a 37% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 05/23/2006 on ASA and clopidogrel. The site reported the patient experienced recurrent exertional dyspnea for about a month and was hospitalized for an anginal equivalent. Repeat angiography on 11/15/2006 for recurrent clinical symptoms without a functional ischemia study revealed a site reported 75% restenosis of the target lesion. The Angiographic Core Lab reported a 50.4% intra-stent restenosis with the notation moderate to severe neointimal hyperplasia. A Cardiac Catheterization Report noted successful angioplasty with placement of a stent in the left CX. The patient underwent repeat revascularization with balloon angioplasty and stent placement of the proximal CX.

Site Patient	Treatment Group	Narrative
----------	Endeavor	Cardiac Death, Stent Thrombosis 2 days post-procedure The patient was a 74 year-old man with a history of former smoking, dyslipidemia and a MI on 10/28/2005 who presented with CCS Class II stable angina and a positive functional ischemia study. On 06/08/2006 at 15:08 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal CX. There was a site reported grade A proximal edge dissection with a 10% diameter stenosis and TIMI 3 flow after pre-treatment. A second assigned stent was placed in the target lesion to cover the dissection. The Angiographic Core Lab reported a 16% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK drawn on 06/08/2006 at 15:07 was 262 (nl 329, ratio <1) with an elevated CKMB of 5.6 (nl 5, ratio 1.5). The post-procedure CKs decreased to 226 and 196 with a re-elevation on 6/9/06 at 08:30 to 239 (ratio <1) with a CKMB peak of 7.4 (ratio, 1.5). The ECG Core Lab reported new persistent PR prolongation with no new major ST-T abnormalities and no new Q waves. The post-procedure course was uncomplicated and the patient was discharged on 06/09/2006 on ASA and clopidogrel. The patient was found dead at home on 06/10/2006. No autopsy was performed and the official cause of death was reported as sudden cardiac death with severe coronary artery disease according to the Certificate of Death. The Clinical Events Committee determined that the event on 06/10/2006 met the criteria for a cardiac death and a subacute stent thrombosis.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Vessel Revascularization-PTCA 157 days post-procedure The patient is a 62 year-old man with a history of dyslipidemia, hypertension, current smoking, and premature CAD in a 1st degree relative who presented with CCS Class III angina. On 06/09/2006 at 17:18 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal RCA. Enoxaparin was administered and the stent was post-dilated. The Angiographic Core Lab reported that an aneurysm present in the proximal RCA at baseline was covered with the stent and noted a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/10/2006 on ASA and clopidogrel. Repeat angiography on 11/13/2006 for recurrent angina and with a positive functional ischemia study revealed an 11% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent and an irregularity due to an aneurysm from pre-procedure. The Interventional Catheterization Report noted the distal RCA had a focal 90% eccentric lesion and an 80-90% stenosis of the 1st OM. The Angiographic Core Lab further reported a remote target vessel revascularization of the distal RCA and a non-target vessel revascularization of the 1st OM. The patient underwent repeat revascularization with balloon angioplasty and placement of drug-eluting stents in the distal RCA and in the 1st OM.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Vessel Revascularization-PTCA 259 days post-procedure The patient is a 59 year-old man with a history of CABG surgery in 6/2005, dyslipidemia, hypertension, former smoking, and premature CAD in a 1st degree relative who presented with CCS Class III angina. On 04/12/2006 at 14:38 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/13/2006 on ASA and clopidogrel. Repeat angiography on 12/27/2006 for recurrent chest pain and with a positive functional ischemia study revealed a 23% in-lesion restenosis reported by the Angiographic Core Lab with the notation remote target vessel revascularization of the proximal CX and non-target vessel revascularization of the LAD. A Cardiac Procedure Report noted a widely patent study stent, a 70% lesion of the proximal CX, and a 70-80% lesion of the mid LAD. The patient underwent repeat revascularization with balloon angioplasty and placement of stents in the proximal CX and in the mid LAD.
----------	----------	Taxus	Non-Q wave MI day of procedure The patient is a 63 year-old woman with a history of former smoking, dyslipidemia, and hypertension who presented with a positive functional ischemia study. On 03/23/2006 at 10:35 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 03/23/2006 at 07:41 were 49 (nl 135, ratio <1) and 0.7 (nl 5, ratio <1) respectively. The CK peaked post-procedure on 03/24/2006 at 11:20 at 316 (ratio 2.3) with a non-concurrent CKMB at 07:15 of 23.7 (ratio 4.7). The site reported a non-Q wave MI. The ECG Core Lab reported new major persistent inferolateral T wave inversions and no new Q waves. The patient was discharged on 03/25/2006 on ASA and clopidogrel.

Site Patient	Treatment Group	Narrative
----------	Taxus	Target Vessel Revascularization-PTCA 89 days post-procedure The patient is a 71 year-old man with a history of dyslipidemia, hypertension, and premature CAD in a 1st degree relative who presented with CCS Class IV angina. On 03/16/2006 at 15:29 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal CX and the stent was post- dilated. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the 1st OM with a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/17/2006 on ASA and clopidogrel. Repeat angiography on 06/13/2006 for recurrent angina without a functional ischemia study revealed a 30% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent, a non-target lesion revascularization of diagonal and remote target vessel revascularization of the 2nd. An Interventional Catheterization Report noted the patient underwent repeat revascularization with stenting of the 2nd diagonal and cutting balloon angioplasty at the ostium of the 2nd OM for a 90% lesion. The site reported a target vessel and a non-target vessel revascularization. The patient was discharged home on 06/14/2006.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Stroke 46 days post-procedure The patient is a 67 year-old woman with a history of diabetes, dyslipidemia, hypertension and premature CAD in a first degree relative who presented with CCS Class III stable angina and a positive functional ischemia study. On 10/18/2005 at 14:47 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/19/2005 on ASA and clopidogrel. A physician's history and physical examination indicated that at baseline the patient has difficulty with speech secondary to a prior CVA; however on 12/03/2005 at home the patient developed worsening dysarthria with speech and facial deficits. She was rehospitalized on 12/04/2005. Initial examination revealed an alert and oriented patient with dysarthric speech; left facial weakness, otherwise normal cranial nerves II - XII; positive drift on right upper extremity; good bilateral hand grips; sensations were grossly intact; and bilateral down going babinski responses. The indication for the un-enhanced brain CT scan on 12/04/2005, as noted on the report, was right-sided weakness and expressive aphasia. The CT scan revealed the following findings: no evidence of hemorrhage or acute ischemic change; the presence of periventricular lucencies, consistent with small vessel disease; a hypodensity in the right basal ganglia, which likely represented an old lacunar infarct; a hypodensity just lateral to the left frontal horn which may represent an old lacunar infarct as well; and calcification within both internal carotid arteries. On 12/05/2005 extracranial triplex cerebrovascular evaluation, with a clinical indication of stroke, revealed no hemodynamically significant extracranial cerebrovascular stenosis. The site also reported a CVA. The duration of the neurological deficits was greater than 24 hours. She underwent physical and speech therapy. The discharge date for this admission was not reported. The six-month AE log did note that the worsening dysarthria had improved by 04/16/2006. The site was unable to provide any additional information.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA 182 days post-procedure The patient is a 62 year-old woman with a history of former smoking, dyslipidemia, hypertension, premature CAD in a 1st degree relative, and PTCA with stenting of the target vessel in 2001 who presented with CCS Class II stable angina. On 10/12/2005 at 13:20 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the R-PDA. The stent was post-dilated and there were no clinical sequelae. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/13/2005 on ASA and clopidogrel. On 04/11/2006 the patient was rehospitalized through the ER with a one day history of chest pain. Repeat angiography on 04/12/2006 for recurrent clinical symptoms without a functional ischemia study revealed a 72% focal body in-stent restenosis reported by the Angiographic Core Lab. The patient underwent repeat revascularization with balloon angioplasty of the R-PDA.

Site Patient	Treatment Group	Narrative
----------	Taxus	Non-Q wave MI day of procedure The patient is a 65 year-old woman with a history of current smoking, dyslipidemia, and hypertension who presented with CCS Class I angina. On 06/02/2006 at 12:08 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. The Angiographic Core Lab reported a 26% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 06/02/2006 at 07:22 were 97 (nl 195, ratio <1) and 2.1 (nl 5, ratio <1) respectively. The CK and CKMB drawn on 06/02/2006 at 19:45 were 590 (ratio 3.02) and 6.4 (ratio 1.28) respectively. The CK drawn on 06/03/2006 at 01:05 was 795 (ratio 4.07) with a CKMB peak of 8.6 (ratio 1.78). The CK and CKMB drawn on 06/03/2006 at 19:35 were 986 (ratio 5.05) and 4.6 (ratio <1) respectively. The CK peaked on 06/05/2006 at 13:20 at 2471 (ratio 12.7) with a CKMB of 3.0 (ratio <1). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The post-procedure course was further complicated by development of a right groin femoral thrombus. An ultrasound taken on 06/05/2006 reported deep vein thrombosis at the junction of the right common femoral and superficial veins. The thrombus extends into the right common femoral vein. The site reported the patient underwent drug treatment for this event and also reported they were unable to provide a discharge summary for this hospitalization. The patient was discharged on 06/07/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------	----------	Endeavor	Target Vessel Revascularization-PTCA 268 days post-procedure The patient is a 71 year-old woman with a history of PCI of a non-target vessel, diabetes, dyslipidemia and hypertension who presented with CCS Class II angina and a positive functional ischemia study. On 09/06/2005 at 13:42 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA and eptifibatide was administered. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the proximal RCA with a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/07/2005 on ASA and clopidogrel. Repeat angiography on 06/01/2006 for recurrent unstable angina and without a functional ischemia study revealed a 34% in-lesion restenosis reported by the Angiographic Core Lab with the notation remote target vessel revascularization of the distal RCA/PLSA. An Operative Report describes an intervention in the right coronary artery and noted an 80% stenosis in the posterolateral branch. The patient underwent repeat revascularization with balloon angioplasty of the 1st RPL, noted by the site as a non-target vessel revascularization. The CEC ruled the event met the criteria for a clinically driven target vessel revascularization.
----------	----------	Taxus	Non-Q wave MI day of procedure The patient is a 58 year-old woman with a history of former smoking, dyslipidemia, hypertension, CAD in a first degree relative, and CABG surgery of the target vessel on 01/01/1996 who presented with CCS Class II angina and a recent positive functional ischemia study. On 09/30/2005 at 13:01 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 25% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK drawn on 09/30/2005 at 11:00 was 56 (nl 204, ratio <1) The CKMB was not done. The CK peaked post-procedure on 10/01/2005 at 10:00 at 556 (ratio 2.7) with a CKMB of 59.7 (nl 7, ratio 8.5). The site reported a non-Q wave MI. The ECG Core Lab reported new major intermittent anterolateral/apical ST depressions and no new Q waves. The patient was discharged on 10/01/2005 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Vessel Revascularization-CABG 251 days post-procedure The patient is a 56 year-old man with a history of dyslipidemia, hypertension, and premature CAD in a 1st degree relative who presented with CCS Class II angina and a positive functional ischemia study. On 11/30/2005 at 15:12 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal CX. The site reported the target vessel had a second lesion with 50% diameter stenosis by visual estimate. No treatment was reported for the second lesion. The Angiographic Core Lab reported a 31% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation that the 2nd diagonal was wired; however no intervention was visualized. The post-procedure course was complicated by a site reported vagal episode with a drop in blood pressure during sheath removal that resolved after administration of atropine. The patient was discharged on 12/01/2005 on clopidogrel only, due to a history of ASA allergy. Repeat angiography on 08/02/2006 for recurrent angina and shortness of breath in the absence of a functional ischemia study revealed a 21% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent. An Interventional Catheterization Report revealed a 90% lesion of the distal CX, a 60% lesion of the mid LAD, a 90% lesion to the 1st diagonal, and total occlusion of the RCA. The patient was scheduled for CABG surgery and on 08/08/2006 underwent off pump CABG surgery with placement of a LIMA to the LAD, a SVG to the R-PDA, a SVG to OM, and a SVG to the diagonal.

Site Patient	Treatment Group	Narrative
----------	Endeavor	Target Lesion Revascularization-PTCA 217 days post-procedure The patient is a 54 year-old man with a history of diabetes, dyslipidemia, hypertension, current smoking, and a MI in 1999 who presented with CCS Class IV angina. On 11/10/2005 at 08:17 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/11/2005 on ASA and clopidogrel. Repeat angiography on 06/15/2006 for recurrent clinical symptoms without a functional ischemia study revealed a 61% marginal in-stent restenosis reported by the Angiographic Core Lab with the notation of a target lesion revascularization. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. The CEC ruled the event met the criteria for a clinically driven target lesion revascularization.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Vessel Revascularization-PTCA 45 days post-procedure The patient is an 84 year-old man with a history of diabetes and dyslipidemia who presented with CCS Class IV angina and a recent positive functional ischemia study. On 06/21/2005 at 11:30 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. The stent was post-dilated and there were no clinical sequelae. The Angiographic Core Lab reported a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/22/2005 on ASA and clopidogrel. A supplied narrative reported that an endoscopy was planned and for 07/16/2005 so clopidogrel and coumadin were discontinued. An endoscopy on 07/21/2005 revealed duodenal ulcers and clopidogrel and coumadin remained on hold. On 08/02/2005 the patient presented to the Emergency Room with several days of severe intermittent chest pressure rated 12 on a scale of 1 to 10. A query response indicates that enoxaparin and bivalirudin were initiated and the site further reported that clopidogrel was reloaded followed by a daily dose of 75 mg. The initial CK and CKMB drawn on 08/02/2005 at 17:17 were 48 (nl 195, ratio <1) and 2 (nl 7, ratio <1). Four subsequent sets of CK and CKMB were reported with a peaked CK drawn on 08/04/2005 at 07:44 of 56 (ratio <1) with a CKMB of 5 (ratio <1) and a troponin I of 0.5 (nl .05, ratio 10). The ECG Core Lab reported new persistent major anterolateral/apical "primary T wave abnormalities [inversions] associated with V-pacing" and noted the tracings were uninterpretable due to a paced rhythm. The site noted negative cardiac enzymes and initially reported both a Q wave MI and a non-Q wave MI; however the SAE was corrected to report only a Q wave MI. The CEC ruled the event did not meet the criteria for Q wave MI or a non-Q wave MI. Repeat angiography on 08/05/2005 for recurrent clinical symptoms with a negative functional ischemia study performed on 07/19/2005 revealed no thrombus and a 28% in-lesion restenosis reported by the Angiographic Core Lab with the notation of neointimal hyperplasia distally within the assigned stent; stenosis distal to the assigned stent treated with an overlapping drug-eluting stents; remote target vessel revascularization. The SAE narrative reported an 80% restenosis of the target lesion without stent thrombosis and noted a target vessel/target lesion revascularization with in-stent restenosis at the distal end of study stent extending distally to the stent. The patient underwent repeat revascularization with placement of a stent in the mid LAD. The CEC ruled the event on 08/05/2005 met the criteria for a clinically driven target vessel revascularization.

