

APPENDIX 3

Endeavor II CA 24 Month Report

**(Table 31. Detailed Patient Listing was Sent
Electronically to FDA)**

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

A Randomized Controlled Trial to Evaluate the Safety and Efficacy of the Medtronic AVE ABT-578 Eluting Driver Coronary Stent in *De Novo* Native Coronary Artery Lesions

**Endeavor II – Continued Access Sub-Study
Clinical Study Report (Index Procedure through 720 Days)**

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Date Report Finalized:	10 November 2006
Version:	Final version 6.0

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table of Contents

List of Tables and Figures..... iii
Section I: Structured Abstract..... 4
Section II: Detailed Summary..... 16
 A. Definitions 16
 B. Study Design..... 23
 C. Objectives 28
 D. Study Procedure..... 29
 E. Clinical Events 36
 F. Statistical Methods of Analysis..... 38
Section III. Tables and Figures 40

List of Tables and Figures

Table 1: Principal Effectiveness and Safety Results	9
Table 2. Number of Patients Treated by Investigator	40
Table 3. Data Compliance	41
Table 4. Baseline Demographics and Clinical Characteristics	42
Table 5. Baseline Lesion Characteristics	45
Table 6. Quantitative Angiographic Analysis	49
Table 7. Quantitative Angiographic Analysis (Interpolated)	60
Table 8. Procedural Characteristics	71
Table 9. Acute Gain and Late Loss	73
Figure 1. Cumulative Frequency Distribution of In-Stent Percent Diameter Stenosis	78
Figure 2. Cumulative Frequency Distribution of In-Segment Diameter Stenosis	79
Figure 3. Cumulative Frequency Distribution of In-Stent Minimum Lumen Diameter	80
Figure 4. Cumulative Frequency Distribution of In-Segment Minimum Lumen Diameter	81
Figure 5. Acute Procedure Success	82
Table 10. Post-Procedure Morphology and length of Hospital Stay	83
Table 11. Follow-Up Morphology	84
Table 12. Major Adverse Cardiac Events – In and Out Of –Hospital (to 30 days)	85
Table 13. Major Adverse Cardiac Events – (to 30 days)	91
Table 14. Major Adverse Cardiac Events – (to 180 days)	94
Table 15. Major Adverse Cardiac Events – (to 270 days)	97
Table 16. Major Adverse Cardiac Events – (to 360 days)	100
Table 17. Major Adverse Cardiac Events – (to 720 days)	103
Figure 6. Survival Free from Major Adverse Cardiac Events (at 720 days)	106
Figure 7. Survival Free from Target Lesion Revascularization (at 720 days)	107
Figure 8. Survival Free from Target Vessel Revascularization (at 720 days)	108
Figure 9. Survival Free from Target Vessel Failure (at 720 days)	109
Table 18. Total Stent Length Implanted Per Patient	110
Table 19. Quantitative Intravascular Ultrasound Analysis (Post-Stent Implantation)	111
Table 20. Frequency of Incomplete Stent Apposition	114
Table 21. Major Protocol Deviation by Type	115
Table 22. Major Protocol Deviation by Site	117
Table 23. Adverse Events (to 720 days)	119
Table 24. Serious Adverse Events (to 720 days)	126
Table 25. Site Reported Major Adverse Events (to 720 days)	130
Table 26. Laboratory – Cardiac Enzymes Findings	131
Table 27. Medication – Anti-coagulants Use	132
Table 28. Summary of Device Performance	133
Table 29. Narrative Summaries of Device Performance	134
Table 30. Narrative Summaries of Major Adverse Cardiac Events	136
Table 31. Detailed Patient Listing	204
Appendix A. Methods for Qualifying Angiograms	205

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Section I: Structured Abstract

Title: Endeavor II - A Randomized Controlled Trial to Evaluate the Safety and Efficacy of the Medtronic AVE ABT-578 Eluting Driver Coronary Stent in *De Novo* Native Coronary Artery Lesions – Continued Access Sub-Study.

Design: A prospective, multi-center, single-arm, open-label sub-study to expand the acute safety information and performance data of the Medtronic Endeavor Drug Eluting Stent (Medtronic ABT-578 Eluting Driver Stent System).

The primary analytical subset for this trial is the Intent-to-Treat (ITT) population, defined as all patients who signed the written informed consent and for whom the study device was introduced through the guide catheter. This 720-day report analyzed the “Intent to treat” patient population.

Two further secondary analyses were performed, on the subset of the ITT sample that was directly stented and on the subset of the ITT sample on whom pre-dilatation was performed.

Purpose: To expand the acute safety information and performance data of the Endeavor Drug Eluting Stent (Medtronic ABT-578 Eluting Driver Coronary Stent System) for the treatment of single *de novo* lesions in native coronary arteries 2.25-3.5 mm in diameter.

Clinical Sites: Fifteen (15) study sites in Europe enrolled subjects into this trial.

Enrollment: Two hundred ninety seven (297) subjects with symptomatic ischaemic heart disease due to stenotic lesions of native coronary arteries with reference vessel diameters between 2.25 mm and 3.5 mm and lesion lengths of ≥ 14 mm and ≤ 27 mm that were amenable to percutaneous treatment with stenting were enrolled in this trial. For one patient, the lesion was pre-treated with rotational atherectomy and, after a failed attempt to implant the stent, a rotablator was used. Because of the protocol deviations, this patient was excluded from the intent to treat analysis. A total of 296 patients were included in the intent to treat (ITT) analysis. Tables in this report represent evaluable data for the intent to treat population. A total number of 287 patients were included in the per protocol (PP) analysis.

Methods: Baseline clinical and angiographic data were collected on standardized case report forms by clinical research coordinators at the study sites and by the Angiographic Core Laboratory personnel. Clinical follow-up for all subjects was performed at 30 days. Telephone follow-up had occurred at 6, 9, 12 months and 2 year, and will occur annually thereafter out to 5 years. An independent Angiographic Core Laboratory and an independent IVUS Core Laboratory analyzed all baseline angiograms and IVUS images. Follow-up angiography was scheduled at 8 months for the first 150 consecutive patients enrolled. IVUS evaluation occurred at 8 months post-index procedure as a sub-study at selected sites for approximately 100 patients.

The primary endpoint for this trial is the Major Adverse Cardiac Events (MACE) rate at 30 days post-procedure, defined as death, MI (Q wave and non-Q wave), emergent cardiac bypass surgery, or target lesion revascularization (repeat PTCA or CABG).

The secondary endpoints for this trial include: device success defined as attainment of <50% in-stent residual stenosis using only the assigned device; lesion success defined as attainment of <50% in-stent residual stenosis using any percutaneous method, procedure success defined as attainment of <50% in-stent residual stenosis using any percutaneous method and no in-hospital MACE (Major Adverse Cardiac Events (MACE) defined as death, MI (Q wave and non-Q wave), emergent bypass surgery, or target lesion revascularization (TLR)), MACE at 6, 9 and 12 months and annually thereafter out to 5 years, late loss at 8 months as measured by QCA, defined as the difference between the post-index procedure minimal lumen diameter (MLD) and the follow-up MLD; angiographic in-stent and in-lesion binary restenosis rate ($\geq 50\%$ diameter stenosis) at 8 months post-index procedure; in-stent and in-lesion minimum lumen diameter (MLD) at 8 months post-index procedure; neointimal hyperplastic volume at 8 months as measured by intravascular ultrasound (IVUS); Target Lesion Revascularization (TLR) at 270 days post-procedure; Target Vessel Revascularization (TVR) at 270 days post-procedure; Target Vessel Failure (TVF) at 270 days post-procedure.

Analysis Population: The primary analytical set for this trial is the Intent-to-Treat population, defined as all patients who signed the written informed consent and for whom the study device was introduced through the guide catheter. The primary endpoint analysis is also performed for the Per-Protocol (PP) subset.

Two further secondary analyses were performed, on the subset of the ITT sample that was directly stented and on the subset of the ITT sample on whom pre-dilatation was performed.

The data in this report is based on the data available as of 15 September 2006.

Results:

A total of 296 patients were enrolled in 15 study sites in Europe (see Table 2). The number of major and minor protocol deviations by site are indicated in Table 22. The total number of major protocol deviations, defined as any deviation from patient inclusion and exclusion criteria or patient informed consent procedures, was 37. The total number of minor protocol deviations defined as deviations 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. was 1092. The data compliance by site can be found in Table 3.

Baseline patient and lesion characteristics:

Baseline patient characteristics for the ITT set are shown in Table 4. The mean age was 64.3 years. The population included 75.0% male, 29.1% had unstable angina or a recent MI, 45.9% had multivessel coronary artery disease, and the mean left ventricular ejection fraction was 62.7%. A total of 25.8% (76/295) of the patients had diabetes. Baseline lesion characteristics and quantitative angiographic data are shown in Tables 5 and 6. Baseline angiographic results were obtained for all 296 patients on whom treatment was attempted. Effectiveness measures were reported for 296 patients with available baseline and angiographic data. The ACC/AHA lesion classification was B2 or C for 74.4% of the lesions. The mean reference vessel diameter was 2.63 ± 0.45 mm and the mean lesion length was 16.49 ± 7.86 mm. The mean minimum lumen diameter was 0.78 ± 0.33 mm and the mean percent diameter stenosis $70.03 \pm 11.83\%$. These

results are comparable to what has been found in similar studies and are consistent with a moderate risk patient population.

Acute procedural results and device performance:

For the total ITT population, the clinical and angiographic results showed that the lesion success rate was 99.7% (295/296), the device success rate 98.3% (292/297) and the procedure success rate 94.9% (280/295). The device-specific procedure success, defined as attainment of <50% in-stent residual stenosis using only the assigned device and no in-hospital MACE, was 93.6% (277/296). As summarized in Table 1a, in-hospital MACE occurred for 4.7% of the patients in the ITT set. For the PP set, the lesion success rate was 99.7% (286/287); the device success rate 99.0% (284/287), the procedure success rate 95.1% (273/287) and the device specific procedure success rate 94.4% (271/287). In-hospital MACE occurred for 4.5% of the patients in the PP set (see table 1b). The acute angiographic results are shown in Table 6. The final angiographic results showed a mean in-stent percent diameter stenosis of $5.27 \pm 9.45\%$ and a mean in-segment percent diameter stenosis of $17.76 \pm 9.57\%$. The acute gain within the stent was $1.77 \pm 0.47\text{mm}$ and the in-segment acute gain was $1.45 \pm 0.50\text{mm}$ (see Table 9).

Thirty-day MACE and subacute stent thrombosis:

The effectiveness and safety results for the Endeavor Drug Eluting Coronary Stent System are summarized in Table 1a. The incidence of MACE was 5.4% (16/296) at 30 days. The individual safety components are presented in Table 12. Review of the individual safety components shows that subacute stent thrombosis occurred in 0% of the patients. The rate of 30-day Q-wave MI was 0.3%, the percentage of Target Lesion Revascularization was 0.3% and the percentage of non-Q wave MI was 4.4%.

Eight-month follow-up angiographic and IVUS results:

Of the 296 enrolled patients, 150 were prospectively enrolled in a routine angiographic follow-up subset. Qualifying follow-up angiography was available for 117 patients and is reported in Table 6 and Table 9. The 8 months in-stent late loss was $0.58 \pm 0.58\text{mm}$. At 8 months the binary in-stent restenosis rate was 15.4% and the binary in-segment restenosis rate was 17.1% (Table 6). The in-stent MLD at 8 months was 1.92mm and the in-segment MLD 1.81mm. Approximately 100 patients at selected centers were enrolled for routine IVUS follow-up. A qualifying follow-up IVUS was available for 43 patients. The data is reported in Table 19. The Neointimal hyperplastic volume at 8 months was 29.66mm^3 .

Nine, twelve and twenty-four month clinical outcomes:

The 720 days clinical follow-up was available for 288 patients. At 270 days the TLR rate was 5.1%, the TVR rate 8.9% and the TVF rate 13.0%. The incidence of MACE was 6.8% (20/295) at 180 days, 10.6% (31/293) at 270 days, 12.3% (36/292) at 360 days and 12.8% (37/288) at 720 days. Review of the individual safety components shows that the rates of stent thrombosis at 720 days was 0%. The rate of 270-day Q-wave MI was 0.3%, the percentage of Target Lesion Revascularization was 5.1% and the percentage of non Q wave MI was 4.8%. At 360 days the rate of Q-wave MI was 0.3%, the Target Lesion Revascularization 6.5% and the percentage of non Q-wave MI 5.1%. At 720 days the rate of Q-wave MI was 0.3%, the Target Lesion Revascularization 7.3% and the percentage of non Q-wave MI 5.6%. The Kaplan-Meier estimate

of freedom from MACE was 89.5% at 270 days, 87.8% at 360 days and 87.4% at 720 days post procedure.

Safety and efficacy outcomes for the direct stenting and predilatation subgroups:

Of the 296 patients enrolled, 126 patients (127 lesions) were treated with direct stenting and for 170 patients pre-dilatation was performed. The baseline patient and lesion characteristics of both subgroups are shown in Table 4 and Table 5. Baseline patient characteristics were comparable for both subgroups except for age, which was significantly higher in the pre-dilatation subgroup (65.3 years vs 62.9 years, $p=0.04$). The lesion characteristics showed some differences between both subgroups as expected per protocol, as only lesions with a length <20 mm could be treated by direct stenting. The lesion length was smaller in the direct stenting subgroup as compared to the pre-dilatation subgroup (14.29 ± 6.41 mm vs 18.16 ± 8.46 mm, $p<0.0001$). The MLD was smaller in the pre-dilatation subgroup as compared to the direct stenting subgroup (0.71 ± 0.29 mm vs 0.89 ± 0.36 mm, $p<0.0001$) and the % diameter stenosis pre procedure was smaller in the direct stenting subgroup as compared to the pre-dilatation subgroup ($66.5\pm 12.0\%$ vs $72.7\pm 11.0\%$, $p<0.0001$). In addition, the lesion location between both subgroups also showed a difference (proximal 34.1% in the pre-dilatation subgroup vs 53.5% in the direct stenting subgroup, mid 57.6% in the pre-dilatation subgroup vs 40.9% in the direct stenting subgroup, distal 7.6% in the pre-dilatation subgroup vs 4.7% in the direct stenting subgroup and ostial 0.6% in the pre-dilatation subgroup vs 0.8% in the direct stenting subgroup, $p=0.009$). Overall, the patient populations for the subgroups were comparable for most baseline demographic or lesion characteristics except for the age, lesion location, and several pre-procedure angiographic parameters (lesion length, MLD, lesion location and % diameter stenosis).

The in-hospital MACE and the MACE at 30, 180, 270 and 360 days were comparable for both subgroups (see Table 1c). In-hospital incidences of MACE were 5.6% for the direct stenting subset and 4.1% for the pre-dilatation subset. The MACE rate at 30 days, 270 days, 360 days and 720 days in the direct-stenting subgroup was 6.3%, 10.3%, 11.2% and 11.4% respectively. The MACE rate at 30 days, 270 days, 360 days and 720 days for the pre-dilatation subgroup was 4.7%, 10.8%, 13.2% and 13.9% respectively.

The lesion, device, procedure and device-specific procedure success rates were also comparable for both subgroups. The lesion success rate was 99.4% for the pre-dilatation subset and 100% for the direct stenting subset. The device success rate was 98.2% for the pre-dilatation subset and 98.4% for the direct stenting subset. The procedure success rate was 95.3% for the pre-dilatation subset and 94.4% for the direct stenting subset. The device-specific procedure success rate was 94.1% for the pre-dilatation subset and 92.9% for the direct stenting subset.

At 8 months the in-stent binary restenosis rate for the direct stenting subgroup was 10.4% and for the pre-dilatation subgroup 18.8% ($p=0.2989$). The in-stent acute gain was 1.75 ± 0.46 mm for the direct stenting subset and 1.79 ± 0.48 mm for the pre-dilatation subset ($p=0.3994$, see Table 9b). The 8 month in-stent late loss was 0.56 ± 0.56 mm for the direct stenting subset and 0.59 ± 0.60 mm for the pre-dilatation subset ($p=0.7839$). Therefore, the angiographic parameters were comparable between both subgroups.

Discussion of Results: This analysis reports the final 24-months results of the ENDEAVOR II Continued Access Study in the areas including the baseline characteristics, procedural device

performance, the 9, 12 and 24-month safety outcomes, the 8-month angiographic and IVUS outcomes and the 9, 12 and 24-month secondary clinical outcomes. These data include the primary endpoint analysis of MACE (any death, MI, emergent cardiac bypass surgery or target lesion revascularization) at 30 days and the secondary endpoint analyses of device success (attainment of <50% in-stent residual stenosis using only the assigned device), lesion success (attainment of <50% in-stent residual stenosis using any percutaneous method), procedure success (attainment of <50% in-stent residual stenosis using any percutaneous method and no in-hospital MACE), device-specific procedure success (attainment of <50% in-stent residual stenosis using only the assigned device and no in-hospital MACE), MACE at 6, 9, 12 and 24 months, 8 months angiographic late loss as measured by QCA (difference between minimum lumen diameter within the stent immediately post-procedure and at 8 months follow-up as measured by the angiographic core laboratory), 8 months angiographic in-stent and in-lesion binary restenosis rate ($\geq 50\%$ diameter stenosis), in-stent and in-lesion minimum lumen diameter (MLD) at 8 months, neointimal hyperplastic volume at 8 months as measured by intravascular ultrasound (IVUS), Target Lesion Revascularization at 9 months (TLR, defined as clinically-driven repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel), Target Vessel Revascularization at 9 months (TVR, defined as any clinically-driven repeat percutaneous intervention of the target vessel or bypass surgery of the target vessel) and Target Vessel Failure at 9 months (TVF, defined as cardiac death, MI or clinically-driven repeat revascularization of the target vessel).

In summary the 720-day results of the Endeavor II Continued Access Sub-study show that the Endeavor stent is safe and effective. The lesion, device and procedure success rates were high. No stent thrombosis was observed up to 720 days. The 30 day, 180 day, 270 day, 360 day and 720 day MACE rates were comparable to the MACE rates in similar studies, taken into account the relatively high patient age, high percentage of diabetes patients and long lesion length. The safety and efficacy outcomes in the direct stenting subgroup and in the pre-dilatation subgroup were comparable, indicating that the good safety and effectiveness data for the Endeavor stent were maintained with direct stenting for lesions <20mm.

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

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

	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
Effectiveness Measures	
Lesion Success % (#/n)	99.7%(295/296)
Device Success % (#/n)	98.3%(292/297)
Procedure Success % (#/n)	94.9%(280/295)
Device-Specific Procedure Success % (#/n)	93.6%(277/296)
Post-index Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)	
Mean±SD (n)	2.56±0.43 (296)
Range (min, max)	(1.03,4.11)
Post-index Procedure In-Stent Percent Diameter Stenosis (%DS)	
Mean±SD (n)	5.27±9.45 (296)
Range (min, max)	(-31.46,51.72)
Post-index Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)	
Mean±SD (n)	2.24±0.46 (296)
Range (min, max)	(0.99,4.04)
Post-index Procedure In- Segment Percent Diameter Stenosis (%DS)	
Mean±SD (n)	17.76±9.57 (296)
Range (min, max)	(-11.17,51.72)
Eight-Month In-Stent Minimal Lumen Diameter (MLD, in mm)	
Mean±SD (n)	1.92±0.65 (117)
Range (min, max)	(0.00,3.12)
Eight-Month Procedure In-Stent Percent Diameter Stenosis (%DS)	
Mean±SD (n)	27.67±21.95 (117)
Range (min, max)	(-3.30,100.00)
Eight-Month Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)	
Mean±SD (n)	1.81±0.61 (117)
Range (min, max)	(0.00,3.12)
Eight-Month Procedure In- Segment Percent Diameter Stenosis (%DS)	
Mean±SD (n)	31.93±20.54 (117)
Range (min, max)	(2.00,100.00)
Eight-Month Late Loss in-Stent (mm)	
Mean±SD (n)	0.58±0.58 (117)
Range (min, max)	(-0.51,2.44)
Eight-Month Late Loss in-Segment (mm)	
Mean±SD (n)	0.39±0.56 (117)
Range (min, max)	(-0.71,2.24)
Eight-Month in-Stent Binary Restenosis	15.4%(18/117)
Eight-Month in-Segment Binary Restenosis	17.1%(20/117)
TLR-Free at 720 days	92.7%
TVR-Free at 720 days	87.6%
TVF-Free at 720 days	83.9%
MACE-Free at 720 days	87.4%
Safety Measures (to 30 days) % (#/n)	
In-Hospital MACE	4.7%(14/296)
Out-of-Hospital MACE to 30 days	0.7%(2/296)
MACE to 30 days	5.4%(16/296)
Death	0%(0/296)
Vascular Complications	0.3%(1/296)
Stent Thrombosis	0%(0/296)
Acute Stent Thrombosis	0%(0/296)
Sub-Acute Stent Thrombosis	0%(0/296)
Late Stent Thrombosis	0%(0/296)

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
Cerebrovascular Accident (CVA)	0%(0/296)
Perforation	0.3%(1/296)
Target Vessel Revascularization	1.4%(4/296)
Target Lesion Revascularization	0.3%(1/296)
Target Vessel Failure	5.7%(17/296)
Safety Measures (to 270 days) % (#/n)	
Out-of-Hospital MACE to 270 days	6.5%(19/293)
MACE to 270 days	10.6%(31/293)
Death	0.7%(2/293)
Vascular Complications	0.3%(1/293)
Stent Thrombosis	0%(0/293)
Acute Stent Thrombosis	0%(0/293)
Sub-Acute Stent Thrombosis	0%(0/293)
Late Stent Thrombosis	0%(0/293)
Cerebrovascular Accident (CVA)	0.3%(1/293)
Target Vessel Revascularization	8.9%(26/293)
Target Lesion Revascularization	5.1%(15/293)
Target Vessel Failure	13.0%(38/293)
Safety Measures (to 360 days) % (#/n)	
Out-of-Hospital MACE to 360 days	8.2%(24/292)
MACE to 360 days	12.3%(36/292)
Death	0.7%(2/292)
Vascular Complications	0.3%(1/292)
Stent Thrombosis	0%(0/292)
Acute Stent Thrombosis	0%(0/292)
Sub-Acute Stent Thrombosis	0%(0/292)
Late Stent Thrombosis	0%(0/292)
Cerebrovascular Accident (CVA)	0.3%(1/292)
Target Vessel Revascularization	11.6%(34/292)
Target Lesion Revascularization	6.5%(19/292)
Target Vessel Failure	15.8%(46/292)
Safety Measures (to 720 days) % (#/n)	
Out-of-Hospital MACE to 720 days	9.0%(26/288)
MACE to 720 days	12.8%(37/288)
Death	1.4%(4/288)
Vascular Complications	0.3%(1/288)
Stent Thrombosis	0%(0/288)
Acute Stent Thrombosis	0%(0/288)
Sub-Acute Stent Thrombosis	0%(0/288)
Late Stent Thrombosis	0%(0/288)
Cerebrovascular Accident (CVA)	0.3%(1/288)
Target Vessel Revascularization	12.5%(36/288)
Target Lesion Revascularization	7.3%(21/288)
Target Vessel Failure	16.3%(47/288)

n = Number of patients/lesions with evaluable data

Lesion Success: Attainment of <50% in-stent residual stenosis using any percutaneous method

Device Success: Attainment of <50% in-stent residual stenosis using only the assigned device

Procedure Success: Attainment of <50% in-stent residual stenosis using any percutaneous method and no in-hospital MACE

Device-Specific Procedure Success: Attainment of <50% in-stent residual stenosis using only the assigned device and no in-hospital MACE.