Site Patient	Treatment Group	Narrative
----------	Endeavor	Non-Q wave MI day of procedure The patient is a 63 year-old woman with a history dyslipidemia, hypertension, a MI in 1963, and PCI of a non-target vessel who presented with CCS Class III angina. On 03/17/2006 at 14:41 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. Eptifibatide was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK and CKMB drawn on 03/17/2006 at 12:03 were elevated at 432 (nl 204, ratio 2.1) and 31.3 (nl 5, ratio 6.3) respectively. The CK peaked on 03/17/2006 at 21:00 at 2029 (ratio 10) with a CKMB of 192 (ratio 38). The site reported a non-Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 03/19/2006 on ASA and clopidogrel.
----------	Endeavor	Target Lesion Revascularization-PTCA, Target Vessel Revascularization-PTCA 253 days post-procedure The patient is a 70 year-old man with a history of former smoking and hypertension who presented with CCS Class I stable angina and a positive functional ischemia study. On 09/27/2005 at 13:16 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 09/28/2005 on ASA and clopidogrel. Protocol re-study on 06/07/2006 without recurrent clinical symptoms or a functional ischemia study revealed a 73% focal intra-stent restenosis reported by the Angiographic Core Lab. The site additionally reported a 6.6 mm2 IVUS reading and noted an 85% in-stent restenosis and a progressive proximal target vessel disease. The patient underwent repeat revascularization with balloon angioplasty and placement of two stents in the mid RCA and one stent in the proximal RCA.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-cardiac Death 76 days post-procedure The patient was a 54 year-old man with a history of MI, hypertension, current smoking, and premature CAD in a 1st degree relative who presented with CCS Class III angina and a positive functional ischemia study. On 06/23/2006 at 16:47 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal CX. Eptifibatide was administered and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 06/24/2006 on ASA and clopidogrel. The patient's wife reported finding her husband on the ground when she came home from work on 09/04/2006. According to a Discharge Summary, the patient suffered a fall from the stairs at the doorstep of his home. He was found unresponsive by emergency medical services and was intubated in the field. He initially had a dilated right pupil but developed bilateral fixed dilated pupils before arrival at the hospital. Diagnostic testing revealed a high alcohol level and right subdural hemorrhage with significant 2 cm midline shift and uncal herniation. By 09/07/2006 he was found to have no brain stem reflexes and was pronounced brain dead. He expired at 18:30 on 09/07/2006. The site reported the categorical cause of death as non-cardiac and a Death Certificate listed subdural hemorrhage and brain herniation as the cause of death with chronic alcohol abuse as a contributing factor. Initially the site reported an autopsy was performed; however a letter from the Office of the Medical Examiner states no autopsy was performed. The letter further indicates an external examination of the body was done and provides that report which does not give any additional information about the cause and manner of death.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-PTCA 245 days post-procedure The patient is a 71 year-old man with a history of diabetes, dyslipidemia, and hypertension who presented with CCS Class I angina and a positive functional ischemia study. On 10/11/2005 at 10:35 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. Eptifibatide was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/12/2005 on ASA and clopidogrel. Protocol re-study on 06/13/2006 without recurrent clinical symptoms and with a positive functional ischemia study revealed a 53% focal body in-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. The site reported a positive IVUS reading. The patient underwent repeat revascularization with balloon angioplasty and placement of a stent in the mid LAD.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-cardiac Death 131 days post-procedure The patient was an 84 year-old woman with a history of dyslipidemia and hypertension who presented with a positive functional ischemia study. On 11/15/2005 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 2nd OM. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK drawn on 11/15/2005 at 11:54 was 60 (nl 295, ratio <1). A CKMB was not performed. The CK peaked on 11/16/2005 at 17:49 at 238 (ratio <1) with a non-concurrent CKMB of 19.1 (ratio, 4.8). The ECG Core Lab reported ST-T abnormalities not applicable and MI uninterpretable due to a paced rhythm. The site reported a non-Q wave MI and noted in a narrative patient experienced shortness of breath on the evening of 11/15/2005. The CEC ruled the event did not meet the criteria for protocol-defined non-Q wave MI. The patient was discharged on 11/17/2005 on ASA and clopidogrel. The site reported the patient was diagnosed with acute myelogenous leukemia in February 2006 and was treated with multiple transfusions and platelets. She was rehospitalized at a non-study hospital for pneumonia on 03/04/2006 and on transferred to a terminal care facility on 03/23/2006. She subsequently expired on 03/26/2006. No autopsy was performed and the official cause of death is listed as overwhelming carcinomatosis.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-PTCA 136 days post-procedure The patient is an 86 year-old man with a history of dyslipidemia and hypertension who presented with a positive functional ischemia study. On 12/05/2005 at 12:54 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. The stent was post-dilated. Bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 30% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was complicated by worsening hypertension which was treated with medication and the patient was discharged on 12/06/2005 on ASA and clopidogrel. A narrative reported the patient experienced a three week history of classic exertional angina; however enzyme testing was negative. Repeat angiography on 04/20/2006 for recurrent clinical symptoms without a functional ischemia study revealed a 73% proliferative in-stent restenosis reported by the Angiographic Core Lab. The site reported a 40% restenosis of the target lesion and a 99% stenosis of the proximal LAD, proximal to the study stent and reported a target lesion revascularization and a target vessel revascularization. The patient underwent repeat revascularization with implantation of one CYPHER® stent proximal to and overlapping the study stent. A 65% lesion was noted distal to the study stent and a second CYPHER® stent was placed distal to and overlapping the study stent. The CEC ruled the event met the criteria for a clinically driven target lesion revascularization.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA 206 days post-procedure The patient is a 59 year-old woman with a history of dyslipidemia and former smoking who presented with CCS Class IV angina and a positive functional ischemia study. On 04/21/2006 at 16:54 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD and the stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported a 20% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/22/2006 on ASA and clopidogrel. Repeat angiography on 11/13/2006 for substernal chest pain and without a functional ischemia study revealed a 51% intra-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. A Discharge Summary noted a 60% in-stent restenosis diagnosed by IVUS. The patient underwent repeat revascularization with cutting balloon angioplasty in the mid LAD.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-Q wave MI 19 days post-procedure The patient is a 77 year-old man with a history of dyslipidemia and hypertension who presented with a positive functional ischemia study. On 10/25/2005 at 15:26 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. Eptifibatide was administered. The Angiographic Core Lab reported a 10% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/26/2005 on ASA and clopidogrel. On 11/11/2005 the patient was rehospitalized at a non-study site with fever, sepsis, pneumonia and near syncope and treated with antibiotics and IV fluids He developed supraventricular tachycardia and fluid overload which were treated with cardiazem and lasix. The initial CK drawn on 11/13/2005 at 12:12 was elevated at 788 (nl 195, ratio 4) with an elevated CKMB of 72.1 (nl 4, ratio 18) respectively. On 11/16/2005 at 08:25 the CK and CKMB decreased to 131 (ratio <1) and 6.9 (ratio 1.7) respectively. There was subsequent decreases of CK and CKMB on 11/16/2005 at 08:25 with a CK of 99 (ratio <1) and the CKMB was not done. The ECG Core Lab reported new intermittent major anterolateral/apical T wave inversions and no new Q waves on tracings of inadequate quality due to severe artifact. The CEC ruled the event met the criteria for a non-Q wave MI.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Q wave MI, Subacute Closure/Stent Thrombosis, Target Lesion Revascularization-PTCA 1 day post-procedure The patient is a 75 year-old man with a history of dyslipidemia and hypertension who presented with CCS Class II angina and a recent positive functional ischemia study. On 05/16/2006 at 14:41 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. The stent was post-dilated. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the proximal LAD with a 33% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation "stent not properly expanded." The pre-procedure CK and CKMB were 32 (nl 225, ratio <1) and 0.7 (nl 3.5, ratio <1). Two sets of post-procedure cardiac enzymes were within normal range and on 05/17/2006 at 03:54 the CK was 55 (ratio <1) with a CKMB of 2.9 (ratio <1). The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The day after the procedure the patient developed chest pain and the site reported ST elevations in the precordial leads. He was brought back to the catheterization lab and underwent repeat angiography 05/17/2006 at 11:07 which revealed site reported stent thrombosis. The Angiographic Core Lab reported on a lesion in the proximal LAD with a 35% in-lesion renarrowing with TIMI 3 flow with the notation of thrombus in the mid part of stent. The patient underwent repeat revascularization with balloon angioplasty of the mid LAD. The CK peaked on 05/17/2006 at 18:40 at 536 (ratio 2.4) with a CKMB peak of 33.2 (ratio 10). The site reported a non-Q wave MI. The ECG Core Lab reported limb leads were not interpretable due to interchange of RA and RL leads on 05/17/2006 at 11:56; however it further noted that the precordial leads were interpretable and reported anteroseptal Q wave MI, anterolateral intermittent ST elevations, and persistent anterolateral T wave inversions. After a review of the ECGs, the CEC determined the event met the criteria of a Q wave MI. The Discharge Summary reported appropriate compliance to the ASA and clopidogrel regimen. The patient was discharged on 05/20/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-PTCA 24 days post-procedure The patient is a 51 year old man with a history of former smoking, dyslipidemia, hypertension, a MI in 2001 and PCI of a non-target vessel who presented with a positive functional ischemia study. On 02/20/2006 at 07:21 he underwent the index procedure; however several attempts to pass the pre-treatment balloon in the target lesion in the distal CX were unsuccessful. A very small dissection was noted; however the patient remained asymptomatic. The procedure was aborted. The Angiographic Core Lab reported an 86% final residual in-lesion stenosis with a grade B dissection and TIMI 2 flow. The post-procedure course was uncomplicated and the patient was discharged on 02/21/2006 on ASA and clopidogrel. The 9 month contact revealed the patient underwent treatment of the target lesion at a non-study hospital during March 2006. (The site reported the patient had been lost to follow-up and did not return for 30-day or 6 month follow-up visits.) According to a query response a routine functional ischemia study, performed on 02/20/2006 revealed lateral wall ischemia. Repeat angiography on 03/16/2006 in the absence of recurrent angina with an abnormal functional ischemia study revealed a 90% lesion of the distal CX and an 80% lesion in the tortuous mid part of the distal CX site reported 90% diameter stenosis of the target lesion reported in the Interventional Catheterization Report. The Angiographic Core Lab Report and Discharge Summary are not available. The patient underwent balloon angioplasty and placement of three CYPHER® stents in the proximal CX and the mid CX, reported as a target lesion revascularization.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Lesion Revascularization-CABG 119 days post-procedure The patient is a 75 year-old woman with a history of hypertension who presented with CCS Class II angina and a positive functional ischemia study on 02/09/2006. On 03/30/2006 at 14:19 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. Eptifibatide was administered and the stent was post dilated. Following stent placement there was a plaque shift into the AV groove requiring balloon angioplasty. The Angiographic Core Lab reported a 14% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/31/2006 on ASA and clopidogrel. Repeat angiography on 07/19/2006 for recurrent angina in the absence of a functional ischemia study revealed a site reported 80% restenosis of the target lesion and 4 plus mitral regurgitation. The Angiographic Core Lab reported a 56% focal body in-stent restenosis. On 07/27/2006 the patient underwent elective CABG surgery with placement of a SVG to the 1st OM and a SVG to the distal RCA as well as a tricuspid valve repair and mitral and aortic valve replacements.
----------		Taxus	Cardiac Death 52 days post-procedure The patient was a 63 year-old woman with a history of MI in April 2005, CABG surgery on 03/08/2005, hypertension, dyslipidemia, diabetes, and current smoking who presented with CCS Class III angina. On 04/14/2006 at 17:07 she underwent the index procedure with pre-treatment balloon angioplasty. The site reported a grade B proximal edge dissection after pre-treatment was treated with placement of two assigned stents in the proximal RCA. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation of a small grade C dissection after first balloon with placement of two stents with long overlap. The post-procedure course was uncomplicated and the patient was discharged on 04/15/2006 on ASA and clopidogrel. On 06/05/2006 the patient was found dead at home by a family member. The Death Certificate reported the immediate causes of death as cardiac arrest and CAD with diabetes and hyperlipidemia noted as other significant conditions. No autopsy was performed.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA 141 days post-procedure The patient is a 47 year-old man with a history of dyslipidemia, hypertension, a MI on 03/06/1996, and premature CAD in a 1st degree relative who presented with CCS Class II angina and a recent positive functional ischemia study. On 05/11/2006 at 16:04 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal LAD. The Angiographic Core Lab reported a 6% final residual in-lesion stenosis with the presence of thrombus, distal embolization, no dissection and TIMI 3 flow. The patient was discharged on 05/13/2006 on ASA and clopidogrel. Repeat angiography on 09/29/2006 for recurrent angina and with a positive functional ischemia study revealed a 76% intra-stent restenosis reported by the Angiographic Core Lab with the notation target lesion revascularization. The patient underwent repeat revascularization with balloon angioplasty and placement of a stent in the proximal LAD.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Target Lesion Revascularization-PTCA 86 days post-procedure, Late Stent Thrombosis 83 days post-procedure The patient is an 87 year-old female with a history of diabetes, hypertension, and premature CAD in a 1st degree relative who presented with CCS Class II angina and a negative functional ischemia study. On 04/24/2006 at 15:48 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. There were no clinical sequelae. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 04/26/2006 on ASA and clopidogrel. According to a Discharge Summary, the patient was rehospitalized with chest pain on 07/16/2006 and diagnosed with a non-Q wave MI based on a troponin rise to 2.4. (nl 0.09, ratio 27). The Summary noted prior to admission ASA and clopidogrel were discontinued for a planned carotid procedure. The site confirmed clopidogrel was discontinued on 07/14/2006 and restarted on 07/16/2006. The initial CK and CKMB on 07/16/2006 at 16:13 were 48 (nl 215, ratio <1) and 3.2 (nl 5, ratio <1) respectively. On 07/17/2006 at 05:25 the CK peaked at 113 (ratio <1) with a peaked CKMB of 20.7 (ratio 4.1) respectively. On 07/17/2006 at 12:00 the CK was 92 (ratio <1) with a CKMB of 15.7 (ratio 3.1). The ECG Core Lab reported poor quality of the ECG tracings dated 07/16/2006 to 07/20/2006 with the notation of intermittent ventricular pacing unchanged and resulting in uninterpretable ST-T changes and masking of Q waves "if any," in leads V1- V3 on 07/20/2006 at 09:07. The CEC ruled the event did not meet criteria for a non-Q wave MI. Repeat angiography on 07/19/2006 for recurrent clinical symptoms with a positive functional ischemia study revealed an 83% severe intra-stent restenosis reported by the Angiographic Core Lab with the notation of the presence of thrombus with TIMI 2 flow. The Interventional Catheterization Report noted a severe 99% in-stent restenosis with TIMI 2 flow. The site reported stent thrombosis and/or subacute closure on a Repeat Angiography Form. On 07/19/2006 she underwent repeat revascularization with balloon angioplasty and cutting balloon angioplasty of the 1st OM.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Non-Q wave MI day of procedure The patient is a 68 year-old man with a history of dyslipidemia, hypertension, former smoking and premature CAD in a first degree relative who presented with CCS Class II angina. On 05/26/2006 at 14:42 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the 1st OM. Eptifibatide was administered. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the 2nd OM with a 21% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The pre-procedure CK drawn on 05/26/2006 at 10:51 was 132 (nl 232, ratio <1) with an elevated CKMB of 15.7 (nl 3.6, ratio 4.4) respectively. The CK peaked on 05/26/2006 at 22:15 at 727 (ratio 3.1) with a CKMB of 156.7 (ratio 43.5). The site reported a non-Q wave MI. The ECG Core Lab reported persistent inferior T wave inversions and no new Q waves. The patient was discharged on 05/29/2006 on ASA and clopidogrel.
----------		Taxus	Non-Q wave MI day of procedure The patient is a 58 year-old man with a history of dyslipidemia who presented with a positive functional ischemia study. On 05/25/2006 at 10:43 he underwent the index procedure with pre-treatment balloon angioplasty; however the Cardiac Catheterization Report noted the assigned stent could not be delivered to the distal LAD target lesion due to disease in the mid segment of the vessel. The site reported after pre-dilation there was a grade C dissection with a 90% worst diameter stenosis. Attempts to deliver the assigned stent in the distal vessel failed. There was subsequent successful delivery of two mini VISION™ stents in the distal LAD, two mini VISION™ stents in the mid LAD and one assigned stent in the proximal LAD. The Angiographic Core Lab reported a 42% final residual in-lesion stenosis with a proximal grade C dissection and TIMI 3 flow with the notation of some apositioning of the proximal stent. The pre-procedure CK and CKMB drawn on 05/25/2006 at 09:15 were 108 (nl 269, ratio <1) and 1.2 (nl 5, ratio <1) respectively. The CK peaked post-procedure on 05/26/2006 at 11:19 at 594 (ratio 2.2) with a non-concurrent CKMB peak at 07:09 of 57.7 (ratio 12). The site reported an asymptomatic non-Q wave MI. The ECG Core Lab reported no new major ST-T abnormalities and no new Q waves. The patient was discharged on 05/26/2006 on ASA and clopidogrel.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-cardiac Death 248 days post-procedure, Target Lesion Revascularization-PTCA 223 days post-procedure The patient was a 74 year-old man with a history of MI on 04/28/2004 with a target vessel PCI, dyslipidemia and hypertension who presented with CCS Class III angina and a positive functional ischemia study. On 05/30/2006 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the proximal RCA. Eptifibatide was administered. The Angiographic Core Lab reported a 13% final residual in-lesion stenosis with no dissection and TIMI 3 flow with the notation of an aneurysm in pre-treatment image, covered by stent. The post-procedure course was uncomplicated and the patient was discharged on 05/31/2006 on ASA and clopidogrel. The patient presented in the Emergency Room on 01/07/2007 with back pain. The site reported a non-Q wave MI with elevated troponin levels. On 01/07/2007 at 01:05 the CK peaked at 91 (nl 269, ratio <1) with a CKMB of 5.1 (nl 5, ratio 1). On 01/07/2007 at 09:00 the CK was 88 (ratio <1) with a CKMB peak of 10.6 (ratio 2.1). A peak troponin of 0.72 (nl 0.40, ratio 1.8) was reported on 01/09/2007 at 06:05. The ECG Core Lab reported on ischemic ECG tracings dated 01/07/2007; 01/08/2007; and 01/09/2007; noting an inadequate tracing quality with intermittent inferolateral ST depressions, intermittent inferolateral T wave inversions, and no new Q waves. The CEC ruled the event did not meet criteria for a non-Q wave MI. Repeat angiography on 01/08/2007 for recurrent unstable angina and in the absence of a functional ischemia study revealed a site reported 90% restenosis of the target lesion. The Angiographic Core Lab reported a 53% marginal in-stent restenosis and with the notation of ostial in-stent restenosis, target lesion revascularization. The patient underwent repeat revascularization of the proximal RCA. On 02/02/2007 the patient underwent microlaryngoscopy with biopsy and right modified neck dissection for a right neck mass. Post-operatively the patient experienced difficulty breathing and there was an inability to intubate secondary to hematoma in the pharynx requiring an emergency tracheostomy. The patient experienced cardiac arrest, and after multiple resuscitation efforts, expired on 02/02/2007. The Discharge Summary reported the final diagnoses of coronary artery disease with cardiac arrest, refractory ventricular fibrillation, difficult airway and shock. An autopsy was not performed. The CEC ruled the event met the criteria for a non-cardiac death.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Target Vessel Revascularization-PTCA 153 days post-procedure The patient is a 75 year-old man with a history of an MI on 05/16/2004, prior PCI of a non-target vessel, dyslipidemia and hypertension who presented with CCS Class III angina. On 05/30/2006 at 13:50 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the ramus. During placement of the assigned stent in the ostial ramus the site reported the proximal LAD was compromised and this was successfully treated with placement of an additional assigned stent. An Interventional Catheterization Report noted the original stent was somewhat more distal than the ostium and therefore a second assigned stent was placed proximally to the first to cover the ostium. Eptifibatide was administered. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis with no dissection and TIMI 3 flow and noted placement of two stents in the proximal ramus with overlap and 1 stent in the proximal LAD. The post-procedure course was uncomplicated and the patient was discharged on 05/31/2006 on ASA and clopidogrel. Repeat angiography on 10/30/2006 for recurrent angina and without a functional ischemia study revealed a 16% in-lesion restenosis reported by the Angiographic Core Lab with the notation of a patent study stent with irregularities further distal, remote target vessel revascularization. An Interventional Catheterization Report noted a 50% stenosis of the ostial ramus, a 70% stenosis of the distal ramus, and an 80% stenosis of the proximal CX. The patient underwent balloon angioplasty with placement of one stent in the ramus, distal to the target site, and one stent in the proximal CX.

Adjudicated Deaths beyond 270 days are presented below.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Non-cardiac Death 395 days post-procedure The patient was an 85 year-old woman with a history of MI in 1966, dyslipidemia, hypertension, former smoking, and premature CAD in a 1st degree relative who presented with CCS Class IV angina and a positive functional ischemia study. On 11/22/2005 at 13:29 she underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the distal CX. There were no clinical sequelae. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 11/24/2005 on ASA and clopidogrel. A Discharge Summary reported the patient was admitted to the hospital on 12/03/2006 after a fall at a rehabilitation hospital where she was recovering following a left hip fracture repair. She was admitted with weakness, abdominal pain, and anemia. She was transfused with 2 units PRBCs. Cholecystitis was also diagnosed and she underwent a cholecystectomy. The patient was placed on an Amiodarone drip for a recurrence of previously diagnosed atrial fibrillation. Following surgery she experienced nausea and difficulty eating and refused nutrition and physical therapy. The family refused to have a feeding tube placed and the patient was transferred to hospice care on 12/15/2006 with a diagnosis of failure to thrive. She died on 12/22/2006 according to the hospice records. The official cause of death is listed as failure to thrive and no autopsy was performed.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Cardiac Death 308 days post-procedure The patient was a 55 year-old man with a history of dyslipidemia, hypertension, former smoking and premature CAD in a first degree relative who presented with CCS Class III angina and a positive functional ischemia study. On 03/17/2006 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. Bivalirudin was administered. The Angiographic Core Lab reported on a lesion in the distal RCA with a 24% in-lesion stenosis with no dissection and TIMI 3 flow with the notation distal RCA, 1 stent into the R-PDA. The post-procedure course was uncomplicated and the patient was discharged on 03/18/2006 on ASA and clopidogrel. The site reported the patient experienced worsening depression and suicidal thoughts starting in December 2006. On 01/19/2007 the patient was found dead in his room at a hospitality house. A toxicology report was negative and the autopsy report listed the cause of death as ischemic heart disease secondary to coronary artery disease and noted the proximal RCA stent was intact and patent. The site reported the categorical cause of death as non-cardiac.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Cardiac Death 349 days post-procedure, Stroke 82 days post-procedure
			The patient was a 73 year-old man with a history of MI on 05/08/2002, diabetes, hypertension, and former smoking who presented with a positive functional ischemia study. On 02/22/2006 at 08:33 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. There were no clinical sequelae. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 02/23/2006 on ASA and clopidogrel. An Adverse Event log provided by the site reports a "light stroke of the left eye" on 05/15/2006. A query for an event form and additional information regarding this event yielded a Radiology Consultation Report dated 07/05/2006 that noted the patient had a history of visual changes in both eyes. A Progress Note dated 10/09/2006 reported the patient was informed by the VA Hospital on an unknown date that he had suffered a stroke in the left eye. The patient was rehospitalized on 01/25/2007 for complaints of neck pain, problems with balance, and upper and lower extremity weakness. An MRI showed a benign spinal tumor at the C2 level and the patient underwent C2-C3 decompression with meningioma removal and resection on 01/25/2007. According to the Discharge Summary the patient became hypotensive and exhibited signs of septic shock and multi organ failure post-operatively and was started on dopamine, levophed, and antibiotics. On 01/27/2007 the patient experienced respiratory failure and was intubated. He had an elevation of troponin (value not reported) and subsequently experienced multiple episodes of ventricular tachycardia/fibrillation which was shocked 21 times. The Summary noted another "cardiac event" on 1/31/2007; however treatment was not reported. On 02/04/2007 a head CT showed increasing bilateral subdural hematomas with bifrontal pneumocephalus. A decision was made by the patient's family to discontinue medications and nutrition on 02/05/2007 and the patient expired on 02/06/2007. The official cause of death was cardiac arrest and the categorical cause of death was reported as cardiac. No autopsy was performed.

Site	Patient	Treatment Group	Narrative
----------		Taxus	Cardiac Death 414 days post-procedure The patient is a 57 year-old man a history of a non-target vessel PCI, diabetes, dyslipidemia, hypertension, current smoking, and premature CAD in a first degree relative who presented with CCS Class I angina and a positive functional ischemia study. On 02/28/2006 at 09:06 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid LAD. A second assigned stent was placed in the proximal LAD for adequate lesion coverage. There were no clinical sequelae. The Angiographic Core Lab reported on a lesion in the proximal RCA with a 19% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 03/01/2006 on ASA and clopidogrel. Repeat angiography on 01/30/2007 for recurrent clinical symptoms and a positive functional ischemia study performed on 01/19/2007 revealed a 23% in-lesion restenosis of a lesion in the mid LAD reported by the Angiographic Core Lab with the notation of moderate neointimal hyperplasia, remote target vessel revascularization of the proximal LAD. The site reported an 80% restenosis of the target lesion and noted stent thrombosis and/or subacute closure of the target lesion on the Repeat Angiography Form. The patient underwent repeat revascularization with balloon angioplasty of the proximal LAD, reported by the site as a target lesion revascularization. A narrative indicated the patient was scheduled for treatment of the RCA in approximately two weeks. On 02/13/2007 the patient underwent a re-study and PCI of a non-target vessel in the proximal RCA and the 1st RPL. Late evening on 04/17/2007 after taking Viagra around 22:00 (possibly before midnight), the patient was rehospitalized through the Emergency Room and diagnosed with an acute massive MI complicated by cardiogenic shock. Also, according to a Preoperative Diagnosis statement prior to the incident the patient stopped his clopidogrel [date not known at the time] at the request of a physician for an upcoming endoscopy. The site reported a Q wave MI. A single CK drawn on 04/18/2007 at 00:21 was 108 (nl 174, ratio <1) and the CKMB was not performed. There were no further cardiac enzyme levels performed. The ECG Core Lab reported an acute anterior Q wave MI with persistent anterior hyperacute T waves, anterior ST-elevations, inferior ST depressions, and inferior T wave inversions. According to a Procedure Summary he was intubated and taken urgently to the Cardiac Catheterization Lab on 04/18/2007. Repeat angiography for MI revealed a total occlusion of the proximal LAD without thrombus, with TIMI 0 flow reported by the Angiographic Core Lab with the notation of a remote target vessel revascularization and target lesion revascularization with multiple attempts, some flow at the end of the procedure. It also noted embolization in RCA. The Summary further noted the left main trunk distally was clotted all the way to the distal left anterior descending coronary artery and there was no flow. Also, the circumflex coronary artery was clotted. The patient underwent unsuccessful repeat revascularization with balloon angioplasty of the LMCA, proximal LAD, mid LAD and distal LAD along with placement of a mini Vision stent in the LMCA, extending into the LAD. Eptifibatide and IV amiodarone were administered and an IABP was inserted. He and was treated for ventricular tachycardia and recurrent ventricular fibrillation with lidocaine and electrical cardioversion. A temporary pacemaker was placed to treat asystole. Despite maximum medical treatment he expired on 04/18/2007. The site reported an official cause of death of massive anterior MI complicated by cardiogenic shock. No autopsy was performed.

Site	Patient	Treatment Group	Narrative
----------		Endeavor	Non-cardiac Death 340 days post-procedure The patient was a 45 year-old man with a history of dyslipidemia, hypertension, current smoking, and premature CAD in a 1st degree relative who presented with CCS Class III unstable angina. On 10/28/2005 at 13:32 he underwent the index procedure with pre-treatment balloon angioplasty and delivery of the assigned stent in the mid RCA. The stent was post dilated and bivalirudin was administered. There were no clinical sequelae. The Angiographic Core Lab reported a 22% final residual in-lesion stenosis with no dissection and TIMI 3 flow. The post-procedure course was uncomplicated and the patient was discharged on 10/29/2005 on ASA and clopidogrel. During December 2005 the patient was admitted with gastro-intestinal bleeding and was treated with blood transfusions. In March 2006 the patient was admitted for treatment of acute renal failure. On 08/18/2006 the patient was hospitalized with acute renal failure and hyponatremia secondary to dehydration, and was diagnosed with hepatic encephalopathy and hepatomegaly consistent with a history of alcohol abuse. On 08/24/2006 the patient was transferred to a facility for alcohol treatment. He was admitted to hospice care on 09/28/2006 and died on 10/03/2006. No autopsy was performed and the official cause of death was listed as hepatorenal syndrome and alcoholic cirrhosis.

Table 27. Detailed Patient Listing

Section IV. Methods for Qualifying Angiograms

Ascertainment of Qualifying Angiograms

1. Identify patients in the angiographic subset.
2. Identify experimental lesions in the angiographic subset; discard non-experimental lesions:
    a. Compare post and pre films to see if the CASS numbers match;
    b. Compare the FU with baseline. If any CASS numbers do not match, then issue query and await resolution.
3. Reconcile duplicate QCA readings or inappropriate QCA readings (e.g., follow-up reads on baseline CRF's). The angiographic core laboratory will receive queries regarding duplicate or inappropriate QCA readings. Once the readings are reconciled, the duplicate or inappropriate readings will be discarded.
4. Perform all analyses as lesion-based, NOT patient or vessel-based.
5. Exemptions from Angiographic F/U:
    a. Intent to Treat analyses:
        i. Peri-procedural CABG (within 14 days);
        ii. Death before F/U QCA due in the absence of a qualifying angiogram.
    b. Per-protocol analyses:
        i. Patients who withdraw consent for further follow-up, including angiograms;
        ii. Lesion never successfully treated with assigned device strategy.
6. Define the upper window that will be acceptable for qualifying angiograms. Three Hundred Sixty (360) days is the upper window for 8-month follow-up.
7. All QCA ≤ 14 days post-procedure and instances of subacute closure will not be included for analysis of restenosis.
8. All QCA after any TVR (clinically indicated or NOT) that occurs >14 days post-procedure are censored; TVR changes natural history of the lesion. TVRs occurring within the first 14 days post-procedure should NOT be used for excluding subsequent QCA's (unless it's a CABG, which exempts the patient).
9. Define a date cut-off as the earliest acceptable date for qualifying angiograms:
    a. One Hundred Fifty (150) days is the cut-off for 8-month follow-up.
    b. If QCA between days 15-150 and in-segment QCADS ≥70%, angiogram qualifies as restenosis.
    c. If QCA between days 15-150 and in-segment QCADS <50% and NO clinically-driven TLR occurred within a reasonable time window (vide infra), the angiogram is censored.
    d. If QCA between days 15-150 and in-segment QCADS <50% but is associated with a TLR that the CEC has deemed clinically-driven (despite the fact that the QCADS <50%), then this angiogram should be considered *qualified* and should NOT be censored. This lesion will have undergone a clinically-driven TLR in the absence of angiographic restenosis.
    e. If QCA between days 15-150 and in-segment QCADS 50-69.9% and a TVR (clinically indicated or NOT) occurs within a reasonable time window (e.g., 30 days after the QCA), the angiogram qualifies as restenosis.
    f. If QCA between days 15-150 and QCADS 50-69.9% and NO TVR occurs within a reasonable time window, the angiogram is censored.
10. In case of multiple qualifying angiograms, first take the one associated with TVR and/or TLR, whichever occurs first, then use the one closest to the follow-up date, and then take the latest one (to allow for vessel remodeling).
11. If a QCA has an in-lesion diameter stenosis which qualifies (e.g., in-lesion DS 53% with TVR at day 60), then the entire angiogram should qualify, even if the in-stent diameter stenosis <50%.
12. If the in-lesion MLD is 0 (total occlusion) upstream (proximal to) the experimental stent, then the in-stent MLD should be set to zero. The two situations where in-stent MLD is not zero (even if in-lesion MLD is zero) are in cases where no stent was deployed during the index procedure or where the total occlusion is distal to the stent (in which case the in-stent MLD should be available and >0).

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APPENDIX 6

Endeavor PK 9 Month Report

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APPENDIX 7

Endeavor Japan 9 Month Report

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APPENDIX 8

Endeavor V

To Evaluate the 'Real World' Clinical Performance of the Medtronic Endeavor™ Zotarolimus-Eluting Coronary Stent System; A Prospective, Multicenter Registry

E-Five Registry

Interim Report: 30-Day Results of the First 2015 Patients

Sponsor:	Medtronic Vascular, Inc. Santa Rosa, CA USA
	Medtronic Bakken Research Center The Netherlands
Principal Investigators:	Prof. I.T. Meredith Australia
	Prof. M.T. Rothman United Kingdom
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Report Prepared By:	Medtronic Vascular Santa Rosa, CA
	Medtronic Bakken Research Center The Netherlands
Date Report Finalized:	14 November 2006
Version:	1.0 FINAL

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Section I: Structured Abstract

Title: Endeavor-Five Registry – To Evaluate the 'Real World' Clinical Performance of the Medtronic Endeavor™ Zotarolimus-Eluting Coronary Stent System; a Prospective, Multi-center Registry.

Objectives: The primary objective of this registry is to document the safety and overall clinical performance of the Endeavor™ Zotarolimus-Eluting CSS (Coronary Stent System) in a "real world" patient population requiring stent implantation.

The secondary objective of this registry trial is to assess the event rate in patient subgroups with specific clinical indications and /or vessel- or lesion characteristics. This objective is not covered in this interim report.

The purpose of this interim report is to provide 30-day drug experience on the first 2015 enrolled patients.

Design: The E-Five Registry is a prospective, multicenter registry to evaluate the 'real world' clinical performance of the Medtronic Endeavor stent system. By design, the E-Five Registry is a Post Market Release Registry, meaning that patients are only enrolled in countries where the Endeavor Stent System has obtained national regulatory approval and is commercially available. Patients included in the E-Five registry are receiving the same treatment as any other patients would under normal hospital routine.

The primary endpoint for this trial is the Major Adverse Cardiac Events (MACE) rate at 12 months post-procedure, defined as death, myocardial infarction (Q-wave and non-Q wave), emergent cardiac bypass surgery or clinically driven target lesion revascularization (repeat PTCA or CABG).

Secondary endpoints are MACE rate at 30 days and at 6 months, stent thrombosis rate (acute <24h; subacute 2-30 days; late >30 days), procedural success rate, device success rate and lesion success rate.

Clinical Sites: Approximately 200 centers located in Europe, Asia, Australia, New Zealand and South America are recruiting patients into this registry. This interim report includes results from 73 centers.

Enrollment: All patients with an indication for coronary stent implantation according to the 'Instructions for Use' of the Endeavor Stent System could be enrolled into the E-Five registry. The registry expects to include all consecutive patients who receive one or more Endeavor stents in one or more target lesions. However, lesions should meet the specific vessel and lesion characteristics as described in the 'Instructions for Use' to be selected for implantation with the Endeavor Stent. Choice of stents for lesions not meeting these characteristics was left at physician's discretion.

In total 8000 patients will be included into this registry. Patient enrollment started in September 2005 and is currently ongoing.

This interim analysis is performed at request of the FDA to support the Endeavor Pre Market Application and provides interim results for the first 2015 patients with 30-day clinical follow-up. To determine the patients to be included in the subset for the interim analysis the date of procedure was used. The procedure date of March 16, 2006, yielded 2130 enrolled patients. Out of the 2130 patients, a total of 114 from two centers were excluded from the analysis because of European privacy laws. Both centers used their standard patient informed consent for registries which did not specifically mention the transfer of data to the United States of America where the European Directive on Data Protection does not apply. Because a corrective action regarding the informed consent and data transfer was still in progress at the time of the analysis, the data of these patients had been excluded. One patient was enrolled into the trial but no Endeavor stent was attempted to be used, hence data from this patient was not presented in this report.

As a result, this report presents data from 2015 consecutive patients in the 73 centers with data transfer allowance.

Methods: Baseline clinical and follow-up data are entered on an electronic Case Report Form by clinical research coordinators at the study sites.

Follow-up assessments are performed at 30 days, 6 months and 12 months. These clinical follow-ups can be done by phone or preferably by outpatient clinic visit. Clinical follow-up is extended to 2 years in a limited number of centers for specific patient subsets.

In order to ensure data quality, a pre-defined percentage of the clinical sites will be visited for source data verification. The aim is to monitor 10% (approximately 800 patients) of all patients with focus on study endpoints and to ensure accurate safety data reporting. For the patient subset studied in this interim report, 24 monitoring visits have been conducted at 23 different hospitals. In total 243 patients included in this interim analysis have been monitored, which results in 12.1% of the analyzed patients.

An independent Clinical Event Committee adjudicates all major adverse cardiac events (MACE) and stent thrombosis events, and an independent Data Safety Monitoring Board monitors the trial.

Analysis Population: The primary analytical set for analysis are all patients who signed the written informed consent and for whom the Endeavor device was introduced through the guide catheter. The lesion related parameters are also analyzed for all the target lesions, defined as lesions on which the Endeavor device was introduced.

Results:
A total of 2015 patients were included into the analysis from 73 study sites located in Europe, Asia and South America (see Table 2).

Baseline patient and lesion characteristics:
Baseline patient characteristics are shown in Table 3. Demographics and clinical characteristics show a mean age of 63.05±11.45 years and 76.6% male enrollment. Patient history revealed a previous percutaneous coronory intervention (PCI) in 24.0%, previous coronary artery bypass graft (CABG) in 6.7%, diabetes mellitus in 35.2% with insulin dependent diabetes in 8.8% of the patients. Current cardiac status at baseline was unstable angina in 31.5% and recent myocardial infarction in 21.8% of the patients.

Baseline lesion characteristics are shown in Table 4. The 2015 patients had 2458 lesions in which Endeavor stents were implanted or attempted, which were included in the analysis. 67.9% of the patients had one lesion being treated, most frequent vessel location was the LAD in 48.6% of the cases. In total, 15.7% of the lesions involved a bifurcation. The ACC/AHA lesion classification was reported by sites as type B2 or C for 59.9% of the lesions.

Angiographic measurements were done by the sites by visual estimate and are shown in Table 6. Mean lesion length was 18.28±9.91mm and the mean reference vessel diameter was 2.92±0.45mm; the mean minimum lumen diameter was 0.54±0.43mm and the mean pre-procedure diameter stenosis reported was 81.53±14.22%. The post-procedure angiographic results showed a mean diameter stenosis of 2.13±6.84%.

Table 7 shows the summary of the stent implantation. In 86.7% of the lesions, one Endeavor stent was implanted. The mean of total stent length implanted was 23.35±11.98mm. The minimum diameter of the Endeavor stents used was ≤ 2.75mm in 43.6% of the target lesions. The Endeavor stent was successfully delivered in 99.4% (2444/2458). The reason for unsuccessful delivery was mostly failure to reach the target lesion (9/14). Implantation of an Endeavor stent in combination with other Drug Eluting Stents occurred in 3.3% of the target lesions, with Bare Metal Stents in 2.2% of the target lesions.

Discussion of Results:
This interim analysis is performed at request of the FDA to provide supplementary 30-day drug experience on approximately 2000 patients. The purpose of the E-Five registry is to document the safety and overall clinical performance of the Endeavor Stent in a "real world" patient population. This report provides the baseline demographics, lesion characteristics and 30-day clinical outcomes on 2015 patients of the total 8000 patients to be recruited in this registry. This data contains an interim analysis of the safety endpoints: Major Adverse Cardiac Events (MACE) at 30-day post-procedure defined as death, myocardial infarction (Q-wave and non-Q wave), and emergent cardiac bypass surgery or target lesion revascularization (repeat PTCA or CABG). In addition, early stent thrombosis (acute (<24h) and sub-acute (2-30

days) stent thrombosis), procedural success, device success and lesion success are included.

Acute procedural results and device performance:
In the lesions with at least one Endeavor stent implanted or attempted, the clinical and site reported angiographic results showed that the lesion success rate was 99.6% (2449/2458), and the procedure success rate 98.6% (1987/2015). The device success rate was 94.2% (2316/2458) and the device-specific procedure success rate, defined as attainment of <50% residual stenosis using only the Endeavor device and no in-hospital MACE, was 92.6% (1866/2015).

Interim MACE and early stent thrombosis rates at 30-days:

The interim safety results at 30 day follow-up of 2015 ”real world” patients included in the E-Five registry is presented in Table 1. The incidence of MACE was 1.7% (34/1982) at 30 days. The individual safety components are presented in Table 10. Review of the individual safety components shows that death occurred in 0.9% (17/1982) and early stent thrombosis in 0.9% (18/1982) of the patients. The section below addresses the adjudicated deaths and stent thrombotic events. The rate of 30-day Q-wave MI was 0.3% (6/1982), the percentage of target lesion revascularization was 0.4% (8/1982) and the percentage of non-Q wave MI was 0.6% (11/1982).

For one patient (study ID 132003) the site reported a stent thrombosis and a revascularization. However, despite strong efforts, the Investigator had not signed the respective event forms at the time of data transfer for this interim analysis. The study team decided that this patient needed to be adjudicated by the Clinical Event Committee based on the data available. The narrative of this patient can be found in Table 11.

In Endeavor I, II, III, IV, and Endeavor II Continued Access studies, Medtronic has utilized a single CEC (HCRI) to adjudicate all events for the Endeavor Clinical Program. At the time of the initiation of the Endeavor-Five registry, the Cardialysis CEC was established to perform a clinical review with access through web based documents sent to Cardialysis by the sites, according to the Cardialysis standard opertaing procedures.

Announcements by competitor DES programs regarding stent thrombosis events and the safety concerns discussed during the annual conferences, TCT and ESC, precipitated FDA convening the Advisory Panel on Stent Thrombosis. This prompted the Sponsor to update the clinical discussion for purposes of this document and submission. Specifically, the FDA conversations with Medtronic allowed insight into the fact that FDA is especially interested in reviewing the data available from registries and the types of lesion/patient cohorts not seen in the regular registration studies. With this information, the sponsor is submitting detailed case narratives to capture the available information concerning the deaths and stent thrombotic events.

Adjudication of the events is an ongoing process and when new information is made available from the sites regarding the events, it will prompt re-adjudication by the Clinical Events Committee, as deemed appropriate, to allow for accurate adjudication and revision.

Medtronic elected to submit the E-Five data as outlined in this registry at time of submission data freeze with queries to the CEC pending readjudication. Medtronic is providing the additional detailed narratives which confirm some of the issues adjudicating the cases with (a) more than one stent, (b) default adjudication where all deaths within the first 30 days is given a "stent thrombosis" relationship.

The section below provides insight to the discussion between the sponsor and the CEC for re-adjudicating events in the ongoing trial with an open database. The submission of the E-Five dataset is provided as a supplement (requested by FDA) to the safety and efficacy in the clinical trials database yielding over 2000 subjects.

Discussion of the Deaths and Stent Thrombotic events.

Summary of the sponsor review of the stent thrombotic events

The events outlined below were reviewed by the sponsor in an effort to align the Cardialysis adjudication with the Harvard Clinical Research Institute (HCRI) definitions and procedures, which were used to adjudicate events for Endeavor I, II, II Continued Access and III trials. Based on the sponsor's review, these are classified into the following categories as a way to enhance the reviewers understanding of the event and time course of events. There are pending and outstanding items under review by the CEC and is listed below for the reviewer.

a) Stent thrombotic events that were likely attributable to the Endeavor stent and the sponsor agrees with the adjudication

This includes the following patients:

i. —IDDM, 26 mm stent
ii. —non IDDM, 24 mm stent, underployed stent
iii. —IDDM, 30 mm stent, not on antiplatelets
iv. —85 y/o, 48 mm stent , overlap,
v. —IDDM, left main stent, 2.5x 14 mm
vi. —AMI 2 days before, TIMI 0 flow at intervention

The narratives on the patients listed above give enough documentation to allow for adjudication of early stent thrombosis without competing diagnosis or non-Endeavor stent. The attached narratives are available with the report to enable the reviewer with the patient characteristics, procedure issues, and compliance of medications contributing to the stent thrombotic event during the first 30 days.

b) Stent thrombotic events with questionable relationship to the Endeavor stent. Outlined below are the details for five (5) patients who met this criteria:

i. Patient [redacted] is adjudicated as a stent thrombotic event. Upon review of the case report form and source documentation, the sponsor requested that the event be re-adjudicated by the CEC. The case report forms indicate the patient presents with an occluded RCA with three lesions treated and an apparent open artery demonstrated while the patient is being supported with inotropes and with placement of an intra aortic balloon pump. This patient died with apparent pump failure and the etiology supported by ejection fraction of 35%, and prior Q wave MI allowing for minimal added muscle damage in the cath lab. The fact the patient has a documented open artery while demanding hemodynamic support in the cath lab would not support the designation of stent thrombosis.

ii. Patient [redacted] experienced an MI 7 days post stenting with both the RCA and the prox LAD receiving stents. The MI is described as anterior related to the LAD myocardial distribution . However, the coverage of the LAD was with both an Endeavor and another DES stent. The sponsor has asked the site to submit the film for review and details on the assignment of the event to the appropriate stent. Should the CEC not be able to adjudicate to either stent, then this event becomes thrombotic event number 7. Of interest the patient stopped clopidogrel on discharge.

iii. For patient [redacted] the site did not report the stent thrombosis as an event related to the stent. There is minimal information provided by the site. This coupled with the fact that the patient never left the hospital and died in his sleep, supports the sponsor's request for additional information from the site and the event to be re-adjudicated by the CEC. If it is decided that this is Endeavor related due to limited information to allow a more defined review, then this would be thrombotic event number 8.

iv. Subject [redacted] is an 80 year old with LVEF of 32% who presents with diminished flow in the proximal LAD with a 24 mm stent placed. The patient subsequently dies of cardiogenic shock some 2 to 3 days later with the site clearly adjudicating the event as cardiogenic shock and the patient not having left the hospital following his PCI. The low ejection fraction at initiation at the PCI associated with an MI in a proximal LAD, and site reported cardiogenic shock, provide a situation that may indicate "pump failure". Hence, the site was requested to provide more information and a revisit of the case by the CEC.

v. Subject [redacted] presented with a long clot noted at initial PCI with patient on Integrilin for some time following PCI. Patient comes back

with MI suggesting stent thrombosis but site adjudicates the clot having the same appearance as the initial PCI. The CEC will review the documentation for a new MI and confirm if the clot extended from the original MI or if this is a separate and new thrombotic event. If it is decided that this is Endeavor stent related and a new MI,then this would be thrombotic event number 9.

Note that the sponsor believes that cases [redacted] are more likely pump failure than stent thrombosis.

c) Patients who received Endeavor and other stents

Subjects [redacted] have multiple stents. In the case of [redacted] the site is very specific and attributes the thrombotic event to the Coroflex blue stent. Case [redacted] involves both bare metal and Endeavor stents placed in separate arteries with sudden death and no autopsy, therefore making it difficult to determine which stent caused the event. The event will be re-adjudicated by CEC and the sponsor acknowledges the possibility of this event to be adjudicated as stent thrombosis. In this case, this will be event 10. For both cases, the lack of angiographic films or autopsy may have contributed to some overestimation of the event rate.

The sponsor has requested the CEC to review both events and accepts the possibility of events to be ruled a thrombotic event attributed to Endeavor.

d) Endeavor Placed In Patients Presenting With Acute MI

i. Patient [redacted] is a 71 year old male who presented with an acute MI and multiple stents were placed in the mid LAD and the mid circumflex arteries. The patient dies of acute MI on day 0 and the CEC adjudicates "no stent thrombosis" and the sponsor agrees.

ii. Patient [redacted] is adjudicated as stent thrombosis with onset of acute MI and presentation of occluded prox LAD treated with 3.0x 18 mm Endeavor stent. The patient never leaves the hospital and dies in his sleep 5 days later of myocardial infarction complications. The sponsor has requested a time course in hospital assessment of events since hospitalized patients under dual antiplatelet therapy have been unlikely to have stent thrombosis. There is a possibility of complications associated with MI on presentation, and the sponsor requested more detailes on the progress of the patient. If upon review of additional information, the CEC adjudicates stent thrombosis vs MI complications, then the case would represent number 11 stent thrombotic event.

iii. Patient [redacted] presented with an acute MI who dies of LV rupture on day 0, a few hours following procedure. The CEC ruled this was not a stent thrombosis, and cause of death was left ventricular rupture following MI.

iv. Patient [redacted] presented with RCA total occlusion and is described as having post PCI renal failure, requiring dialysis, and CHF with the CEC adjudicating the event as stent thrombosis. Since the case report forms indicate a cause of death as probably related to CHF and associated renal failure, the sponsor requested that this event to be re-adjudicated by the CEC.

v. Patient [redacted] is a case adjudicated by the CEC as not stent thrombosis related and is attributed to ventricular septal rupture. This patient died on procedure day 0, three days following his acute MI. This demise is not related to the Endeavor stenting procedure.

vi. Patient [redacted] is a patient who died suddenly following stenting of three lesions in two coronary arteries with 3 separate DES in each artery. The patient presented with TIMI 0 flow in the mid LAD and had a Cypher stent placed; A 2.25 Endeavor stent was placed in the distal circumflex and the case report forms describes abrupt closure A Taxus stent was placed in the OM vessel. Patient dies of arrhythmias in the post op unit and the sponsor believes that the attribution of the CEC to Endeavor is inappropriate since the Endeavor was placed on a small vessel location with less muscle likely at risk. The appropriate adjudication would be abrupt closure and not stent thrombosis.

e) Death due to reasons other than acute MI

Patient [redacted] presented with poor LVEF at 30% and noted to have cardiomyopathy with renal failure requiring support for cardiogenic shock . The patient underwent stenting to two vessels with very long stents placed (48 +14=62mm stent length) with both LAD and RCA coverage. The sponsor believes this is a pump failure with the adjudication being cardiogenic shock. There is an autopsy with no mention of stent thrombosis. However, the autopsy confirms the poor myocardial function. This does not appear like a stent thrombosis and we have sent this case back to the CEC for readjudication.

f) Deaths of Non-Cardiac nature

i. Patient [redacted] died of a perforated colon on day 4.

ii. Patient [redacted] is 78 year old with prior Q wave MI (no EF reported), with diabetes who had 46 mm of total stenting with site reporting post PCI renal insufficiency as the cause of death. The sequence of probable impaired LV function with prior Q wave MI, and significant dye load for this much stenting in a diabetic makes the attribution by the site of renal insufficiency the likely cause of death. The sponsor has requested added review by the CEC.

iii. Patient [redacted] died of sepsis secondary to the ischemic bowel developed 20 days following PCI. The site reports the event related to an ischemic bowel with sepsis, which clearly is not related to stent thrombosis.

iv. Patient [redacted] is adjudicated appropriately as a CVA and not a stent thrombosis. This was confirmed by a neurologist.

In essence, the narratives have recently been upgraded with additional information and are available with this report. The recent sponsor review of the events characterized as death and thrombosis prompted queries to the CEC because the sponsor believes the 0.9% rate of stent thrombosis may reflect an over estimation The tables are reported as a snapshot in time pending the readjudication of the events with new information and questions posed to better define the course of events. The Sponsor has utilized the above review of thrombotic events and deaths to provide a rationale for the cases to be reassesed by the CEC. Based on the present CEC adjudication, the estimation of the stent thrombosis event rate at 30 days in this "real world" population is 18/1982 (as presented in the tables); again, this may be an overestimation of the rate.

A thorough assessment and readjudication of the cases involving events may result in an event rate that is approximately half the rate presented in this report. Utilizing the upgraded narratives, the sponsor identifies approximately 11 events that may remain after the readjudication process. Given the complexity of the cases involving events and the challenges of monitoring real world registries the suggestion of 11 events may be an overestimation as well.

Table 1. Principal Effectiveness and Safety Results

Effectiveness Measures	E-Five (Number of Patients = 2015 Number of Lesions* = 2458)
Lesion Success % (#/n)	99.6%(2449/2458)
Device Success % (#/n)	94.2%(2316/2458)
Procedure Success % (#/n)	98.5%(1985/2458)
Device-Specific Procedure Success % (#/n)	92.5%(1864/2458)
Post-index Procedure Percent Diameter Stenosis (%DS) (Visual measurement)	
Mean±SD (n)	2.13± 6.84(2458)
Range (min, max)	0- 100
Safety Measures (to 30 days) % (#/n)	
In-Hospital MACE	1.0%(21/2015)
Out-of-Hospital MACE to 30 days	0.7%(13/1982)
MACE to 30 days	1.7%(34/1982)
Death	0.9%(17/1982)
Stent Thrombosis	0.9%(18/1982)
Acute	0.1%(2/1982)
Sub-Acute	0.8%(16/1982)
Target Vessel Revascularization	0.5%(9/1982)
Target Lesion Revascularization	0.4%(8/1982)
Target Vessel Failure	1.7%(34/1982)

n = Number of patients/lesions with evaluable data
Lesion Success: Attainment of <50% residual stenosis (visual measurement) of the target lesion using any percutaneous method
Device Success: Attainment of <50% residual stenosis (visual measurement) of the target lesion using only the assigned device
Procedure Success: Attainment of <50% residual stenosis (visual measurement) of the target lesion using any percutaneous method and no in-hospital MACE
Device-Specific Procedure Success: Attainment of <50% residual stenosis (visual measurement) of the target lesion using only the assigned device and no in-hospital MACE.
* Target lesion is defined as: at least one Endeavor stent was implanted or attempted.

Section II: Detailed Summary

A. Definitions

ABRUPT CLOSURE

Abrupt closure is defined as the occurrence of new (during the index procedure) severely reduced flow (TIMI grade 0 or 1) within the target vessel that persists and requires rescue by a non-assigned treatment strategy (including emergency surgery), or results in myocardial infarction or death. Abrupt closure requires proven association with a mechanical dissection of the treatment site or instrumented vessel, coronary thrombus, or severe spasm.

Abrupt closure does not connote "no reflow" (due to microvascular flow limitation), in which the epicardial artery is patent but has reduced flow. Abrupt closure also does not connote transient closure with reduced flow in which the index treatment application does reverse the closure.

Subabrupt closure: defined as abrupt closure that occurs after the index procedure is completed (and the patient left the catheterization laboratory) and before the 1 Month follow-up endpoint.

Threatened abrupt closure: defined as a grade B dissection and ≥50% diameter stenosis or any dissection of grade C or higher.

ACUTE SUCCESS

Device Success: Attainment of <50% residual stenosis of the target lesion using only the assigned device.
Lesion Success: Attainment of <50% residual stenosis of the target lesion using any percutaneous method.
Procedure Success: Attainment of <50% residual stenosis of the target lesion and no in-hospital MACE.
Device-Specific Procedure Success: Attainment of <50% residual stenosis of the target lesion using only the assigned device and no in-hospital MACE.
* All analyses to determine aucte success measures were conducted utilizing visual measurement of the post procedure residual stentosis values.

BLEEDING COMPLICATIONS

Bleeding complications are defined as a procedure related hemorrhagic event that requires a transfusion or surgical repair. These may include a hematoma requiring treatment, retroperitoneal bleed.

CALCIFICATION

Calcification is defined as readily apparent radiopacities within the vascular wall at the site of the stenosis and is classified as none/mild, moderate (radiopacities noted only during the cardiac cycle before contrast injection), and severe (radiopacities

noted without cardiac motion before contrast injection generally compromising both sides of the arterial lumen).

CEREBROVASCULAR ACCIDENT (CVA) OR STROKE

Cerebrovascular accident is defined as sudden onset of vertigo, numbness, dysphasia, weakness, visual field defects, dysarthria or other focal neurological deficits due to vascular lesions of the brain such as haemorrhage, embolism, thrombosis, or rupturing aneurysm, that persists >24 hours.

DE NOVO LESION

De Novo Lesion is defined as a coronary lesion not previously treated.

DEATH

Death is divided into two categories:

Cardiac death is defined as death due to any of the following:

1. Acute myocardial infarction.
2. Cardiac perforation/pericardial tamponade.
3. Arrhythmia or conduction abnormality.
4. Cerebrovascular accident within 30 days of the procedure or suspected of being related to the procedure.
5. Death due to complication of the procedure, including bleeding, vascular repair, transfusion reaction, or bypass surgery.
6. Any death in which a cardiac cause cannot be excluded.

Non-cardiac death is defined as a death not due to cardiac causes (as defined above).

DISSECTION NHLBI (NHLBI – National Heart, Lung, and Blood Institute) CLASSIFICATION

Type A Small radiolucent area within the lumen of the vessel disappearing with the passage of the contrast material.

Type B Appearance of contrast medium parallel to the lumen of the vessel disappearing within a few cardiac cycles.

Type C Dissection protruding outside the lumen of the vessel persisting after passage of the contrast material.

Type D Spiral shaped filling defect with or without delayed run-off of the contrast material in the antegrade flow.

Type E Persistent luminal filling defect with delayed run-off of the contrast material in the distal lumen.

Type F Filling defect accompanied by total coronary occlusion.

EMERGENT BYPASS SURGERY

Emergent Bypass Surgery is defined as coronary bypass surgery performed on an urgent or emergent basis for severe vessel dissection or closure, or treatment failure resulting in new ischemia.

INTRACORONARY THROMBUS

Intracoronary Thrombus is defined as the presence of a filling defect within the lumen, surrounded by contrast material seen in multiple projections in the absence of calcium within the filling defect, or the persistence of contrast material within the lumen or a visible embolization of intraluminal material downstream.

LESION CLASSIFICATION (American College of Cardiology/ American Heart Association Class)

Type A Minimally complex, discrete (length <10 mm), concentric, readily accessible, non angulated segment (<45°), smooth contour, little or no calcification, less than totally occlusive, not ostial in location, no major side branch involvement, and an absence of thrombus.

Type B Moderately complex, tubular (length 10 to 20 mm), eccentric, moderate tortuosity of proximal segment, moderately angulated segment (>45°, <90°), irregular contour, moderate or heavy calcification, total occlusions <3 months old, ostial in location, bifurcation lesions requiring double guidewires, and some thrombus present.
Type B1: One type B characteristic
Type B2: Two or more type B characteristics

Type C Severely complex, diffuse (length >2 cm), excessive tortuosity of proximal segment, extremely angulated segments >90°, total occlusions >3 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions.

MAJOR ADVERSE CARDIAC EVENTS (MACE)

MACE is defined as death, MI (Q wave and non-Q wave), emergent cardiac bypass surgery, or target lesion revascularization (repeat PTCA or CABG).

MYOCARDIAL INFARCTION

A positive diagnosis of myocardial infarction is made when one of the following criteria is met:

1. Q wave MI (QMI): requires one of the following criteria:

   a. Chest pain or other acute symptoms consistent with myocardial ischaemia and new pathological Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC, in the absence of timely cardiac enzyme data.

   b. New pathologic Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC and elevation of cardiac enzymes. In the absence of ECG data the CEC may adjudicate Q wave MI based on the clinical scenario and appropriate cardiac enzyme data.

2. Non-Q Wave MI (NQWMI): defined as elevated CK > 2X the upper laboratory normal with the presence of elevated CK-MB (any amount above the institution's upper limit of normal) in the absence of new pathological Q waves.

PERFORATION

Perforation is classified as follows:

Angiographic: perforation detected by the clinical site, the core laboratory or independent review of the CEC at any point during the procedure.

Clinical: perforation requiring additional treatment (including efforts to seal the perforation or pericardial drainage), or resulting in significant pericardial effusion, abrupt closure, myocardial infarction, or death.

Pericardial hemorrhage/tamponade: perforation resulting in cardiac tamponade.

STENT THROMBOSIS

Stent Thrombosis is defined as angiographic thrombus or subacute closure within the stented vessel at the time of the clinically driven angiographic restudy for documented ischaemia (chest pain and ECG changes). Any death not attributed to a non-cardiac cause within the first 30 days is considered a surrogate for stent thrombosis in the absence of documented angiographic stent patency.