MACE: Death, MI, emergent cardiac bypass Surgery, or target lesion revascularization (repeat PTCA or CABG) as determined by the independent

Clinical Events Committee (CEC)

*One (1) patient (603-35) with two lesions treated with Endeavor stents

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

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

	Endeavor Continued Access (Number of Patients =287)
Effectiveness Measures	
Lesion Success % (#/n)	99.7%(286/287)
Device Success % (#/n)	99.0%(284/287)
Procedure Success % (#/n)	95.1%(273/287)
Device-Specific Procedure Success % (#/n)	94.4%(271/287)
Post-index Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)	
Mean±SD (n)	2.56±0.42 (287)
Range (min, max)	(1.46,4.11)
Post-index Procedure In-Stent Percent Diameter Stenosis (%DS)	
Mean±SD (n)	5.09±9.18 (287)
Range (min, max)	(-31.46,51.72)
Post-index Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)	
Mean±SD (n)	2.24±0.46 (287)
Range (min, max)	(1.14,4.04)
Post-index Procedure In- Segment Percent Diameter Stenosis (%DS)	
Mean±SD (n)	17.60±9.38 (287)
Range (min, max)	(-11.17,51.72)
Eight-Month In-Stent Minimal Lumen Diameter (MLD, in mm)	
Mean±SD (n)	1.93±0.65 (115)
Range (min, max)	(0.00,3.12)
Eight-Month Procedure In-Stent Percent Diameter Stenosis (%DS)	
Mean±SD (n)	27.80±22.10 (115)
Range (min, max)	(-3.30,100.00)
Eight-Month Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)	
Mean±SD (n)	1.82±0.62 (115)
Range (min, max)	(0.00,3.12)
Eight-Month Procedure In- Segment Percent Diameter Stenosis (%DS)	
Mean±SD (n)	32.03±20.68 (115)
Range (min, max)	(2.00,100.00)
Eight-Month Late Loss in-Stent (mm)	
Mean±SD (n)	0.59±0.58 (115)
Range (min, max)	(-0.40,2.44)
Eight-Month Late Loss in-Segment (mm)	
Mean±SD (n)	0.40±0.56 (115)
Range (min, max)	(-0.71,2.24)
Eight-Month in-Stent Binary Restenosis	15.7%(18/115)
Eight-Month in-Segment Binary Restenosis	17.4%(20/115)
TLR-Free at 720 days	92.5%
TVR-Free at 720 days	87.9%
TVF-Free at 720 days	84.1%
MACE-Free at 720 days	87.7%
Safety Measures (to 30 days) % (#/n)	
In-Hospital MACE	4.5%(13/287)
Out-of-Hospital MACE to 30 days	0.3%(1/287)
MACE to 30 days	4.9%(14/287)
Death	0%(0/287)
Vascular Complications	0.3%(1/287)
Stent Thrombosis	0%(0/287)
Acute Stent Thrombosis	0%(0/287)
Sub-Acute Stent Thrombosis	0%(0/287)
Late Stent Thrombosis	0%(0/287)

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

	Endeavor Continued Access (Number of Patients =287)
Cerebrovascular Accident (CVA)	0%(0/287)
Perforation	0.3%(1/287)
Target Vessel Revascularization	1.0%(3/287)
Target Lesion Revascularization	0.3%(1/287)
Target Vessel Failure	5.2%(15/287)
Safety Measures (to 270 days) % (#/n)	
Out-of-Hospital MACE to 270 days	6.3%(18/284)
MACE to 270 days	10.2%(29/284)
Death	0.7%(2/284)
Vascular Complications	0.4%(1/284)
Stent Thrombosis	0%(0/284)
Acute Stent Thrombosis	0%(0/284)
Sub-Acute Stent Thrombosis	0%(0/284)
Late Stent Thrombosis	0%(0/284)
Cerebrovascular Accident (CVA)	0.4%(1/284)
Target Vessel Revascularization	8.5%(24/284)
Target Lesion Revascularization	5.3%(15/284)
Target Vessel Failure	12.7%(36/284)
Safety Measures (to 360 days) % (#/n)	
Out-of-Hospital MACE to 360 days	8.1%(23/283)
MACE to 360 days	12.0%(34/283)
Death	0.7%(2/283)
Vascular Complications	0.4%(1/283)
Stent Thrombosis	0%(0/283)
Acute Stent Thrombosis	0%(0/283)
Sub-Acute Stent Thrombosis	0%(0/283)
Late Stent Thrombosis	0%(0/283)
Cerebrovascular Accident (CVA)	0.4%(1/283)
Target Vessel Revascularization	11.3%(32/283)
Target Lesion Revascularization	6.7%(19/283)
Target Vessel Failure	15.5%(44/283)
Safety Measures (to 720 days) % (#/n)	
Out-of-Hospital MACE to 720 days	9.0%(25/279)
MACE to 720 days	12.5%(35/279)
Death	1.4%(4/279)
Vascular Complications	0.4%(1/279)
Stent Thrombosis	0%(0/279)
Acute Stent Thrombosis	0%(0/279)
Sub-Acute Stent Thrombosis	0%(0/279)
Late Stent Thrombosis	0%(0/279)
Cerebrovascular Accident (CVA)	0.4%(1/279)
Target Vessel Revascularization	12.2%(34/279)
Target Lesion Revascularization	7.5%(21/279)
Target Vessel Failure	16.1%(45/279)

n = Number of patients/lesions with evaluable data

Lesion Success: Attainment of <50% in-stent residual stenosis using any percutaneous method

Device Success: Attainment of <50% in-stent residual stenosis using only the assigned device

Procedure Success: Attainment of <50% in-stent residual stenosis using any percutaneous method and no in-hospital MACE

Device-Specific Procedure Success: Attainment of <50% in-stent residual stenosis using only the assigned device and no in-hospital MACE.

MACE: Death, MI, emergent cardiac bypass Surgery, or target lesion revascularization (repeat PTCA or CABG) as determined by the independent Clinical Events Committee (CEC)

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 1.c. Principal Effectiveness and Safety Results – Pre-Dilatation vs. Direct Stenting

	Pre Dilatation Subset (Number of Patients =170) Number of Lesions = 170)	Direct Stenting Subset (Number of Patients = 126) Number of Lesions = 127*	Effect Size **	P-value
Effectiveness Measures				
Lesion Success % (#/n)	99.4%(169/170)	100.0%(126/126)	0.99 [0.98, 1.01]	1.0000
Device Success % (#/n)	98.2%(167/170)	98.4%(125/127)	1.00 [0.97, 1.03]	1.0000
Procedure Success % (#/n)	95.3%(162/170)	94.4%(118/125)	1.01 [0.96, 1.07]	0.7919
Device-Specific Procedure Success % (#/n)	94.1%(160/170)	92.9%(117/126)	1.01 [0.95, 1.08]	0.8112
Post-index Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)				
Mean±SD (n)	2.50 ±0.46 (170)	2.64 ±0.38 (126)	-0.14[-0.24,-0.04]	0.0037
Range (min, max)	(1.03,4.11)	(1.46,3.43)		
Post-index Procedure In-Stent Percent Diameter Stenosis (%DS)				
Mean±SD (n)	6.24%±10.04% (170)	3.98%±8.45% (126)	2.26[0.09,4.44]	0.0367
Range (min, max)	(-21.71%,51.72%)	(-31.46%,20.10%)		
Post-index Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)				
Mean±SD (n)	2.17 ±0.49 (170)	2.32 ±0.42 (126)	-0.14[-0.25,-0.04]	0.0083
Range (min, max)	(0.99,4.04)	(1.31,3.36)		
Post-index Procedure In- Segment Percent Diameter Stenosis (%DS)				
Mean±SD (n)	18.95%±10.20% (170)	16.14%±8.44% (126)	2.81[0.62,5.01]	0.0100
Range (min, max)	(-11.17%,51.72%)	(0.00%,48.15%)		
Eight-Month In-Stent Minimal Lumen Diameter (MLD, in mm)				
Mean±SD (n)	1.82 ±0.69 (69)	2.07 ±0.55 (48)	-0.25[-0.49,-0.02]	0.0356
Range (min, max)	(0.00,3.12)	(0.49,2.98)		
Eight-Month Procedure In-Stent Percent Diameter Stenosis (%DS)				
Mean±SD (n)	30.17%±23.90% (69)	24.08%±18.45% (48)	6.09[-2.04,14.22]	0.1405
Range (min, max)	(-3.30%,100.00%)	(1.10%,79.50%)		
Eight-Month Procedure In-Segment Minimal Lumen Diameter (MLD, in mm)				
Mean±SD (n)	1.70 ±0.65 (69)	1.97 ±0.54 (48)	-0.26[-0.49,-0.04]	0.0223
Range (min, max)	(0.00,3.12)	(0.49,2.98)		
Eight-Month Procedure In- Segment Percent Diameter Stenosis (%DS)				
Mean±SD (n)	34.47%±22.48% (69)	28.28%±16.94% (48)	6.19[-1.40,13.78]	0.0924
Range (min, max)	(2.00%,100.00%)	(5.50%,79.50%)		
Eight-Month Late Loss in-Stent (mm)				
Mean±SD (n)	0.59 ±0.60 (69)	0.56 ±0.56 (48)	0.03[-0.19,0.25]	0.7839
Range (min, max)	(-0.51,2.44)	(-0.12,2.34)		
Eight-Month Late Loss in-Segment (mm)				
Mean±SD (n)	0.41 ±0.57 (69)	0.37 ±0.55 (48)	0.05[-0.16,0.26]	0.6597
Range (min, max)	(-0.53,2.08)	(-0.71,2.24)		

	Pre Dilatation Subset (Number of Patients =170) Number of Lesions = 170)	Direct Stenting Subset (Number of Patients = 126) Number of Lesions = 127*	Effect Size **	P-value
Eight-Month in-Stent Binary Restenosis	18.8%(13/ 69)	10.4%(5/ 48)	1.81 [0.69, 4.74]	0.2989
Eight-Month in-Segment Binary Restenosis	21.7%(15/ 69)	10.4%(5/ 48)	2.09 [0.81, 5.36]	0.1374
TLR-Free at 720 days	90.3%	96.0%	-5.7% [-11.4%, 0.0%]	0.07
TVR-Free at 720 days	86.0%	89.6%	-3.6% [-11.1%, 3.9%]	0.38
TVF-Free at 720 days	82.6%	85.7%	-3.1% [-11.5%, 5.3%]	0.55
MACE-Free at 720 days	86.2%	88.9%	-2.7% [-10.2%, 4.9%]	0.46
Safety Measures (to 30 days) % (#/n)				
In-Hospital MACE	4.1%(7/170)	5.6%(7/126)	0.74 [0.27, 2.06]	0.5899
Out-of-Hospital MACE to 30 days	0.6%(1/170)	0.8%(1/126)	0.74 [0.05, 11.74]	1.0000
MACE to 30 days	4.7%(8/170)	6.3%(8/126)	0.74 [0.29, 1.92]	0.6073
Death	0.0%(0/170)	0.0%(0/126)	--[--,--]	--
Vascular Complications	0.0%(0/170)	0.8%(1/126)	--[--,--]	0.4257
Stent Thrombosis	0.0%(0/170)	0.0%(0/126)	--[--,--]	--
Acute Stent Thrombosis	0.0%(0/170)	0.0%(0/126)	--[--,--]	--
Sub-Acute Stent Thrombosis	0.0%(0/170)	0.0%(0/126)	--[--,--]	--
Late Stent Thrombosis	0.0%(0/170)	0.0%(0/126)	--[--,--]	--
Cerebrovascular Accident (CVA)	0.0%(0/170)	0.0%(0/126)	--[--,--]	--
Perforation	0.0%(0/170)	0.8%(1/126)	--[--,--]	0.4257
Target Vessel Revascularization	1.2%(2/170)	1.6%(2/126)	0.74 [0.11, 5.19]	1.0000
Target Lesion Revascularization	0.6%(1/170)	0.0%(0/126)	--[--,--]	1.0000
Target Vessel Failure	4.7%(8/170)	7.1%(9/126)	0.66 [0.26, 1.66]	0.4512
Safety Measures (to 270 days) % (#/n)				
Out-of-Hospital MACE to 270 days	0.6%(1/167)	0.8%(1/126)	0.75 [0.05, 11.95]	1.0000
MACE to 270 days	10.8%(18/167)	10.3%(13/126)	1.04 [0.53, 2.05]	1.0000
Death	0.6%(1/167)	0.8%(1/126)	0.75 [0.05, 11.95]	1.0000
Vascular Complications	0.0%(0/167)	0.8%(1/126)	--[--,--]	0.4300
Stent Thrombosis	0.0%(0/167)	0.0%(0/126)	--[--,--]	--
Acute Stent Thrombosis	0.0%(0/167)	0.0%(0/126)	--[--,--]	--
Sub-Acute Stent Thrombosis	0.0%(0/167)	0.0%(0/126)	--[--,--]	--
Late Stent Thrombosis	0.0%(0/167)	0.0%(0/126)	--[--,--]	--
Cerebrovascular Accident (CVA)	0.6%(1/167)	0.0%(0/126)	--[--,--]	1.0000
Target Vessel Revascularization	9.0%(15/167)	8.7%(11/126)	1.03 [0.49, 2.16]	1.0000
Target Lesion Revascularization	6.6%(11/167)	3.2%(4/126)	2.07 [0.68, 6.36]	0.2845
Target Vessel Failure	12.6%(21/167)	13.5%(17/126)	0.93 [0.51, 1.69]	0.8615
Safety Measures (to 360 days) % (#/n)				
Out-of-Hospital MACE to 360 days	0.6%(1/167)	0.8%(1/125)	0.75 [0.05, 11.85]	1.0000
MACE to 360 days	13.2%(22/167)	11.2%(14/125)	1.18 [0.63, 2.21]	0.7198
Death	0.6%(1/167)	0.8%(1/125)	0.75 [0.05, 11.85]	1.0000

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

	Pre Dilatation Subset (Number of Patients =170) Number of Lesions = 170)	Direct Stenting Subset (Number of Patients = 126) Number of Lesions = 127*)	Effect Size **	P-value
Vascular Complications	0.0%(0/167)	0.8%(1/125)	--[--,--]	0.4281
Stent Thrombosis	0.0%(0/167)	0.0%(0/125)	--[--,--]	--
Acute Stent Thrombosis	0.0%(0/167)	0.0%(0/125)	--[--,--]	--
Sub-Acute Stent Thrombosis	0.0%(0/167)	0.0%(0/125)	--[--,--]	--
Late Stent Thrombosis	0.0%(0/167)	0.0%(0/125)	--[--,--]	--
Cerebrovascular Accident (CVA)	0.6%(1/167)	0.0%(0/125)	--[--,--]	1.0000
Target Vessel Revascularization	12.6%(21/167)	10.4%(13/125)	1.21 [0.63, 2.32]	0.5869
Target Lesion Revascularization	8.4%(14/167)	4.0%(5/125)	2.10 [0.78, 5.67]	0.1556
Target Vessel Failure	16.8%(28/167)	14.4%(18/125)	1.16 [0.68, 2.01]	0.6289
Safety Measures (to 720 days) % (#/n)				
Out-of-Hospital MACE to 720 days	0.6%(1/165)	0.8%(1/123)	0.75 [0.05, 11.80]	1.0000
MACE to 720 days	13.9%(23/165)	11.4%(14/123)	1.22 [0.66, 2.28]	0.5952
Death	1.8%(3/165)	0.8%(1/123)	2.24 [0.24, 21.24]	0.6384
Vascular Complications	0.0%(0/165)	0.8%(1/123)	--[--,--]	0.4271
Stent Thrombosis	0.0%(0/165)	0.0%(0/123)	--[--,--]	--
Acute Stent Thrombosis	0.0%(0/165)	0.0%(0/123)	--[--,--]	--
Sub-Acute Stent Thrombosis	0.0%(0/165)	0.0%(0/123)	--[--,--]	--
Late Stent Thrombosis	0.0%(0/165)	0.0%(0/123)	--[--,--]	--
Cerebrovascular Accident (CVA)	0.6%(1/165)	0.0%(0/123)	--[--,--]	1.0000
Target Vessel Revascularization	13.9%(23/165)	10.6%(13/123)	1.32 [0.70, 2.50]	0.4725
Target Lesion Revascularization	9.7%(16/165)	4.1%(5/123)	2.39 [0.90, 6.33]	0.1068
Target Vessel Failure	17.6%(29/165)	14.6%(18/123)	1.20 [0.70, 2.06]	0.5241

n = Number of patients/lesions with evaluable data

Lesion Success: Attainment of <50% in-stent residual stenosis using any percutaneous method

Device Success: Attainment of <50% in-stent residual stenosis using only the assigned device

Procedure Success: Attainment of <50% in-stent residual stenosis using any percutaneous method and no in-hospital MACE

Device-Specific Procedure Success: Attainment of <50% in-stent residual stenosis using only the assigned device and no in-hospital MACE.

MACE: Death, MI, emergent cardiac bypass Surgery, or target lesion revascularization (repeat PTCA or CABG) as determined by the independent Clinical Events Committee (CEC)

*One (1) patient (603-35) with two lesions treated with Endeavor stents

**Effect size is mean treatment difference [95% CI] for continuous outcomes, relative risk [95% CI] (Pre dilatation vs. Direct stenting) for dichotomous outcomes (lesion, device and procedure success and safety measures).

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 subject left the catheterization laboratory) and before the 14-day follow-up endpoint.

Threatened Abrupt Closure. Defined as a grade B dissection and $\geq 50\%$ 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

Device Success: Attainment of $<50\%$ in-stent residual stenosis using only the assigned device.

Lesion Success: Attainment of $<50\%$ in-stent residual stenosis using any percutaneous method.

Procedure Success: Attainment of $<50\%$ in-stent residual stenosis using any percutaneous method and no in-hospital MACE

Device-Specific Procedure Success: Attainment of $<50\%$ in-stent residual stenosis using only the assigned device and no in-hospital MACE.

BLEEDING COMPLICATIONS

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)

- 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.

CBC (COMPLETE BLOOD COUNT)

Includes:

Hematocrit (HCT)
 Hemoglobin (HB)
 Platelet count
 Red blood cell (RBC) count
 White Blood Cell (WBC)
 White Blood Cell (WBC) Differential

CHEMISTRY PANEL

Includes:

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

* 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.

DEVICE-SPECIFIC PROCEDURE SUCCESS: Attainment of <50% in-stent residual stenosis using only the assigned device and no in-hospital MACE.

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

Any adverse event for which a causal relationship between the device and the event is at least a reasonable possibility.

DEVICE SUCCESS

Attainment of <50% in-stent residual stenosis using only the assigned device.

DISSECTION, 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.

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 ischaemia.

IN-LESION MEASUREMENT (ALSO IN-SEGMENT MEASUREMENT)

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

IN-STENT MEASUREMENT

Defined as the measurements within the stented segment.

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 >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.

LESION SUCCESS

Attainment of <50% in-stent residual stenosis using any percutaneous method.

MAJOR ADVERSE CARDIAC EVENTS (MACE)

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

MINIMAL LUMINAL DIAMETER (MLD)

Defined as the mean minimum lumen diameter derived from two orthogonal views (by the quantitative coronary angiography laboratory).

MYOCARDIAL INFARCTION

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

1. **Q wave MI (QMI):** will require one of the following criteria:
 - 1.1. 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.
 - 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.

2. **Non-Q wave MI (NQWMI):** for this trial NQWMI will be defined as elevated CK \geq 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.

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 haemorrhage/tamponade: perforation resulting in cardiac tamponade.

PROCEDURE SUCCESS

Attainment of <50% in-stent residual stenosis using any percutaneous method and no in-hospital MACE.

RECURRENT MI

Any myocardial infarction that occurs after the index procedure.

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.

RESOURCES

Defined as hospital and physician resources associated with treatment that are paid by government or private insurers.

RESTENOTIC LESION

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

STENT THROMBOSIS

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.

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 haemorrhage, embolism, thrombosis, or rupturing aneurysm, that persists >24 hours.

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 subject inclusion and exclusion criteria or subject informed consent procedures.

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

TARGET LESION REVASCULARIZATION (TLR)

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 subject has a positive functional study, ischaemic ECG changes at rest in a distribution consistent with the target vessel, or ischaemic symptoms. Revascularization of a target lesion with an in-segment diameter stenosis $\geq 70\%$ (by QCA) in the absence of the above-mentioned ischaemic signs or symptoms is also considered clinically-driven. In the absence of QCA data for relevant follow-up angiograms, the clinical need for revascularization is adjudicated using the presence or absence of ischaemic signs and symptoms.

Non-clinically driven repeat target lesion revascularizations are those in which the subject 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)

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 event.
3. Target vessel revascularization is determined.

TARGET VESSEL REVASCULARIZATION (TVR)

Defined as any clinically driven (as defined for TLR) repeat percutaneous intervention of the target vessel or bypass surgery of the target vessel.

TIMI FLOW 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)

Defined as any serious 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. Other serious problems associated with the device that affects the rights or welfare of study subjects may also be considered UADEs.

VASCULAR COMPLICATIONS

Vascular complications may include the following:

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

B. Study Design

This is a prospective, multi-center, single-arm study, open-label sub-study that enrolled 296 subjects with symptomatic ischaemic heart disease attributable to stenotic lesions of the native coronary arteries that were amenable to treatment by percutaneous stenting.

Study subjects may have had multiple vessel disease but only a single lesion per subject should have been treated in this trial. The target lesion must have been *de novo* and in a native coronary artery.

Clinical follow-up for all subjects was to be performed at 30 days. Telephone follow-up for all patients was performed at 6, 9, 12 and 24 months, and will be performed annually thereafter out to 5 years post-index procedure.

A subset of 150 subjects was selected for angiographic follow-up at 8 months post-procedure, and 117 had qualified images for the analysis at follow up.

A sub-study with IVUS evaluation at pre-selected sites was performed at baseline and at 8 months post-procedure. These subjects were drawn from the angiographic cohort. It was estimated that approximately 100 patients will be included in the IVUS sub-study, and 76 had qualified images for the analysis at follow up.

Selection of Subjects

This trial includes 296 subjects with *de novo* native coronary artery lesions who met eligibility criteria and agreed to participate in the study.

Subject Selection Criteria

Inclusion Criteria: Candidates were included in the study only if all the following conditions were met:

Note: Subjects could only be included in the study once.

1. The subject was ≥ 18 years of age (or minimum age dictated by local regulations).
2. The subject was an acceptable candidate for PTCA, stenting, and emergent CABG.
3. The subject had clinical evidence of ischaemic heart disease or a positive functional study.
4. The subject had single vessel disease or had multi-vessel disease with only moderate stenosis (max 50-60% or total occlusion (100%) for which no interventions were planned at the time of study inclusion).
5. The target lesion / vessel must have met the following criteria:
 - a. The target lesion was a single *de novo* lesion that had not been previously treated with any interventional procedure. Only one lesion was treated per subject.
 - b. The target vessel was a native coronary artery with a stenosis of $\geq 50\%$ and

- <100%.
- c. The target lesion was ≥ 14 mm and ≤ 27 mm in length.
 - d. The target vessel reference diameter was ≥ 2.25 mm and ≤ 3.5 mm.
(Measurements were made by careful visual estimate, on-line quantitative coronary angiography, or intravascular ultrasound.)
6. Female subjects of childbearing potential had a negative pregnancy test within seven (7) days before the procedure.
 7. The subject or the subject'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 of the respective clinical site.
 8. The subject and the treating physician agreed that the subject would comply with all required post-index procedure follow-up.

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

1. A documented left ventricular ejection fraction $< 30\%$.
2. A known hypersensitivity or contraindication to aspirin, heparin, clopidogrel, cobalt, nickel, chromium, or a sensitivity to contrast media, which could not be adequately pre-medicated.
3. Had a history of an allergic reaction or significant sensitivity or receiving drugs similar to/or synergistic to ABT-578 (rapamycin, tacrolimus, sirolimus, CCI-779 or other analogues).
4. A platelet count $< 100,000$ cells/mm³ or $> 700,000$ cells/mm³, or a WBC $< 3,000$ cells/mm³.
5. Had 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 $\geq 2X$ the upper laboratory normal with the presence of a CK-MB elevated above the Institution's upper limit of normal).
6. Creatinine > 2.0 mg/dl
7. A previous coronary interventional procedure of any kind within the 30 days prior to the procedure.
8. The subject required planned interventional treatment of either the target or any non-target vessel within 30 days post-index procedure.
9. The target lesion required 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.).
10. Had previous stenting anywhere in the target vessel.
11. The target vessel had evidence of thrombus or was excessively tortuous (2 bends $> 90^\circ$ to reach the target lesion).
12. Had significant ($> 50\%$) stenosis proximal or distal to the target lesion that might have required revascularization or impede run off.
13. Target lesion located in native vessel distally to anastomosis with vein graft or LIMA.
14. 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 45° bend in the vessel.
 - d) Was severely calcified.
15. Had an unprotected left main coronary artery disease (an obstruction greater than 50% in the left main coronary artery).
 16. Had a history of a stroke or transient ischaemic attack within the prior 6 months.
 17. Had an active peptic ulcer or upper GI bleeding within the prior 6 months.
 18. The subject had a history of bleeding diathesis or coagulopathy or would refuse blood transfusions.
 19. Had a concurrent medical condition with a life expectancy of less than 12 months.
 20. Had any previous or planned treatment with anti-restenotic therapies including, but not limited to, drug-eluting stents and brachytherapy.
 21. Was 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. [Note: Trials requiring extended follow-up for products that were investigational, but had since become commercially available, were not considered investigational trials.]

Baseline and Screening

Subject Screening

All patients admitted for potential percutaneous revascularization of the native coronary arteries were screened for study eligibility. A member of the Institution's research team assigned to the Medtronic Vascular Endeavor II Continued Access Trial reviewed the subject's medical and cardiac history to screen for study eligibility. A screening log was provided to study sites to maintain a cumulative log of all the screened subjects.

Informed Consent

All potential subjects were consented prior to performing any study related procedures. Once the investigator had determined the subject's eligibility for the study, the background of the proposed study and the benefits and risks of the procedures and study were explained to the subject. The subject (or the subject's legal representative) signed the site's Ethical Committee approved informed consent prior to participation. Failure to provide informed consent rendered the subject ineligible for the study. All patients in the study signed the informed consent.

Subject Withdrawal

Following the introduction into the guide catheter of the study device, all living subjects were required to complete all assigned follow-ups, including angiography and IVUS if applicable. Subjects were exempt from follow-up only if they withdraw their consent. A study subject that had been withdrawn from the study was not replaced. No patients in the study withdrew the informed consent. Five patients were lost to follow up as they could not be contacted anymore. Two patients were lost to follow up between 6 and 9 months, one patient between 9 and 12 months and two patients between 12 and 24 months follow up.

Clinical Laboratory Procedures and Tests

Clinical laboratory procedures and tests were performed for all subjects prior to the procedure to guarantee eligibility (see Schedule of Treatments):

1. *Within seven days of the procedure*, CBC, chemistry panel, and in addition, a pregnancy test (β HCG subunit) for women of childbearing potential was obtained.
2. *Within 72 hours of the procedure*, a 12-lead electrocardiogram and a creatine kinase (CK) enzyme and creatine kinase myocardial-band (CK-MB) isoenzyme test was obtained. Troponin measurements may have been made in addition to CK. Centers that had the capability were strongly encouraged to measure Troponin levels.
3. *Following arterial access*, a baseline activated clotting time (ACT) was determined. ACT and subsequent heparin 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.

Enrollment

All subjects who met eligibility requirements were asked to participate. Subjects were considered enrolled into the study after:

1. Signed informed consent had been obtained
2. The study device was introduced into the guide catheter.

The subject enrollment and device tracking CRFs were faxed to Medtronic within 24 hours of enrollment. In case a patient was deregistered from the study, a 'De-Registered Patient Form' was also faxed to Medtronic.

Data Safety Monitoring Board (DSMB)

The Data Safety Monitoring Board (DSMB) was composed of five members (four physicians from the fields of cardiology and interventional cardiology and one biostatistician), who were not directly involved in the conduct of the trial. The DSMB will review the study on a periodic basis.

Clinical Events Committee

The Clinical Events Committee is made up of interventional and non-interventional cardiologists who are not participants in the study. The Clinical Events Committee is charged with the development of specific criteria used for the categorization 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.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Once the specific criteria for clinical events and endpoints were established by the Clinical Events Committee, the Harvard Clinical Research Institute (HCRI) was responsible for categorizing all clinical events when all necessary data were available.

Schedule of Treatments and Assessments

Event	INDEX HOSPITALIZATION			FOLLOW-UP				
	Screen	Procedure	Post Procedure	30 Day	6 Month	8 Month	9 Month	12 month to 5 year
Type of Contact				Office visit	Telephone	Angio ⁷ / IVUS ⁸	Telephone	Telephone
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}							
CBC with differential, platelet count	X ²			X				
CK & CK-MB	X ⁴		X ⁵					
Troponin	X ⁹		X ⁹					
12-Lead Electrocardiogram	X ⁴		X ³					
ACT Measurements ¹⁰		X						
Medication Regimen ⁶	X	X	X	X	X		X	X
Adverse Event Monitoring			X	X	X	X	X	X
Angiography (QCA)	X	X				X ⁷		
IVUS		X ⁸				X ⁸		

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 comes first
4. Within 72 hours prior to procedure
5. Within 6-8, 12-16, and 20-24 hours post-procedure or prior to hospital discharge, whichever comes first
6. It is expected that clopidogrel will be used, unless the patient is allergic or sensitive to this medication. For patients unable to take clopidogrel, or at the discretion of the physician, ticlopidine will be used
7. The first 150 consecutive study subjects enrolled will have angiographic follow-up at 8 months as well as patients implanted with two or more stents from the second 150 consecutive patients.
8. Selected clinical sites only for IVUS sub study of approx. 100 patients and patients from all sites implanted with two or more stents
9. Optional- Measurement is recommended if the lab has the capability.
10. ACT measurements should be performed during the procedure.

C. Objectives

Primary Objective

The primary objective of this study is to expand the acute safety information and performance data of the Endeavor Drug Eluting Stent coated with 10 µg/mm ABT-578 for the treatment of single *de novo* lesions in native coronary arteries 2.25-3.5 mm in diameter.

The primary endpoint is the Major Adverse Cardiac Events (MACE) rate defined as death, MI (Q wave and non-Q wave), emergent cardiac bypass surgery, or target lesion revascularization (repeat PTCA or CABG) at 30 days post-procedure.

Secondary Objectives

The secondary objectives of this trial are to assess the medium and long-term safety and efficacy of the Endeavor Drug Eluting Stent (Medtronic ABT-578 Eluting Driver Stent System). The secondary endpoints of this study include:

- Device Success defined as attainment of <50% in-stent residual stenosis using only the assigned device.
- Lesion Success defined as attainment of <50% in-stent residual stenosis using any percutaneous method.
- Procedure Success defined as attainment of <50% in-stent residual stenosis using any percutaneous method and no in-hospital MACE
- Major Cardiac Adverse Events (MACE) defined as death, MI (Q wave and non-Q wave), emergent cardiac bypass surgery, or target lesion revascularization (TLR) at 6, 9, and 12 months, and annually thereafter out to 5 years.
- Late loss at 8 months as measured by QCA, defined as the difference between the post-procedure minimal lumen diameter (MLD) and the follow-up angiography MLD.
- Angiographic in-stent and in-lesion binary restenosis rate ($\geq 50\%$ diameter stenosis) at 8 months post-procedure.
- In-stent and in-lesion minimum lumen diameter (MLD) at 8 months post-procedure.
- Neointimal hyperplastic volume at 8 months as measured by intravascular ultrasound (IVUS).
- Target Lesion Revascularization (TLR) at 9 months post-procedure.
- Target Vessel Revascularization (TVR) at 9 months post-procedure
- Target Vessel Failure (TVF) rate at 9 months post procedure

D. Study Procedure

Procedure

Preparation, Angiography and Intravascular Ultrasound

1. Using standard procedures for balloon angioplasty, an introducer sheath of at least 6 French was introduced using the standard approach.
2. The guiding catheter used during the stent procedure was to have had a minimum internal diameter of 0.064" and the guide wire diameter should not have been larger than 0.014".
3. After catheter introduction, heparin with or without a glycoprotein IIb/IIIa receptor blocker was administered and supplemented as needed to maintain anticoagulation throughout the procedure.
4. Following intracoronary injection of GTN, baseline angiography of the vessel was performed in at least two near-orthogonal views that showed the target lesion free of foreshortening or vessel overlap, using a 6 French or larger guiding catheter.
5. Intravascular ultrasound (IVUS) with automated pullback was then performed in the selected IVUS sub-study sites.

Lesion/Vessel Pre-treatment

The target lesion could have been pre-treated with standard percutaneous transluminal balloon angioplasty. Predilatation was to be performed at the physician's discretion for lesions that were readily accessible and ≤ 20 mm in length. Predilatation was required for lesions > 20 mm and for moderately tortuous and/or calcified lesions. Of the 296 patients enrolled, 126 patients (127 lesions) were treated with direct stenting and for 170 patients predilatation was performed.

Pre-dilatation was to have been performed with a balloon with a diameter at least 0.5 mm smaller than the stent to create a channel through the lesion to facilitate the crossing of the stent in order to avoid damage to the coating. Also, a balloon length was to have been selected matching the lesion length to avoid dilatation of the vessel wall adjacent to the stent. The length of the predilatation balloon was to have been shorter than the stent that was intended to be implanted.

The use of other approved therapy (DCA, Laser, Rotational Atherectomy, etc.) was not allowed.

Stenting Procedure

The stenting procedure was performed according to the Instructions for Use. Care was taken to select the stent package from the correctly labeled treatment arm (A or B) as designated by randomization.

No more than one study stent was to have been used to treat the lesion. The only exception was insufficient lesion coverage or a bailout procedure.

The delivery system was advanced over the guidewire until the ends of the stent, identified by the balloon markers, bracketed the target lesion. Stent position was confirmed by angiography.

A stent was to have been selected long enough to cover the lesion completely. If more than one stent was needed to cover the lesion completely, it was recommended to overlap the stents 1-2 mm. The 8 or 9 mm stent was only to be used as a secondary stent to cover dissection post stent deployment, or if the primary stent failed to cover the lesion completely.

No more than 48 mm of total study stent length was to be used per patient. If additional stents were required, an uncoated Driver stent should have been used.

Stent deployment was to have been performed by careful visual assessment of stent expansion and apposition guided by on-line QCA measurement of the Minimal Lumen Diameter (MLD) function. The aim was to reach a Diameter Stenosis < 10% with avoidance of proximal or distal dissections.

After stent deployment the delivery balloon was deflated and the delivery catheter was carefully withdrawn on negative pressure with the guidewire remaining across the lesion.

At procedure completion, intracoronary injection of GTN was to have been administered and final angiography of the vessel performed in the two near-orthogonal views that were taken at baseline, showing the target lesion free of foreshortening or vessel overlap, using a 6 French or larger guiding catheter.

AVAILABLE STENT DIAMETERS AND LENGTHS

Diameters (mm)	Lengths (mm)				
	8.0*	9.0*	18.0	24.0	30.0
2.25	✓		✓	✓	✓
2.50	✓		✓	✓	✓
3.0		✓	✓	✓	✓
3.5		✓	✓	✓	✓

*To be used as a secondary stent only (in cases of insufficient lesion coverage or bailout).

IVUS Evaluation

At selected sites, an intravascular ultrasound (IVUS) evaluation was to have been performed after the stent implantation was considered optimal by careful visual assessment and / or eventually by on-line QCA measurement of the MLD-function. A system with automated pullback was to have been used. It was up to the investigator's discretion whether the stent implantation was IVUS guided or IVUS was only for documentary purposes.

Bailout Procedures

If the subject experienced a major dissection or an occlusive complication manifested as decreased target vessel flow, chest pain or ischaemic ECG changes which did not respond to repeat balloon inflations or intracoronary vasodilators (GTN, verapamil, diltiazem, nitroprusside), other bailout procedures were to have been performed which might include further stenting. For a total of 58 patients, 2 or more stents were implanted to cover the long lesion or to treat a possible dissection (see Table 18). If the subject required additional stents, a study stent was to have been used. If it was considered appropriate by the operator, a study stent with a length of 8 or 9 mm (depending on diameter) was to have been used in this instance. Please note that the total length of stent used should not have exceeded 48 mm. If additional stenting is required beyond total length of 48 mm, then an uncoated Driver stent was to have been used.

Treatment Failures

Failure to implant the Medtronic Vascular Driver Coronary Eluting Stent System at the intended target lesion was to have been recorded on the CRF as a treatment failure. In the event of a failure to implant the stent, the investigator could have chosen to treat the target lesion with an approved device. The investigator must have returned any damaged or unused stents to Medtronic Vascular. All devices that were unused were sent back to Medtronic Vascular at the end of the study except for one device that was lost in the hospital

Post-Index Procedure

Subject Management

Immediately following the procedure:

1. Heparin was to have been discontinued
2. ACT was to have been monitored in accordance with hospital protocol.
3. Vascular sheaths were to have been removed according to usual hospital practice.
4. Approved vascular closure devices might be used at the discretion of the investigator in accordance with the manufacturer's directions.

Antiplatelet / Anticoagulation Regimen

All subjects were to have received at least 75 mg aspirin indefinitely and clopidogrel 75mg daily for at least 12 weeks. The ACT or other appropriate laboratory testing was to have been monitored and recorded on source documents while being maintained at therapeutic levels. All patients except for one were discharged on aspirin/clopidogrel.

Clinical and Laboratory Procedures

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

An ECG was to have been performed within 24 hours post-index procedure or prior to discharge (whichever occurred first). A 12-lead ECG was required to document any suspicious cardiac ischaemic episode.

CK and CK-MB was to have been measured post-index procedure between:
6-8 hours,
12-16 hours, and
20-24 hours (or discharge whichever came first).

If total CK values were within normal ranges, CK-MB measurements were not mandated to be performed per hospital standards. It was strongly encouraged however that CK-MB measurements were obtained with every total CK drawn, even if CK values were within normal limits.

Every effort was to have been made to obtain cardiac enzyme values within the specified time ranges, to help determine the presence or absence of myocardial infarction post-index procedure. Results of all cardiac enzyme tests, even tests performed outside the time range, were documented on the case report forms.

If any CK elevation was noted post-index procedure, CK and CK-MB measurements were to have been continued to be performed every 8 hours for 24 hours, starting from when the first elevation was noted, and recorded on the appropriate case report form.

If a patient was discharged prior to 20 hours, the 20-24 hour blood draw may have been omitted. Every effort was to have been made to obtain a blood sample prior to hospital discharge.

Troponin measurements could have been made in addition to CK. Centers that had the capability were strongly encouraged to measure Troponin levels. CRP levels were measured before and after the procedure by selected sites able to measure CRP quantitatively.

A complete blood count with differential, platelets and chemistry was done on all patients within 24 hours post-index procedure or before discharge, whichever came first.

Concomitant Medical Therapy

It was strongly recommended that all subjects received the medication regimen listed below. All medications administered were to have been recorded in the subject's medical record. All concomitant medications taken by the patient for 30 days post-index procedure were to have been reported on the study case report form. All anti-platelet and anti-coagulant medication taken throughout the study was to have been reported on the study case report form.

<u>Prior to Procedure</u>	IV Heparin Aspirin Clopidogrel ^{1, 2}	PRN At least 75 mg QD 300 mg loading dose (if patient not currently taking clopidogrel).
	The specification of pre-procedure medications can be found in Table 27. A total of 93.9% (278/296) of the patients received aspirin and 85.8% (254/296) received clopidogrel.	
<u>During Procedure</u>	IV Heparin Intracoronary Nitroglycerin	To maintain ACT \geq 250 sec., or 200-250 sec. if GP IIb/IIIa blocker is used 100-200 mcg <i>prior to baseline</i> and post intervention angiograms
<u>Post-Index Procedure</u>	IV Heparin Aspirin Clopidogrel ¹	PRN At least 75 mg QD indefinitely 75 mg po QD (for 12 weeks)

1. It was expected that clopidogrel was used, unless the patient was allergic or sensitive to this medication. For patients unable to take clopidogrel, or at the discretion of the physician, ticlopidine was used. No clopidogrel allergies were reported. No patients received ticlopidine instead of clopidogrel. For patients on ticlopidine, CBCs were to be performed as per the drug labeling.
2. If the patient had been on clopidogrel for at least 48 hours prior to the procedure, the daily dose was continued and no additional loading dose given prior to the procedure.

Follow-up Procedures

Follow-up procedures for this trial included/will include:

1. Blood draws according to hospital standard or medication regimen.
2. Documentation of referring physicians, including general practitioners as well as cardiologists, family members, and neighbors, for assistance in locating patient if lost to follow-up. Any planned long absences from the area were recorded to facilitate continued ability to contact a study subject.
3. In case where the telephone contact at the required follow-up is not documented in the hospital file, the CRF may serve as a source document.
4. Subjects enrolled will be followed for five years after the index procedure.

6-8 Hours, 12-16 Hours, 20-24 Hours Post-Index Procedure

CK and CK-MB were to have been measured within the specific time ranges to help determine the presence or absence of myocardial infarction post-index procedure.

An ECG was to have been performed within 24 hours post-index procedure or prior to discharge (whichever comes first).

Thirty Days Post-Index Procedure (± 5 days)

A clinic visit was scheduled at thirty days. The assessment consisted of angina status (according to the Canadian Cardiovascular Society Classification of angina), **all** adverse events, CBC with differential, platelets, chemistry panel, **all** concomitant medications and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization).

Six Months Post-Index Procedure (± 14 days)

A telephone assessment will be performed at six months. The assessment will consist of angina status (according to the Canadian Cardiovascular Society Classification of angina), **all** adverse events, concomitant anti-platelet/anti-coagulant medications and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization).

Eight Months Post-Index Procedure (± 14 days)

A subset of the first 150 consecutively enrolled study subjects will undergo an angiogram at eight months. Angiographies should be performed in the same manner as described in Section 5.5 and appendix B. Additionally, subjects will undergo IVUS at baseline and eight-months post-index procedure as a sub-study at selected sites.

Nine Months Post-Index Procedure (± 14 days)

A telephone assessment will be scheduled at nine-months post-index procedure and will consist of angina status assessment (according to the Canadian Cardiovascular Society Classification of angina), **all** adverse events, chemistry panel concomitant anti-platelet/anti-coagulant medications and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization).

Twelve-Month Post-Index Procedure (± 30 days) and annually thereafter out to five years

A telephone assessment will be performed and will consist of an assessment of angina status (according to the Canadian Cardiovascular Society Classification of angina); serious adverse events including major adverse cardiac events, concomitant anti-platelet/anti-coagulant medications and any interventional treatment that occurred since the previous contact (e.g., repeat revascularization).