TARGET LESION REVASCULARIZATION (TLR)

TLR is defined as any clinically driven repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel.

Clinically-driven revascularizations are those in which the patient had a positive functional study, ischemic ECG changes at rest in a distribution consistent with the target vessel, or ischemic symptoms. Revascularization of a target lesion with an in-lesion diameter stenosis ≥70% (by QCA) in the absence of the above-mentioned ischemic signs or symptoms is also considered clinically driven.

In the absence of QCA data for relevant follow-up angiograms, the clinical need for revascularization will be adjudicated using the presence or absence of ischemic signs and symptoms.

Non-clinically driven repeat target lesion revascularizations are those in which the patient undergoes a non-emergent revascularization for a diameter stenosis <50% (by QCA). Non-emergent repeat target lesion revascularization for a diameter stenosis <70% (by QCA) in subjects without either a positive functional study or angina are also considered non-clinically driven.

TARGET VESSEL FAILURE (TVF)

TVF is defined as target vessel revascularization (defined below), recurrent Q or Non Q-Wave myocardial infarction, or cardiac death that could not be clearly attributed to a vessel other than the target vessel.

Target vessel failure is a more conservative and broader category and includes any target vessel revascularization as well as any recurrent MI or any cardiac death that cannot be clearly attributed to a non-target vessel. Target vessel failure, thus, includes any revascularization or adverse endpoint due to renarrowing of any portion of the target vessel, and assumes that the entire vessel is vulnerable to late failures because of guide catheter or guide wire trauma or progression of disease remote from the treatment site.

Target vessel failure will be reported when:

1. Recurrent MI occurs in territory not clearly other than that of the target vessel.
2. Cardiac death not clearly due to a non-target vessel endpoint.
3. Target vessel revascularization is determined.

TARGET VESSEL REVASCULARIZATION (TVR)

TVR is defined as any clinically driven (as defined for TLR) repeat percutaneous intervention of the target vessel or bypass surgery of the target.

TIMI CLASSIFICATION

TIMI 0 No perfusion.

TIMI 1 Penetration with minimal perfusion. Contrast fails to opacify the entire bed distal to the stenosis for the duration of the cine run.

TIMI 2 Partial perfusion. Contrast opacifies the entire coronary bed distal to the stenosis. However, the rate of entry and/or clearance is slower in the coronary bed distal to the obstruction than in comparable areas not perfused by the dilated vessel.

TIMI 3 Complete perfusion. Filling and clearance of contrast equally rapid in the coronary bed distal to stenosis as in other coronary beds.

VASCULAR COMPLICATION

Vascular complication may include the following:

1. Pseudo aneurysm
2. Arteriovenous fistula
3. Peripheral ischemia/nerve injury
4. Vascular event requiring transfusion or surgical repair

B. Study Design

The E-Five Registry is a prospective, multicenter registry to evaluate the 'real world' clinical performance of the Medtronic Endeavor stent system, that will recruit a total of 8000 patients. This interim report provides 30-day results on approximately the first 2000 patients that have been recruited into the registry.

By design, the E-Five Registry is a Post Market Release Registry, hence the patients are only enrolled in countries where the Endeavor Stent System has obtained national regulatory approval and is commercially available. The treatment of the patient is at the discretion of the physician and according to the 'Instructions for Use' of the Endeavor stent system. Patients included in the E-Five registry are receiving the usual hospital routine treatment. The rationale for this design is to document the clinical performance of the Endeavor stent system in a 'real world' patient population.

Follow-up assessments are performed on at least 3 time points: at 30 days, at 180 days (6 months), and at 365 days (12 months). These clinical follow-ups can be done by means of a telephone call or a clinic visit and focuses on the onset of new symptoms and/or new events (especially MACE and stent thrombosis events).

For approximately 3000 patients, clinical follow-up will be extended to 24 months (2 years). This additional follow-up will be in a limited number of centers for specific patient subsets and will include the same data collection requirements as for the 12 months follow-up. Centers to be included will be selected after patient recruitment has been completed.

Selection of Subjects

The E-Five registry targets to include a total of 8000 patients. Patient enrollment started in September 2005 and is currently ongoing. This interim analysis is performed at the request of the FDA to support the Endeavor Post Market Application and provides interim results of approximately the first 2000 enrolled patients up until their 30-day clinical follow-up.

All patients with an indication for coronary stent implantation according to the 'Instructions for Use' of the Endeavor Stent System can be enrolled. The registry expects to include all consecutive patients who receive one or more Endeavor stents in one or more target lesions. However, lesions receiving the Endeavor stent should meet the specific vessel and lesion characteristics as described in the 'Instructions for Use' to be selected for implantation with the Endeavor Stent. Choice of stents for lesions not meeting these characteristics is at physician's discretion.

Subject Selection Criteria

Inclusion Criteria: the following inclusion criteria identify patients suitable for receiving an Endeavor stent and therefore eligible for enrollment to the registry.

Note: Subjects could only be included in the study once.

1. Patient is ≥ 18 years of age (or minimum age as required by local regulations).
2. The patient has consented to participate by signing the "Patient Informed Consent Form" and/or has authorized the collection and release of his medical information by signing the "Patient Data Release Consent Form".
3. Patient is suitable for implantation of one or more Endeavor™ ZOTAROLIMUS Eluting Coronary Stent System in one or more native artery target lesions.
4. Lesion length and vessel diameter of the target lesion(s) are according to the 'Indications for Use' as mentioned in the 'Instructions for Use' that comes with every Endeavor ™ ZOTAROLIMUS Eluting Coronary Stent System.
5. The patient is willing and able to cooperate with registry procedures and required follow up visits.

Exclusion Criteria: the following exclusion criteria indicate patients who are not supposed to be suitable for receiving an Endeavor stent and/or not an eligible candidate for enrollment to the E-Five registry.

1. Women with known pregnancy or who are lactating.
2. Patients with hypersensitivity or allergies to aspirin, heparin, clopidogrel, ticlopidine, drugs such as ZOTAROLIMUS, rapamycin, tacrolimus, sirolimus or similar drugs, or any other analogue or derivative, cobalt, chromium, nickel, molybdenum or contrast media.
3. Patients in whom anti-platelet and/or anticoagulation therapy is contraindicated.
4. Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.
5. Current medical condition with a life expectancy of less than 12 months.
6. The subject is participating in another device or drug study. Subject must have completed the follow-up phase of any previous study at least 30 days prior to enrollment in this trial. The subject may only be enrolled in this E-five registry once.
7. Patients with medical conditions that preclude the follow-up as defined in the protocol or that otherwise limits participation in this registry.

Baseline and Screening

Subject Screening

Screening of eligible patients takes place on patients with an indication for placement of a drug-eluting stent according to the 'Instructions for Use'. All

patients with one or more lesions, who receive (or have received) at least one Endeavor stent, can be approached by the institution's research team to be included into the E-Five registry.

Informed Consent

Even though all patients receive the same treatment regardless of their participation in the E-Five registry, each patient must authorize the treating physician(s) and institution to release the necessary personal information about them before any data can be recorded into the electronic data capture system. The patient should either have signed a "Patient Data Release Form" or a "Patient Informed Consent form" in the appropriate local language. The kind of consent form a study site needs to use is dependant on requirements of local laws or Ethical Committee.

Potential subjects need to sign at least a "Patient Data Release Form" in local language before they can be considered recruited, and allowing their data being entered into the electronic Case Report Form (eCRF). This form explains how collected data will be processed, confirms patient anonymity, allows medical record access and contains a sign off sheet for the release of personal data. The data release form is a minimally required consent form for all patients and can be obtained before or after the procedure.

If full informed consent is required by local laws or requested by the Ethical Committee, the "Patient Informed Consent Form" document will be given to the patient. This includes the patient data release text as well as more detailed information to the patient regarding the registry, such as background, expected benefits, possible risks and alternatives. In principle, for centers in which ethics approval is required, the Patient Informed Consent Form should be obtained prior to the procedure. The Ethical Committee approved version of the informed consent needs to be signed by the patient before any data can be recorded on the eCRF.

Failure to obtain consent renders patient withdrawal from the study and of the subject's information in the eCRF. In this interim report patient data of two sites is excluded from the interim analysis because the consent form failed to mention transfer of data to parties in the United States of America, which is a European privacy requirement. A corrective action was ongoing at the time of the data analysis was conducted.

Subject Withdrawal

All living patients who have signed a consent form and have passed the point of enrollment are required to complete all assigned follow-ups. Subjects are exempted from follow-up if they withdraw their consent. A study subject that is withdrawn from the study will not be replaced. So far, no patients in the study have withdrawn their consent.

Clinical Laboratory Procedures and Tests

Clinical laboratory procedures and tests are performed according to normal hospital routine to determine patient eligibility for Endeavor stent implantation. Patients need to have an indication for placement of a drug-eluting stent according to the 'Instructions for Use'. No further laboratory procedures or tests are required to determine if a patient is eligible for participation to the registry.

Only results from laboratory procedures and tests that are performed as part of the patient treatment because of a MACE or stent thrombosis event need to be provided for the purposed of event adjudication.

Enrollment

All subjects who receive an Endeavor stent should be asked to participate to the registry. Subjects are considered enrolled into the registry when the following 2 conditions have been met:

1. A signed consent form is obtained
2. The study device is introduced into the guide catheter.

The site research staff enters the recruited subject on the electronic Case Report Form to enroll the patient.

Monitoring

Monitoring is performed on approximately 800 (10%) of the patients, which are randomly selected on most of the occassions. In order to obtain an optimal overview of the site performance, the goal is to monitor different patients for each follow-up.

A number of sites are randomly selected for monitoring on a quartely basis. The sites to be included in the selection need to have enough patients for monitoring (i.e. minimally 10 patients) and should not have been monitored yet. Likewise the site location is take into consideration (i.e. of the participating centers, ±60% sites are located in Western Europe, ±20% in Eastern Europe, India and South America and ±20% in Asia Pacific). Furthermore MACE and stent thrombosis events can also trigger a center to be selected for monitoring.

It is the aimed that the list of patients to be involved in this process is randomly determined in minimally 75%. A maximum of 25% patients to be monitored is selected based on possible inconsistencies or reported events.

For the patient subset studied in this interim report, 24 monitoring visits have been conducted at 23 different hospitals. In total 243 patients included in this interim analysis have been monitored, which results in 12.1% of the analyzed patients. A full list of monitored patients that have been included in this interim analysis can be found in appendix A.

Data Safety Monitoring Board (DSMB)

The Data Safety Monitoring Board (DSMB) is composed of three members (two physicians from the fields of cardiology and interventional cardiology and one bio-statistician), who are not directly involved in the conduct of the trial. The DSMB reviews the registry on a periodic basis.

Clinical Events Committee

The Clinical Events Committee is made up of cardiologists who are not participants in the registry. The Clinical Events Committee is charged with the adjudication of clinical events and clinical endpoints in the trial.

At the onset of the trial, the Clinical Events Committee established explicit rules outlining the minimum amount of data required, and the algorithm followed in order to classify a clinical event.

Once the specific criteria for clinical events and endpoints had been established by the Clinical Events Committee, Cardialysis (Rotterdam, the Netherlands) became responsible for categorizing all clinical events when all necessary data were available.

The Clinical Events Committee adjudicates the following events:

- Death
- Myocardial infarctions (Q-wave and non-Q-wave)
- Emergent Cardiac Bypass Surgery
- Repeat PTCA (except for staged procedures) or CABG
- Stent Thrombosis

Schedule of Treatments and Assessments

This registry does not require any specific test or procedure that falls outside a standard stenting procedure as routinely done in the hospital. The table below summarizes the data being collected prospectively within this registry.

Summary of registry procedures

	Baseline	Procedure	Discharge	Follow-up[4]
Eligibility criteria	X	-	-	-
Demographics	X	-	-	-
Cardiac Risk Factors	X	-	-	-
Current Cardiac Status	X	-	-	X
Lesion Characteristics	X	-	-	-
Pre-procedure angiography (visual)	X	-	-	-
Procedure data (number of lesions treated; devices used; implantation technique etc.)	-	X	-	-
Angiographic outcome (visual)	-	X	-	-
Anti-Platelet medication	-	X	X	X
MACE	-	X	X	X
Cardiac enzymes	-	X	-	-
ECG	-	X	-	-
Event related:				
- Peak CK and CK-MB values[1]	-	-	X	X
- ECG[2]	-	-	X	X
- Angiogram[3]	-	-	X	X

1. If a Myocardial Infarction has occurred after procedure, peak CK and CK-MB values will be collected on the Myocardial Infarction Form.
2. Printouts of ECG will be collected for specific ischaemic - or MACE event that occurs after the index procedure for adjudication.
3. There is no mandatory angiographic follow-up in the protocol. If the patient had an angiography performed with a clinical indication, then the angiogram might be needed for adjudication of the event by the Clinical Event Committee. Only those angiograms will be collected that are possibly related to a study endpoint, like but not limited to a target lesion revascularization.
4. Follow-up is planned after 30 days, 6 months, and 12 months. For specific patients subsets and for a limited number of centers, patient's follow-up will be extended to 24 months.

C. Objectives

Primary Objective

The primary objective of this study is to document the safety and overall clinical performance of the Endeavor™ Zotarolimus-Eluting Coronary Stent System in a "real world" patient population requiring stent implantation.

The primary endpoint is the Major Adverse Cardiac Events (MACE) rate at 12 months post-procedure. MACE is defined as the composite endpoint of: death, myocardial infarction (Q wave and non-Q wave), emergent cardiac bypass surgery, or target lesion revascularization (repeat PTCA or CABG).

Secondary Objectives

The secondary objectives of this trial are to assess the event rate in patient subgroups with specific clinical indications and/or vessel- or lesion characteristics.

The secondary endpoints of this study include:

- Major Adverse Cardiac Events rate (MACE) at 30 days and at 6 months
- Stent thrombosis rate (acute <24 h; subacute 2-30 days; late >30 days)
- Procedural success rate
- Device success rate
- Lesion success rate

D. Registry Procedure

Procedure

The E-Five registry is a Non-Interventional, Post Market Release Registry that is conducted in areas where the Endeavor device is commercially available. The principle of the E-Five registry is to document the safety and performance of the Endeavor stent in a 'real world' setting. Therefore the registry does not require any additional procedure outside normal hospital routine.

The stenting procedure of the Endeavor stent should be performed according to the 'Instructions for Use' of the Endeavor Stent. It is advised to maintain a homogeneous treatment strategy, and to use the Endeavor stent for all lesions treated. Lesions should meet the specific vessel and lesion characteristics as described in the 'Instructions for Use' to be selected for implantation with the Endeavor stent system. Choice of stents for lesions not meeting these characteristics is at physician's discretion. Simultaneous implantation of other bare metal or drug eluting stents than Endeavor stent during the stenting procedure is allowed if the investigator considers this to be beneficial to the patient.

Treatment Failures

Failure to reach the intended target lesion with the Endeavor Stent delivery system and to deploy the stent at the target lesion is recorded on the electronic Case Report Form as an unsuccessful delivery. Reasons for unsuccessful delivery could be failing to reach or cross the target lesion or proximal stent, or as a result of a device malfunction. Table 7 provides a summary of the stent implantation which shows the reasons for unsuccessful stent delivery. In case of a device malfunction, a Device Event Form needs to be completed. In the first 2015 patients of this interim analysis, no device malfunction was reported, which is shown in Table 8.

The investigator is required, whenever it is possible, to return devices with a failure or malfunction to Medtronic Vascular.

Antiplatelet/Anticoagulation Regimen

Antiplatelet medication should be administered as indicated in the 'Instructions for Use' of the device.

It is recommended to use the following regimen:

- Clopidogrel 75 mg per day for 3 days pre-procedure, or a pre-procedural loading dose of a minimum of 300 mg Clopidogrel should be administered for patients not taking Clopidogrel.
- Post-procedure: Clopidogrel 75 mg for at least 12 weeks
- Aspirin at least 75 mg QD indefinitely

All other co-medication use is at the discretion of the investigator and according to hospital routine practice.

All patients except for one were discharged on anti-platelet therapy, predominantly Aspirin and Clopidogrel. Table 5 reveals that in the remainder of the cases Ticlopidine was usually prescribed.

Clinical and Laboratory Procedures

This registry does not require any specific test or procedure that fall outside the standard stenting procedure as routinely done in the hospital.

In the occurrence of a MACE or stent thrombosis event, the ECGs, angiograms, and cardiac enzymes are collected for adjudication purposes by the Clinical Event Committee.

Electrocardiograms and angiograms are made according to local hospital practice. Visual estimation of lesion characteristics in relation to the index procedure is done by the operator and recorded on the electronic Case Report Form. There is no mandatory angiographic follow-up in the protocol.

Cardiac enzymes are measured according to local hospital practice including measurement of CK, CK-MB and Troponin. If a Myocardial Infarction (non-Q-wave or Q-wave) has occurred after procedure, peak CK and CK-MB values are collected on a Myocardial Infarction Form.

Concomitant Medical Therapy

It is recommended that all subjects receive the medication regimen listed below. Anti-platelet and anti-coagulant medications administered are recorded on the electronic Case Report Form.

<u>Prior to Procedure:</u>

Clopidogrel 75 mg per day for 3 days pre-procedure; or a pre-procedural loading dose of a minimum of 300 mg Clopidogrel should be administered for patients not taking Clopidogrel.

Post-procedure:

Clopidogrel 75 mg for at least 12 weeks
Aspirin at least 75 mg QD indefinitely

Specification of pre-procedure medications and at 30-day follow-up can be found in Table 5.
All other co-medication use is at the discretion of the investigator and according to hospital routine practice.

Follow-up Procedures

Clinical follow-up assessments are performed at 30 days ± 5 days, at 180 ± 14 days (6 months), and at 365 days (12 months; visit window: -14 / +30 days) after the index procedure. Each follow-up can be done by a routine outpatient clinic visit or by telephone. Clinical follow-up will be extended to 2 years in a limited number of centers for specific patient subsets and will include the same date collection procedure as for the 1-year follow-up.

At each follow-up the following information is recorded:

- Date of follow-up
- Type of follow-up visit (telephone or routine clinic visit)
- Current cardiac status (asymptomatic, silent ischaemia, stable angina or unstable angina)
- Any new MACE or stent thrombosis events since discharge or previous visit
- Anti-platelet medication

There are no mandatory Angiographic or IVUS follow-up requirements for this registry. Angiographic documentation is requested for adjudication purposes in case certain events occurred, like but not limited to revascularization events.

E. Clinical Events

Adverse Events

Adverse event collection in this registry is mainly limited to collection of Major Adverse Cardiac Events (MACE) events. In addition, data related to complaints, stent delivery performance and stent thrombosis, whether or not it is related to a MACE, is collected. All MACE, stent thrombosis events and complaints need to be reported to Medtronic within 24 hours after the investigator becomes aware of the event. This is done by the sites' study team using the web-based electronic Case Report Form.

Serious Adverse Event (SAE)

An adverse event that:

- Led to death
- Led to a serious deterioration in the health of a subject that

1. Resulted in a life-threatening illness or injury
2. Resulted in a permanent impairment of a body structure or body function
3. Required in-patient hospitalization or prolonged hospitalization
4. Resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function

- Led to fetal distress, fetal death or a congenital abnormality or birth defect

Adverse Device Effect (ADE)
Any untoward and unintended response to a medical device.

Note: Includes any event resulting from insufficiencies or inadequacies in the instructions for use or the deployment of the device. Includes any event resulting from a user error.

Serious Adverse Device Effect (SADE)
An ADE that has resulted in any of the consequences characteristic of a SAE or that might have led to any of these consequences if suitable action had not been taken or intervention had not been made or if circumstances had been less opportune.
Note: the definition of SADE includes incidents and near incidents.

Complaints

All complaints with respect to CE-marked Medtronic products need to be reported to Medtronic within 24 hours after the investigator becomes aware of the event. The investigator should indicate in the electronic Case Report Form that a complaint has been observed. Medtronic Field Assurance will be notified of all complaints.
Following definitions are based on Medical Device Directive 93/42/EEC and MEDDEV 2.12-1 rev 4.

Complaint: Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution

Vigilance Reportable Complaint: The reporting of an incident or near incident, which reasonably suggests that a patient death or serious deterioration in the state of health of a patient associated with the use of one of Medtronic products which carries the CE mark has occurred or could occur in future.

Adverse Incident (MDD) - Where malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or instructions for use which might have led to a death or serious deterioration in the state of health of a patient.

Incident: An alleged malfunction or deterioration in the characteristics and/or performance of a device which:

- Led to a death
- Led to a serious deterioration in the state of health of patient, user or other person.

Near Incident: An alleged malfunction or deterioration in the characteristics and/or performance of a device or any alleged inadequacy in the labeling or the instructions for use which did not result in death of a patient or user or in a serious deterioration in his/her health but which could result in such an outcome if it occurred again.

Note: Complaint is a broad term and includes device malfunctions including, but not limited to stent dislodgement, balloon rupture before RBP, incorrect information on the label, and Serious Adverse Device Effect (SADE).

All MACE and complaints need to be reported to Medtronic within 24 hours after the investigator becomes aware of the event. Reporting is done using the web-based electronic Case Report Form.

Table 8 shows that there were no device events reported in this patient subset.

F. Statistical Methods of Analysis

This is a prospective, multicenter registry designed to evaluate the safety, effectiveness and overall clinical performance of the Endeavor™ Zotarolimus-Eluting Coronary Stent System in a "real world" patient population requiring stent implantation.

Interim Analysis

This is an interim analysis that has been conducted at the request of the FDA of approximately the first 2000 patients of the total 8000 patients to be enrolled. As no formal hypothesis is being tested, no adjustment for multiple testing is needed.

Primary Analysis Sample

The primary analytical set for analysis are all patients who signed the written informed consent and for whom the Endeavor device was introduced through the guide catheter. The lesion related parameters are also analyzed for all the target lesions, defined as lesions on which at least one Endeavor device was attempted to be used.

Method

This interim report does not have information for the primary endpoint (12 months MACE rate).

All other secondary endpoints are tabulated with contingency tables. Counts and event rates are provided.

All clinically relevant baseline variables are tabulated. Categorical variables are reported using contingency tables, and continuous variables are reported by giving the number of known values, the mean, standard deviation, minimum and maximum values.