Summary of Follow-Up Procedures

Contact Period	Type of follow-up required
30 days \pm 5 days	Clinic Visit CBC with differential, platelets, chemistry panel
6 months \pm 14 days	Telephone Assessment
8 months \pm 14 days	Angiographic follow-up for subset 150 patients IVUS follow-up for subset of subjects
9 months \pm 14 days	Telephone Assessment
12 months \pm 30 days, and annually thereafter out to 5 years.	Telephone Assessment

Angiographic Follow-up

All ELECTIVE angiograms performed during the 5-year follow-up period should be preceded by a physician evaluation during which the physician will indicate whether or not the subject's clinical status warrants revascularization. Angiograms, including unscheduled angiograms, were sent to the Angiographic Core Laboratory for review.

A subset of 150 subjects underwent repeat angiography at approximately 8 months after the index procedure.

If repeat angiography was performed any time after the first month (≥ 30 days) and it demonstrated restenosis of the target vessel in association with objective evidence of recurrent ischaemia, that angiogram was analyzed as the follow-up angiogram, and the subjects were not required to undergo additional repeat angiography.

In some cases, recurrent ischaemia might have developed less than 30 days after successful stent placement. If angiography demonstrated a significant stenosis or sub-acute thrombotic occlusion of the target vessel, the subject was considered an acute failure, and continued to be included in the follow-up analysis that measures angiographic restenosis. In this situation, recurrent ischaemia was attributed to sub-abrupt closure, rather than restenosis. Even if subjects assigned to the angiographic follow-up cohort did undergo a repeat percutaneous intervention within 30 days, they were required to return for the follow-up angiogram at approximately 8 months.

As a general principle, clinically driven angiograms performed within 5 months after the procedure were not considered follow-up angiograms unless a target lesion intervention was performed. Clinically driven angiograms after 5 months post-index procedure might have been considered as a follow-up angiogram and might not have been repeated at 8 months post-index procedure. A final decision whether this angiogram was considered as a follow-up angiogram was made by the Angiographic Core lab. The schemes for qualifying angiograms

from the Angiographic Core lab can be found in Appendix A. Films will be qualified at follow-up based on the qualification scheme in the appendix. Specifically, the lower window and upper window for qualifying QCA follow-up are 150 and 360 days, respectively.

IVUS Follow-up

Patients who were part of the IVUS substudy at baseline underwent an IVUS evaluation during the follow-up angiography (at 8 months or earlier if a re-intervention was performed). The IVUS sites were notified and instructed to stop IVUS evaluation once the recruitment for the angiographic sub-study had been completed. However, these IVUS sites could continue to enroll patients (without performing IVUS procedures).

E. Clinical Events

Adverse Events

An adverse event was any undesirable medical occurrence in a clinical study subject, whether it was 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.

Serious adverse events information will be collected throughout the study and documented in the subject's medical record. All adverse events occurring up to 9 months post-index procedure whether associated with the investigational product or not, were recorded on the case report forms by the Investigator or other appropriate site personnel.

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

After 9 months, only serious adverse events including major adverse cardiac events and device related adverse events will be recorded on the case report forms.

Device related adverse event

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

Serious Adverse Events and Death

The Investigator decided whether each event 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, requires intervention to prevent permanent impairment/damage, or an event that resulted in congenital anomaly, malignancy, hospital admission or prolongation of hospitalization.

Any serious adverse event or subject death occurring during the 5 year follow-up period, regardless of cause, should be reported to Medtronic within one working day after the investigator first learns of the event.

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 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 effect the rights or welfare of study subjects might also be considered UADEs.

UADEs must be reported to the sponsor and the IRB/EC (if required) within one working day after the investigator first learns of the effect.

Device Failures, Malfunctions and Near Incidents

All device failures, malfunctions and near incidents were documented and reported. In case of a device failure, malfunction or near incident related to the investigational device, the device was returned to Medtronic Vascular, Inc for analysis.

Device Failure: A device had failed if it was used in accordance with the Instructions for Use, but did not perform according to Instructions for Use and negatively impacted the treatment.

Device Malfunction: A device malfunction was an unexpected change to the device that was contradictory to the Instructions for Use and did or did 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 was such that if it occurred again, it might lead to death or serious deterioration in health.

Device Misuse: A misused device (one that was used by the investigator in a manner that was contradictory to the Instructions for Use) was not considered a malfunction. No device misuse was reported.

Details on device performance issues can be found in Tables 28 and 29.

F. Statistical Methods of Analysis

This is a prospective, multi-center, single-arm, open-label, continued access sub-study enrolled 296 patients with the objective to expand the safety information available for the Medtronic Endeavor Drug Eluting Stent (ABT-578 Eluting Driver Stent System).

The sub-study was conducted at up to 15 centers.

The data of patient subset from the Continued Access Sub-study was analysed independently from the randomised part of the Endeavor II.

Interim Analysis

Interim analyses were planned after 30 day follow up and after 9 months follow up.

Primary Analysis Sample

The primary analysis sample was based on the principle of intent-to-treat (ITT). For this study, all patients who signed the written informed consent and where the study device was introduced in the guide catheter were counted in the primary analysis.

Primary Endpoint

The primary endpoint is the Major Adverse Cardiac Events (MACE) rate at 30 days post-procedure. This endpoint is defined as death, MI (Q wave and non-Q wave), emergent cardiac bypass surgery, or target lesion revascularization (repeat PTCA or CABG).

This single-arm study estimated the rate of MACE in this population. In addition, a 95% Confidence Interval for this rate is to be provided.

Analysis on Baseline Characteristics:

All clinically relevant baseline variables in this sub-study is tabulated. Categorical variables are reported using contingency tables, and continuous variables are reported by giving the number of known values, the mean, standard deviation, and minimum and maximum values.

Endpoints:

All statistical analyses were performed using SAS for Windows (version 6.12 or higher) or other widely accepted statistical or graphical software. Patient data listings and tabular and graphical presentations of results are provided.

The primary endpoint, Major Adverse Cardiac Events (MACE) rate at 30 days post-procedure, are estimated and reported along with the 95% confidence interval for the estimate.

The dichotomous secondary endpoints of device success, lesion success, procedure success, MACE rate (at 6, 9, and 12 months post-procedure and annually thereafter out to 5 years), target lesion revascularization (TLR) rates, target vessel revascularization (TVR) rates, target vessel failure (TVF) rates, and 8-month binary restenosis rate are reported in tables which includes frequency and percent of each outcome.

The secondary endpoints of in-stent and in-segment late lumen loss, in-stent and in-segment minimum luminal diameter (MLD), and neointimal hyperplastic volume are reported by giving the number of known values, the mean, standard deviation, and minimum and maximum values. These endpoints were measured on the subset of subjects undergoing the relevant procedure.

Section III. Tables and Figures

Table 2. Number of Patients Treated by Investigator

Endeavor Continued Access ITT Population (N=296)				
Site			Principal	Number of patients enrolled
Number	Clinical Site	City Name	Investigator	n (%)
601	Allgemeines Krankenhaus Sankt Georg	Hamburg	K-H. Kuck	29 (9.8%)
602	Kerckhoff-Klinik GmbH	Bad Nauheim	C.W. Hamm	7 (2.4%)
603	Helios Klinikum Siegburg	Siegburg	E. Grube	36 (12.2%)
604	Krankenhaus Der Barmherzigen Bruder	Trier	E Hauptmann	19 (6.4%)
605	Medizinische Klinik St. Johannes Hospital	Dortmund	H. Heuer	23 (7.8%)
606	Universitat Leipzig Herzzentrum	Leipzig	P. Sick	16 (5.4%)
607	Universitätskliniken des Saarlandes	Homburg/Saar	B. Scheller	5 (1.7%)
608	Universitätsklinikum Hamburg-Eppendorf Klinik und Poliklinik für Innere Medizin	Hamburg	T. Heitzer	19 (6.4%)
609	Universitätsklinikum Benjamin Franklin	Berlin	H.P. Schultheiss	45 (15.2%)
610	Universitätsklinikum Charite, Campus Mitte	Berlin	W. Rutsch	19 (6.4%)
611	Klinikum der Johann-Wolfgang-Goethe	Frankfurt/Main	A.M. Zeiher	7 (2.4%)
612	Praxis Dr. Silber	Munich	S. Silber	13 (4.4%)
613	Catharina Ziekenhuis	Eindhoven	J.J.R.M. Bonnier	14 (4.7%)
614	Onze Lieve Vrouwe Gasthuis	Amsterdam	G.J. Laarman	18 (6.1%)
615	St. Antonius Ziekenhuis	Nieuwegein	M.J. Suttorp	26 (8.8%)

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 3. Data Compliance

Endeavor Continued Access ITT Set (N=296)									
Site	Index Form*	30-Day Contact	270-Day Contact	360-Day Contact	720-Day Contact	Baseline QCA	8-Month QCA	Baseline IVUS	8-Month IVUS
601	29/29(100.0%)	29/29(100.0%)	27/29(93.1%)	28/29(96.6%)	28/29(96.6%)	29/29(100.0%)	15/21(71.4%)	0/0 (0%)	0/0 (0%)
602	7/7(100.0%)	7/7(100.0%)	7/7(100.0%)	7/7(100.0%)	6/7(85.7%)	7/7(100.0%)	2/4(50.0%)	2/4(50.0%)	2/4(50.0%)
603	36/36(100.0%)	36/36(100.0%)	35/36(97.2%)	35/36(97.2%)	34/36(94.4%)	36/36(100.0%)	22/25(88.0%)	23/25(92.0%)	25/25(100.0%)
604	19/19(100.0%)	19/19(100.0%)	19/19(100.0%)	19/19(100.0%)	18/19(94.7%)	19/19(100.0%)	9/11(81.8%)	11/11(100.0%)	11/11(100.0%)
605	23/23(100.0%)	23/23(100.0%)	23/23(100.0%)	23/23(100.0%)	23/23(100.0%)	23/23(100.0%)	13/13(100.0%)	0/0 (0%)	0/0 (0%)
606	16/16(100.0%)	16/16(100.0%)	16/16(100.0%)	16/16(100.0%)	16/16(100.0%)	16/16(100.0%)	8/8(100.0%)	0/0 (0%)	0/0 (0%)
607	5/5(100.0%)	5/5(100.0%)	2/5(40.0%)	5/5(100.0%)	4/5(80.0%)	5/5(100.0%)	2/2(100.0%)	0/2(0.0%)	0/2(0.0%)
608	19/19(100.0%)	19/19(100.0%)	18/19(94.7%)	18/19(94.7%)	18/19(94.7%)	19/19(100.0%)	6/8(75.0%)	0/0 (0%)	0/0 (0%)
609	45/45(100.0%)	44/45(97.8%)	42/45(93.3%)	43/45(95.6%)	38/45(84.4%)	45/45(100.0%)	18/21(85.7%)	7/21(33.3%)	5/21(23.8%)
610	19/19(100.0%)	19/19(100.0%)	19/19(100.0%)	19/19(100.0%)	19/19(100.0%)	19/19(100.0%)	11/13(84.6%)	2/13(15.4%)	2/13(15.4%)
611	7/7(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%)	0/0 (0%)	0/0 (0%)
612	13/13(100.0%)	13/13(100.0%)	12/13(92.3%)	12/13(92.3%)	12/13(92.3%)	13/13(100.0%)	3/4(75.0%)	0/0 (0%)	0/0 (0%)
613	14/14(100.0%)	14/14(100.0%)	14/14(100.0%)	14/14(100.0%)	14/14(100.0%)	14/14(100.0%)	3/3(100.0%)	3/3(100.0%)	2/3(66.7%)
614	18/18(100.0%)	18/18(100.0%)	18/18(100.0%)	18/18(100.0%)	17/18(94.4%)	18/18(100.0%)	6/7(85.7%)	6/7(85.7%)	6/7(85.7%)
615	26/26(100.0%)	26/26(100.0%)	26/26(100.0%)	26/26(100.0%)	26/26(100.0%)	26/26(100.0%)	6/6(100.0%)	6/6(100.0%)	6/6(100.0%)
Total	296/296(100.0%)	295/296(99.7%)	285/296(96.3%)	290/296(98.0%)	280/296(94.6%)	296/296(100.0%)	125/147(85.0%)	60/92(65.2%)	59/92(64.1%)

Page 1 of 1

*Index=Baseline and Enroll

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 4.a. Baseline Demographics and Clinical Characteristics – ITT Set

Subject Characteristics	Endeavor Continued Access (N=296)
Age (year)	
n	296
Mean	64.25
SD	9.69
Median	65
1 st quartile	57
3 rd quartile	71
Min-Max	37- 87
Gender % (#/n)	
Male	75% (222/296)
Female	25% (74/296)
Race % (#/n)	
White	99.3% (294/296)
Black	0.3% (1/296)
Hispanic	0% (0/296)
Asian	0.3% (1/296)
Other	0% (0/296)
Prior MI % (#/n)	29.2% (86/295)
Prior Percutaneous Coronary Revascularization % (#/n)	32.8% (97/296)
Prior CABG % (#/n)	5.1% (15/296)
Diabetes Mellitus % (#/n)	25.8% (76/295)
History of Hyperlipidemia % (#/n)	75.3% (220/292)
History of Hypertension % (#/n)	81.7% (241/295)
Current Smoker % (#/n)	27.1% (79/291)
Premature CAD in First Degree Relative* % (#/n)	34.1% (87/255)
Revascularization for Angina or MI % (#/n)	
Stable	70.9% (197/278)
Unstable	19.4% (54/278)
MI	9.7% (27/278)
CCS Class** % (#/n)	
I	12.2% (32/262)
II	46.9% (123/262)
III	17.9% (47/262)
IV	21.4% (56/262)
Positive Stress Test % (#/n)	49.8% (112/225)
Major Coronary Arteries >50% Stenosed % (#/n)	
Single	54.1% (160/296)
Double	26.4% (78/296)
Triple	19.6% (58/296)

Page 1 of 2

n = Number of patients with evaluable data

*Premature CAD for male relatives <55 years of age and female relative <65 years of age

** CCS – Canadian Cardiovascular Society angina class

Table 4.a. Baseline Demographics and Clinical Characteristics – ITT Set (Continued)

Subject Characteristics	Endeavor Continued Access (N=296)
Ejection Fraction	
n	237
Mean	62.68
SD	10.99
Median	64
1 st quartile	56
3 rd quartile	70
Min-Max	32- 87
GP IIb/IIIa Inhibitors % (#/n)	7.1% (21/296)

Page 2 of 2

n = Number of patients with evaluable data

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 4.b. Baseline Demographics and Clinical Characteristics – Pre Dilatation vs. Direct Stenting

Subject Characteristics	Pre Dilatation Subset N = 170	Direct stenting Subset N=126	Difference [95% CI]	p-value
Age (year)			2.4 [-0.2, 4.6]	0.04
n	170	126		
Mean	65.27	62.87		
SD	9.37	9.98		
Median	66	64		
1 st quartile	59	56		
3 rd quartile	72	71		
Min-Max	39- 87	37- 84		
Gender % (#/n)				
Male	74.7% (127/170)	75.4% (95/126)	-0.7% [-11.0%, 9.0%]	1.000
Race % (#/n)				0.258
White	100% (170/170)	98.4% (124/126)		
Black	0% (0/170)	0.8% (1/126)		
Hispanic	0% (0/170)	0% (0/126)		
Asian	0% (0/170)	0.8% (1/126)		
Other	0% (0/170)	0% (0/126)		
Prior MI % (#/n)	28.4% (48/169)	30.2% (38/126)	-1.8% [-12.0%, 9.0%]	0.796
Prior Percutaneous Coronary Revascularization % (#/n)	31.8% (54/170)	34.1% (43/126)	-2.4% [-13.0%, 8.0%]	0.708
Prior CABG % (#/n)	4.7% (8/170)	5.6% (7/126)	-0.8% [-6.0%, 4.0%]	0.793
Diabetes Mellitus % (#/n)	29.6% (50/169)	20.6% (26/126)	9.0% [-1.0%, 19.0%]	0.106
History of Hyperlipidemia % (#/n)	77.2% (129/167)	72.8% (91/125)	4.4% [-6.0%, 15.0%]	0.412
History of Hypertension % (#/n)	84.6% (143/169)	77.8% (98/126)	6.8% [-2.0%, 16.0%]	0.170
Current Smoker (30days) % (#/n)	24.6% (41/167)	30.6% (38/124)	-6.1% [-17.0%, 4.0%]	0.287
Premature CAD in First Degree Relative % (#/n)	33.3% (48/144)	35.1% (39/111)	-1.8% [-14.0%, 10.0%]	0.791
Revascularization for Angina or MI % (#/n)	94.7% (161/170)	92.9% (117/126)		0.624
Stable	68.9% (111/161)	73.5% (86/117)		
Unstable	23% (37/161)	14.5% (17/117)		
MI	8.1% (13/161)	12% (14/117)		
CCS Class III or IV	37.6% (56/149)	41.6% (47/113)	-4.0% [-16.0%, 8.0%]	0.526
Positive Stress Test % (#/n)	45.5% (56/123)	54.9% (56/102)	-9.4% [-22.0%, 4.0%]	0.182
Major Coronary Arteries >50% Stenosed % (#/n)				0.423
Single	52.4% (89/170)	56.3% (71/126)		
Double	26.5% (45/170)	26.2% (33/126)		
Triple	21.2% (36/170)	17.5% (22/126)		
Ejection Fraction			-0.9 [-3.7, 2.0]	0.55
n	136	101		
Mean	62.32	63.18		
SD	10.55	11.6		
Median	63	64		
1 st quartile	58	56		
3 rd quartile	70	72		
Min-Max	32- 83	32- 87		
GP IIb/IIIa Inhibitors % (#/n)	8.2% (14/170)	5.6% (7/126)	2.7% [-3.0%, 8.0%]	0.494

N = Total number of patients enrolled
n = Number of patients with evaluable data

Table 5.a. Baseline Lesion Characteristics – ITT Set

Baseline Lesion Characteristics	Endeavor Continued Access (Number of Patients=296 Number of Lesions = 297*)
Vessel Location % (#/n)	
LAD	50.5% (150/297)
LCX	22.6% (67/297)
RCA	26.9% (80/297)
LMCA	0% (0/297)
Lesion Location % (#/n)	
Proximal	42.4% (126/297)
Mid	50.5% (150/297)
Distal	6.4% (19/297)
Ostial	0.7% (2/297)
Lesion Length % (#/n)	
Discrete (<10mm)	19.1% (56/293)
Tubular (10-19.9mm)	54.3% (159/293)
Diffuse (>=20mm)	26.6% (78/293)
Eccentric % (#/n)	41.2% (122/296)
Bend % (#/n)	
<45 degrees	76.7% (227/296)
>=45 degrees to <90 degrees	19.9% (59/296)
>=90 degrees	3.4% (10/296)
Thrombus % (#/n)	3.4% (10/297)
Tortuosity % (#/n)	
None	91.9% (271/295)
Moderate	5.8% (17/295)
Severe	2.4% (7/295)
Calcification % (#/n)	
Mild	77.8% (231/297)
Moderate	18.9% (56/297)
Severe	3.4% (10/297)
Ulcerate % (#/n)	6.1% (18/295)
Aneurysm % (#/n)	3.7% (11/295)
Intimal Flap % (#/n)	0.7% (2/295)
TIMI Flow % (#/n)	
0	1% (3/297)
1	1% (3/297)
2	4% (12/297)
3	93.9% (279/297)
Total Occlusion % (#/n)	2% (6/297)
Branch Vessel Disease % (#/n)	21.5% (62/289)

Page 1 of 2

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

All variables are from assessment by the Angiographic Core Laboratory

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 5.a. Baseline Lesion Characteristics – ITT Set (Continued)

Baseline Lesion Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions = 297*)
Sidebranch Stenosis %	
n	126
Mean	39.33
SD	31.41
Median	42.5
1 st quartile	0
3 rd quartile	60
Min-Max	0- 95
Modified ACC/AHA Lesion Class** % (#/n)	
A	5.7% (17/297)
B1	19.9% (59/297)
B2	30.6% (91/297)
C	43.8% (130/297)

Page 2 of 2

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**American College of Cardiology/American Heart Association Lesion Class

All variables are from assessment by the Angiographic Core Laboratory

Table 5.b. Baseline Lesion Characteristics – Pre Dilatation vs. Direct Stenting

Baseline Lesion Characteristics	Pre Dilatation Subset N=170	Direct Stenting Subset N = 127	Difference	
			[95% CI]	p-value
Vessel Location % (#/n)				0.370
LAD	47.1% (80/170)	55.1% (70/127)		
LCX	24.7% (42/170)	19.7% (25/127)		
RCA	28.2% (48/170)	25.2% (32/127)		
LMCA	0% (0/170)	0% (0/127)		
Lesion Location % (#/n)				0.009
Proximal	34.1% (58/170)	53.5% (68/127)		
Mid	57.6% (98/170)	40.9% (52/127)		
Distal	7.6% (13/170)	4.7% (6/127)		
Ostial	0.6% (1/170)	0.8% (1/127)		
Lesion Length % (#/n)				<.001
Discrete (<10mm)	14.5% (24/166)	25.2% (32/127)		
Tubular (10-19.9mm)	50% (83/166)	59.8% (76/127)		
Diffuse (>=20mm)	35.5% (59/166)	15% (19/127)		
Eccentric % (#/n)	39.1% (66/169)	44.1% (56/127)	-5.0% [-16.4%, 6.4%]	0.405
Bend % (#/n)				0.263
<45 degrees	74% (125/169)	80.3% (102/127)		
>=45 degrees to <90 degrees	23.7% (40/169)	15% (19/127)		
>=90 degrees	2.4% (4/169)	4.7% (6/127)		
Thrombus % (#/n)	4.1% (7/170)	2.4% (3/127)	1.8% [-2.4%, 5.9%]	0.525
Tortuosity % (#/n)				0.485
None	92.9% (156/168)	90.6% (115/127)		
Moderator	4.8% (8/168)	7.1% (9/127)		
Severe	2.4% (4/168)	2.4% (3/127)		
Calcification % (#/n)				0.341
Mild	75.9% (129/170)	80.3% (102/127)		
Moderator	20% (34/170)	17.3% (22/127)		
Severe	4.1% (7/170)	2.4% (3/127)		
Ulcerate % (#/n)	6% (10/168)	6.3% (8/127)	-0.3% [-5.9%, 5.2%]	1.000
Aneurysm % (#/n)	4.8% (8/168)	2.4% (3/127)	2.4% [-2.0%, 6.8%]	0.361
Intimal Flap % (#/n)	0% (0/168)	1.6% (2/127)	-1.6% [-3.5%, 0.3%]	0.185
TIMI Flow % (#/n)				0.068
0	1.8% (3/170)	0% (0/127)		
1	1.2% (2/170)	0.8% (1/127)		
2	5.3% (9/170)	2.4% (3/127)		
3	91.8% (156/170)	96.9% (123/127)		
Total Occlusion % (#/n)	2.9% (5/170)	0.8% (1/127)	2.2% [-1.1%, 5.4%]	0.244
Branch Vessel Disease % (#/n)	20.7% (34/164)	22.4% (28/125)	-1.7% [-11.3%, 8.0%]	0.773
Sidebranch Stenosis %			-4.8% [-16.1%, 6.4%]	0.40
n	74	52		
Mean	37.32	42.17		
SD	31.48	31.39		
Median	40	50.5		
1 st quartile	0	5		
3 rd quartile	60	70		

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Baseline Lesion Characteristics	Pre Dilatation Subset	Direct Stenting Subset	Difference	
	N=170	N = 127	[95% CI]	p-value
Min-Max	0- 90	0- 95		
Modified ACC/AHA Lesion Class* % (#/n)				0.149
A	4.7% (8/170)	7.1% (9/127)		
B1	17.6% (30/170)	22.8% (29/127)		
B2	28.2% (48/170)	33.9% (43/127)		
C	49.4% (84/170)	36.2% (46/127)		

n = Number of treated lesions with evaluable data

*American College of Cardiology/ American Heart Association Lesion Class

Table 6.a. Quantitative Angiographic Analysis Pre and Post Procedure – ITT Set

Lesion Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
Pre-Procedure	
Reference Vessel diameter (mm)	
n	297
Mean	2.63
SD	0.45
Median	2.61
1st quartile	2.32
3rd quartile	2.93
Min-Max	1.59- 4.47
MLD (mm)	
n	297
Mean	0.78
SD	0.33
Median	0.74
1st quartile	0.54
3rd quartile	0.99
Min-Max	0- 1.82
% Stenosis**	
n	297
Mean	70.03
SD	11.83
Median	70.61
1st quartile	62.12
3rd quartile	78.8
Min-Max	39.59- 100
Lesion Length (mm)	
n	293
Mean	16.49
SD	7.86
Median	15
1st quartile	11.09
3rd quartile	20.41
Min-Max	3.76- 52.44
Post-index Procedure	
Reference Vessel diameter (mm)	
n	296
Mean	2.71
SD	0.45
Median	2.71
1st quartile	2.39
3rd quartile	3
Min-Max	1.65- 4.59

Page 1 of 4

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on proximal normal and distal normal projections in the angiographic data.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

**Table 6.a. Quantitative Angiographic Analysis Pre and Post Procedure – ITT Set
(Continued)**

Lesion Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
In-Segment	
MLD (mm)	
n	296
Mean	2.24
SD	0.46
Median	2.25
1st quartile	1.94
3rd quartile	2.55
Min-Max	0.99- 4.04
% Stenosis**	
n	296
Mean	17.76
SD	9.57
Median	15.94
1st quartile	10.77
3rd quartile	23.01
Min-Max	-11.17- 51.72
Within the Stent	
MLD (mm)	
n	296
Mean	2.56
SD	0.43
Median	2.53
1st quartile	2.29
3rd quartile	2.85
Min-Max	1.03- 4.11
Mean Diameter (mm)	
n	296
Mean	2.86
SD	0.42
Median	2.83
1st quartile	2.56
3rd quartile	3.15
Min-Max	1.87- 4.59
% Stenosis**	
n	296
Mean	5.27
SD	9.45
Median	5.28
1st quartile	0.78
3rd quartile	10.68
Min-Max	-31.46- 51.72

Page 2 of 4

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on proximal normal and distal normal projections in the angiographic data.

**Table 6.a. Quantitative Angiographic Analysis Pre and Post Procedure – ITT Set
(Continued)**

Lesion Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
Proximal Edge (mm)	
MLD (mm)	
n	277
Mean	2.68
SD	0.58
Median	2.65
1st quartile	2.3
3rd quartile	3.03
Min-Max	1.39- 4.51
Mean Diameter (mm)	
n	277
Mean	2.87
SD	0.56
Median	2.83
1st quartile	2.5
3rd quartile	3.19
Min-Max	1.67- 4.72
% Stenosis**	
n	277
Mean	1.13
SD	12.69
Median	0.39
1st quartile	-7.21
3rd quartile	9.13
Min-Max	-31.1- 37.61
Distal Edge (mm)	
MLD (mm)	
n	295
Mean	2.34
SD	0.53
Median	2.34
1st quartile	1.96
3rd quartile	2.71
Min-Max	1.11- 4.59
Mean Diameter (mm)	
n	295
Mean	2.54
SD	0.5
Median	2.49
1st quartile	2.17
3rd quartile	2.87
Min-Max	1.38- 4.79

Page 3 of 4

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on proximal normal and distal normal projections in the angiographic data.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

**Table 6.a. Quantitative Angiographic Analysis Pre and Post Procedure – ITT Set
(Continued)**

Lesion Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
% Stenosis**	
n	295
Mean	13.97
SD	11.78
Median	12.64
1st quartile	5.81
3rd quartile	20.9
Min-Max	-19.94- 51.08

Page 4 of 4

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on proximal normal and distal normal projections in the angiographic data.

Table 6.b. Quantitative Angiographic Analysis at 8 Months – ITT Set

Lesion Characteristics	Endeavor Continued Access (Number of Patients =117 Number of Lesions =117)
8-Month Follow-up	
Reference Vessel diameter (mm)	
n	117
Mean	2.66
SD	0.41
Median	2.63
1st quartile	2.36
3rd quartile	2.91
Min-Max	1.72- 4.13
In-Segment	
MLD (mm)	
n	117
Mean	1.81
SD	0.61
Median	1.94
1st quartile	1.56
3rd quartile	2.23
Min-Max	0- 3.12
% Stenosis**	
n	117
Mean	31.93
SD	20.54
Median	27.1
1st quartile	17.8
3rd quartile	36
Min-Max	2- 100
Within the Stent	
MLD (mm)	
n	117
Mean	1.92
SD	0.65
Median	2.12
1st quartile	1.64
3rd quartile	2.33
Min-Max	0- 3.12
Mean Diameter (mm)	
n	117
Mean	2.42
SD	0.53
Median	2.48
1st quartile	2.18
3rd quartile	2.76
Min-Max	0- 3.52

Page 1 of 3

n = Number of lesions with evaluable data at Angio subset

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on proximal normal and distal normal projections in the angiographic data.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

**Table 6.b. Quantitative Angiographic Analysis at 8 Months – ITT Set
(Continued)**

Lesion Characteristics	Endeavor Continued Access (Number of Patients =117 Number of Lesions =117)
% Stenosis**	
n	117
Mean	27.67
SD	21.95
Median	22.6
1st quartile	13.6
3rd quartile	34.1
Min-Max	-3.3- 100
Proximal Edge (mm)	
MLD (mm)	
n	109
Mean	2.44
SD	0.62
Median	2.45
1st quartile	2.01
3rd quartile	2.91
Min-Max	0.72- 4.07
Mean Diameter (mm)	
n	109
Mean	2.7
SD	0.55
Median	2.67
1st quartile	2.26
3rd quartile	3.06
Min-Max	1.55- 4.12
% Stenosis**	
n	109
Mean	8.54
SD	17.05
Median	5.6
1st quartile	-3.4
3rd quartile	18.8
Min-Max	-22.7- 71.4

Page 2 of 3

n = Number of lesions with evaluable data at Angio subset

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on proximal normal and distal normal projections in the angiographic data.

**Table 6.b. Quantitative Angiographic Analysis at 8 Months – ITT Set
(Continued)**

Lesion Characteristics	Endeavor Continued Access (Number of Patients =117 Number of Lesions =117)
Distal Edge (mm)	
MLD (mm)	
n	116
Mean	2.23
SD	0.5
Median	2.23
1st quartile	1.92
3rd quartile	2.56
Min-Max	1- 3.79
Mean Diameter (mm)	
n	116
Mean	2.42
SD	0.48
Median	2.46
1st quartile	2.12
3rd quartile	2.69
Min-Max	1.21- 3.95
% Stenosis**	
n	116
Mean	15.98
SD	13.7
Median	13.8
1st quartile	6.6
3rd quartile	24.05
Min-Max	-17.7- 60.6
Binary Restenosis	
In-Segment	17.1%(20/117)
Within the Stent	15.4%(18/117)
Proximal Edge	3.7%(4/109)
Distal Edge	3.4%(4/116)

Page 3 of 3

n = Number of lesions with evaluable data at Angio subset

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on proximal normal and distal normal projections in the angiographic data.

Table 6.c. Quantitative Angiographic Analysis Pre and Post Procedure – Pre Dilatation vs. Direct Stenting

Lesion Characteristics	Pre Dilatation Subset (Number of Patients =170 Number of Lesions =170)	Direct Stenting Subset (Number of Patients =126 Number of Lesions =127*)	Difference	P-value
			[95% CI]	
Pre-Procedure				
Reference Vessel diameter (mm)				
Mean±SD (n)	2.61±0.48 (170)	2.67±0.41 (127)	-0.06[-0.16,0.04]	0.2468
Range (min, max)	(1.59,4.47)	(1.62,4.04)		
MLD (mm)				
Mean±SD (n)	0.71±0.29 (170)	0.89±0.36 (127)	-0.19[-0.26,-0.11]	<.0001
Range (min, max)	(0.00,1.46)	(0.14,1.82)		
% Stenosis**				
Mean±SD (n)	72.7% ±11.0% (170)	66.5% ±12.0% (127)	6.2%[3.5%,8.8%]	<.0001
Range (min, max)	(40.8%,100.0%)	(39.6%,94.9%)		
Lesion Length (mm)				
Mean±SD (n)	18.16±8.46 (166)	14.29±6.41 (127)	3.87[2.09,5.64]	<.0001
Range (min, max)	(4.20,52.44)	(3.76,47.58)		
Post-index Procedure				
Reference Vessel diameter (mm)				
Mean±SD (n)	2.68±0.48 (170)	2.76±0.41 (126)	-0.08[-0.19,0.02]	0.1123
Range (min, max)	(1.65,4.59)	(1.77,4.21)		
In-Segment				
MLD (mm)				
Mean±SD (n)	2.17±0.49 (170)	2.32±0.42 (126)	-0.14[-0.25,-0.04]	0.0083
Range (min, max)	(0.99,4.04)	(1.31,3.36)		
% Stenosis**				
Mean±SD (n)	19.0% ±10.2% (170)	16.1% ±8.4% (126)	2.8%[0.6%,5.0%]	0.0100
Range (min, max)	(-11.2%,51.7%)	(0.0%,48.2%)		
Within the Stent				
MLD (mm)				
Mean±SD (n)	2.50±0.46 (170)	2.64±0.38 (126)	-0.14[-0.24,-0.04]	0.0037
Range (min, max)	(1.03,4.11)	(1.46,3.43)		
Mean Diameter (mm)				
Mean±SD (n)	2.82±0.44 (170)	2.91±0.38 (126)	-0.10[-0.19,0.00]	0.0490
Range (min, max)	(1.87,4.59)	(2.01,3.87)		
% Stenosis**				
Mean±SD (n)	6.2% ±10.0% (170)	4.0% ±8.5% (126)	2.3%[0.1%,4.4%]	0.0367

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Lesion Characteristics	Pre Dilatation Subset (Number of Patients =170 Number of Lesions =170)	Direct Stenting Subset (Number of Patients =126 Number of Lesions =127*)	Difference	P-value
			[95% CI]	
Range (min, max) Proximal Edge (mm)	(-21.7%,51.7%)	(-31.5%,20.1%)		
MLD (mm)				
Mean±SD (n)	2.64±0.61 (163)	2.74±0.54 (114)	-0.10[-0.24,0.04]	0.1751
Range (min, max)	(1.39,4.51)	(1.44,4.23)		
Mean Diameter (mm)				
Mean±SD (n)	2.85±0.60 (163)	2.90±0.50 (114)	-0.05[-0.19,0.08]	0.4280
Range (min, max)	(1.67,4.72)	(1.82,4.31)		
% Stenosis**				
Mean±SD (n)	1.6% ±13.6% (163)	0.5% ±11.2% (114)	1.1%[-2.0%,4.1%]	0.4809
Range (min, max)	(-30.4%,37.6%)	(-31.1%,28.6%)		
Distal Edge (mm)				
MLD (mm)				
Mean±SD (n)	2.28±0.55 (169)	2.43±0.48 (126)	-0.14[-0.27,-0.02]	0.0193
Range (min, max)	(1.11,4.59)	(1.33,3.82)		
Mean Diameter (mm)				
Mean±SD (n)	2.48±0.53 (169)	2.62±0.46 (126)	-0.14[-0.25,-0.02]	0.0215
Range (min, max)	(1.38,4.79)	(1.45,4.15)		
% Stenosis**				
Mean±SD (n)	15.2% ±12.3% (169)	12.3% ±10.8% (126)	2.9%[0.2%,5.7%]	0.0337
Range (min, max)	(-11.7%,51.1%)	(-19.9%,48.5%)		

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on proximal normal and distal normal projections in the angiographic data.

Table 6.d. Quantitative Angiographic Analysis at 8 Months – Pre Dilatation vs. Direct Stenting

Lesion Characteristics	Pre Dilatation Subset (Number of Patients =69 Number of Lesions =69)	Direct Stenting Subset (Number of Patients =48 Number of Lesions =48)	Difference [95% CI]	P-value
8-Month Follow-up				
Reference Vessel diameter (mm)				
Mean±SD (n)	2.60±0.42 (69)	2.75±0.39 (48)	-0.15[-0.30,0.00]	0.0521
Range (min, max)	(1.86,4.13)	(1.72,3.62)		
In-Segment				
MLD (mm)				
Mean±SD (n)	1.70±0.65 (69)	1.97±0.54 (48)	-0.26[-0.49,-0.04]	0.0223
Range (min, max)	(0.00,3.12)	(0.49,2.98)		
% Stenosis**				
Mean±SD (n)	34.5% ±22.5% (69)	28.3% ±16.9% (48)	6.2%[-1.4%,13.8%]	0.0924
Range (min, max)	(2.0%,100.0%)	(5.5%,79.5%)		
Within the Stent				
MLD (mm)				
Mean±SD (n)	1.82±0.69 (69)	2.07±0.55 (48)	-0.25[-0.49,-0.02]	0.0356
Range (min, max)	(0.00,3.12)	(0.49,2.98)		
Mean Diameter (mm)				
Mean±SD (n)	2.33±0.57 (69)	2.56±0.44 (48)	-0.23[-0.42,-0.03]	0.0215
Range (min, max)	(0.00,3.52)	(1.13,3.43)		
% Stenosis**				
Mean±SD (n)	30.2% ±23.9% (69)	24.1% ±18.5% (48)	6.1%[-2.0%,14.2%]	0.1405
Range (min, max)	(-3.3%,100.0%)	(1.1%,79.5%)		
Proximal Edge (mm)				
MLD (mm)				
Mean±SD (n)	2.37±0.65 (64)	2.53±0.58 (45)	-0.15[-0.39,0.09]	0.2052
Range (min, max)	(0.72,4.07)	(0.98,3.49)		
Mean Diameter (mm)				
Mean±SD (n)	2.64±0.57 (64)	2.78±0.51 (45)	-0.14[-0.36,0.07]	0.1791
Range (min, max)	(1.55,4.12)	(1.58,3.68)		
% Stenosis**				
Mean±SD (n)	9.2% ±17.6% (64)	7.5% ±16.4% (45)	1.7%[-4.9%,8.3%]	0.6111
Range (min, max)	(-22.7%,71.4%)	(-22.3%,69.5%)		
Distal Edge (mm)				
MLD (mm)				
Mean±SD (n)	2.17±0.49 (68)	2.32±0.51 (48)	-0.15[-0.33,0.04]	0.1156

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Lesion Characteristics	Pre Dilatation Subset (Number of Patients =69 Number of Lesions =69)	Direct Stenting Subset (Number of Patients =48 Number of Lesions =48)	Difference [95% CI]	P-value
Range (min, max)	(1.00,3.79)	(1.26,3.38)		
Mean Diameter (mm)				
Mean±SD (n)	2.34±0.48 (68)	2.54±0.47 (48)	-0.20[-0.38,-0.02]	0.0283
Range (min, max)	(1.21,3.95)	(1.54,3.64)		
% Stenosis**				
Mean±SD (n)	16.3% ±13.7% (68)	15.5% ±13.8% (48)	0.9%[-4.2%,6.0%]	0.7320
Range (min, max)	(-15.7%,60.6%)	(-17.7%,53.1%)		
Binary Restenosis				
Within the Stent	18.8%(13/ 69)	10.4%(5/ 48)	8.4% [-4.2%, 21.1%]	0.2989
In-Segment	21.7%(15/ 69)	10.4%(5/ 48)	11.3% [-1.7%, 24.3%]	0.1374
Proximal Edge	4.7%(3/ 64)	2.2%(1/ 45)	2.5% [-4.3%, 9.2%]	0.6412
Distal Edge	2.9%(2/ 68)	4.2%(2/ 48)	-1.2% [-8.2%, 5.7%]	1.0000

n = Number of lesions with evaluable data

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on proximal normal and distal normal projections in the angiographic data.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 7.a. Quantitative Angiographic Analysis (Interpolated) Pre and Post Procedure – ITT Set

Lesion Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
Pre-Procedure	
Reference Vessel diameter (mm)	
n	297
Mean	2.54
SD	0.48
Median	2.51
1st quartile	2.21
3rd quartile	2.88
Min-Max	1.29- 4.58
MLD (mm)	
n	297
Mean	0.78
SD	0.33
Median	0.74
1st quartile	0.54
3rd quartile	0.99
Min-Max	0- 1.82
% Stenosis**	
n	297
Mean	69.04
SD	11.73
Median	68.65
1st quartile	60.75
3rd quartile	77.78
Min-Max	32.91- 100
Lesion Length (mm)	
n	293
Mean	16.49
SD	7.86
Median	15
1st quartile	11.09
3rd quartile	20.41
Min-Max	3.76- 52.44
Post-index Procedure	
Reference Vessel diameter (mm)	
n	296
Mean	2.7
SD	0.46
Median	2.68
1st quartile	2.4
3rd quartile	3.01
Min-Max	1.43- 4.63

Page 1 of 4

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on "inter" normal projections in the angiographic data.

Table 7.a. Quantitative Angiographic Analysis (Interpolated) Pre and Post Procedure – ITT Set (Continued)

Lesion Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
In-Segment	
MLD (mm)	
n	296
Mean	2.24
SD	0.46
Median	2.25
1st quartile	1.94
3rd quartile	2.55
Min-Max	0.99- 4.04
% Stenosis**	
n	296
Mean	17.28
SD	9.8
Median	15.5
1st quartile	10.15
3rd quartile	23.83
Min-Max	-11.17- 51.21
Within the Stent	
MLD (mm)	
n	296
Mean	2.56
SD	0.43
Median	2.53
1st quartile	2.29
3rd quartile	2.85
Min-Max	1.03- 4.11
Mean Diameter (mm)	
n	296
Mean	2.86
SD	0.42
Median	2.83
1st quartile	2.56
3rd quartile	3.15
Min-Max	1.87- 4.59
% Stenosis**	
n	296
Mean	4.79
SD	9.24
Median	5.13
1st quartile	-0.08
3rd quartile	10.36
Min-Max	-30.35- 51.21

Page 2 of 4

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on "inter" normal projections in the angiographic data.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 7.a. Quantitative Angiographic Analysis (Interpolated) Pre and Post Procedure – ITT Set (Continued)

Lesion Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
Proximal Edge (mm)	
MLD (mm)	
n	277
Mean	2.68
SD	0.58
Median	2.65
1st quartile	2.3
3rd quartile	3.03
Min-Max	1.39- 4.51
Mean Diameter (mm)	
n	277
Mean	2.87
SD	0.56
Median	2.83
1st quartile	2.5
3rd quartile	3.19
Min-Max	1.67- 4.72
% Stenosis**	
n	277
Mean	-0.14
SD	19
Median	0.71
1st quartile	-10.82
3rd quartile	10.34
Min-Max	-65.53- 44.5
Distal Edge (mm)	
MLD (mm)	
n	295
Mean	2.34
SD	0.53
Median	2.34
1st quartile	1.96
3rd quartile	2.71
Min-Max	1.11- 4.59
Mean Diameter (mm)	
n	295
Mean	2.54
SD	0.5
Median	2.49
1st quartile	2.17
3rd quartile	2.87
Min-Max	1.38- 4.79

Page 3 of 4

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on "inter" normal projections in the angiographic data.

Table 7.a. Quantitative Angiographic Analysis (Interpolated) Pre and Post Procedure – ITT Set (Continued)

Lesion Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions =297*)
% Stenosis**	
n	295
Mean	13.44
SD	12.09
Median	11.56
1st quartile	4.47
3rd quartile	19.67
Min-Max	-10.64- 51.16

Page 4 of 4

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

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Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 7.b. Quantitative Angiographic Analysis (Interpolated) at 8 Months – ITT Set

Lesion Characteristics	Endeavor Continued Access (Number of Patients =117 Number of Lesions =117)
8-Month Follow-up	
Reference Vessel diameter (mm)	
n	117
Mean	2.5
SD	0.44
Median	2.54
1st quartile	2.2
3rd quartile	2.72
Min-Max	1.46- 4.05
In-Segment	
MLD (mm)	
n	117
Mean	1.81
SD	0.61
Median	1.94
1st quartile	1.56
3rd quartile	2.23
Min-Max	0- 3.12
% Stenosis**	
n	117
Mean	27.08
SD	21.93
Median	20.4
1st quartile	12.6
3rd quartile	30.4
Min-Max	-6.3- 100
Within the Stent	
MLD (mm)	
n	117
Mean	1.92
SD	0.65
Median	2.12
1st quartile	1.64
3rd quartile	2.33
Min-Max	0- 3.12
Mean Diameter (mm)	
n	117
Mean	2.42
SD	0.53
Median	2.48
1st quartile	2.18
3rd quartile	2.76
Min-Max	0- 3.52

Page 1 of 3

n = Number of lesions with evaluable data

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on “inter” normal projections in the angiographic data.