Section III. Tables and Figures

Table 2. Number of Patients Treated by Site

		E-Five (N=2015)	
Site Nr	Clinical Site	Principal Investigator	Number of patients enrolled % (n)
101	Universitätsklinik Graz, Graz	LUHA O.	0.2%(5/2015)
102	AKH Wien, Vienna	GLOGAR D.	2.5%(51/2015)
103	Salzburger Landeskliniken, Salzburg	PICHLER M.	2.0%(40/2015)
104	Landeskrankenhaus Innsbruck-Universitätskliniken, Innsbruck	PACHINGER O.	1.4%(28/2015)
105	Allg. öffentl. Landeskrankenhaus, Bruck a.d. Mur	ZENKER G.	2.9%(58/2015)
121	Klinikum Nuernberg - Medizinische Klinik 8, Nürnberg	ZAHN R.	0.3%(6/2015)
122	Universitätsklinik Freiburg, Freiburg	HEHRLEIN C.	1.7%(34/2015)
123	Universitätsklinik Heidelberg, Heidelberg	TIEFENBACHER C.	3.8%(77/2015)
124	Rotes Kreuz, Frankfurt	HAASE J.H.	2.0%(41/2015)
127	Medizinische Klinik Villingen Schweningen, Villingen Schweningen	BIRKEMEYER R.	1.1%(23/2015)
130	University of Rostock, Rostock	NIENABER C.N.	1.8%(36/2015)
131	Johanneshospital Dortmund, Dortmund	HEUER H.	3.7%(74/2015)
132	St.Marienhospital, Siegen	SCHUSTER P.	0.2%(5/2015)
136	Stadtkrankenhaus Pirmasens, Pirmasens	HENNEN B.	0.3%(6/2015)
137	Ambulantes Herzzentrum Kassel, Kassel	APPEL K.F.	3.0%(61/2015)
138	St. Vincenz Krankenhaus, Limburg	KREUZER J.	0.1%(3/2015)
142	Universitätskrankenhaus Eppendorf, Hamburg	HEITZER T.	0.6%(12/2015)
144	Herz- und Diabeteszentrum Bad Oeynhausen, Bad Oeynhausen	WIEMER M.	0.0%(1/2015)
146	Herzzentrum Lahr / Baden GmbH & Co. KG	FREIHERR VON HODENBERG E.	0.2%(4/2015)
165	Istituto Clinico Humanitas, Rozzano	PRESBITERO P.	0.3%(7/2015)
169	A.O. Vittorio Emanuele Ferrarotto S. Bambino, Catania	TAMBURINO C.	0.3%(6/2015)
176	Casa Di Cura Montevergine, Mercogliano	RUBINO P.	2.5%(51/2015)
192	Leyenburg, Den Haag	SCHOTBORGH C.	0.0%(1/2015)
193	AMC, Amsterdam	DE WINTER R.	1.2%(24/2015)
194	Medisch Spectrum Twente, Enschede	LOUWERENBURG J.	1.3%(27/2015)

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Table 2. Number of Patients Treated by Site (Continued)

		E-Five (N=2015)	
Site Nr	Clinical Site	Principal Investigator	Number of patients enrolled % (n)
195	VUMC, Amsterdam	BRONZWAER J.	0.8%(16/2015)
203	Satakunta Central Hospital, Pori	YLITALO A.	0.5%(11/2015)
221	Unidade de Intervenção Cardiovascular, Alvor	PALOS J.L.	0.5%(11/2015)
222	SMIC - Serviço Medico de Imagem Computorizada, SA, Porto	CARVALHO H.C.	0.6%(12/2015)
224	Hospital Pulido Valente, Lisbon	ADÃO M.	0.1%(4/2015)
230	Hospital Infanta Cristina, Badajoz	MERCHAN HERRERA A.	3.2%(66/2015)
231	Hospital Puerta de Hierro, Madrid	GOICOLEA F.	0.2%(5/2015)
232	Hospital de la Santa Creu i Sant Pau, Barcelona	SABATE TENAS M.	0.5%(11/2015)
233	Hospital General Universitario Gregorio Marañón, Madrid	GARCIA FERNANDEZ E.	1.9%(39/2015)
234	Hospital Virgen de la Salud, Toledo	MOREU BURGOS J.	0.1%(2/2015)
235	Hospital Universitario Son Dureta, Palma de Mallorca	BETHENCOURT GONZALEZ A.	2.6%(53/2015)
236	Hospital de León, León	FERNANDEZ – VAZQUES F.	0.7%(14/2015)
239	Hospital Juan Ramón Jímenez, Huelva	DIAZ FERNANDEZ J.D.	1.7%(35/2015)
241	Hosp. Virgen de la Arrixaca, Murcia	VALDES CHAVARRI M.	1.2%(24/2015)
242	Hospital General de Alicante, Alicante	RUIZ NODAR J.M.	3.8%(76/2015)
244	Hospital Universitario de La Princesa, Madrid	MARTINEZ ELBAL L.	1.9%(38/2015)
245	Hosp. Universitario Virgen de la Victoria, Málaga	HERNANDEZ GARCIA J.M.	2.3%(46/2015)
246	Hosp. Universitario Salamanca, Salamanca	SANTOS RODRIGUEZ I.	0.8%(17/2015)
247	Hospital General Yagüe, Burgos	DURAN HERNANDEZ J.M.	0.9%(18/2015)
248	Hospital de San Juan de Alicante, Alicante	FRUTOS GARCIA A.	0.8%(17/2015)
330	Queen Elizabeth Hospital, Hong Kong	CHAN K.T.	1.0%(20/2015)
333	Princess Margaret Hospital, Hong Kong	WU C. W.	0.0%(1/2015)
340	National Heart Institute (IJN), Kuala Lumpur	ZAMBAHARI R.	5.0%(100/2015)
341	Sarawak General Hospital, Kuching Sarawak	SIM K. H.	0.8%(18/2015)
342	Hospital Universiti Kebangsaan, Kuala Lumpur	MASKON O.	0.7%(14/2015)

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Table 2. Number of Patients Treated by Site (Continued)

		E-Five (N=2015)	
Site Nr	Clinical Site	Principal Investigator	Number of patients enrolled % (n)
343	Penang General Hospital, Pulau Pinang	ISMAIL O.	0.0%(1/2015)
344	University Malaya Medical Centre, Kuala Lumpur	WAN AHMAD	0.2%(5/2015)
345	Kedah Medical Center, Alor Selar	MOHD SANI M. A.	0.9%(19/2015)
405	Regional Hospital Karlovy Vary, Karlovy Vary	KOVAC J.	0.1%(2/2015)
410	P.Stradins University Hospital, Riga	ERGLIS A.	2.8%(57/2015)
440	1st IKA- Interventional Cardiology Dept, Athens	SIONIS D.	1.4%(7/2015)
441	Hippokratio, Athens	STEFANADIS C.	0.2%(5/2015)
442	University Hospital of Patra, Patra	ALEXOPOULOS D.	1.8%(38/2015)
443	Ahepa Univeristy Hospital, Thessaloniki	HADJIMILTIADES S.	1.5%(21/2015)
444	Onassis Cardiac Surgery Center, Athens	COKKINOS D.	1.3%(26/2015)
451	Medical Park Hospital, Istanbul	SANCAKTAR O.	0.1%(2/2015)
453	Ege Saglik Hastanesi, Izmir	AKIN M.	0.4%(9/2015)
461	Max Devki Devi Heart & Vascular Institute, New Delhi	CHANDRA P.	2.0%(40/2015)
462	SGPGI LUCKNOW, Lucknow	SINHA N.	4.4%(89/2015)
463	Apollo Hospital, Hyderabad	RATH P.C.	1.1%(23/2015)
464	Bombay Hospital & Medical Research Center, Bombay	GOYAL B.	2.0%(41/2015)
465	The Heart Clinic, Ahmedabad	PARIKH K.	3.8%(76/2015)
466	Ruby Hall Clinic, Pune	HIREMATH S.	1.0%(20/2015)
467	Sterling Hospital, Ahmedabad	PATEL T.	0.8%(16/2015)
501	Instituto Nacional de Cirugia Cardiaca, Montevideo	FIRSZT A.	0.9%(18/2015)
505	Instituto Dante Pazzanese de Cardiologia, São Paulo	FERES F.	5.0%(100/2015)
510	Pontificada Universidad Católica de Chile, Santiago	MARTINEZ A.	0.1%(3/2015)
520	Instituto Nacional de Cardiologia, Mexico	BAN HAYASHI E.	0.7%(14/2015)

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Table 3. Baseline Demographics and Clinical Characteristics

Subject Characteristics	E-Five (N=2015)
Age (year)	
Mean±SD (n)	63.05±11.45(2015)
Range (min, max)	(23.00,93.00)
Number of men % (#/n)	76.6%(1543/2015)
Smoking % (#/n)	48.7%(1033/2015)
Current % (#/n)	22.4%(451/2015)
Ex-smoker % (#/n)	26.4%(531/2015)
Diabetes Mellitus % (#/n)	35.2%(710/2015)
Insulin Dependent % (#/n)	8.8%(178/2015)
Hypertension % (#/n)	69.3%(1397/2015)
Hypercholesterolemia % (#/n)	60.9%(1228/2015)
Family history of cardiovascular disease % (#/n)	23.5%(473/2015)
Left ventricular function %	
Mean±SD (n)	53.59±12.79(1126)
Range (min, max)	(0.60,85.00)
Previous Q MI % (#/n)	25.0%(504/2015)
Previous Non-Q MI % (#/n)	12.4%(250/2015)
Previous PTCA % (#/n)	24.0%(484/2015)
Previous CABG % (#/n)	6.7%(136/2015)
Cardiac status % (#/n)	
Silent ischemia	6.9%(140/2015)
Stable angina	39.8%(801/2015)
Unstable angina	31.5%(635/2015)
Recent MI*	21.8%(439/2015)
Serum Creatinine (mg/dl)	
Mean±SD (n)	1.09±0.67(1580)
Range (min, max)	(0.00,13.30)

n = Number of patients with evaluable data
* patient presented with an MI before the enrollment

Table 4. Target Lesion Characteristics

Baseline Lesion Characteristics	E-Five (Number of Patients=2015 Number of Target Lesions* =2458)
Total number of lesions† treated per patient% (#/n)	
1	67.9%(1369/2015)
2	24.8%(500/2015)
3	6.0%(120/2015)
4	1.3%(26/2015)
Vessel Location % (#/n)	
LAD	48.6%(1195/2458)
LCX	21.9%(539/2458)
RCA	26.3%(646/2458)
Left main	1.8%(44/2458)
SVG	1.4%(34/2458)
Lesion Location % (#/n)	
Ostial	4.2%(104/2458)
Proximal	39.9%(981/2458)
Mid	40.0%(984/2458)
Distal	13.5%(332/2458)
Bifurcation % (#/n)	15.7%(386/2458)
TIMI Flow % (#/n)	
0	8.7%(213/2458)
1	8.0%(197/2458)
2	17.5%(430/2458)
3	65.8%(1618/2458)
Lesion Class % (#/n)	
A	8.3%(204/2458)
B1	31.8%(781/2458)
B2	37.5%(922/2458)
C	22.4%(551/2458)
Lesion Type % (#/n)	
De Novo	94.2%(2315/2458)
Restenosis after previous PTCA	1.2%(29/2458)
In stent restenosis	4.1%(102/2458)
Other	0.5%(12/2458)
Calcification % (#/n)	
None / mild	68.6%(1686/2458)
Moderate	25.1%(618/2458)
Severe	6.3%(154/2458)
Tortuosity % (#/n)	
< 45	74.2%(1824/2458)
45- 90	22.9%(563/2458)
> 90	2.9%(71/2458)
Thrombus % (#/n)	8.9%(218/2458)

n = Number of lesions with evaluable data

* Target lesion is defined as: at least one Endeavor stent was implanted or attempted to be implanted.

† Total number of lesions treated includes non-target lesions

Table 5. Baseline and 30-Day Medications

	E-Five (Number of Patients=2015)
Baseline	
Aspirin % (#/n)	95.7%(1928/2015)
Clopidogrel % (#/n)	88.5%(1784/2015)
Ticlopidine % (#/n)	4.2%(83/2015)
GP IIb/IIIa % (#/n)	20.4%(411/2015)
At 30-Day Follow Up	
Aspirin % (#/n)	98.0%(1927/1966)
Clopidogrel % (#/n)	93.4%(1836/1966)
Ticlopidine % (#/n)	6.2%(121/1966)

n = Number of patients with evaluable data

Table 6. Pre and Post-procedure Angiographic Outcomes (visual measurement)

	E-Five (Number of Patients= 2015 Number of Lesions* =2458)
Reference Vessel Diameter	
Mean±SD (n)	2.92±0.45(2458)
Range (min, max)	(1.20,4.70)
Minimum Lumen Diameter	
Mean±SD (n)	0.54±0.43(2458)
Range (min, max)	(0.00,3.30)
Pre-procedure Diameter Stenosis (%)	
Mean±SD (n)	81.53±14.22(2458)
Range (min, max)	(0.00,100.00)
Lesion Length	
Mean±SD (n)	18.28±9.91(2458)
Range (min, max)	(0.00,80.00)
Post-procedure Diameter Stenosis (visual estimate) (%)	
Mean±SD (n)	2.13±6.84(2458)
Range (min, max)	(0.00,100.00)
Lesion Success % (#/n)	99.6%(2449/2458)
Device Success % (#/n)	94.2%(2316/2458)
Procedure Success % (#/n)	98.6%(1987/2015)
Device-Specific Procedure Success% (#/n)	92.6%(1866/2015)

n = Number of lesions with evaluable data
Lesion Success: Attainment of <50% residual stenosis (visual measurement) of the target lesion using any percutaneous method
Device Success: Attainment of <50% residual stenosis (visual measurement) of the target lesion using only the assigned device
Procedure Success: Attainment of <50% residual stenosis (visual measurement) of the target lesion using any percutaneous method and no in-hospital MACE
Device-Specific Procedure Success: Attainment of <50% residual stenosis (visual measurement) of the target lesion using only the assigned device and no in-hospital MACE.
* Target lesion is defined as: at least one Endeavor stent was implanted or attempted.

Table 7. Summary of Stent Implantation

	E-Five (Number of Patients=2015 Number of Lesions* =2458)
Number of Endeavor stents implanted or attempted per lesion % (#/n)	
Single	86.7%(2132/2458)
Multiple	13.3%(326/2458)
Stents relationship if multiple	
Overlapping	74.8%(244/326)
Abutting	14.7%(48/326)
Minimum Stent Diameter (mm) % (#/n)	
2.25	6.0%(147/2458)
2.5	21.4%(527/2458)
2.75	16.2%(399/2458)
3.0	34.9%(858/2458)
3.5	17.6%(433/2458)
4.0	3.8%(94/2458)
Total Stent length (mm)	
Mean±SD (n)	23.35±11.98(2458)
Range (min, max)	(8.00,99.00)
Endeavor stent(s) delivery success % (#/n)	99.4%(2444/2458)
Reason for unsuccessful delivery % (#/n)	
Failed to reach target lesion	0.4%(9/2458)
Failed to cross the target lesion	0.1%(3/2458)
Failed to cross the proximal stent	0.0%(0/2458)
Device malfunction	0.0%(0/2458)
Other	0.1%(3/2458)
Other DES used % (#/n)	3.3%(81/2458)
Other BMS used % (#/n)	2.2%(54/2458)

n = Number of lesions with evaluable data
* Target lesion is defined as: at least one Endeavor stent was implanted or attempted.
† One lesion had unsuccessessful delivery because of two reasons: stent fail to reach target lesion and no proper Endeavor size was available.

Table 8. Summary of Site Reported Device Events

	E-Five (Number of Patients=2015)
Stent detached from balloon before deployment	0
Balloon rupture	0
Balloon not inflating	0
Balloon not deflating	0
Shaft breakage	0
Other*	0

* One patient (study ID 410029) had a unsuccesful delivery of the Endeavor stent and was wrongly reported a device event.

Table 9. Major Adverse Cardiac Events – In and Out of Hospital (to 30 days)

Description of Event In-Hospital complications	E-Five (N=2015) Number %
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	1.0%(21/2015)
Death	0.5%(10/2015)
MI (Q Wave or Non-Q wave)	0.5%(11/2015)
Q Wave MI	0.2%(4/2015)
Non-Q Wave MI	0.3%(7/2015)
Emergent CABG	0% (0/2015)
Target Lesion Revascularization	0% (0/2015)
TL-CABG	0% (0/2015)
TL-PTCA	0% (0/2015)
Target Vessel Revascularization not involving Target Lesion	0% (0/2015)
TV/non-TL-CABG	0% (0/2015)
TV/non-TL-PTCA	0% (0/2015)
Target Vessel Revascularization	0% (0/2015)
Target Vessel Failure	1.0%(20/2015)
Stent Thrombosis	0.3%(6/2015)
Acute	0.0%(1/2015)
Subacute	0.2%(5/2015)
Out-of-Hospital complications to 30 days	
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	0.7%(13/1982)
Death	0.4%(7/1982)
MI (Q Wave or Non-Q wave)	0.3%(6/1982)
Q Wave MI	0.1%(2/1982)
Non-Q Wave MI	0.2%(4/1982)
Emergent CABG	0% (0/1982)
Target Lesion Revascularization	0.4%(8/1982)
TL-CABG	0% (0/1982)
TL-PTCA	0.4%(8/1982)
Target Vessel Revascularization not involving Target Lesion	0.1%(2/1982)
TV/non-TL-CABG	0% (0/1982)
TV/non-TL-PTCA	0.1%(2/1982)
Target Vessel Revascularization	0.5%(9/1982)
Target Vessel Failure	0.7%(14/1982)
Stent Thrombosis	0.6%(12/1982)
Acute	0.1%(1/1982)
Subacute	0.6%(11/1982)

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Table 9. Major Adverse Cardiac Events – In and Out of Hospital (to 30 days) (Continued)

Description of Event	E-Five (N=2015)
Combined In-and Out-of-Hospital complications to 30 days	Number %
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	1.7%(34/1982)
Death	0.9%(17/1982)
MI (Q Wave or Non-Q wave)	0.9%(17/1982)
Q Wave MI	0.3%(6/1982)
Non-Q Wave MI	0.6%(11/1982)
Emergent CABG	0% (0/1982)
Target Lesion Revascularization	0.4%(8/1982)
TL-CABG	0% (0/1982)
TL-PTCA	0.4%(8/1982)
Target Vessel Revascularization not involving Target Lesion	0.1%(2/1982)
TV/non-TL-CABG	0% (0/1982)
TV/non-TL-PTCA	0.1%(2/1982)
Target Vessel Revascularization	0.5%(9/1982)
Target Vessel Failure	1.7%(34/1982)
Stent Thrombosis	0.9%(18/1982)
Acute	0.1%(2/1982)
Subacute	0.8%(16/1982)

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Table 10. Major Adverse Cardiac Events (to 30 days)

	E-Five (N=2015)
Hierarchical Complications (to 30 days)	Number %
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	1.7%(34/1982)
Death	0.9%(17/1982)
Non-fatal Q Wave MI	0.3%(6/1982)
Non-fatal Non-Q Wave MI	0.5%(9/1982)
Emergent CABG without Death or MI	0% (0/1982)
TL-CABG without Death or MI	0% (0/1982)
TL-PTCA without Death, MI, or TL-CABG	0.1%(2/1982)
Non-Hierarchical Complications (to 30 days)	
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	1.7%(34/1982)
Death	0.9%(17/1982)
MI (Q Wave or Non-Q wave)	0.9%(17/1982)
Q Wave MI	0.3%(6/1982)
Non-Q Wave MI	0.6%(11/1982)
Emergent CABG	0% (0/1982)
Target Lesion Revascularization	0.4%(8/1982)
TL-CABG	0% (0/1982)
TL-PTCA	0.4%(8/1982)
Target Vessel Revascularization not involving Target Lesion	0.1%(2/1982)
TV/non-TL-CABG	0% (0/1982)
TV/non-TL-PTCA	0.1%(2/1982)
Target Vessel Revascularization	0.5%(9/1982)
Target Vessel Failure	1.7%(34/1982)
Stent Thrombosis	0.9%(18/1982)
Acute	0.1%(2/1982)
SubAcute	0.8%(16/1982)

Table 11. Narrative Summaries of Major Adverse Events

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	16 November 2005	13	The patient is a 76-year-old female with IDDM and a family history of cardiovascular disease. She presented with unstable angina.	Non-Q-wave MI
		Repeat revascularization	16 November 2005	13	On **November 03, 2005** two lesions were treated. The creatinine level was 0.99 mg/dl, LVEF was not measured. The patient was pre-treated with dual antiplatelet therapy. No GP IIb/IIIa inhibitors were administered to the patient during the procedure. The first lesion was a type B2, moderately tortuous, De Novo lesion in the **proximal LCX**. The lesion was 10mm long which was 38% stenosed (RVD 4.2mm) and involved a bifurcation. One Endeavor stent (3.5x12mm) was successfully implanted without predilation of the lesion. The side branch was not stented. The site reported a 10% final residual stenosis in the lesion (visual estimate). The second target lesion was a type B1, moderately tortuous, De Novo lesion in the **distal LCX**, which was 52% stenosed (RVD 2.3mm) over 15mm. One Endeavor (2.25x14mm) stent was implanted after predilation of the lesion. The site reported a successful implantation of the stent with a 22% residual stenosis (visual estimate). The patient was discharged on November 11, 2005 on ASA and clopidogrel.	Target lesion revascularization
		Stent thrombosis	16 November 2005	13		Sub-acute stent thrombosis
		Death	26 November 2005	23		Cardiac death

					On **November 16, 2005** the patient presented with elevated enzymes with a peak CK of 636 (uln 170, ratio 3.7) and CK-MB of 30 (uln 24, ratio 1.3) on November 17, 2005. The same day the **distal LCX** was treated during a PTCA following Myocardial Infarction and bradycardia. The investigator reported stent thrombosis and angiographic evidence of thrombus but no ECG changes. The patient was on anti-platelets within 24 hours prior to the events. On **November 26, 2005** the patient died. The investigator reported a non-sudden, cardiac death associated with MI but without evidence of stent thrombosis. The circumstances and cause of the death were reported as follows: "new MI and bradycardia 16-11, cardiogenic shock, treatment with catecholamines, pneumonia".	

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	January 18, 2006	0	The patient is an 89 year old man. He is treated for hypertension and hypercholesterolemia and has a family history of cardiovascular disease. He has had a previous PTCA and a previous CABG and presented with unstable angina. On **January 18, 2006** one lesion in the mid **LCX** was treated with two Endeavor stents after predilation. The total implanted stent length was 35 mm and the residual stenosis (visual estimate) was 0%. On **January 18, 2006** the patient presented with elevated enzymes with CK of 680 (uln 190, ratio 3.6) and CK-MB of 80 (uln 24, ratio 3.3). On January 19, 2006 the patient presented with CK of 776 (uln 190, ratio 4.1) and CK-MB of 55 (uln 24, ratio 2.3). There were no new Q-waves on the ECG. The investigator assessed this as unstable angina. On January 21, 2006 the patient was discharged on aspirin and Clopidogrel. On February 13, 2006 a 30 day follow up visit was performed. The patient was free of symptoms and did not report any events.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	October 7, 2005	0	The patient is a 55 year old woman. She has IDDM is treated for hypertension and hypercholesterolemia. She has a family history of cardiovascular disease. She presented with an (acute) MI without ST elevation on October 3, 2005 On **October 7, 2005** one lesion in the prox **LAD** was treated with one Endeavor stent after predilation. The total implanted stent length was 24 mm and the residual stenosis (visual estimate) was 0%. On the same day the CK peaked to 99 (uln 174, ratio 0.6) and CK-MB to 10 (uln 24, ratio 0.4). On October 9, 2005 the patient was discharged on aspirin and Clopidogrel. On **November 4, 2005** a 30 day follow up visit was performed. The patient presented with stable angina and did not report any events.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	October 7, 2005	0	The patient is a 54 year old man. He is an ex-smoker with non-IDDM and is treated for hypertension and hypercholesterolemia. He has had a previous non-Q wave MI, a previous PTCA and a previous CABG. He presented with unstable angina. On **October 7, 2005** three lesions were treated. The first lesion, in the **proximal SVG**, was implanted with one Endeavor stent. The second lesion, in the **distal SVG**, was treated with one Endeavor stent after predilation. The third lesion, in the **distal SVG** was treated with one Endeavor stent after predilation. All stents were delivered successfully and the site reported residual stenosis of 0% (visual estimate) in all three lesions. On the same day, the CK peaked to 260 (uln 174, ratio 1.5) and CK-MB to 34 (uln 24, ratio 1.4). On October 11, 2005 the patient was discharged on aspirin and Clopidogrel. On **November 10, 2005**, a 30 day follow up visit was performed. The patient presented free of symptoms and reported no events.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	October 8, 2005	0	The patient is a 56 year old man. He is a current smoker, has IDDM and is treated for hypertension and hypercholesterolemia. He has had a previous PTCA. He presented with unstable angina. On **October 8, 2005** one lesion in the **proximal LCX** was treated with one Endeavor stent by direct stenting. The stent was delivered successfully and the residual stenosis reported (visual estimate) was 0%. During the procedure the CK peaked to 132 (uln 174, ratio 0.8) and the CK-MB peaked to 806 (uln 24, ratio 33.6). On October 15, 2005 he was discharged on aspirin and Clopidogrel. On **November 8, 2005** a 30 day follow up visit was performed. The patient presented free of symptoms and did not report any events.	Non Q wave Myocardial Infarction