**Table 7.b. Quantitative Angiographic Analysis (Interpolated) at 8 Months – ITT Set
(Continued)**

Lesion Characteristics	Endeavor Continued Access (Number of Patients =117 Number of Lesions =117)
% Stenosis**	
n	117
Mean	22.49
SD	23.8
Median	16.2
1st quartile	6.9
3rd quartile	29.6
Min-Max	-18.8- 100
Proximal Edge (mm)	
MLD (mm)	
n	109
Mean	2.44
SD	0.62
Median	2.45
1st quartile	2.01
3rd quartile	2.91
Min-Max	0.72- 4.07
Mean Diameter (mm)	
n	109
Mean	2.7
SD	0.55
Median	2.67
1st quartile	2.26
3rd quartile	3.06
Min-Max	1.55- 4.12
% Stenosis**	
n	109
Mean	1.07
SD	23.21
Median	0
1st quartile	-11.1
3rd quartile	15
Min-Max	-64.2- 72.8

Page 2 of 3

n = Number of lesions with evaluable data

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on "inter" normal projections in the angiographic data.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

**Table 7.b. Quantitative Angiographic Analysis (Interpolated) at 8 Months – ITT Set
(Continued)**

Lesion Characteristics	Endeavor Continued Access (Number of Patients =117 Number of Lesions =117)
Distal Edge (mm)	
MLD (mm)	
n	116
Mean	2.23
SD	0.5
Median	2.23
1st quartile	1.92
3rd quartile	2.56
Min-Max	1- 3.79
Mean Diameter (mm)	
n	116
Mean	2.42
SD	0.48
Median	2.46
1st quartile	2.12
3rd quartile	2.69
Min-Max	1.21- 3.95
% Stenosis**	
n	116
Mean	10.21
SD	13.46
Median	8.6
1st quartile	2.65
3rd quartile	14.45
Min-Max	-21.3- 61.7
Binary Restenosis	
In-Segment	17.1%(20/117)
Within the Stent	15.4%(18/117)
Proximal Edge	3.7%(4/109)
Distal Edge	2.6%(3/116)

Page 3 of 3

n = Number of lesions with evaluable data

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on “inter” normal projections in the angiographic data.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 7.c. Quantitative Angiographic Analysis (Interpolated) Pre and Post Procedure – Pre Dilatation vs. Direct Stenting

Lesion Characteristics	Pre Dilatation Subset (Number of Patients =170 Number of Lesions =170)	Direct Stenting Subset (Number of Patients =126 Number of Lesions =127*)	Difference	
			[95% CI]	P-value
Pre-Procedure				
Reference Vessel diameter (mm)				
Mean±SD (n)	2.50±0.51 (170)	2.60±0.44 (127)	-0.11[-0.22,0.01]	0.0612
Range (min, max)	(1.29,4.58)	(1.42,4.05)		
MLD (mm)				
Mean±SD (n)	0.71±0.29 (170)	0.89±0.36 (127)	-0.19[-0.26,-0.11]	<.0001
Range (min, max)	(0.00,1.46)	(0.14,1.82)		
% Stenosis**				
Mean±SD (n)	71.6% ±11.0% (170)	65.7% ±11.9% (127)	5.9%[3.2%,8.5%]	<.0001
Range (min, max)	(32.9%,100.0%)	(40.0%,94.9%)		
Lesion Length (mm)				
Mean±SD (n)	18.16±8.46 (166)	14.29±6.41 (127)	3.87[2.09,5.64]	<.0001
Range (min, max)	(4.20,52.44)	(3.76,47.58)		
Post-index Procedure				
Reference Vessel diameter (mm)				
Mean±SD (n)	2.67±0.51 (170)	2.75±0.39 (126)	-0.07[-0.18,0.03]	0.1570
Range (min, max)	(1.43,4.63)	(1.67,3.86)		
In-Segment				
MLD (mm)				
Mean±SD (n)	2.17±0.49 (170)	2.32±0.42 (126)	-0.14[-0.25,-0.04]	0.0083
Range (min, max)	(0.99,4.04)	(1.31,3.36)		
% Stenosis**				
Mean±SD (n)	18.5% ±10.4% (170)	15.7% ±8.8% (126)	2.8%[0.6%,5.1%]	0.0112
Range (min, max)	(-11.2%,51.2%)	(-1.2%,35.5%)		
Within the Stent				
MLD (mm)				
Mean±SD (n)	2.50±0.46 (170)	2.64±0.38 (126)	-0.14[-0.24,-0.04]	0.0037
Range (min, max)	(1.03,4.11)	(1.46,3.43)		
Mean Diameter (mm)				
Mean±SD (n)	2.82±0.44 (170)	2.91±0.38 (126)	-0.10[-0.19,0.00]	0.0490
Range (min, max)	(1.87,4.59)	(2.01,3.87)		
% Stenosis**				
Mean±SD (n)	5.8% ±9.7% (170)	3.4% ±8.5% (126)	2.4%[0.2%,4.5%]	0.0296
Range (min, max)	(-24.1%,51.2%)	(-30.4%,19.8%)		

Lesion Characteristics	Pre Dilatation Subset (Number of Patients =170 Number of Lesions =170)	Direct Stenting Subset (Number of Patients =126 Number of Lesions =127*)	Difference	
			[95% CI]	P-value
Proximal Edge (mm)				
MLD (mm)				
Mean±SD (n)	2.64±0.61 (163)	2.74±0.54 (114)	-0.10[-0.24,0.04]	0.1751
Range (min, max)	(1.39,4.51)	(1.44,4.23)		
Mean Diameter (mm)				
Mean±SD (n)	2.85±0.60 (163)	2.90±0.50 (114)	-0.05[-0.19,0.08]	0.4280
Range (min, max)	(1.67,4.72)	(1.82,4.31)		
% Stenosis**				
Mean±SD (n)	0.1% ±20.1% (163)	-0.5% ±17.4% (114)	0.6%[-4.0%,5.1%]	0.8085
Range (min, max)	(-65.5%,44.5%)	(-52.5%,37.6%)		
Distal Edge (mm)				
MLD (mm)				
Mean±SD (n)	2.28±0.55 (169)	2.43±0.48 (126)	-0.14[-0.27,-0.02]	0.0193
Range (min, max)	(1.11,4.59)	(1.33,3.82)		
Mean Diameter (mm)				
Mean±SD (n)	2.48±0.53 (169)	2.62±0.46 (126)	-0.14[-0.25,-0.02]	0.0215
Range (min, max)	(1.38,4.79)	(1.45,4.15)		
% Stenosis**				
Mean±SD (n)	14.7% ±12.7% (169)	11.8% ±11.0% (126)	2.9%[0.1%,5.7%]	0.0410
Range (min, max)	(-9.0%,51.2%)	(-10.6%,41.1%)		

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.
Calculations are based "inter" normal projections in the angiographic data.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 7.d. Quantitative Angiographic Analysis (Interpolated) at 8 Months – Pre Dilatation vs. Direct Stenting

Lesion Characteristics	Pre Dilatation Subset (Number of Patients =69 Number of Lesions =69)	Direct Stenting Subset (Number of Patients =48 Number of Lesions =48)	Difference	
			[95% CI]	P-value
8-Month Follow-up				
Reference Vessel diameter (mm)				
Mean±SD (n)	2.45±0.44 (69)	2.55±0.44 (48)	-0.10[-0.26,0.06]	0.2292
Range (min, max)	(1.63,4.05)	(1.46,3.53)		
In-Segment				
MLD (mm)				
Mean±SD (n)	1.70±0.65 (69)	1.97±0.54 (48)	-0.26[-0.49,-0.04]	0.0223
Range (min, max)	(0.00,3.12)	(0.49,2.98)		
% Stenosis**				
Mean±SD (n)	30.3% ±23.9% (69)	22.5% ±18.0% (48)	7.7%[-0.3%,15.7%]	0.0481
Range (min, max)	(-6.3%,100.0%)	(-0.4%,75.4%)		
Within the Stent				
MLD (mm)				
Mean±SD (n)	1.82±0.69 (69)	2.07±0.55 (48)	-0.25[-0.49,-0.02]	0.0356
Range (min, max)	(0.00,3.12)	(0.49,2.98)		
Mean Diameter (mm)				
Mean±SD (n)	2.33±0.57 (69)	2.56±0.44 (48)	-0.23[-0.42,-0.03]	0.0215
Range (min, max)	(0.00,3.52)	(1.13,3.43)		
% Stenosis**				
Mean±SD (n)	25.8% ±25.2% (69)	17.7% ±21.0% (48)	8.1%[-0.7%,16.8%]	0.0698
Range (min, max)	(-6.7%,100.0%)	(-18.8%,75.4%)		
Proximal Edge (mm)				
MLD (mm)				
Mean±SD (n)	2.37±0.65 (64)	2.53±0.58 (45)	-0.15[-0.39,0.09]	0.2052
Range (min, max)	(0.72,4.07)	(0.98,3.49)		
Mean Diameter (mm)				
Mean±SD (n)	2.64±0.57 (64)	2.78±0.51 (45)	-0.14[-0.36,0.07]	0.1791
Range (min, max)	(1.55,4.12)	(1.58,3.68)		
% Stenosis**				
Mean±SD (n)	3.0% ±21.6% (64)	-1.7% ±25.3% (45)	4.8%[-4.2%,13.6%]	0.2948
Range (min, max)	(-44.8%,72.8%)	(-64.2%,67.9%)		
Distal Edge (mm)				
MLD (mm)				
Mean±SD (n)	2.17±0.49 (68)	2.32±0.51 (48)	-0.15[-0.33,0.04]	0.1156

Lesion Characteristics	Pre Dilatation Subset (Number of Patients =69 Number of Lesions =69)	Direct Stenting Subset (Number of Patients =48 Number of Lesions =48)	Difference	
			[95% CI]	P-value
Range (min, max)	(1.00,3.79)	(1.26,3.38)		
Mean Diameter (mm)				
Mean±SD (n)	2.34±0.48 (68)	2.54±0.47 (48)	-0.20[-0.38,-0.02]	0.0283
Range (min, max)	(1.21,3.95)	(1.54,3.64)		
% Stenosis**				
Mean±SD (n)	11.2% ±13.7% (68)	8.9% ±13.2% (48)	2.3%[-2.7%,7.3%]	0.3623
Range (min, max)	(-21.3%,61.7%)	(-12.5%,53.6%)		
Binary Restenosis				
In-Segment	21.7%(15/ 69)	10.4%(5/ 48)	11.3% [-1.7%, 24.3%]	0.1374
Within the Stent	18.8%(13/ 69)	10.4%(5/ 48)	8.4% [-4.2%, 21.1%]	0.2989
Proximal Edge	4.7%(3/ 64)	2.2%(1/ 45)	2.5% [-4.3%, 9.2%]	0.6412
Distal Edge	2.9%(2/ 68)	2.1%(1/ 48)	0.9% [-4.8%, 6.6%]	1.0000

n = Number of lesions with evaluable data

**Percentage Stenosis corresponding to MLD and RVD measurement, not Mean Diameter.

Calculations are based on “inter” normal projections in the angiographic data.

Table 8. Procedural Characteristics – ITT Set

Subject Characteristics	Endeavor Continued Access (Number of Patients =296 Number of Lesions = 297*)
Pre-Stent Balloon Angioplasty	
Nominal Diameters (mm)	
n	170
Mean	2.45
SD	0.29
Median	2.5
1 st quartile	2.5
3 rd quartile	2.5
Min-Max	1.5 - 3
Maximum Pressure (atm)	
n	167
Mean	11.29
SD	3.22
Median	12
1 st quartile	8
3 rd quartile	14
Min-Max	4 - 22
Stenting Procedure	
Maximum Pressure (atm)	
n	294
Mean	13.63
SD	2.83
Median	14
1 st quartile	12
3 rd quartile	16
Min-Max	8 - 20
Post-Stent Balloon Dilatation	
Nominal Diameters (mm)	
n	68
Mean	3.21
SD	0.5
Median	3.25
1 st quartile	3
3 rd quartile	3.5
Min-Max	2 - 4
Maximum Pressure (atm)	
n	67
Mean	15.33
SD	3.75
Median	16
1 st quartile	12
3 rd quartile	18
Min-Max	6 - 25

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 8. Procedural Characteristics – ITT Set (Continued)

Subject Characteristics	Endeavor Continued Access (Number of Patient =296) Number of Lesion = 297*)
2nd Post-Stent Balloon Dilatation	
Nominal Diameters (mm)	
n	23
Mean	3.13
SD	0.46
Median	3
1 st quartile	3
3 rd quartile	3.5
Min-Max	2.5 - 4
Maximum Pressure (atm)	
n	24
Mean	13.08
SD	3.75
Median	12
1 st quartile	10
3 rd quartile	16
Min-Max	6 - 20
Maximum Balloon Pressure (atm)	
n	76
Mean	14.97
SD	3.85
Median	16
1 st quartile	12
3 rd quartile	18
Min-Max	6 - 25
Nominal Balloon Diameter (mm)	
n	76
Mean	3.22
SD	0.5
Median	3.5
1 st quartile	3
3 rd quartile	3.5
Min-Max	2 - 4

Page 2 of 2

n = Number of patients with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

This Table is not based on Angiographic Core Lab assessment.

Table 9.a. Acute Gain and Late Loss – ITT Set

Lesion Characteristic	Endeavor Continued Access (Number of Patients =296 Number of Lesions = 297*)
Acute Gain (mm)	
In-Segment	
n	296
Mean	1.45
SD	0.5
Median	1.44
1st quartile	1.1
3rd quartile	1.77
Min-Max	0.09- 3.49
Within the Stent	
n	296
Mean	1.77
SD	0.47
Median	1.72
1st quartile	1.46
3rd quartile	2.04
Min-Max	0.43- 3.49
8-Month Late Loss (mm)	
In-Segment Late Loss	
n	117
Mean	0.39
SD	0.56
Median	0.24
1st quartile	0.04
3rd quartile	0.61
Min-Max	-0.71- 2.24
Within the Stent	
In-Stent Late Loss	
n	117
Mean	0.58
SD	0.58
Median	0.45
1st quartile	0.19
3rd quartile	0.82
Min-Max	-0.51- 2.44
Mean Diameter Late Loss	
n	117
Mean	0.39
SD	0.41
Median	0.34
1st quartile	0.16
3rd quartile	0.63
Min-Max	-0.36- 2.42
Within the Proximal Edge (mm)	

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Lesion Characteristic	Endeavor Continued Access (Number of Patients =117 Number of Lesions = 117)
MLD Late Loss (mm)	
n	107
Mean	0.24
SD	0.44
Median	0.23
1st quartile	-0.1
3rd quartile	0.49
Min-Max	-0.78- 2.05
Mean Diameter Late Loss	
n	107
Mean	0.17
SD	0.34
Median	0.18
1st quartile	-0.06
3rd quartile	0.4
Min-Max	-0.89- 0.88
Within the Distal Edge (mm)	
MLD Late Loss (mm)	
n	116
Mean	0.08
SD	0.42
Median	0.05
1st quartile	-0.17
3rd quartile	0.33
Min-Max	-0.94- 1.52
Mean Diameter Late Loss	
n	116
Mean	0.09
SD	0.34
Median	0.06
1st quartile	-0.13
3rd quartile	0.28
Min-Max	-0.7- 1.23
Loss Index	
In-Segment	
Arithmetic	
n	117
Mean	0.25
SD	0.47
Median	0.18
1st quartile	0.03
3rd quartile	0.42
Min-Max	-1.6- 1.68
Regression	
Coefficient ± SE	0.30± 0.03
Within the Stent	
Arithmetic	
n	117
Mean	0.34
SD	0.38
Median	0.27
1st quartile	0.12

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Lesion Characteristic	Endeavor Continued Access (Number of Patients =117 Number of Lesions = 117)
3rd quartile	0.45
Min-Max	-1.19- 1.49
Regression Coefficient ± SE	0.34± 0.03

All variables are from assessment by Angiographic Core Laboratory

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

In-Segment – The Axial length between the proximal and distal reference vessels, including the 5 mm proximal and distal margins of the stent.

Acute Gain was defined as the immediate dimensional change in minimal lumen diameter (in mm) that occurred after the final post dilatation as compared with minimal lumen diameter at baseline and measured by quantitative coronary angiography from the average from 2 orthogonal views

Table 9.b. Acute Gain and Late Loss – Pre Dilatation vs. Direct Stenting

Lesion Characteristic	Pre Dilatation Subset (Number of Patients =170	Direct Stenting Subset (Number of Patients =126	Difference	
	Number of Lesions = 170)	Number of Lesions = 127*)	[95% CI]	P-value
Acute Gain (mm)				
In-Segment				
Mean±SD (n)	1.47±0.52 (170)	1.42±0.48 (126)	0.05[-0.07,0.16]	0.4396
Range (min, max)	(0.09,3.49)	(0.45,2.60)		
Within the Stent				
Mean±SD (n)	1.79±0.48 (170)	1.75±0.46 (126)	0.05[-0.06,0.15]	0.3994
Range (min, max)	(0.43,3.49)	(0.91,3.05)		
8-Month Late Loss (mm)				
In-Segment Late Loss				
Mean±SD (n)	0.41±0.57 (69)	0.37±0.55 (48)	0.05[-0.16,0.26]	0.6597
Range (min, max)	(-0.53,2.08)	(-0.71,2.24)		
Within the Stent				
In-Stent Late Loss				
Mean±SD (n)	0.59±0.60 (69)	0.56±0.56 (48)	0.03[-0.19,0.25]	0.7839
Range (min, max)	(-0.51,2.44)	(-0.12,2.34)		
Mean Diameter Late Loss				
Mean±SD (n)	0.42±0.45 (69)	0.35±0.36 (48)	0.06[-0.09,0.22]	0.4299
Range (min, max)	(-0.36,2.42)	(-0.23,1.50)		
Within the Proximal Edge (mm)				
MLD Late Loss (mm)				
Mean±SD (n)	0.24±0.45 (64)	0.25±0.44 (43)	-0.01[-0.18,0.17]	0.9322
Range (min, max)	(-0.78,1.26)	(-0.36,2.05)		
Mean Diameter Late Loss				
Mean±SD (n)	0.18±0.37 (64)	0.16±0.28 (43)	0.02[-0.12,0.15]	0.8032
Range (min, max)	(-0.89,0.88)	(-0.33,0.84)		
Within the Distal Edge (mm)				
MLD Late Loss (mm)				
Mean±SD (n)	0.07±0.37 (68)	0.10±0.48 (48)	-0.03[-0.19,0.13]	0.6956

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Lesion Characteristic	Pre Dilatation Subset (Number of Patients =69 Number of Lesions = 69)	Direct Stenting Subset (Number of Patients =48 Number of Lesions =48)	Difference [95% CI]	P-value
Range (min, max)	(-0.67,1.12)	(-0.94,1.52)		
Mean Diameter Late Loss				
Mean±SD (n)	0.10±0.35 (68)	0.07±0.31 (48)	0.03[-0.10,0.15]	0.6910
Range (min, max)	(-0.70,1.23)	(-0.63,0.79)		
Loss Index				
In-Segment				
Arithmetic				
Mean±SD (n)	0.28±0.50 (69)	0.21±0.43 (48)	0.06[-0.11,0.24]	0.4818
Range (min, max)	(-0.97,1.68)	(-1.60,1.49)		
Regression				
Coefficient ± SE	0.30± 0.04	0.30± 0.05		
Within the Stent				
Arithmetic				
Mean±SD (n)	0.35±0.43 (69)	0.32±0.29 (48)	0.03[-0.11,0.17]	0.6216
Range (min, max)	(-1.19,1.45)	(-0.09,1.49)		
Regression				
Coefficient ± SE	0.34± 0.04	0.35± 0.04		

All variables are from assessment by Angiographic Core Laboratory

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

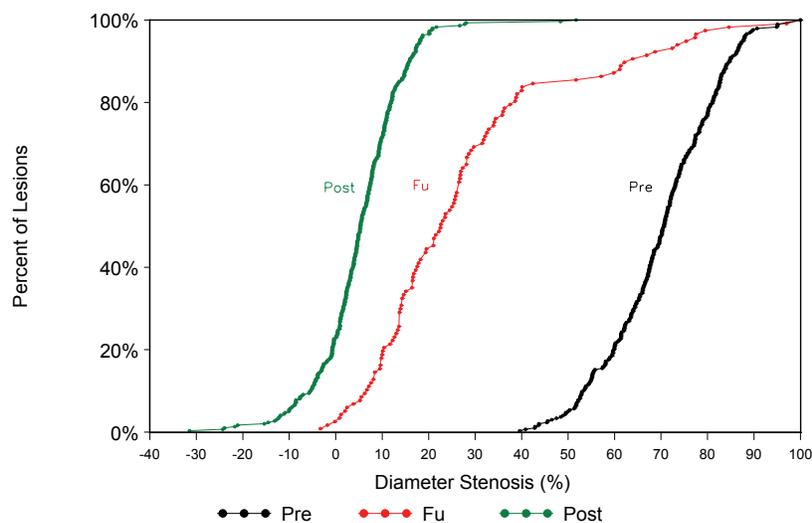
In-Segment – The Axial length between the proximal and distal reference vessels, including the 5 mm proximal and distal margins of the stent.