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	October 21, 2005	1	The patient is a 75 year old man. He is an ex smoker, treated for hypertension. He presented with unstable angina. On **October 20, 2005** three lesions were treated. The first lesion was a bifurcation in the **mid Left Main** in which one Endeavor stent was implanted without predilation. The second lesion was in the **mid LAD** in which one other DES stent was implanted after predilation. The third lesion was in the **mid LCX** in which one Endeavor was successfully implanted by direct stenting. The site reported a residual stenosis (visual estimate) of 0% in all three lesions. On **October 21, 2005** the site reported elevated cardiac enzymes, CK peaked to 167 (uln 174, ratio 0.96) and the CK-MB to 29 (uln 24, ratio 1.2). On October 23, 2005 the patient was discharged on Clopidogrel. On **November 20, 2005** a 30 day follow up visit was performed. The patient presented with stable angina and did not report any events.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	November 4, 2005	0	The patient is a 63 year old man. He is a current smoker and is treated for hypertension. He presented with silent ischaemia. On **November 4, 2005**, one lesion in the **proximal LAD** was treated by implantation of one Endeavor stent after predilation. Residual stenosis (visual estimate) was 0%. After the procedure the patient presented with ECG changes compared to baseline. The investigator assessed this as unstable angina. On November 6, 2005 the patient was discharged on ASA and Clopidogrel. A 30 day follow up visit was performed on December 5, 2005. The patient presented with silent ischaemia but reported no events.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	March 1, 2006	0	The patient is a 46 year old man. He is treated for hypertension and hypercholesterolemia. He has had a previous Q-wave MI and a previous PTCA. He presented with silent ischaemia. On **March 1, 2006** two lesions were treated. In the **mid LAD**, one Endeavor stent was implanted after predilation. In the **distal LAD**, one Bare Metal Stent was implanted after predilation. Residual stenosis (visual estimate) of 0% was reported in both lesions. On the same day the CK peaked to 131 (uln 174, ratio 0.8). The CK-MB was not measured. On March 3, 2006, the patient was discharged on aspirin and Clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	October 9, 2005	0	The patient is a 38 man. He is a current smoker. He presented a Myocardial Infarction with ST elevation and with date of onset October 9, 2005. On **October 9, 2005** one lesion was treated. In the **proximal LAD** two Endeavor stents were successfully implanted after predilation. The total implanted stent length was 31 mm and the residual stenosis (visual estimate) was 0%. On the same day the CK peaked to 3196 (uln 170, ratio 18.8) and the CK-MB peaked to 186 (uln 25, ratio 7.4). On October 11, 2005 the patient was discharged on aspirin and Clopidogrel. On **November 4, 2005** a 30 day follow up visit was performed. The patient presented with free of symptoms and did not report any events. ***CEC: The CEC commented: "Acute MI, already present before procedure. No MI."***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	11 Oct 2006	0	The patient is a 64-year-old male known with Diabetes Mellitus (Non-IDDM), hypertension and hyperlipidemia. The patient presented with a Myocardial Infarction with ST elevation and date of onset October 11, 2005. On **October 11 2005**, after pre-dilatation, the **proximal LAD** was treated with a single Endeavor stent. The site reported a successful implantation of the stent with 100% final residual stenosis in this lesion (visual estimate). On **October 12** the patient experienced a rise in cardiac enzymes; CK peaked to 267 U/L (170 uln, ratio 1.6) and CKMB to 12 U/L (25 uln, ratio 0.5). The patient was discharged on **October 18 2005** on ASA and Clopidogrel. No other events occurred and the patient did not experience any anginal complaints up until the 30-day follow-up.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	18 Oct 2006	0	The patient is a 75-year-old female known with hypertension. She presented with a Myocardial Infarction with ST elevation and with date of onset October 18, 2005. On **October 18 2005**, after pre-dilatation, the **mid LAD** was treated with a single Endeavor stent. The site reported a successful implantation of the stent with 40% final residual stenosis in this lesion (visual estimate). On **October 18** the patient experienced a rise in enzymes; CK peaked to 5215 U/L (145 uln, ratio 35.97) and CKMB to 436 U/L (22 uln, ratio 19.8). The patient was discharged on October 20 2005 on ASA, LMH and Clopidogrel. No other events occurred and the patient did not experience any anginal complaints up until the 30-day follow-up. ***CEC: The CEC commented: "Acute MI, already present before procedure. No MI."***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	09 Jan 2006	0	The patient is a 65-year-old female known with hypertension and hyperlipidemia. She is an ex-smoker who has had a previous Non-Q- wave MI and PTCA. The patient presented with a Myocardial Infarction with ST elevation and date of onset January 6 2006. On **January 9 2006**, after pre-dilatation, the **mid LAD** was treated with two overlapping Endeavor stents, with a total stent length of 38mm. The site reported a successful implantation of the stent with 0% final residual stenosis in this lesion (visual estimate). On **January 9** the patient experienced a rise in enzymes; CK peaked to 398 U/L (145 uln, ratio 2.7) and CKMB to 28 U/L (22 uln, ratio 1.3). The patient was discharged on **January 16 2006** on ASA and Clopidogrel. No other events occurred and the patient did not experience any anginal complaints up until the 30-day follow-up. ***CEC: The CEC commented: "Acute MI, already present before procedure. No MI."***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	07 Feb 2006	0	The patient is a 66-year-old female known with hypertension, hyperlipidemia and a family history of CAD.The patient presented with stable angina. On **February 7, 2006**, the **proximal LAD** was treated with a single Endeavor stent. The site reported a successful implantation of the stent with 0% final residual stenosis in this lesion (visual estimate). The **mid LAD** was also successfully stented with one Endeavor stent (0% final residual stenosis). Another Endeavor stent was successfully deployed in the **mid LAD** after pre-dilatation (0% final residual stenosis). On **February 8, 2006** the patient experienced a rise in enzymes; CK peaked to 344 U/L (145 uln, ratio 2.4) and CKMB to 26 U/L (22 uln, ratio 1.2). The patient was discharged on February 9, 2006 on ASA and Clopidogrel. No other events occurred and the patient did not experience any anginal complaints up until the 30-day follow-up.	Non Q wave Myocardial Infarction

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	13 Mar 2006	0	The patient is a 64-year-old male with a previous Q wave MI and a history of IDDM, hypertension, hypercholesterolemia and a family history of cardiovascular disease. He presented with a Myocardial Infarction without ST elevation. Date of onset was March 12, 2006. On **March 13, 2006** two lesions were treated. The first lesion was in the **ostial LCX** in which one Endeavor stent was implanted with predilation of the lesion. The site reported a successful implantation of the stent with 0% residual stenosis in the lesion (visual estimate). The second lesion was in the **mid LAD** in which two Endeavor stents and one other DES were implanted with predilation of the lesion. The total stent length implanted for this lesion was 42 mm. The site reported a successful implantation of the stents with a 0% residual stenosis in the lesion (visual estimate). On **March 13, 2006** the patient presented with elevated enzymes with on March 14, 2006 a peak CK of 388 (uln 190, ratio 2.0). The CK-MB was not measured. The investigator reported a **non-Q wave MI**. The patient was discharged on March 24, 2006 on ASA and clopidogrel.	Non Q wave Myocardial Infarction

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	27 Jan 2006	17	The patient is a 93-year-old male known with Diabetes Mellitus (Non-IDDM), hypertension and hyperlipidemia. The patient presented with an (acute) Myocardial Infarction without ST elevation. Date of onset was January 9 2006. On **January 10 2006**, the **mid LAD** was treated with a single Endeavor stent. The site reported a successful implantation of the stent with 7% final residual stenosis in the lesion (visual estimate). The patient was discharged on January 12 2006 on ASA and Clopidogrel. On **January 27, 2006** the site reported that the patient experienced a Non-Q-wave Myocardial Infarction. Lab values from February 3 [CK 180 U/L (190 uln, ratio 0.9)], as well as the ECG did not show any signs for this Myocardial Infarction. No other events occurred and the patient did not experience any anginal complaints up until the 30-day follow-up.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	11 Jan 2006	1	The patient is a 44-year-old male known with hypertension, hyperlipidemia and a family history of CAD. He is a current smoker and presented with stable angina. On **January 10 2006**, the **distal RCA** was treated with a single Endeavor stent, without predilation of the lesion. Two Bare Metal Stents were implanted by direct stenting due to a dissection distal to the Endeavor stent. The total stent length was 54mm. The site reported a successful implantation of all stents with 5% final residual stenosis in this lesion (visual estimate). On **January 11 2006** the patient experienced a rise in enzymes; CK 277 U/L (190 uln, ratio 1.5). The patient was discharged on **January 13 2006** on ASA and Clopidogrel. No other events occurred and the patient did not experience any anginal complaints up until the 30-day follow-up.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	16 Jan 2006	4	The patient is an 84-year-old female known with diabetes (Non-IDDM), hypertension, hyperlipidemia and a family history of CAD. Her history revealed a previous Q-wave MI and PTCA. She presented with a Myocardial Infarction without ST elevation with date of onset January 9, 2006. On **January 12, 2006**, a delayed PCI was performed to the **mid LAD**. The patient was pre-treated with dual antiplatelet therapy; no GP IIb/IIIa inhibitors were administered. A LVEF of 35% was measured. The patient had a creatinine of 1.61 mg/dl and was dialyzed. The target lesion involved a 30mm, moderately calcified, type B2, De Novo lesion, which was stenosed for 92% (RVD 2.5mm). After pre-dilatation, one Endeavor stent (2.5x24mm) was successfully implanted with one Bare Metal stent. Total stent length was 32mm. The site reported a 5% final residual stenosis (visual estimate). On **January 16 2006**, during index hospitalization, the patient was transported to surgery with abdominal pain. Radiologically free abdominal air was found. Explorative laparotomy showed second quadrant peritonitis, perforation of sigmoid at the bottom of diverticulitis. During and after surgery hypotony which deteriorated in spite of aimed volume substitution and maximal cathelogamine therapy. The patient died in shock. No autopsy was performed.	Non cardiac death

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	18 Jan 2006	1	The patient is an 81-year-old female known with hypertension and hypercholesterolemia. The patient had a previous Q wave MI and a PTCA. She presented with stable angina. On **January 17, 2006** after pre-dilatation, a lesion was treated in the **proximal RCA** in which two Endeavor stents were implanted with a total length of 32mm. The site reported a successful implantation of both stents with 3 % final residual stenosis in the lesion (visual estimate). After the procedure the patient experienced a rise in Troponin T (0,12 ug/l while 0,02 uln). The patient was discharged on January 18 with ASA and Clopidogrel. No events occurred and the patient experienced no anginal complaints up until the 30-day follow-up visit.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	1 Feb 2006	1	The patient is an 84 year-old male known with hypertension and hyperlipidemia. The patient had a previous Q-wave MI, non-Q-wave MI and PTCA. The patient was admitted to hospital with a Myocardial Infarction without ST elevation. Date of onset was January 31, 2006. On **January 31, 2006** three totally occluded lesions in the RCA were treated. The patient had a LVEF of 35% and creatinine of 1.38 mg/dl. He was pre-treated with ASA only and received a Clopidogrel loading of 600mg at the day of the procedure, but no GP IIb/IIIa inhibitors. The first target lesion was in the **distal RCA**, which was a type C, De Novo lesion with TIMI 0 flow without thrombus. Lesion length was 35mm with a RVD of 2.7mm. One Endeavor (2.75x18mm) stent was successfully implanted after pre-dilatation. One other DES was also implanted in this lesion. The total length of stents was 38mm. The second lesion was in the **mid RCA**, which was a type C, De Novo lesion with TIMI 0 flow without thrombus. This lesion was 19mm long, had a RVD of 3mm and was treated with one other DES of 20mm after pre-dilatation. The third lesion in the **ostial RCA** was a type C lesion with in-stent restonosis, lesion length 12mm and TIMI 0 flow without thrombus (RVD 3.5mm). It was treated with one other DES of 12mm after pre-dilatation. The site reported 4% final residual stenosis in each of the three lesions (visual estimate). During the intervention Brachycardia and hypotony occurred. Patient was transported to CCU under cathecholamine therapy and IABP. During the night the hemodynamical state deteriorated, and despite the maximal cathecholamine therapy and intensive reanimation the blood pressure fell further with subsequent death. ***CEC: The cardiogenic shock following MI was confirmed as cardiac death. As cardiac death occurred within 24 hours, the CEC ruled this as an acute stent thrombosis. The angio was not available during this adjudication.***	Cardiac death Acute stent thrombosis

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	1 Feb 2006	0	The patient is a 70-year-old male known with hyperlipidemia and hypertension. The patient had a previous Q-wave and Non-Q wave MI, as well as a PTCA and a CABG. The patient was admitted with stable angina. On February 1 2006, after pre-dilatation, one lesion was treated in the distal SVG (Saphenous Vein Graft) with three Endeavor stents with a total stent length of 72mm. The lesion was predilated and the stents were implanted abutting. The site reported a successful implantation of all stents with 3% final residual stenosis in this lesion (visual estimate). The patient had a rise in enzymes after the procedure; CK 343 U/L (190 uln, ratio 1.8). On February 8 the patient was discharged with ASA and Clopidogrel. No events occurred and the patient experienced no anginal complaints up until the 30-day follow-up.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction Revasc. PCI target lesion	11 Feb 2006 11 Feb 2006	1 1	The patient is a 74 year old man. He is treated for hypertension and hypercholesterolemia. He presented with stable angina. On **February 10, 2006**, one lesion in the **distal LCX** was treated with one Endeavor stent. Total implanted stent length was 18 mm and the residual stenosis (visual estimate) was 3%. On **February 11, 2006**, the patient presented with a peak CK of 102 (uln 190, ratio 0.5). CK-MB was not measured. The investigator assessed this as a non Q-wave MI. A repeat angiogram was performed. On **February 11, 2006**, the **distal LCX** was treated during a re-PTCA. On February 13, 2006 the patient was discharged on aspirin and Clopidogrel. On March 10, 2006 a 30 day follow up visit was performed. The patient presented with stable angina but reported no events.	Change to no event Target lesion revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	21 Feb 2006	0	The patient is a 72-year-old female known with hyperlipidemia and hypertension. The patient had a previous Q wave MI and PTCA. She presented with stable angina. On **February 21, 2006** the **distal LCX** was treated after pre-dilatation of the lesion. One Endeavor stent was successfully implanted with three Bare Metal Stents. The total stent length was 64mm. The site reported 7% final residual stenosis in this lesion (visual estimate). The patient showed a rise in enzymes after the procedure. On February 22 CK 255 U/L (170 uln, ratio 1.5) and on February 23 CK 238 U/L. (170 uln, ratio 1.4). The patient was discharged on February 23 on ASA and Clopidogrel. No events occurred and the patient experienced no anginal complaints up until the 30-day follow-up.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	13 Dec 2005	0	The patient is a 67-year-old male known with Diabetes Mellitus (IDDM), hyperlipidemia and hypertension as well as a previous PTCA. The patient was admitted with stable angina. On **December 13, 2005** three lesions were treated. The **proximal LAD** was treated with one other DES after pre-dilatation. The **mid LAD** was successfully treated with an Endeavor stent (residual stenosis 0%). The third lesion was a bifurcation at the **diagonal of the LAD.** One other DES was implanted after pre-dilatation. After the procedure the patient showed a rise in enzymes. On **December 14, 2006** CK was 1140 U/L (190 uln, ratio 6) and CKMB was 106 U/L (24 uln, ratio 4.4). The patient was discharged on December 19 on ASA and Clopidogrel. No events occurred and the patient experienced no anginal complaints up until the 30-day follow-up.	Non Q wave Myocardial Infarction

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction Stent thrombosis Re-PTCA	January 27, 2006 January 27, 2006 January 27, 2006	10 10 10	The patient is a 75 year old man. He is treated for non-IDDM, hypertension and hypercholesterolemia. He presented with stable angina. On **January 17, 2006** a type C, De Novo lesion in the **mid LAD** was treated. The lesion was severely calcified and had a stenosis of 90% (RVD 3.0mm) over a lesion length of 20mm. The patient had a LVEF of 60% and creatinine of 0.8 mg/dl. He was pre-treated with dual antiplatelets, no GP IIb/IIIa inhibitors were administered during the procedure. One Endeavor stent (3.0x24mm) was successfully implanted after predilation. The residual stenosis (visual estimate) was 20%. On January 18, 2006 the patient was discharged on aspirin and Clopidogrel with no evidence of periprocedural MI. On **January 27, 2006**, the patient presented with an anterior Qwave Myocardial Infarction. The CK peaked to 2727 (uln 171, ratio 15.9) and CK-MB peak was 110 (uln 6, ratio 18.3). A repeat angiogram confirmed stent thrombosis. The patient was on anti-platelets within 24 hours prior to the event. The investigator added: "Endeavor stent was not fully expanded during first implantation". The **proximal LAD** was treated on the same day during a re-PTCA. On **February 22, 2006** a 30-day follow up visit was performed. The patient was free of symptoms and no further events were reported.	Q-wave Myocardial Infarction Sub-acute stent thrombosis Target lesion revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	18 Jan 2006	0	The patient is an 85-year-old male known with hyperlipidemia, hypertension and known with a family history of CAD. He is an ex-smoker who has had a previous Q wave MI and a PTCA. The patient was admitted with a Myocardial Infarction with ST elevation and date of onset January 17, 2006. On **January 18 2006,** after pre-dilatation the **mid LAD** was treated with three Endeavor stents, with a total stent length of 72mm. The site reported a successful implantation of all stents with 0% final residual stenosis in this lesion (visual estimate). After the procedure the patient has a rise in enzymes; CK peaked to 857 U/L (171 uln, ratio 5.0) and CKMB to 78 U/L (72 uln, ratio 13). The patient was discharged on January 19 on ASA and Clopidogrel. No events occurred and the patient experienced no anginal complaints up until the 30-day follow-up.	Non Q wave Myocardial Infarction

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	1 Mar 2006	0	The patient is an 85-year-old male known with hyperlipidemia and a previous PTCA. The patient was admitted with stable angina. On **March 1, 2006** the **proximal LAD** was pre-dilated and treated with two Endeavor stents with a total stent length of 60mm. The site reported a successful implantation of both stents with 0% final residual stenosis in this lesion (visual estimate). On **March 2, 2006** the patient had a rise in enzymes; CK peaked to 204 U/L (171 uln, ratio 1.2), CKMB was not measured. The patient was discharged on March 2 on ASA and Clopidogrel. No events occurred and the patient experienced no anginal complaints up until the 30-day follow-up.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	23 Dec 2005	0	The patient is a 57-year-old male known with hypertension and hyperlipidemia. He is a current smoker and had a previous Q wave MI and a PTCA. The patient presented with silent ischaemia. On **December 22, 2005** the **proximal LAD** was treated with one Endeavor stent. The lesion was not predilated before implantation. The site reported a successful implantation of the stent with 0% final residual stenosis in this lesion (visual estimate). On **December 23, 2005** the patient had a rise in cardiac enzymes; CK peaked to 370 U/L (171 uln, ratio 2.2) and CKMB to 46 U/L (28 uln, ratio 1.6). The patient was discharged on December 23 on ASA and Clopidogrel. No events occurred and the patient experienced no anginal complaints up until the 30-day follow-up.	Non-Q-wave MI

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stent Thrombosis Myocardial Infarction Re-PTCA	27 Feb 2006 27 Feb 2006 27 Feb 2006	7 7 7	The patient is a 65-year-old male known with Diabetes Mellitus (Non-IDDM), hypertension and family history of cardiovascular disease. He presented with stable angina. On February 20 2006 two lesions were treated. He was pre-treated with dual antiplatelets and had GP IIb/IIIa inhibitors administered during the procedure. The site reported a LVEF of 55% and a creatinine level of 1 mg/dl. The lesion in the mid RCA was a type B1, De Novo lesion of 5mm, which was 72% stenosed (RVD 2.5) and successfully treated with a single Endeavor stent (2.5x12mm) by direct stenting. The residual stenosis (visual estimate) was 0%. A second lesion located in the proximal LAD was a type B1, De Novo, moderate calcified but highly tortuous (>90%) lesion of 13mm with a 76% diameter stenosis (RVD 2.5mm). After pre-dilatation one Endeavor stent (2.5x18mm) was implanted. Due to a dissection of the target vessel, another DES was overlapped with the Endeavor stent. The total stent length was 22mm. The site reported 25% final residual stenosis in this lesion (visual estimate). The patient was discharged on February 24, 2006 on ASA and Clopidogrel, but the patient stopped taking Clopidogrel the same day. The patient was re-admitted on February 27, 2006 with an anterior myocardial infarction. Cardiac enzymes peaked to 1901 CK (uln 171, ratio 11.1) and CKMB to 184 (uln 28, ratio 6.1). The MI was caused by a thrombosis in the proximal LAD at the beginning of the Endeavor stent. PCI was unsuccessful; no stent was placed. The site reported that the target vessel was completely occluded but the patient was stable and had no chest pain. No other events occurred and the patient experienced no anginal complaints up until the 30-day follow-up.	Sub-acute stent thrombosis Q-wave MI Target lesion revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	24 Oct 2005	0	The patient is a 67-year-old male known with Diabetes Mellitus (Non-IDDM) hypertension and hyperlipidemia. The patient is an ex-smoker who has had a previous Q wave MI and a PTCA. The patient presented with unstable angina. On **October 24, 2005** the **distal LCX** was successfully treated with a single Endeavor stent. The lesion had not been predilated before implantation. The site reported a residual stenosis of 0% (visual estimate). On **October 25, 2005** the patient had a rise in enzymes; CK 348 U/L (171 uln, ratio 2.0) and CKMB 26 U/L (28 uln, ratio 0.9). The patient was discharged on October 28 on ASA and Clopidogrel. No other events occurred up until the 30-day follow-up. The patient did however experience anginal complaints (stable angina). ***CEC: The CEC commented that it considered it no MI according to the WHO definition because CK-MB was normal. Troponin (reported as raised in eCRF) is usually elevated after PCI.***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	29 Jan 2006	0	The patient is a 61-year-old male smoker known with hypertension. The patient presented with a Myocardial Infarction with ST elevation and date of onset January 29, 2006. On **January 29, 2006** the **mid LAD** was treated successfully with two Endeavor stents with a total length of 33mm. The lesion was not predilated before implantation. The site reported 0% final residual stenosis in this lesion (visual estimate). On **January 30, 2006** the patient had a rise in cardiac enzymes; CK peaked to 1076 U/L (171 uln, ratio 6.3) and CKMB to 122 U/L (28 uln, ratio 4.4). The patient was discharged on February 1 on ASA and Clopidogrel. No other events occurred and the patient experienced no anginal complaints up until the 30-day follow-up. ***CEC: The CEC commented that the "MI was already in progress before index procedure; therefore this was adjudicated as no event."***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stent Thrombosis Myocardial Infarction Re-PTCA	17 Mar 2006 17 Mar 2006 17 Mar 2006	8 8 8	The patient is a 67-year-old male known with Diabetes Mellitus (IDDM), hypertension and hypercholesterolemia. The patient had a serum creatinine level of 1.1mg/dl and presented with stable angina. On **March 9, 2006**, one type C, De Novo lesion in the **proximal LAD** was treated. It was a severely calcified lesion with TIMI 2 flow without thrombus in a bifurcation which was 87% stenosed (RVD 3.1) and had a lesion length of 28mm. LVEF measurement was not performed. The patient was pre-treated with ASA only and was given 500mg ASA on the procedure day. No Clopidogrel and no GP IIb/IIIa inhibitors were administered during the procedure. After pre-dilatation, a single Endeavor stent (3.0x30mm) was implanted. The side branch was not stented. The site reported a successful implantation of the stent with 0% final residual stenosis in the lesion (visual estimate). The patient was discharged on March 10, 2006 on ASA and Clopidogrel. On **March 17, 2006** the patient was admitted with a Myocardial Infarction of the **mid LAD**. On March 17, CK was 1255 U/L (171 uln, ratio 7.3) and CKMB 192 U/L (28 uln, ratio 6.9). On March 18, CK was 2031 U/L (ratio 11.9) and CKMB 296 U/L (ratio 10.6). On the repeat angiography the investigator saw a thrombus and performed a PCI. The patient had not been on anti-platelet medication within 24 hours before the event. No other events occurred up until the 30-day follow-up, but the patient did experience anginal complaints (stable angina) at the 30-day follow-up.	Sub-acute stent thrombosis Non-Q-wave MI Target lesion revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stent Thrombosis Re-PTCA	02 Dec 2005 02 Dec 2005	3 3	The patient is a 77-year-old male known with hypertension and hyperlipidemia. He is an ex-smoker who has had a previous Q wave MI and PTCA. The patient had a serum creatinine level of 0.8 mg/dl and presented with stable angina. On November 29, 2005, two lesions in the LAD were treated. LVEF measurement was not performed. The patient was pre-treated with dual antiplatelets. No GP IIb/IIIa inhibitors were administered during the procedure. The first lesion at the proximal LAD was a type A, De Novo lesion of 18mm, which was moderate calcified and 93% stenosed (RVD 3.0mm). One Endeavor (3.0x24mm) stent was successfully implanted after pre-dilatation. The site reported a 10% final residual stenosis in the lesion (visual estimate). A second lesion of 6mm in the mid LAD was 90% stenosed (RVD 3.0mm) and a Bare Metal stent (Coroflex Blue, 8mm) was implanted with direct stenting. Final residual stenosis in this lesion was 0% (visual estimate). The patient was discharged on November 11 on ASA and Clopidogrel. On December 2, 2005 the patient was admitted with a Myocardial Infarction. Cardiac enzymes were not available. A revascularization of the proximal LAD was performed. The investigator reported a stent thrombosis and commented: "patient with 2 stents in the LAD; proximal Endeavor and mid LAD Coroflex blue which was trombosed". The patient had been on anti-platelet medication within 24 hours prior to the event. No other events occurred and the patient did not experience any anginal complaints up until the 30-day follow-up.	Sub-acute stent thrombosis Target vessel (non-target lesion) revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stent Thrombosis	06 Dec 2005	8	The patient is a 67-year-old female with Diabetes Mellitus (Non-IDDM) known with hypertension and hyperlipidemia. She is a current smoker and had a previous Non-Q wave MI and CABG. The patient presented with stable angina. On November 28, 2005, a totally occluded type C lesion of 50mm with a RVD of 2mm was treated in the mid SVG. LVEF was 50%; creatinine was not measured. The patient was pre-treated with ASA only and given a loading of ASA and Clopidogrel at the procedure day, no GP IIb/IIIa inhibitors were administered. After pre-dilatation of the lesion one Endeavor (2.5x18mm) stent was successfully implanted with one other Drug Eluting stent. The total stent length was 46 mm. The site reported 0% final residual stenosis (visual estimate). The patient was discharged on November 29, 2005, on ASA and Clopidogrel. On December 5, 2005 the patient was admitted to a different hospital with retrosternal complaints. An angiography was done the following day, but this could not confirm a thrombus. The patient had not been on antiplatelets within 24 hours prior to the event. The patient was discharged again on December 7, 2005. No other events occurred and the patient did not experience any anginal complaints up until the 30-day follow-up.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stent Thrombosis	30 Jan 2006	25	The patient is a 76-year-old male known with Diabetes Mellitus (IDDM) and hypertension. The patient is an ex-smoker and had a serum creatinine level of 0.96 mg/dl. He presented with stable angina. On January 5, 2006 the proximal LAD was treated. The target lesion was a bifurcation lesion of 20mm, type B1, De Novo which was 80% stenosed (RVD 3mm). No measurement of LVEF was performed. The patient was pre-treated with ASA and was given a 300mg Clopidogrel at the procedure day; no GP IIb/IIIa inhibitors were administered. After pre-dilatation, one Endeavor (3.0x24mm) stent was successfully implanted. Due to a distal dissection, a Bare Metal Stent was implanted, partially overlapping. The total stent length was 37mm; the side branch was not stented. The site reported 20% final residual stenosis (visual estimate). The patient was discharged on November 29 on ASA and Clopidogrel. On January 30, 2006 the patient was admitted with anginal complaints. The patient had not been on anti-platelets within 24 hours prior to the event. The angiographic results did not show any thrombotic event (20% restenosis in both stents). No other events occurred up until the 30-day follow-up.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stent Thrombosis	5 Jan 2006	0	The patient is a 50-year-old male, who is an ex-smoker known with hypertension, hypercholesterolemia, and family history of cardiovascular disease. He had a previous non-Q-wave MI and a previous PTCA. The patient presented with unstable angina. On January 5, 2006 one lesion in the LAD was treated in the procedure. The target lesion was a type B2, De Novo lesion of 12mm located in the proximal LAD which was 80% stenosed (RVD 3mm). LVEF and renal function were not measured. The patient was pre-treated with ASA and received a loading of Clopidogrel, no GP IIb/IIIa inhibitors were administered. One Endeavor (3.0x15mm) stent was implanted without predilation. The site reported a successful implantation of the stent with 10% final residual stenosis in the proximal lesion (visual estimate). On January 5, 2006, two hours after the index procedure, the patient presented with angina pectoris and underwent a repeat angiography. The investigator reported an optimal result in the LAD stent, no angiographic evidence of thrombus and no dissection. The patient was discharged on January 6 on ASA and clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	13 March 2006	0	The patient is a 69-year-old female. She is treated for hypertension. She presented with a stable angina. On March 13, 2006 she underwent a treatment in the mid LAD. After predilation, the implantation of an Endeavor stent was not successful as the stent failed to reach the target lesion. The stent was retrieved successfully. One other DES and one BMS were implanted with predilation of the lesion. The total stent length implanted for this lesion was 18 mm and the final residual stenosis in the lesion was 0% (visual estimate). On March 13, 2006 the patient presented with a myocardial infarction. The ECG did not show a new Q wave; CK and CK-MB values were not measured. The investigator reported a non-Q wave MI. The patient was discharged on March 15, 2006 on ASA and clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		CABG	08 Mar 06	07	The patient is a 75 year old female, who is an ex smoker and has a history of hypertension and previous PTCA. On the admission she presented with silent ischaemia. On March 1, 2006 three totally occluded lesions in the RCA were treated. The first lesion in the mid RCA was predilated before stenting. One Endeavor stent was successfully implanted. The second lesion was a bifurcation at the Ostial RCA. One Endeavor stent was successfully implanted without predilation. The third lesion was also a bifurcation lesion at the Ostial RCA. One Endeavor stent was successfully implanted without predilation. The site reported 0% final residual stenosis (visual estimate) in all three lesions. On March 8, 2006 the patient underwent a partial resection of an Atrial Neoformation, (Atrial Mixoma), during the operation there was a dissection of the mid and distal LAD. CABG LIMA-AIVA SAF-D1 were performed at this same procedure. The patient was discharged on March 14 on ASA and Clopidogrel.	Changed to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	28/12/2005	0	The patient is a 65-year-old male with a history of diabetes mellitus, hyperlipidemia, ex-smoker and having had a previous PTCA. He presented with unstable angina. On December 28, 2005 the patient was treated for two totally occluded lesions in the distal LCX. The first lesion was predilated and one Endeavor stent was successfully implanted. The second lesion in the distal LCX was also predilated. Three Bare Metal stents were implanted with a total stent length implanted of 53mm in this lesion. The site reported a 0% final residual stenosis in both lesions (visual estimate) On December 28, 2005 the patient suffered a Myocardial Infarction. The site reported a non-Q-wave Inferior MI. Only CK-MB enzymes were recorded. CK-MB of 18 (nl 7, ratio 2.6) was measured on December 28 and peaked on December 29 to 35 (ratio 5). The patient was discharged on December 29, 2005 on Aspirin and Clopidogrel. CEC: The CEC adjudicated a Q-wave MI during the procedure.	Q-wave MI during procedure

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	06 Oct 2005	0	This patient is a 48-year-old male with a history of hyperlipidemia, previous MI and ex-smoker. He presented with stable angina. On **October 6, 2005** he underwent the index procedure in the **mid LAD**. After predilation of the lesion, two Endeavor stents were implanted (overlapping) with a total stent length of 42mm. The site reported a 0% final residual stenosis (visual estimate). On **October 6, 2005** the site reported a non-Q-wave MI. CK peaked at 329 (nl 200, ratio 1.65) with a CK-MB of 41 (nl 6, ratio 6.8) on October 7. The patient was discharged on October 8, 2005 on Aspirin and Clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	15 Mar 2006	18	The patient is a 78-year-old male with non insulin dependent diabetes mellitus, hypertension and previous Q-wave MI. He presented with an acute MI with ST-elevation on 23 February 2006. On **February 25, 2006** two vessels were treated in the procedure. The patient was on dual antiplatelet therapy and did not receive GP IIb/IIIa inhibitors. The LVEF and creatinine levels were not measured. The first lesion was located in the **mid LCX**. It concerned a type B2, De Novo lesion with TIMI 2 flow and 92% stenosis without thrombus. The RVD was 2.5mm and the lesion length 18mm. One other (non-Endeavor) drug eluting stent of 16mm was implanted with direct stenting. The second lesion was in the **proximal LAD**, which was a B2, De Novo lesion with TIMI 2 flow without thrombus that had a 92% stenosis (RVD 2.5mm). The lesion length was 25mm. One Endeavor stent (2.5x30mm) was successfully implanted after predilation of the lesion. The site reported a 0% final residual stenosis for both lesions (visual estimate). On **March 15, 2006** patient died of renal insufficiency in a referral hospital. The autopsy report was not available. ***CEC: The CEC added Sub acute stent thrombosis because cardiac death occurred within 30 days. There was no angiogram available.***	Cardiac death Sub-acute stent thrombosis

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	20 Jan 2006	30	The patient is an 85-year-old male smoker with hypercholesterolemia. He presented with unstable angina. On December 21, 2005 one bifurcation lesion in the mid LAD was treated. The patient was pre-treated with ASA and did not receive Clopidogrel or GP IIb/IIIa inhibitors during the procedure. A LVEF of 75% was measured and a creatinine level of 1 µmol/l. The target lesion was a type C, De Novo lesion, which was moderately tortuous and severely calcified and had TIMI 1 flow without thrombus. The lesion was 95.5% stenosed (RVD 2.2mm) over a lesion length of 40mm and involved a bifurcation. Two Endeavor stents (2.5x24mm) were successfully implanted (overlapping) after predilation. The side branch was not stented. The total stent length implanted was 48 mm. The site reported a 0% final residual in the lesion (visual estimate). The patient was discharged on December 22 on ASA and clopidogrel. On January 20, 2006 the patient died suddenly during his sleep. The investigator reported the death as sudden death and no association with MI or stent thrombosis. Autopsy was not performed. CEC: Death was adjudicated as cardiac death. As this occurred at 30 days after procedure, the CEC added sub-acute stent thrombosis. There was no angiogram available.	Cardiac death Sub-acute stent thrombosis

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction	19 December 2005	0	The patient is a 52-year-old female with a history of hypertension. She presented with unstable angina. On December 19, 2005 two lesions were treated. The first lesion was in the mid RCA. Two Endeavor stents were successfully implanted with predilation. Due to a distal type C dissection three Bare Metal stents were implanted without predilation. The total stent length implanted for this lesion was 84 mm. The second lesion was in the mid LAD and one Taxus stent was implanted after predilation. The site reported 0% final residual stenosis in both lesions (visual estimation). The investigator reported a non-typical chest pain for this patient on December 19, 2005. The medical records also report unspecified thoracic pain while in hospital. No ECG was performed, no CK/CK-MB values were measured and no angiography was done. The patient was discharged on December 21, 2005 on ASA and clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	31 January 2006	21	The patient is a 57-year-old female known with IDDM, hypertension, hypercholesterolemia and a family history of cardiovascular disease. She presented with unstable angina. On January 10, 2006 two vessels were treated. The Creatinine level was 1.6 mg/dl but LVEF was not measured. The patient was pre-treated with dual antiplatelet therapy; no GP IIb/IIIa inhibitors were given during the procedure. The first lesion was in the proximal LCX. It concerned a 13mm type B2, De Novo lesion, moderately tortuous, which was 91% stenosed (RVD 3.5mm). After predilation of the lesion, one Endeavor stent (3.5x15mm) was successfully implanted. The second lesion was a type B1, De Novo lesion in the mid LAD. It was a 15mm long and 77% stenosed lesion (RVD 3.5mm) in which one Endeavor (3.5x18mm) stent was successfully implanted by direct stenting. The site reported for both lesions a 0% final residual stenosis (visual estimate). The patient was discharged on January 11, 2006 on ASA and clopidogrel. On January 31, 2006 the patient died. The investigator reported a non-sudden, non-cardiac death due to mesenteric ischaemia and septic shock. CEC: The CEC commented that there was no evidence of stent thrombosis but adjudicated Sub acute stent thrombosis based on the definition. There was no angiogram ***available.***	Cardiac death Sub-acute Stent Thrombosis

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction	24 February 2006	0	The patient is a 56-year-old male with a history of hypertension. He presented with a silent ischaemia. On February 24, 2006 three lesions were treated in the index procedure. The first lesion was in the mid RCA in which two Endeavor stents were implanted without predilation (the total stent length implanted for this lesion was 33 mm). The second lesion was in the proximal RCA in which two Endeavor stents were implanted with predilation (the total stent length implanted for this lesion was 33 mm). The third lesion was in the mid LCX in which one Endeavor stent was implanted with predilation. The site reported a successful implantation of the stents, with 0% final residual stenosis in the three lesions (visual estimation). The investigator reported an inferior Q-wave myocardial infarction for this patient on February 24, 2006. According to the investigator, compared to baseline, there had been changes in the ECG at the time of the event as well as in the CK/CK-MB values (peak CK value of 3929 (uln of 190, ratio 20.68) with a peak CK-MB value of 437 (uln of 6, ratio of 72.83)). No angiography was done. The patient was discharged on March 01, 2006 on ASA and clopidogrel.	Q wave MI

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	13 Feb 2006	0	The patient is a 70-year-old male without any risk factors or cardiac history. He presented with an acute MI with ST elevation on February 13, 2006. On **February 13, 2006** two lesions, one in the LAD and one in the LCX were treated. The patient was not pre-treated with dual antiplatelets and was given 100mg ASA and GP IIb/IIIa inhibitors during the procedure. He was not administered any Clopidogrel. LVEF and serum creatinine were not measured. The first lesion located in the **mid LAD**, was a type B2, De Novo lesion which was totally occluded with thrombus (TIMI 0, RVD 2.7mm) at a length of 40mm. Two bare metal stents, with a total stent length of 44 mm, were implanted using direct stenting. The site reported a 0% final residual stenosis of the lesion (visual estimate). The second lesion was a bifurcation lesion in the **mid LCX** of 30mm, type B2, De Novo which was 71% stenosed (RVD 3.5mm). One Endeavor stent (3.5x15mm) and one Bare metal stent were implanted, both after predilation. The total stent length was 33 mm. The side branch was not treated. Residual stenosis was 0% for this lesion (visual estimate). On **February 13, 2006,** during the index procedure, the patient presented cardio respiratory arrest caused by electro mechanic dissociation with no response to advanced cardiopulmonary resuscitation measures after which the patient died. The investigator reported death as Non-sudden Cardiac death. Autopsy was not performed. ***CEC: The CEC confirmed cardiac death and commented: "no evidence of stent thrombosis. Complication of the procedure. Before procedure LAD completely occluded, acute MI at inclusion. Therefore no Stent Thrombosis".***	Cardiac death

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	13 January 2006	0	***The patient is a 72-year-old female with a history of non-IDDM and hypertension. She presented with a myocardial infarction (started on January 13, 2006) with ST elevation.*** ***On January 13, 2006 one lesion in the proximal LAD was treated. One Endeavor stent was implanted without predilation. The site reported a successful implantation of the stent, with 0% final residual stenosis (visual estimation).*** ***On January 13, 2006 an anterior Q-wave MI was reported. According to the investigator, there had been changes in the ECG at the time of the event compared to baseline, as well as in the CK/CK-MB*** values. Peak CK of 522 (CK uln of 195, ratio 2.68), with a peak CK-MB of 62 (CK-MB uln of 25, ratio 2.48). No angiography was done. ***The patient was discharged on January 20, 2006 on ASA and clopidogrel.*** ***CEC: The CEC commented: "ST elevation on day of procedure, is MI before index procedure and therefore adjudicated as no event."***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction	01 February 2006	2	***The patient is a 68-year-old male, current smoker, and with a history of non-IDDM, hypertension and hypercholesterolemia. He presented with unstable angina.*** ***On January 30, 2006 one lesion in the distal RCA was treated. Two Endeavor stents were implanted without predilation (the total stent length implanted for this lesion was 15 mm). The site reported a successful implantation of the stents, with 2% final residual stenosis (visual estimation).*** ***The investigator reported a ST elevation V3-V6 for this patient on February 1, 2006. The peak CK was of 40 (CK uln of 195, ratio 0.20) with a peak CK-MB of 0 (CK-MB uln of 25, ratio 0). No angiography was done.*** ***The patient was discharged on February 1, 2006 on ASA and clopidogrel.***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	06 February 2006	0	***The patient is a 72-year-old female with a history of hypertension, hypercholesterolemia and family history of cardiovascular disease. She presented with a myocardial infarction (started on February 6, 2006) with ST elevation.*** ***On February 6, 2006 one lesion in the mid LAD was treated in the index procedure. One Endeavor stent was implanted without predilation. The site reported a successful implantation of the stent, with 0% final residual stenosis (visual estimation).*** ***The investigator reported an anterior Q-wave myocardial infarction for this patient on February 6, 2006. The investigator reported that there had been changes in the ECG at the time of the event, as well as in the CK/CK-MB values. The peak CK was of 388 (CK uln of 195, ratio 1.99) with a peak CK-MB of 33 (CK-MB uln of 25, ratio 1.32). No angiography was done.*** ***The patient was discharged on* February 13, 2006** on ASA and clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarc	16 February 2006	2	***The patient is a 72-year-old male with Non-IDDM and a family history of cardiovascular disease. He presented with a myocardial infarction (started on February 07, 2006) with ST elevation.*** ***On February 14, 2006 four lesions were treated.*** ***The first lesion was in the ostial left main in which one Endeavor stent was implanted with predilation (final residual stenosis: 0%, visual estimate).*** ***The second lesion was in the mid LAD in which one Endeavor stent was implanted with predilation (final residual stenosis: 5%, visual estimate).*** ***The third lesion was in the ostial LAD in which one Endeavor stent was implanted with predilation (final residual stenosis: 0%, visual estimate).*** ***The fourth lesion was in the distal LCX in which one Endeavor stent was implanted with predilation (final residual stenosis: 5%, visual estimate).*** ***The site reported a successful implantation of all stents.*** ***The investigator reported negative T from V1 to V4 for this patient on February 16, 2006. No CK/CK-MB values were measured and no angiography was done.*** The patient was discharged on February 16, 2006 on ASA and Clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Repeat revascularization	05 April 2006	21	***The patient is a 72-year-old male with hypertension. He presented with unstable angina.*** ***On March 15, 2006 the patient underwent treatment in the proximal LAD. One Endeavor stent was implanted without predilation of the lesion. The site reported a successful implantation of the stent with 5% residual stenosis (visual estimate).*** ***The patient was discharged on March 17, 2006 on ASA and clopidogrel.*** ***On April 5, 2006 the proximal RCA was treated during a PTCA. Indication for this revascularization was unstable angina.***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction	02 December 2005	0	***The patient is a 58-year-old male, ex-smoker. He presented with unstable angina.*** ***On December 2, 2005 two lesions were treated in the procedure. The first lesion was in the proximal RCA in which one Endeavor stent was implanted with predilation. The second lesion was in the mid LAD in which one Endeavor stent was implanted without predilation. The site reported a successful implantation of all stents, with 0% final residual stenosis (visual estimation).*** ***The investigator reported non-Q-Wave MI for this patient on December 2, 2005. ECG was taken, as well as analysis of the CK/CK-MB values. Peak CK of 460 (uln 170, ratio 2.7) with a peak CK-MB of 42 (CK-MB uln not available). No angiography was done.*** ***The patient was discharged on December 5, 2005 on ASA and clopidogrel.***	Non Q wave Myocardial Infarction

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stent Thrombosis Myocardial Infarction Revasc., PCI Target lesion Death	22 Dec 2005 22 Dec 2005 22 Dec 2006 1 Jan 2006	6 6 6 16	***The patient is a 67-year-old male ex-smoker with insulin dependent diabetes mellitus, hypertension, and hypercholesterolemia. He had a previous non-Q-wave MI and previous CABG (mammary to LAD, SVG to RCA) and the site reported chronic renal failure. He presented with an acute MI without ST elevation on December 14, 2005.*** ***On December 16, 2005 a type B2, De Novo, moderately calcified lesion in the proximal Left Main was treated. The site reported that the lesion was 12mm long and had a RVD of 2.5mm, which was stenosed for 92% and had TIMI 3 flow. The LVEF was measured at 45%, and creatinine at 2.3 mg/dl. The patient was pre-treated with dual antiplatelets and received a Clopidogrel loading of 600mg at the procedure day; no GP IIb/IIIa inhibitors were administered. The target lesion was stented with one Endeavor (2.5x14mm) stent without predilation. The site reported a successful implantation with 0% final residual stenosis (visual estimate).*** ***The patient was discharged on December 19, 2005 on ASA and clopidogrel.*** ***On December 22, 2005 the patient was admitted with angina and raised cardiac enzymes. The highest CK and CKMB values were***	Sub-acute stent thrombosis Non-Q-wave MI Target lesion revascularisation Cardiac death

					respectively 1180 (uln 170, ratio 6.9) and 64 (uln na) on December 22, 2005. The patient underwent revascularization (PTCA) of the proximal Left Main the same day. On **January 1, 2006** patient died because of multifactory cardiogenic shock, probably stent thrombosis, acute renal failure, osmotic hyperglycemia. Autopsy was not performed. The investigator reported a non-Q-wave MI, stent thrombosis and angiographic evidence of thrombus, Re-PTCA of the target lesion and death as Non-sudden Cardiac Death. No autopsy was performed.	

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction	23 January 2006	0	The patient is a 67-year-old male, ex-smoker and with a history of Non-IDDM, hypertension, hypercholesterolemia, previous Q-Wave MI and previous CABG. He presented with a stable angina. On January 23, 2006 two lesions were treated. The first lesion was in the proximal LAD in which no stent was implanted (final residual stenosis: 80%, visual estimate). The second lesion was in the distal SVG in which one Endeavor stent was implanted without predilation. The site reported a successful implantation of the Endeavor stent, with 0% final residual stenosis (visual estimate). The investigator reported non-Q-Wave MI for this patient on January 23, 2006. ECG was taken, as well as analysis of the CK/CK-MB values. Peak CK of 294 (uln for CK 170, ratio 1.73) with a peak CK-MB of 24 (uln for CK-MB not available). No angiography was done. The patient was discharged on January 26, 2006 on ASA and clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	5 Feb 2006	5	The patient is a 65-year-old male smoker with hypertension. He presented with an acute MI with ST elevation on 30 January 2006. On January 31, 2006 one lesion in the proximal LAD was treated. The patient was pre-treated with ASA. No Clopidogrel or GP IIb/IIIa inhibitors were administered before the procedure. LVEF and creatinine measurements were not performed. The target lesion was a type C, De Novo lesion of 16mm 100% occluded (TIMI 0) with thrombus. The RVD was 3mm. One Endeavor (3.0x18mm) stent was successfully implanted after predilation of the lesion. The site reported a 0% final residual stenosis (visual estimate). The patient was still in the hospital on February 5, 2006 when he suddenly died during his sleep. The investigator reported a sudden death. Autopsy was not performed. CEC: The CEC added sub acute stent thrombosis with the comment that no angiogram was available.	Cardiac death Sub acute stent thrombosis

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Repeat revascularization	16 March 2006	8	The patient is a 77-year-old female, with a history of IDDM, hypertension and previous non-Q-Wave MI. She presented with a myocardial infarction (started on March 1, 2006), without ST elevation. On March 8, 2006 one lesion in the distal RCA was treated in the index procedure. One Endeavor stent was implanted with predilation. The site reported a successful implantation of the stent, with 0% final residual stenosis (visual estimate). The patient was discharged on March 8, 2006 on ASA and clopidogrel. The investigator reported repeat revascularization (PTCA) on March 16, 2006 in the mid LAD.	Non-target-vessel related revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Repeat revascularization	06 February 2006	6	The patient is a 64-year-old male, current smoker, and with a history of hypertension. He presented with a myocardial infarction (started on January 28, 2006), without ST elevation. On January 31, 2006 one lesion in the proximal LAD was treated. One Endeavor stent was implanted without predilation. The site reported a successful implantation of the stent, with 0% final residual stenosis (visual estimate). The patient was discharged on February 1, 2006 on ASA and clopidogrel. The investigator reported repeat revascularization (PTCA) on February 6, 2006 in the proximal LCX. Indication for the procedure was unstable angina.	Non-target-vessel related revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction	7 Feb 2006	6	The patient is a 54-year-old male with hypertension, hypercholesterolemia, previous Q-wave MI, previous PTCA and family history of cardiovascular disease. The patient presented with an acute MI on January 30, 2006 without ST elevation. He had a serum creatinine level of 1.1 mg/dl. On February 1, 2006 one lesion in the diagonal of LAD was treated. The lesion was a type C, De Novo, highly tortuous (>90%) lesion which was 100% stenosed (TIMI 0) without the presence of thrombus. The site recorded a RVD of 2.2mm; lesion length of 12mm and LVEF of 46%. The patient was not pre-treated with dual antiplatelet therapy and received 200mg ASA, 75mg Clopidogrel and GP IIb/IIIa inhibitors during the procedure. One Endeavor (2.25x14mm) stent was successfully implanted after predilation of the lesion. The site reported 0% diameter stenosis (final residual stenosis in visual estimate). On February 7, 2006 the patient presented with angina and the investigator reported an anterior Q-wave MI and a stent thrombosis with angiographic evidence of thrombus. No cardiac enzymes were available. The patient had been on anti-platelets 24 hours prior to the event. On February 8, 2006 the patient underwent revascularization (PTCA) of the mid LAD. The occlusion was crossed and angioplasty with a balloon (2.5x15mm) showed good result with TIMI 3 flow and no residual macroscopic thrombus. The patient was discharged on March 10 on ASA and clopidogrel CEC: The CEC commented: "TLR DS > 70%"	Change to no event
		Stent thrombosis	7 Feb 2006	6		Sub-acute stent thrombosis
		Revasc. PCI	8 Feb 2006	7		Target lesion revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction Death	1 Feb 2006 1 Feb 2006	0 0	The patient is an 82-year-old male, ex-smoker, with Insulin dependent diabetes mellitus. He presented with an acute MI (date of onset February 1, 2006) with ST-elevation. On **February 1, 2006** one lesion in the **mid LAD** was treated. A LVEF of 51% was measured and serum creatinine of 1.09 mg/dl. The patient was not pre-treated with dual antiplatelets and received 100mg ASA, a loading of 375 mg Clopidogrel and GP IIb/IIIa inhibitors during the PCI. The lesion was a type B1, De Novo lesion of 13mm which was 80% stenosed (RVD 3.5mm). One Endeavor (3.5x15mm) stent was successfully implanted after predilation. The site reported a 0% final residual stenosis in the lesion (visual estimate). Two hours after the initial stent deployment patient had an abrupt free wall left ventricle rupture with cardiac tamponade confirmed after echocardiographic diagnostics. Patient died on **February 1, 2006**. Autopsy was not performed. The site reported an anterior MI resulting in sudden death. No ECG and no cardiac enzymes were available. ***CEC: Although the cardiac death occurred within 30 days of the index procedure, the CEC did not rule this as a stent thrombosis because the death was clearly due to a rupture and cardiac tamponade.***	Change to no event Cardiac death