Acute Gain was defined as the immediate dimensional change in minimal lumen diameter (in mm) that occurred after the final post dilatation as compared with minimal lumen diameter at baseline and measured by quantitative coronary angiography from the average from 2 orthogonal views

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

**Figure 1. Cumulative Frequency Distribution of In-Stent Percent Diameter Stenosis
ITT Set**



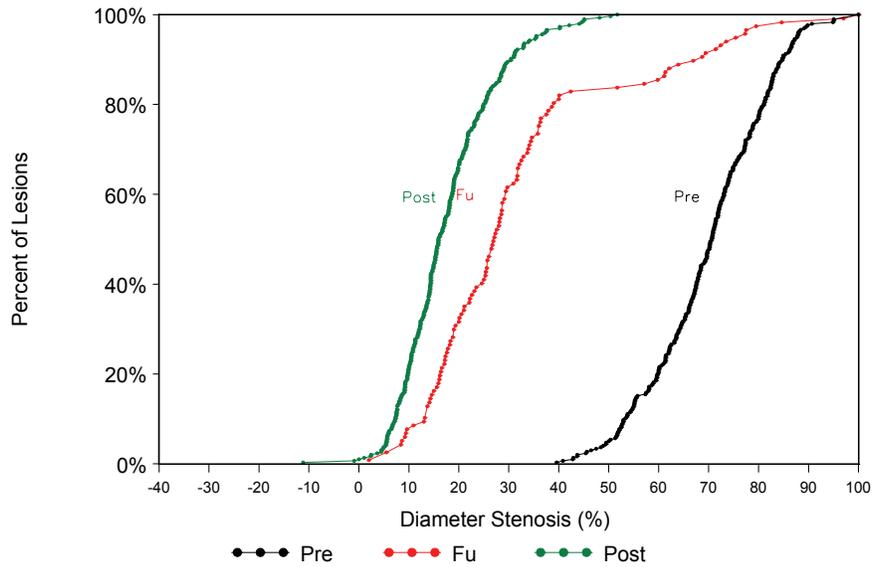
	Pre-Procedure (Number of patients =296)	Eight-Month Follow-up in-stent (Number of patients =147)	Post-index Procedure in-stent (Number of patients =296)
n	297	117	296
Median	70.61%	22.60%	5.28%
Minimum	39.59%	-3.30%	-31.46%
Maximum	100.00%	100.00%	51.72%
Mean	70.03%	27.67%	5.27%
SD	11.83%	21.95%	9.45%
COV	0.17%	0.79%	1.79%

n = Number of lesions with evaluable data

COV: Coefficient of variation

All variables are from assessment by the Angiographic Core Laboratory

**Figure 2. Cumulative Frequency Distribution of In-Segment Percent Diameter Stenosis
ITT Set**



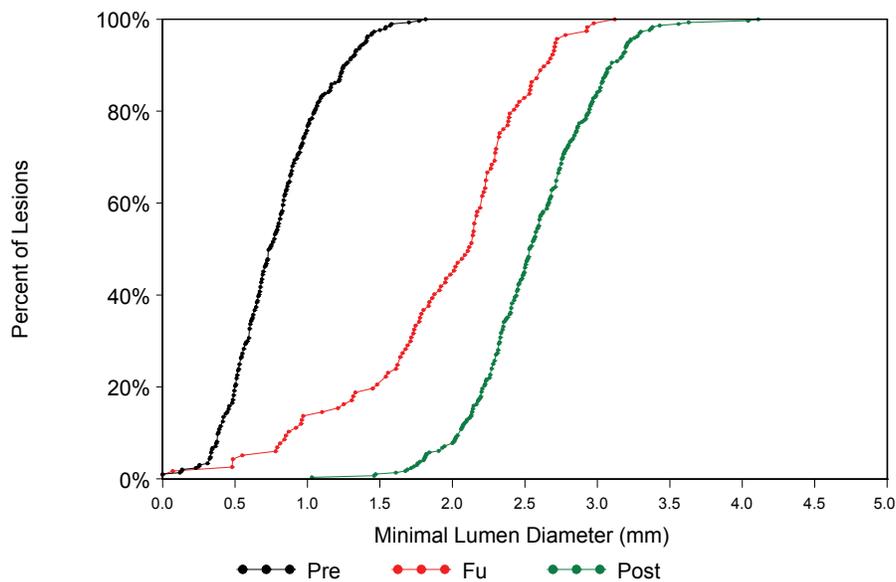
	Pre-Procedure (Number of patients =296)	Eight-Month Follow-up in-Segment (Number of patients =147)	Post-index Procedure in-Segment (Number of patients =296)
n	297	117	296
Median	70.61%	27.10%	15.94%
Minimum	39.59%	2.00%	-11.17%
Maximum	100.00%	100.00%	51.72%
Mean	70.03%	31.93%	17.76%
SD	11.83%	20.54%	9.57%
COV	0.17%	0.64%	0.54%

n = Number of lesions with evaluable data
COV: Coefficient of variation
All variables are from assessment by the Angiographic Core Laboratory

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

**Figure 3. Cumulative Frequency Distribution of In-Stent Minimum Lumen Diameter
ITT Set**



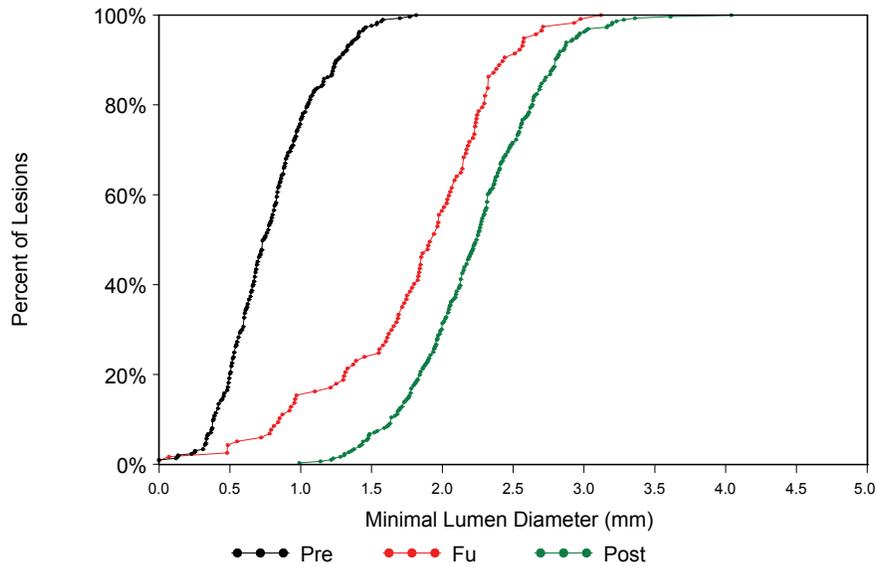
	Pre-Procedure (Number of patients =296)	Eight-Month Follow- up in-stent (Number of patients =147)	Post-index Procedure in-stent (Number of patients =296)
n	297	117	296
Median	0.74	2.12	2.53
Minimum	0.00	0.00	1.03
Maximum	1.82	3.12	4.11
Mean	0.78	1.92	2.56
SD	0.33	0.65	0.43
COV	0.42	0.34	0.17

n = Number of lesions with evaluable data

COV: Coefficient of variation

All variables are from assessment by the Angiographic Core Laboratory

**Figure 4. Cumulative Frequency Distribution of In-Segment Minimum Lumen Diameter
ITT Set**



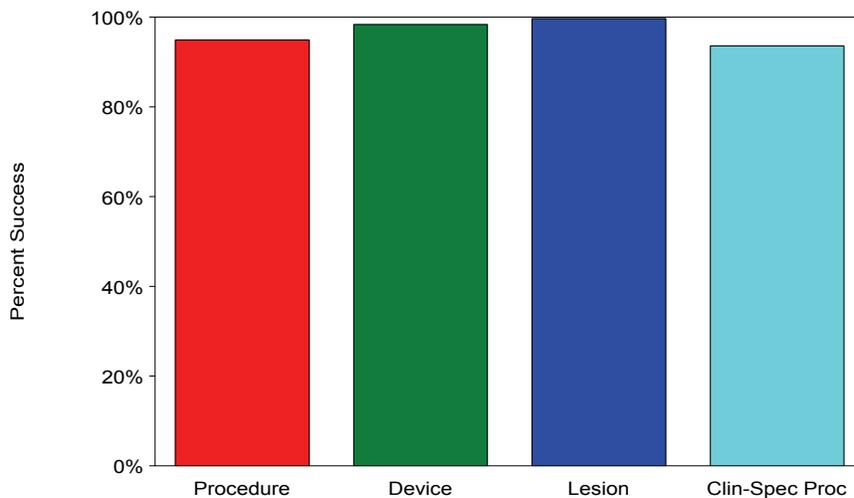
	Pre-Procedure (Number of patients =296)	Eight-Month Follow-up in-Segment (Number of patients =147)	Post-index Procedure in-Segment (Number of patients =296)
n	297	117	296
Median	0.74	1.94	2.25
Minimum	0.00	0.00	0.99
Maximum	1.82	3.12	4.04
Mean	0.78	1.81	2.24
SD	0.33	0.61	0.46
COV	0.42	0.34	0.21

n = Number of lesions with evaluable data

COV: Coefficient of variation

All variables are from assessment by the Angiographic Core Laboratory

**Figure 5. Acute Success
ITT Set**



		Endeavor Continued Access (Number of Patients =296) Number of Lesions = 297*)
Lesion		
Success % (#/n)		99.7% (295/296)
95% CI		(98.1%, 100.0%)
Device		
Success % (#/n)		98.3% (292/297)
95% CI		(96.1%, 99.5%)
Procedure		
Success % (#/n)		94.9% (280/295)
95% CI		(91.8%, 97.1%)
Device-Specific Procedure		
Success % (#/n)		93.6% (277/296)
95% CI		(90.2%, 96.1%)

n = Number of lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

Lesion Success: Attainment of <50% in-stent residual stenosis using any percutaneous method

Device Success: Attainment of <50% in-stent residual stenosis using only the assigned device

Procedure Success: Attainment of <50% in-stent residual stenosis using any percutaneous method and no in-hospital MACE

Device-Specific Procedure Success: Attainment of <50% in-stent residual stenosis using only the assigned device and no in-hospital MACE.

Table 10. Post-Procedure Morphology and Length of Hospital Stay – ITT Set

	Endeavor Continued Access (Number of Patients=296 Number of Lesions = 297*)
Post-Procedure Length of Hospital Stay (days)	
n	296
Mean	2.05
SD	3.15
Median	1
1 st quartile	1
3 rd quartile	2
Min-Max	0- 31
Diameter of stents implanted (per stent)	
2.25 mm	2% (7/355)
2.5 mm	20% (71/355)
3 mm	49.3% (175/355)
3.5 mm	28.7% (102/355)
Post-Procedure Thrombus** % (#/n)	0.3% (1/296)
Post-Procedure Dissection** % (#/n)	
None	98% (290/296)
Type A	0.7% (2/296)
Type B	0.7% (2/296)
Type C	0.3% (1/296)
Type D	0% (0/296)
Type E	0.3% (1/296)
Type F	0% (0/296)
Post-Procedure TIMI** % (#/n)	
0	0% (0/296)
1	0% (0/296)
2	1% (3/296)
3	99% (293/296)

n = Number of patients/lesions with evaluable data

*Patient 603-035 had 2 lesions treated with Endeavor stent

**As assessed by the Angiographic Core Laboratory based on lesion level

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 11. Follow-Up Morphology – ITT Set

	Endeavor Continued Access (Number of Patients=117 Number of Lesions =117)
Eight-Month Follow-up*	
Thrombus	0.9% (1/117)**
TIMI FLOW	
0	0.9% (1/117)**
1	0% (0/117)
2	2.6% (3/117)
3	96.6% (113/117)
Total Occlusion	0.9% (1/117)
In-stent Restenosis Pattern	
IA	5% (1/20)
IB	25% (5/20)
IC	10% (2/20)
ID	0% (0/20)
II	35% (7/20)
III	20% (4/20)
IV	5% (1/20)
ISR Length (mm)	
n	19
Mean	13.7
SD	7.24
Median	13.26
1st quartile	6.91
3rd quartile	19
Min-Max	4.67- 30.32

n = Number of patients/lesions with evaluable data

*As assessed by the Angiographic Core Laboratory based on lesion level

** The Thrombus and TIMI flow 0 at 8 months occurred for patient 61411. The event was adjudicated by the CEC as a total occlusion. No revascularization was performed at the time. Six months later, when the patient had complaints and a non Q-wave MI had occurred, a repeat angiography revealed that revascularization was required. A CABG was performed.

Table 12.a. Major Adverse Cardiac Events – In and Out of Hospital (to 30 days) – ITT Set

Description of Event	Endeavor Continued Access (N=296)	
	Number	%
In-Hospital complications		
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	14	4.7%
Death	0	0%
MI (Q Wave or Non-Q wave)	14	4.7%
Q Wave MI	1	0.3%
Non-Q Wave MI	13	4.4%
Emergent CABG	0	0%
Target Lesion Revascularization	0	0%
TL-CABG	0	0%
TL-PTCA	0	0%
Target Vessel Revascularization not involving Target Lesion	2	0.7%
TV/non-TL-CABG	0	0%
TV/non-TL-PTCA	2	0.7%
Target Vessel Revascularization	2	0.7%
Target Vessel Failure	15	5.1%
Perforation	1	0.3%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	1	0.3%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.3%
Out-of-Hospital complications to 30 days		
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	2	0.7%
Death	0	0%
MI (Q Wave or Non-Q wave)	0	0%
Q Wave MI	0	0%
Non-Q Wave MI	0	0%
Emergent CABG	1	0.3%
Target Lesion Revascularization	1	0.3%
TL-CABG	0	0%
TL-PTCA	1	0.3%
Target Vessel Revascularization not involving Target Lesion	1	0.3%
TV/non-TL-CABG	1	0.3%
TV/non-TL-PTCA	0	0%
Target Vessel Revascularization	2	0.7%
Target Vessel Failure	2	0.7%
Perforation	0	0%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	0	0%

Page 1 of 2

N=Number of patients with 30-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

**Table 12.a. Major Adverse Cardiac Events – In and Out of Hospital (to 30 days) – ITT Set
(Continued)**

Description of Event	Endeavor Continued Access (N=296)	
	Number	%
Combined In- and Out-of-Hospital complications to 30 days		
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	16	5.4%
Death	0	0%
MI (Q Wave or Non-Q wave)	14	4.7%
Q Wave MI	1	0.3%
Non-Q Wave MI	13	4.4%
Emergent CABG	1	0.3%
Target Lesion Revascularization	1	0.3%
TL-CABG	0	0%
TL-PTCA	1	0.3%
Target Vessel Revascularization not involving Target Lesion	3	1.0%
TV/non-TL-CABG	1	0.3%
TV/non-TL-PTCA	2	0.7%
Target Vessel Revascularization	4	1.4%
Target Vessel Failure	17	5.7%
Perforation	1	0.3%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	1	0.3%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.3%

Page 2 of 2

N=Number of patients with 30-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Table 12.b. Major Adverse Cardiac Events – In- and Out-of-Hospital (to 30 days) – Direct Stenting Subset

Description of Event	Endeavor Continued Access (N=126)	
	Number	%
In-Hospital complications		
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	7	5.6%
Death	0	0%
MI (Q Wave or Non-Q wave)	7	5.6%
Q Wave MI	1	0.8%
Non-Q Wave MI	6	4.8%
Emergent CABG	0	0%
Target Lesion Revascularization	0	0%
TL-CABG	0	0%
TL-PTCA	0	0%
Target Vessel Revascularization not involving Target Lesion	1	0.8%
TV/non-TL-CABG	0	0%
TV/non-TL-PTCA	1	0.8%
Target Vessel Revascularization	1	0.8%
Target Vessel Failure	8	6.3%
Perforation	1	0.8%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	1	0.8%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.8%
Out-of-Hospital complications to 30 days		
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	1	0.8%
Death	0	0%
MI (Q Wave or Non-Q wave)	0	0%
Q Wave MI	0	0%
Non-Q Wave MI	0	0%
Emergent CABG	1	0.8%
Target Lesion Revascularization	0	0%
TL-CABG	0	0%
TL-PTCA	0	0%
Target Vessel Revascularization not involving Target Lesion	1	0.8%
TV/non-TL-CABG	1	0.8%
TV/non-TL-PTCA	0	0%
Target Vessel Revascularization	1	0.8%
Target Vessel Failure	1	0.8%
Perforation	0	0%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	0	0%

Page 1 of 2

N=Number of patients with 30-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 12.b. Major Adverse Cardiac Events – In and Out of Hospital (to 30 days) – Direct Stenting Subset (Continued)

Description of Event	Endeavor Continued Access (N=126)	
	Number	%
Combined In- and Out-of-Hospital complications to 30 days		
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	8	6.3%
Death	0	0%
MI (Q Wave or Non-Q wave)	7	5.6%
Q Wave MI	1	0.8%
Non-Q Wave MI	6	4.8%
Emergent CABG	1	0.8%
Target Lesion Revascularization	0	0%
TL-CABG	0	0%
TL-PTCA	0	0%
Target Vessel Revascularization not involving Target Lesion	2	1.6%
TV/non-TL-CABG	1	0.8%
TV/non-TL-PTCA	1	0.8%
Target Vessel Revascularization	2	1.6%
Target Vessel Failure	9	7.1%
Perforation	1	0.8%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	1	0.8%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.8%

Page 2 of 2

N=Number of patients with 30-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Table 12.c. Major Adverse Cardiac Events – In- and Out-of-Hospital (to 30 days) – Pre Dilatation Subset

Description of Event	Endeavor Continued Access (N=170)	
	Number	%
In-Hospital complications		
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	7	4.1%
Death	0	0%
MI (Q Wave or Non-Q wave)	7	4.1%
Q Wave MI	0	0%
Non-Q Wave MI	7	4.1%
Emergent CABG	0	0%
Target Lesion Revascularization	0	0%
TL-CABG	0	0%
TL-PTCA	0	0%
Target Vessel Revascularization not involving Target Lesion	1	0.6%
TV/non-TL-CABG	0	0%
TV/non-TL-PTCA	1	0.6%
Target Vessel Revascularization	1	0.6%
Target Vessel Failure	7	4.1%
Perforation	0	0%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	0	0%
Out-of-Hospital complications to 30 days		
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	1	0.6%
Death	0	0%
MI (Q Wave or Non-Q wave)	0	0%
Q Wave MI	0	0%
Non-Q Wave MI	0	0%
Emergent CABG	0	0%
Target Lesion Revascularization	1	0.6%
TL-CABG	0	0%
TL-PTCA	1	0.6%
Target Vessel Revascularization not involving Target Lesion	0	0%
TV/non-TL-CABG	0	0%
TV/non-TL-PTCA	0	0%
Target Vessel Revascularization	1	0.6%
Target Vessel Failure	1	0.6%
Perforation	0	0%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	0	0%

Page 1 of 2

N=Number of patients with 30-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 12.c. Major Adverse Cardiac Events – In and Out of Hospital (to 30 days) – Pre Dilatation Subset (Continued)

Description of Event	Endeavor Continued Access (N=170)	
	Number	%
Combined In- and Out-of-Hospital complications to 30 days		
MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	8	4.7%
Death	0	0%
MI (Q Wave or Non-Q wave)	7	4.1%
Q Wave MI	0	0%
Non-Q Wave MI	7	4.1%
Emergent CABG	0	0%
Target Lesion Revascularization	1	0.6%
TL-CABG	0	0%
TL-PTCA	1	0.6%
Target Vessel Revascularization not involving Target Lesion	1	0.6%
TV/non-TL-CABG	0	0%
TV/non-TL-PTCA	1	0.6%
Target Vessel Revascularization	2	1.2%
Target Vessel Failure	8	4.7%
Perforation	0	0%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	0	0%

Page 2 of 2

N=Number of patients with 30-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Table 13.a. Major Adverse Cardiac Events (to 30 days) – ITT Set

Hierarchical Complications (to 30 days)	Endeavor Continued Access (N=296)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	16	5.4%
Death	0	0%
Non-fatal Q Wave MI	1	0.3%
Non-fatal Non-Q Wave MI	13	4.4%
Emergent CABG without Death or MI	1	0.3%
TL-CABG without Death or MI	0	0%
TL-PTCA without Death, MI, or TL-CABG	1	0.3%
Non-Hierarchical Complications (to 30 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	16	5.4%
Death	0	0%
MI (Q Wave or Non-Q wave)	14	4.7%
Q Wave MI	1	0.3%
Non-Q Wave MI	13	4.4%
Emergent CABG	1	0.3%
Target Lesion Revascularization	1	0.3%
TL-CABG	0	0%
TL-PTCA	1	0.3%
Target Vessel Revascularization not involving Target Lesion	3	1.0%
TV/non-TL-CABG	1	0.3%
TV/non-TL-PTCA	2	0.7%
Target Vessel Revascularization	4	1.4%
Target Vessel Failure	17	5.7%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	1	0.3%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.3%

N=Number of patients with 30-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 13.b. Major Adverse Cardiac Events (to 30 days) – Direct Stenting Subset

Hierarchical Complications (to 30 days)	Endeavor Continued Access (N=126)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	8	6.3%
Death	0	0%
Non-fatal Q Wave MI	1	0.8%
Non-fatal Non-Q Wave MI	6	4.8%
Emergent CABG without Death or MI	1	0.8%
TL-CABG without Death or MI	0	0%
TL-PTCA without Death, MI, or TL-CABG	0	0%
Non-Hierarchical Complications (to 30 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	8	6.3%
Death	0	0%
MI (Q Wave or Non-Q wave)	7	5.6%
Q Wave MI	1	0.8%
Non-Q Wave MI	6	4.8%
Emergent CABG	1	0.8%
Target Lesion Revascularization	0	0%
TL-CABG	0	0%
TL-PTCA	0	0%
Target Vessel Revascularization not involving Target Lesion	2	1.6%
TV/non-TL-CABG	1	0.8%
TV/non-TL-PTCA	1	0.8%
Target Vessel Revascularization	2	1.6%
Target Vessel Failure	9	7.1%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	1	0.8%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.8%

N=Number of patients with 30-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Table 13.c. Major Adverse Cardiac Events (to 30 days) – Pre Dilatation Subset