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stroke Death	25 Feb 2006 03 Mar 2006	1 7	The patient is a 79-year-old male with a history of smoking and hypertension. He presented with unstable angina. Prior echo-cardio had revealed that ejection fraction was conserved. Creatinine was not measured, but renal function was normal according to the reference hospital. On **February 24, 2006** the patient underwent a procedure in a type B2, De Novo lesion located in the **proximal LAD**. The site reported TIMI 2 flow without thrombus in the lesion, which was 98% stenosed (RVD 4.4mm) with a lesion length of 12mm. The patient was pre-treated with ASA only and he received a loading dose of Clopidogrel; no GP IIb/IIIa inhibitors were administered. One Endeavor stent (4.0x18mm) was implanted without predilation of the lesion. The site reported a successful implantation of the stent with 0% residual stenosis in the lesion (visual estimate). The patient was discharged on **February 25, 2005** on ASA and Clopidogrel. Hours later the patient was admitted again because he experienced a sudden loss of feeling in the left hemi corpus and decreasing levels of consciousness. The event was confirmed as stroke by a neurologist. The type of stroke was unknown. The patient expired on **March 3, 2006.** Autopsy was not performed. ***CEC: Since cardiac death could clearly be assigned to CVA, the CEC ruled that this was not a stent thrombosis.***	Not adjudicated Cardiac death

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction	13 January 2006	0	The patient is a 75-year-old male with a family history of cardiovascular disease. He presented with a myocardial infarction (started on January 05, 2006), without ST elevation. On January 13, 2006 one lesion in the mid RCA was treated in the procedure. Two Endeavor stents were implanted with predilation (the total stent length implanted for this lesion was 42 mm). The site reported a successful implantation of both stents, with 0% final residual stenosis (visual estimate). The investigator reported inferior non-Q-Wave MI for this patient on **January 13, 2006**. According to the investigator, compared to baseline, there were changes in the ECG, as well as in the CK/CK-MB values. On **January 14, 2006** the peak CK was of 672 (uln for CK 195, ratio 3.45), with a peak CK-MB of 32 (uln for CK-MB 5, ratio 6.4). No angiography was done. The patient was discharged on **January 17, 2006** on ASA and clopidogrel.	Non Q wave Myocardial Infarction

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	22 Dec 2005	3	The patient is an 80-year-old male ex-smoker with hypertension and hypercholesterolemia. He presented with unstable angina. On **December 19, 2005** one lesion in the **proximal LAD** was treated. The patient was pre-treated with dual antiplatelet therapy. LVEF was 32%, and the creatinine level was 1 mg/dl. The lesion was a type C, De Novo, severely calcified, moderately tortuous lesion with TIMI 2 flow without thrombus and involving a bifurcation. It had a stenosis of 92% (RVD 2.5mm) and was 22mm long. After predilation of the lesion one Endeavor (2.5x24mm) stent was implanted. The side branch was not treated. The site reported a successful implantation of the stent with 0% final residual stenosis in the proximal lesion (visual estimate). On **December 22, 2005** the patient presented with a vomiting episode with subsequent oxygen desaturation (70%), aspiration procedure was attempted and patient went into respiratory and cardiac arrest due to asystolia. The investigator reported this event as non-sudden, cardiac death and indicated there was no association for a MI or stent thrombosis. Autopsy was not performed. ***CEC: As cardiac death occurred within 30 days of the index procedure, the CEC added sub acute stent thrombosis.***	Cardiac death Sub-acute stent thrombosis

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Repeat Revascularization PTCA	10 Feb 2006	14	The patient is a 73-year-old female with a history of, Non-IDDM, hypertension, hypercholesterolemia and previous PTCA. She presented with stable angina. On January 27, 2006, she underwent the assigned treatment in the proximal LAD. Three Endeavor stents were implanted after predilation using the overlapping technique. The total stent length implanted was 78mm. The site reported a 0% final residual stenosis. The patient was discharged on January 28, 2006 on ASA and Clopidogrel. On February 10, 2006 the patient was readmitted for stable angina and two revascularizations were performed. The first re-PTCA was to the distal LAD and the second in the distal left main stem.	Target lesion revascularization
		Repeat Revascularization PTCA	10 Feb 2006	14		Target vessel (non-target lesion) revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stroke	03 Apr 2006	24	The patient is a 67-year-old male with a previous non-Q wave MI and a history of hypertension and hypercholesterolemia. Patient is being dialyzed. He presented with a stable angina. On March 10, 2006 he underwent the assigned treatment in the mid RCA. Two Endeavor stents were implanted after predilation of the lesion. The total stent length implanted for this lesion was 42 mm. The site reported a successful implantation of the stents with 0% residual stenosis in the lesion (visual estimate). The patient was discharged on March 12, 2006 on clopidogrel. On April 03, 2006 the patient presented with a haemorrhagic stroke. The diagnosis was based on a diagnostic test and confirmed by a neurologist. The investigator reported: "Admit on 3 April for right putaminal ICG; GCS remained 14 to 15, LUL 4, LLL 4; full recover of right side, stroke rehabiliate".	Strokes are not adjudicated by the CEC

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stroke	05 Oct 2005	1	The patient is a 63-year-old male with a history of non-IDDM, hypertension and hypercholesterolemia. He is a current smoker. He presented with a stable angina. On October 04, 2005 he underwent the assigned treatment in the proximal LAD. One Endeavor stent was implanted without predilation of the lesion. The site reported a successful implantation of the stents with 0% residual stenosis in the lesion (visual estimate). On October 05, 2005 the patient presented with a stroke. The investigator reported: "A double vision of sudden onset was experienced by the patient on October 05, 2005. There were no other neurological deficits experienced. CT scan of the brain was done and was reported as normal. The patient's complaint resolved gradually. Inquiry at 30 days FU revealed that the patient was well. It was a transient ischemic event". The patient was discharged on October 06, 2005 on ASA and clopidogrel.	Strokes are not adjudicated by the CEC

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	26 October 2005	0	The patient is a 63-year-old female with Non-IDDM, hyperlipidemia and hypertension. The patient presented with unstable angina. On October 26, 2005 two Endeavor stents were implanted in the mid LAD. The lesion was predilated before stenting. A third stent, another DES, was implanted in the same lesion after predilation. Total stent length implanted was 72mm. The site reported a 0% final residual stenosis. CK-MB was not drawn. On October 26, CK raised to 440 (nl 167, ratio 2.6). On October 27, CK peaked at 1522 (ratio 9.1). The site reported an event of unstable angina. The patient was discharged October 29, 2005 on Aspirin and Clopidogrel.	Q wave MI

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction	2 Mar 2006	6	The patient is a 56-year-old female with hypertension. She presented with an acute MI with ST-elevation and a date of onset of February 24, 2006.	Non-Q-wave MI
		Stent thrombosis	2 Mar 2006	6	On February 24, 2006 a type C, De Novo lesion in the proximal LAD was treated. The 25mm long lesion was 82% stenosed (RVD 2.7mm) and had TIMI 2 flow with the presence of thrombus. Measurements of a LVEF of 50% and a creatinine level of 0.8 mg/dl were reported. The patient was not pre-treated with dual antiplatelets; she was given a loading dose of ASA and Clopidogrel, and GP IIb/IIIa inhibitors during the procedure. One Endeavor (2.75x30mm) stent was successfully implanted after predilation. The site reported a 15% final residual stenosis in the lesion (visual estimate). The patient was discharged on February 26, 2006 on ASA and Clopidogrel. On March 2, 2006 the patient presented with an anterior non-Q-wave MI. CK peaked to 22 ukat/l (uln 3, ratio 7.3) on March 2, 2006. The same day the patient underwent re-PTCA of the mid LAD. The investigator reported stent thrombosis because of angiographic evidence of thrombus, however considered the event not procedure or stent related as it was "the character and length of thrombus containing lesion in acute patient which led to further thrombosis". He commented that the event happened after withdrawal of integrelin. The patient had been on anti-platelets medication 24 hours prior to the event.	Sub-acute stent thrombosis
		Revasc. PCI	2 Mar 2006	6		Target lesion revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction Revascularization PTCA	07 Feb 2006 14 Feb 2006	0 7	The patient is a 43-year-old male with a history of a previous PTCA, hypertension, hyperlipidemia and is currently smoking. He presented with silent ischaemia. On February 7, 2006 a lesion in the distal RCA was treated with an Endeavor stent after predilation of the lesion. The stent was successfully implanted. Two further Bare Metal stents were implanted after predilation. Total stent length implanted in this lesion was 60mm. The site reported 0% final residual (visual estimate). On February 7, 2006, post-procedure, the patient suffered an Inferior MI. On February 8, CK peaked at 920,(nl 204 ratio 4.5) CK-MB 969 (nl 5 ratio 193.8). The patient was discharged on February 10, 2006 on ASA and Clopidogrel. The patient had a repeat angiogram on February 14 and a PTCA was performed to the distal RCA. The investigator commented, 'following IVUS study on a repeat coronary angio. There is suboptimal stent diameter compared to the vessel wall'.	Q wave MI Target lesion revascularization

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Stroke	21 Jan 2006	2	The patient is a 69-year-old male with a previous PTCA and CABG and a history of non-IDDM, hypertension and hypercholesterolemia. He presented with a silent ischaemia. On January 19, 2006 he underwent the assigned treatment in a diagonal branch of the LCX. One Endeavor stent was implanted after predilation of the lesion.The site reported a successful implantation of the stent with 0% residual stenosis in the lesion (visual estimate). The patient was discharged on January 20, 2006 on ASA and clopidogrel. On January 21, 2006 the patient presented with a stroke. The investigator reported: "The patient developed a few days after the procedure symptoms of stroke; he developed hemiparalysis and reduced strength in his left arm. The CT did not reveal neither haemorrhagic nor ischemic lesions; the neurologist diagnosed possible stroke; 26 days after the onset of the symptoms, the patient is in the same condition".	Strokes are not adjudicated by the CEC

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	09 Feb 2006	0	The patient is a 40-year-old male with a history of hyperlipidemia, hypertension and is an ex-smoker. He has a family history of cardiovascular disease. He presented with stable angina. On **February 9, 2006** he underwent the assigned treatment in the **distal LCX** for a totally occluded vessel. One Endeavor stent was implanted after predilation. The investigator reported a 0% final residual stenosis. On **February 9, 2006** the investigator reported the patient had a Non-Q wave MI. On February 10, 2006 CK reading was 398 (uln 190, ratio 2.1), CK-MB 21 (uln 4, ratio 5.3). The patient was discharged on February 12, 2006 on ASA and Clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	25 Feb 2006	0	The patient is a 59-year-old male with a history of hypertension. He presented with a Myocardial Infarction without ST elevation. Date of onset was February 25, 2006. On **February 25, 2006** he underwent the assigned treatment in the **mid LCX**. One Endeavor stent was implanted after predilation of the lesion. The site reported a successful implantation of the stent with 0% residual stenosis in the lesion (visual estimate). On **February 25, 2006** the patient presented with elevated enzymes with a peak CK of 376 (uln 190, ratio 1.98) and CK-MB of 47 (uln 4, ratio 11.8). The investigator reported a non-Q-wave MI. The patient was discharged on March 02, 2006 on ASA and clopidogrel. ***CEC: The CEC adjudicated this event as no event as MI took place before index procedure***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	1 Feb 2006	5	The patient is a 65-year-old male with non-insulin dependant diabetes mellitus. He presented with unstable angina. On **January 27, 2006** two vessels were treated in the procedure. His LVEF was 30% and his creatinine measured at 1.4 mg/dl. The patient pre-treated with dual antiplatelet therapy and received GP IIb/IIIa inhibitors during the procedure. The first lesion was in the **mid LAD**. It was a type B2, De Novo lesion, which was 89% stenosed (RVD 2.7mm) and 12mm long. After predilation of the lesion, one Endeavor (2.75x18mm) stent was successfully implanted. The second lesion was a type B1, De Novo lesion in the **mid RCA**. This lesion was 6mm long and was 80% stenosed (RVD 3mm). One Bare Metal Stent was implanted with direct stenting. The site reported 0% final residual stenosis (visual estimate) in both lesions. The patient was discharged on January 30, 2006 on ASA and clopidogrel. On **February 1, 2006** patient was admitted to a nursing home with complaint of chest discomfort. He was given emergency medical aid however died 30 minutes later due to cardio respiratory arrest. The investigator reported the event as sudden death. ***CEC: The CEC adjudicated Stent thrombosis by definition (cardiac death within 30 days). There was no angiogram available.***	Cardiac death Sub acute stent thrombosis

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	25 Jan 2006	7	The patient is a 50-year-old male with non-Insulin dependent diabetes mellitus, hypertension and previous Q-wave MI. He has no prior cardiac history and presented with a stable angina. On **January 18, 2006** two vessels were treated in the procedure. LVEF was 30% and creatinine was 1.5 mg/dl. The patient was pre-treated with dual antiplatelet therapy; no GP IIb/IIIa inhibitors were administered during the PCI. The first lesion was in the **mid LCX** and involved a type B1, moderately tortuous, De Novo lesion, which was 59% stenosed (RVD 2.7mm) and 12mm long. One Endeavor (2.75x14mm) stent was implanted without predilation. The second lesion was in the **distal and mid RCA**. It concerned a type B2 moderately tonrtuous, De Novo lesion which was 67% stenosed (RVD 2.7mm) and 40mm long. After predilation of the lesion two overlapping Endeavor stents were implanted (smallest diameter 2.75, longest length 30mm). The total stent length was 48 mm. The site reported a successful implantation of all Endeavor stents with 0% final residual stenosis in all lesions (visual estimate). After 48 hours patient started developing hypotension for which inotropic support was increased. The patient's renal function deteriorated and Cardiac Recovery System was deployed on **January 20, 2006**. The patient's renal function partially improved. After removal of the CRS on	Cardiac death Sub-acute stent thrombosis

					January 24, 2006 the patient's renal function started deteriorating gradually. The patient developed hypotension and refractory heart failure which was medically managed with high dose of inotropes. The patient developed refractory hypotension and persistent LVF despite maximum medication. On **January 25, 2006** patient died after cardiac arrest. ***CEC: The CEC commented: "cardiogenic shock, renal failure before discharge: Cardiac death." Sub acute stent thrombosis was added because cardiac death occurred within 30 days. There was no angiogram available.***	

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Death	8 Feb 2006	15	The patient is a 68-year-old male with non-Insulin dependent diabetes mellitus. He presented with a Myocardial Infarction with ST-elevation on January 24, 2006. At this stage the patient had a cardiogenic shock and a severe LV dysfunction. The hospital letter mentions that the "LAD - 90% stenosis after D3; LCX - totally occluded at origin well collaterised from RCA, RCA - 100% mid occlusion with clot". On **January 24, 2006** the patient was taken for primary PTCA of the total occlusion in the RCA. One Endeavor stent was implanted in the **mid RCA** after predilation. The site reported a successful implantation of the stent with 0% final residual stenosis in the lesion (visual estimate). On **January 25, 2006** patient developed hypotension and an IABP was deployed. A repeat angiogram revealed a patent device. On **January 26, 2006** patient had brady cardia and hypotension resuscitated by CPR and put on mechanical ventilation. After this patient developed bilateral pneumonia and ARDS. Patient's condition gradually deteriorated with renal failure. Patient was dialyzed on February 5, 2006. Patient died on **February 8, 2006** after multiorgan dysfunction. ***CEC: The CEC commented: "cardiogenic shock, renal failure before discharge: Cardiac death." Sub acute stent thrombosis was added because cardiac death occurred within 30 days. There was no angiogram available.***	Cardiac death Sub acute stent thrombosis

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction Death	1 Dec 2005 1 Dec 2005	0 0	The patient is a 67-year-old male smoker with non-insulin dependant diabetes mellitus, hypertension and family history of cardiovascular disease. He presented with an acute MI and ST-elevation on November 28, 2005. On **December 1, 2005** one lesion in the **mid LAD** was treated in the procedure. The type B2, De Novo lesion was moderately calcified and 91% stenosed. The RVD was 3mm and the lesion length 23mm. The patient was pre-treated with dual antiplatelet therapy and given GP IIb/IIIa inhibitors during the procedure. The LVEF was not measured; the creatinine level was 1.1 mg/dl. One Endeavor (3.0x24mm) stent was successfully implanted by direct stenting. The site reported 0% final residual stenosis in the lesion (visual estimate). The same day, **December 1, 2005**, patient had a repeat acute anterior septal MI and ventricular septal rupture, after which patient went into a cardiogenic shock and died the same day. The investigator reported death as non-sudden, cardiac death. ***CEC: Although the cardiac death occurred within 30 days of the index procedure, the CEC did not rule this as a stent thrombosis because the acute MI and the ventricular rupture the day of the procedure were clearly cause of cardiac death. No evidence for stent thrombosis was found.***	Change to no event Cardiac death

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	11 Jan 2006	0	The patient is a 72-year-old male with a history of hypertension and hypercholesterolemia. He presented with a stable angina. On **January 11, 2006** three lesions were treated. The first lesion was in the **mid LAD** in which one Endeavor stent was implanted without predilation of the lesion. The site reported a successful implantation of the stent with 4% residual stenosis in the lesion (visual estimate). The second lesion was in the **mid LCX** in which one Endeavor stent was implanted without predilation. The site reported a successful implantation of the stent with 0% residual stenosis in the lesion (visual estimate). The third lesion was in the **distal RCA** in which one Endeavor stent was implanted without predilation. The site reported a successful implantation of the stent with 0% residual stenosis in the lesion (visual estimate). On **January 11, 2006** the patient presented with elevated enzymes which reached peak values on January 12, 2006 with CK of 390 (uln 232, ratio 1.7) and CK-MB of 31 (uln 10, ratio 3.1). The investigator reported a non-Q-wave MI. The patient was discharged on January 13, 2006 on ASA and Ticlopidine.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	02 Feb 2006	1	The patient is a 75-year-old female with a previous non-Q wave MI and a history of hypertension, hypercholesterolemia and a family history of cardiovascular disease. She presented with unstable angina. On **February 1, 2006** she underwent the assigned treatment in the **mid LCX**. One Endeavor stent was implanted after predilation of the lesion. The site reported a successful implantation of the stent with 5% residual stenosis in the lesion (visual estimate). On **February 2, 2006** the patient presented with elevated enzymes with a peak CK of 242 (uln 232, ratio 1.0) and CK-MB of 19 (uln 10, ratio 1.9). The investigator reported: "Systematic measurement of cardiac enzyme after PCI can detect small elevation of this cardiac markers without any clinical or angiographic complication." The patient was discharged on February 2, 2006 on ASA and clopidogrel.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	10 Feb 2006	1	The patient is a 60-year-old male with a family history of cardiovascular disease, diabetes mellitus (insulin-dependant) and hypercholesterolemia. He is a current smoker and presented with stable angina. On **February 09, 2006** he underwent the assigned treatment in the **mid LAD**. One Endeavor stent was implanted without predilation of the lesion. The site reported a successful implantation of the stent with 5% residual stenosis in the lesion (visual estimate). On **February 10, 2006** the patient presented with elevated enzymes with a peak CK of 459 (uln 232, ratio 1.98) and CK-MB of 36 (uln 10, ratio 3.6). The investigator reported a non-Q-wave MI. The patient was discharged on February 11, 2006 on ASA and Ticlopidine.	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial Infarction	22 Feb 2006	0	The patient is a 70-year-old male with a previous Q wave MI with PTCA (1995) and a history of hypertension and hypercholesterolemia. He is a current smoker. He presented with unstable angina. On **February 22, 2006** three lesions were treated. The first lesion was in the **proximal LAD** in which one Cypher and one Taxus stent were implanted after predilation of the lesion. The total stent length implanted was 65 mm and the residual stenosis in the lesion was 0% (visual estimate). The second lesion was in the **proximal LCX** in which one Endeavor stent was implanted without predilation. The site reported a successful implantation of the stent with 0% residual stenosis in the lesion (visual estimate). The third lesion was in the **proximal RCA** in which one Cypher stent was implanted after predilation of the lesion with 0% residual stenosis of the lesion (visual estimate). On **February 22, 2006** the patient presented with elevated enzymes with CK of 101 (uln 187, ratio 0.5) and CK-MB of 181 (uln 6, ratio 30.2). On February 23, 2006 the patient presented with CK of 208 (uln 187, ratio 1.1) and CK-MB of 26 (uln 6, ratio 4.3). The investigator reported: "Post-procedure enzymatic elevation". The patient was discharged on February 25, 2006 on ASA and clopidogrel. ***CEC: The CEC commented that CK-MB was raised >3 times uln, but CK was normal and there were no new Q-waves. Therefore no MI according to the WHO definition.***	Change to no event

Site	Pt	Site reported event	Event Date	# days since proc	Summary	CEC adjudication
		Myocardial infarction Stent thrombosis Death	17 Feb 2006 18 Feb 2006 18 Feb 2006	0 1 1	The patient is a 79-year-old male ex-smoker with hypertension, hypercholesterolemia and previous Q-wave MI. The patient presented with unstable angina. The hospital letter also shows that there had been an extensive anterior infarction without reperfusion on February 14, 2006. On **February 17, 2006** three lesions in two vessels were treated. A LVEF of 30% and creatinine of 1.4 mg/dl were measured. The patient was pre-treated with ASA only and was administered GP IIb/IIIa inhibitors and a loading dose of 375mg Clopidogrel. The first lesion was a total occlusion (TIMI 0) of a type C, De Novo, moderately calcified lesion in the **mid LAD** with thrombus. The RVD was 3.1mm and the lesion length 30mm. One Cypher (3x33mm) stent was implanted after predilation. Residual stenosis was 15% (visual estimate). The second lesion was a bifurcation lesion at the **OM of the distal LCX.** It was a type B2, De Novo, moderately calcified lesion of 22mm which had TIMI 1 flow without thrombus and was 95% stenosed (RVD 2.2mm). One Endeavor (2.25x24mm) stent was implanted with Type F dissection. After predilation of the lesion the stent was delivered successfully, however the vessel presented acute closure; the flow was not recuperated in the vessel and the site reported final residual stenosis of 100% (visual estimate).	Change to no event Acute stent thrombosis Cardiac death

					The third lesion was in the **distal LCX**. The lesion was a type B2, De Novo lesion that was moderately tortuous and calcified. A stenosis of 70% over 13mm with a RVD of 3.1mm was measured. One Taxus stent (3x16mm) was implanted. The site reported 16% final residual stenosis for all lesions (visual estimate). The site reported elevated cardiac enzymes with highest CK level of 436 mg/l (uln 22, ratio 19.9) and CKMB 62 mg/l (uln 6, ratio 10.3) on **14 February 2006**. After epigastric pain and nausea the patient developed ventricular tachycardia and ventricular fibrillation. He died on **February 18, 2006**.The investigator reported a suspected stent thrombosis without angiographic evidence of thrombus. The patient had been on anti-platelets medication 24 hours prior to the event.	

Appendix A: Overview of monitored patients

Hospital	City	Country	Visit date	Patient number
AKH Wien	Vienna	Austria	12/13 Jan 2006	
Salzburger Landeskliniken	Salzburg	Austria	29 Nov 2006	
Universitatsklinik Heidelberg	Heidelberg	Germany	22/23 Jun 2006	

Appendix A: Overview of monitored patients (Continued)

Hospital	City	Country	Visit date	Patient number
University of Rostock	Rostock	Germany	30/31 May 2006	
Johanneshospital Dortmund	Dortmund	Germany	22 Feb 2006	
Ambulantes Herzzentrum	Kassel	Germany	26/27 Jan and 22 Feb 2006	

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Appendix A: Overview of monitored patients (Continued)

Hospital	City	Country	Visit date	Patient number
Ambulantes Herzzentrum (continued)	Kassel	Germany	26/27 Jan and 22 Feb 2006	
Casa di Cura Montevergine	Mercogliano	Italy	27 Mar 2006	
Haga Ziekenhuis Leyenburg	Den Haag	Netherlands	19/20 Sep 2006	
Medisch Spectrum Twente	Enschede	Netherlands	9/10 Aug 2006	
Satakunnan keskussairaala	Pori	Finland	4/5 Jul 2006	

Appendix A: Overview of monitored patients (Continued)

Hospital	City	Country	Visit date	Patient number
Hospital Universitario Son Dureta	Palma de Mallorca	Spain	9/10 Feb 2006	
Hospital General de Alicante	Alicante	Spain	22/23 Feb 2006	
Universitario de la Princessa	Madrid	Spain	7/8 Feb 2006	

Appendix A: Overview of monitored patients (Continued)

Hospital	City	Country	Visit date	Patient number
Universitario de la Victoria	Malaga	Spain	3/4 Oct 2006	
Universitario Salamanca	Salamanca	Spain	6/7 Jun 2006	
National Heart Institute	Kuala Lumpur	Malaysia	23/24 Nov 2005	
P. Stradins University Hospital	Riga	Latvia	10 Mar 2006	

Appendix A: Overview of monitored patients (Continued)

Hospital	City	Country	Visit date	Patient number
1st IKA	Athens	Greece	18/19 Jan 2006	
University Hospital of Patra	Patra	Greece	4/5 Apr 2006	
Ege Saglik Hastanesi	Izmir	Turkey	19/20 Apr 2006	
SGPGI Lucknow	Lucknow	India	8/9 Feb 2006	
The Heart Clinic	Ahmedabad	India	13/14 Feb 2006	

Appendix A: Overview of monitored patients (Continued)

Hospital	City	Country	Visit date	Patient number
Instituto Nacional de Cirugia Cardiaca	Montevideo	Uruguay	29 Aug 2006	