Hierarchical Complications (to 30 days)	Endeavor Continued Access (N=170)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	8	4.7%
Death	0	0%
Non-fatal Q Wave MI	0	0%
Non-fatal Non-Q Wave MI	7	4.1%
Emergent CABG without Death or MI	0	0%
TL-CABG without Death or MI	0	0%
TL-PTCA without Death, MI, or TL-CABG	1	0.6%
Non-Hierarchical Complications (to 30 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	8	4.7%
Death	0	0%
MI (Q Wave or Non-Q wave)	7	4.1%
Q Wave MI	0	0%
Non-Q Wave MI	7	4.1%
Emergent CABG	0	0%
Target Lesion Revascularization	1	0.6%
TL-CABG	0	0%
TL-PTCA	1	0.6%
Target Vessel Revascularization not involving Target Lesion	1	0.6%
TV/non-TL-CABG	0	0%
TV/non-TL-PTCA	1	0.6%
Target Vessel Revascularization	2	1.2%
Target Vessel Failure	8	4.7%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	0	0%

N=Number of patients with 30-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 14.a. Major Adverse Cardiac Events (to 180 days) – ITT Set

Hierarchical Complications (to 180 days)	Endeavor Continued Access (N=295)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	20	6.8%
Death	2	0.7%
Non-fatal Q Wave MI	1	0.3%
Non-fatal Non-Q Wave MI	12	4.1%
Emergent CABG without Death or MI	1	0.3%
TL-CABG without Death or MI	0	0%
TL-PTCA without Death, MI, or TL-CABG	4	1.4%
Non-Hierarchical Complications (to 180 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	20	6.8%
Death	2	0.7%
MI (Q Wave or Non-Q wave)	14	4.7%
Q Wave MI	1	0.3%
Non-Q Wave MI	13	4.4%
Emergent CABG	1	0.3%
Target Lesion Revascularization	4	1.4%
TL-CABG	0	0%
TL-PTCA	4	1.4%
Target Vessel Revascularization not involving Target Lesion	7	2.4%
TV/non-TL-CABG	2	0.7%
TV/non-TL-PTCA	5	1.7%
Target Vessel Revascularization	11	3.7%
Target Vessel Failure	24	8.1%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	1	0.3%
Cerebrovascular Accident (CVA)	1	0.3%
Major Bleeding Complications	1	0.3%

N=Number of patients with 180-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 14.b. Major Adverse Cardiac Events (to 180 days) – Direct Stenting Subset

Hierarchical Complications (to 180 days)	Endeavor Continued Access (N=126)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	9	7.1%
Death	1	0.8%
Non-fatal Q Wave MI	1	0.8%
Non-fatal Non-Q Wave MI	6	4.8%
Emergent CABG without Death or MI	1	0.8%
TL-CABG without Death or MI	0	0%
TL-PTCA without Death, MI, or TL-CABG	0	0%
Non-Hierarchical Complications (to 180 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	9	7.1%
Death	1	0.8%
MI (Q Wave or Non-Q wave)	7	5.6%
Q Wave MI	1	0.8%
Non-Q Wave MI	6	4.8%
Emergent CABG	1	0.8%
Target Lesion Revascularization	0	0%
TL-CABG	0	0%
TL-PTCA	0	0%
Target Vessel Revascularization not involving Target Lesion	4	3.2%
TV/non-TL-CABG	2	1.6%
TV/non-TL-PTCA	2	1.6%
Target Vessel Revascularization	4	3.2%
Target Vessel Failure	11	8.7%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	1	0.8%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.8%

N=Number of patients with 180-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 14.c. Major Adverse Cardiac Events (to 180 days) – Pre Dilatation Subset

Hierarchical Complications (to 180 days)	Endeavor Continued Access (N=169)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	11	6.5%
Death	1	0.6%
Non-fatal Q Wave MI	0	0%
Non-fatal Non-Q Wave MI	6	3.6%
Emergent CABG without Death or MI	0	0%
TL-CABG without Death or MI	0	0%
TL-PTCA without Death, MI, or TL-CABG	4	2.4%
Non-Hierarchical Complications (to 180 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	11	6.5%
Death	1	0.6%
MI (Q Wave or Non-Q wave)	7	4.1%
Q Wave MI	0	0%
Non-Q Wave MI	7	4.1%
Emergent CABG	0	0%
Target Lesion Revascularization	4	2.4%
TL-CABG	0	0%
TL-PTCA	4	2.4%
Target Vessel Revascularization not involving Target Lesion	3	1.8%
TV/non-TL-CABG	0	0%
TV/non-TL-PTCA	3	1.8%
Target Vessel Revascularization	7	4.1%
Target Vessel Failure	13	7.7%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	1	0.6%
Major Bleeding Complications	0	0%

N=Number of patients with 180-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Table 15.a. Major Adverse Cardiac Events (to 270 days) – ITT Set

Hierarchical Complications (to 270 days)	Endeavor Continued Access (N=293)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	31	10.6%
Death	2	0.7%
Non-fatal Q Wave MI	1	0.3%
Non-fatal Non-Q Wave MI	13	4.4%
Emergent CABG without Death or MI	1	0.3%
TL-CABG without Death or MI	1	0.3%
TL-PTCA without Death, MI, or TL-CABG	13	4.4%
Non-Hierarchical Complications (to 270 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	31	10.6%
Death	2	0.7%
MI (Q Wave or Non-Q wave)	15	5.1%
Q Wave MI	1	0.3%
Non-Q Wave MI	14	4.8%
Emergent CABG	1	0.3%
Target Lesion Revascularization	15	5.1%
TL-CABG	1	0.3%
TL-PTCA	14	4.8%
Target Vessel Revascularization not involving Target Lesion	12	4.1%
TV/non-TL-CABG	3	1.0%
TV/non-TL-PTCA	9	3.1%
Target Vessel Revascularization	26	8.9%
Target Vessel Failure	38	13.0%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	1	0.3%
Cerebrovascular Accident (CVA)	1	0.3%
Major Bleeding Complications	1	0.3%

N=Number of patients with 270-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 15.b. Major Adverse Cardiac Events (to 270 days) – Direct Stenting Subset

Hierarchical Complications (to 270 days)	Endeavor Continued Access (N=126)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	13	10.3%
Death	1	0.8%
Non-fatal Q Wave MI	1	0.8%
Non-fatal Non-Q Wave MI	6	4.8%
Emergent CABG without Death or MI	1	0.8%
TL-CABG without Death or MI	0	0%
TL-PTCA without Death, MI, or TL-CABG	4	3.2%
Non-Hierarchical Complications (to 270 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	13	10.3%
Death	1	0.8%
MI (Q Wave or Non-Q wave)	7	5.6%
Q Wave MI	1	0.8%
Non-Q Wave MI	6	4.8%
Emergent CABG	1	0.8%
Target Lesion Revascularization	4	3.2%
TL-CABG	0	0%
TL-PTCA	4	3.2%
Target Vessel Revascularization not involving Target Lesion	7	5.6%
TV/non-TL-CABG	2	1.6%
TV/non-TL-PTCA	5	4.0%
Target Vessel Revascularization	11	8.7%
Target Vessel Failure	17	13.5%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	1	0.8%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.8%

N=Number of patients with 270-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 15.c. Major Adverse Cardiac Events (to 270 days) – Pre Dilatation Subset

Hierarchical Complications (to 270 days)	Endeavor Continued Access (N=167)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	18	10.8%
Death	1	0.6%
Non-fatal Q Wave MI	0	0%
Non-fatal Non-Q Wave MI	7	4.2%
Emergent CABG without Death or MI	0	0%
TL-CABG without Death or MI	1	0.6%
TL-PTCA without Death, MI, or TL-CABG	9	5.4%
Non-Hierarchical Complications (to 270 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	18	10.8%
Death	1	0.6%
MI (Q Wave or Non-Q wave)	8	4.8%
Q Wave MI	0	0%
Non-Q Wave MI	8	4.8%
Emergent CABG	0	0%
Target Lesion Revascularization	11	6.6%
TL-CABG	1	0.6%
TL-PTCA	10	6.0%
Target Vessel Revascularization not involving Target Lesion	5	3.0%
TV/non-TL-CABG	1	0.6%
TV/non-TL-PTCA	4	2.4%
Target Vessel Revascularization	15	9.0%
Target Vessel Failure	21	12.6%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	1	0.6%
Major Bleeding Complications	0	0%

N=Number of patients with 270-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 16.a. Major Adverse Cardiac Events (to 360 days) – ITT Set

Hierarchical Complications (to 360 days)	Endeavor Continued Access (N=292)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	36	12.3%
Death	2	0.7%
Non-fatal Q Wave MI	1	0.3%
Non-fatal Non-Q Wave MI	14	4.8%
Emergent CABG without Death or MI	1	0.3%
TL-CABG without Death or MI	3	1.0%
TL-PTCA without Death, MI, or TL-CABG	15	5.1%
Non-Hierarchical Complications (to 360 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	36	12.3%
Death	2	0.7%
MI (Q Wave or Non-Q wave)	16	5.5%
Q Wave MI	1	0.3%
Non-Q Wave MI	15	5.1%
Emergent CABG	1	0.3%
Target Lesion Revascularization	19	6.5%
TL-CABG	3	1.0%
TL-PTCA	17	5.8%
Target Vessel Revascularization not involving Target Lesion	17	5.8%
TV/non-TL-CABG	5	1.7%
TV/non-TL-PTCA	12	4.1%
Target Vessel Revascularization	34	11.6%
Target Vessel Failure	46	15.8%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	1	0.3%
Cerebrovascular Accident (CVA)	1	0.3%
Major Bleeding Complications	1	0.3%

N=Number of patients with 360-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 16.b. Major Adverse Cardiac Events (to 360 days) – Direct Stenting Subset

Hierarchical Complications (to 360 days)	Endeavor Continued Access (N=125)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	14	11.2%
Death	1	0.8%
Non-fatal Q Wave MI	1	0.8%
Non-fatal Non-Q Wave MI	6	4.8%
Emergent CABG without Death or MI	1	0.8%
TL-CABG without Death or MI	0	0%
TL-PTCA without Death, MI, or TL-CABG	5	4.0%
Non-Hierarchical Complications (to 360 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	14	11.2%
Death	1	0.8%
MI (Q Wave or Non-Q wave)	7	5.6%
Q Wave MI	1	0.8%
Non-Q Wave MI	6	4.8%
Emergent CABG	1	0.8%
Target Lesion Revascularization	5	4.0%
TL-CABG	0	0%
TL-PTCA	5	4.0%
Target Vessel Revascularization not involving Target Lesion	8	6.4%
TV/non-TL-CABG	2	1.6%
TV/non-TL-PTCA	6	4.8%
Target Vessel Revascularization	13	10.4%
Target Vessel Failure	18	14.4%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	1	0.8%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.8%

N=Number of patients with 360-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 16.c. Major Adverse Cardiac Events (to 360 days) – Pre Dilatation Subset

Hierarchical Complications (to 360 days)	Endeavor Continued Access (N=167)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	22	13.2%
Death	1	0.6%
Non-fatal Q Wave MI	0	0%
Non-fatal Non-Q Wave MI	8	4.8%
Emergent CABG without Death or MI	0	0%
TL-CABG without Death or MI	3	1.8%
TL-PTCA without Death, MI, or TL-CABG	10	6.0%
Non-Hierarchical Complications (to 360 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	22	13.2%
Death	1	0.6%
MI (Q Wave or Non-Q wave)	9	5.4%
Q Wave MI	0	0%
Non-Q Wave MI	9	5.4%
Emergent CABG	0	0%
Target Lesion Revascularization	14	8.4%
TL-CABG	3	1.8%
TL-PTCA	12	7.2%
Target Vessel Revascularization not involving Target Lesion	9	5.4%
TV/non-TL-CABG	3	1.8%
TV/non-TL-PTCA	6	3.6%
Target Vessel Revascularization	21	12.6%
Target Vessel Failure	28	16.8%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	1	0.6%
Major Bleeding Complications	0	0%

N=Number of patients with 360-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Table 17.a. Major Adverse Cardiac Events (to 720 days) – ITT Set

Hierarchical Complications (to 720 days)	Endeavor Continued Access (N=288)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	37	12.8%
Death	4	1.4%
Non-fatal Q Wave MI	1	0.3%
Non-fatal Non-Q Wave MI	14	4.9%
Emergent CABG without Death or MI	1	0.3%
TL-CABG without Death or MI	3	1.0%
TL-PTCA without Death, MI, or TL-CABG	14	4.9%
Non-Hierarchical Complications (to 720 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	37	12.8%
Death	4	1.4%
MI (Q Wave or Non-Q wave)	17	5.9%
Q Wave MI	1	0.3%
Non-Q Wave MI	16	5.6%
Emergent CABG	1	0.3%
Target Lesion Revascularization	21	7.3%
TL-CABG	4	1.4%
TL-PTCA	18	6.3%
Target Vessel Revascularization not involving Target Lesion	17	5.9%
TV/non-TL-CABG	5	1.7%
TV/non-TL-PTCA	12	4.2%
Target Vessel Revascularization	36	12.5%
Target Vessel Failure	47	16.3%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	1	0.3%
Cerebrovascular Accident (CVA)	1	0.3%
Major Bleeding Complications	1	0.3%

N=Number of patients with 720-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 17.b. Major Adverse Cardiac Events (to 720 days) – Direct Stenting Subset

Hierarchical Complications (to 720 days)	Endeavor Continued Access (N=123)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	14	11.4%
Death	1	0.8%
Non-fatal Q Wave MI	1	0.8%
Non-fatal Non-Q Wave MI	7	5.7%
Emergent CABG without Death or MI	1	0.8%
TL-CABG without Death or MI	0	0%
TL-PTCA without Death, MI, or TL-CABG	4	3.3%
Non-Hierarchical Complications (to 720 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	14	11.4%
Death	1	0.8%
MI (Q Wave or Non-Q wave)	8	6.5%
Q Wave MI	1	0.8%
Non-Q Wave MI	7	5.7%
Emergent CABG	1	0.8%
Target Lesion Revascularization	5	4.1%
TL-CABG	0	0%
TL-PTCA	5	4.1%
Target Vessel Revascularization not involving Target Lesion	8	6.5%
TV/non-TL-CABG	2	1.6%
TV/non-TL-PTCA	6	4.9%
Target Vessel Revascularization	13	10.6%
Target Vessel Failure	18	14.6%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	1	0.8%
Cerebrovascular Accident (CVA)	0	0%
Major Bleeding Complications	1	0.8%

N=Number of patients with 720-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 17.c. Major Adverse Cardiac Events (to 720 days) – Pre Dilatation Subset

Hierarchical Complications (to 720 days)	Endeavor Continued Access (N=165)	
	Number	%
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	23	13.9%
Death	3	1.8%
Non-fatal Q Wave MI	0	0%
Non-fatal Non-Q Wave MI	7	4.2%
Emergent CABG without Death or MI	0	0%
TL-CABG without Death or MI	3	1.8%
TL-PTCA without Death, MI, or TL-CABG	10	6.1%
Non-Hierarchical Complications (to 720 days)		
Any MACE (Death, Q wave or non-Q wave MI, Em CABG, TLR)	23	13.9%
Death	3	1.8%
MI (Q Wave or Non-Q wave)	9	5.5%
Q Wave MI	0	0%
Non-Q Wave MI	9	5.5%
Emergent CABG	0	0%
Target Lesion Revascularization	16	9.7%
TL-CABG	4	2.4%
TL-PTCA	13	7.9%
Target Vessel Revascularization not involving Target Lesion	9	5.5%
TV/non-TL-CABG	3	1.8%
TV/non-TL-PTCA	6	3.6%
Target Vessel Revascularization	23	13.9%
Target Vessel Failure	29	17.6%
Stent Thrombosis	0	0%
Acute Stent Thrombosis	0	0%
Sub-Acute Stent Thrombosis	0	0%
Late Stent Thrombosis	0	0%
Vascular Complications	0	0%
Cerebrovascular Accident (CVA)	1	0.6%
Major Bleeding Complications	0	0%

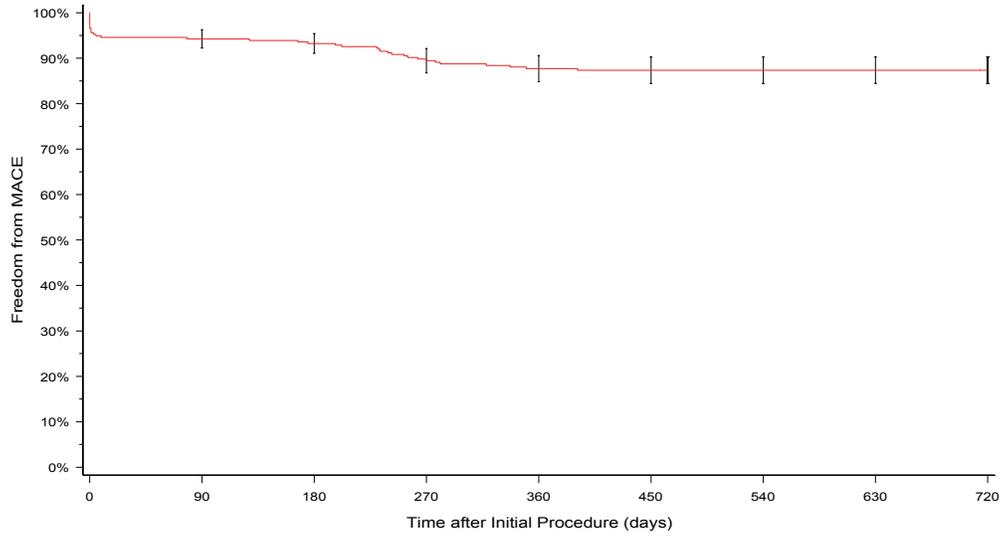
N=Number of patients with 720-day follow-up information

Target Vessel Revascularization not involving the Target Lesion was defined as Target Vessel revascularization at the site other than the target site with or without concomitant target lesion revascularization

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10 November 2006

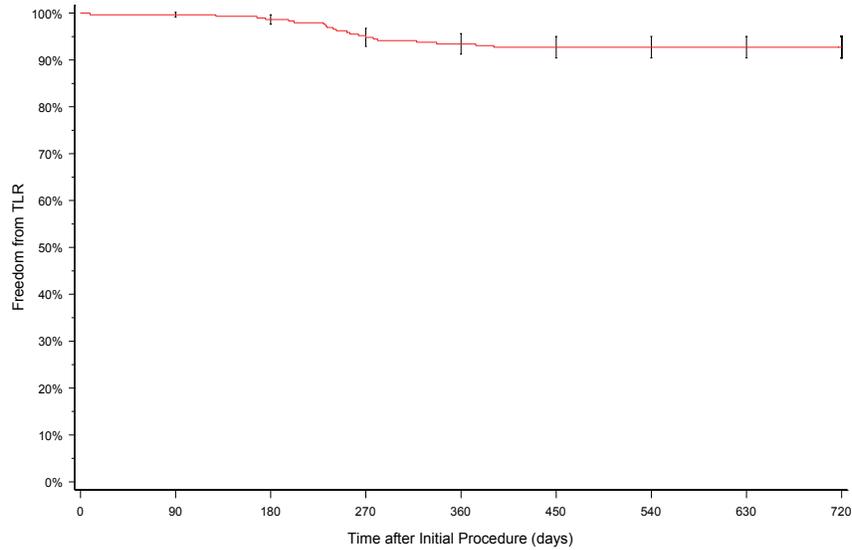
ENDEAVOR II -CA Study
720-Day Clinical Study Report

Figure 6. Survival Free from Major Adverse Cardiac Events (at 720 days)
Event-free Survival + 1.5SE – ITT Set



Day	0	90	180	270	360	450	540	630	720
Endeavor OUS									
#at risk	296	286	279	273	258	252	245	245	245
#censored	0	0	3	4	1	6	0	0	100
#event	10	7	3	11	5	1	0	0	0
%survived	96.6%	94.3%	93.2%	89.5%	87.7%	87.4%	87.4%	87.4%	87.4%
se	1.1%	1.4%	1.5%	1.8%	1.9%	1.9%	1.9%	1.9%	1.9%

**Figure 7. Survival Free from Target Lesion Revascularization (at 720 days)
Event-free Survival + 1.5SE – ITT Set**

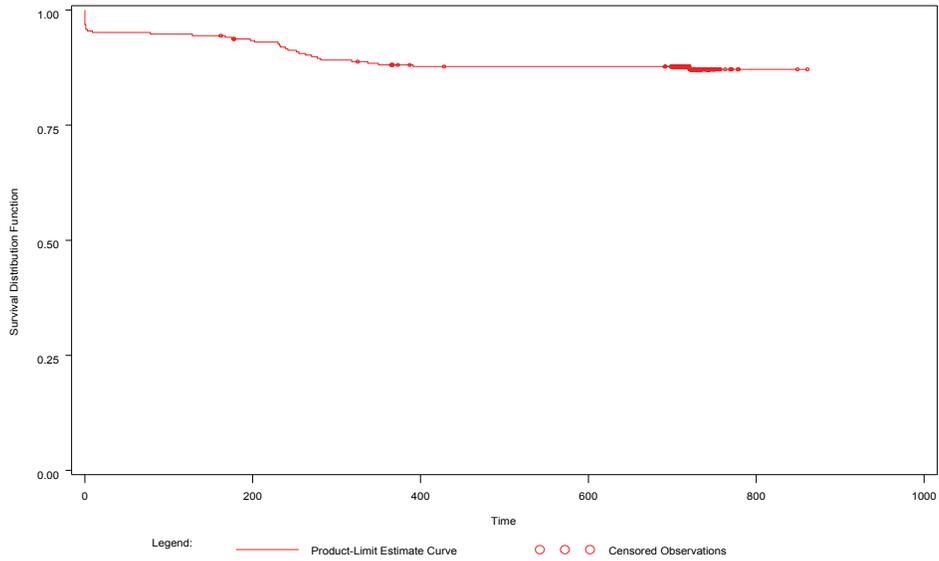


Day	0	90	180	270	360	450	540	630	720
Endeavor OUS									
#at risk	296	296	294	287	272	266	257	257	257
#censored	0	1	4	4	2	7	0	0	107
#event	0	1	3	11	4	2	0	0	0
%survived	100.0%	99.7%	98.6%	94.8%	93.4%	92.7%	92.7%	92.7%	92.7%
se	0.0%	0.3%	0.7%	1.3%	1.5%	1.5%	1.5%	1.5%	1.5%

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10 November 2006

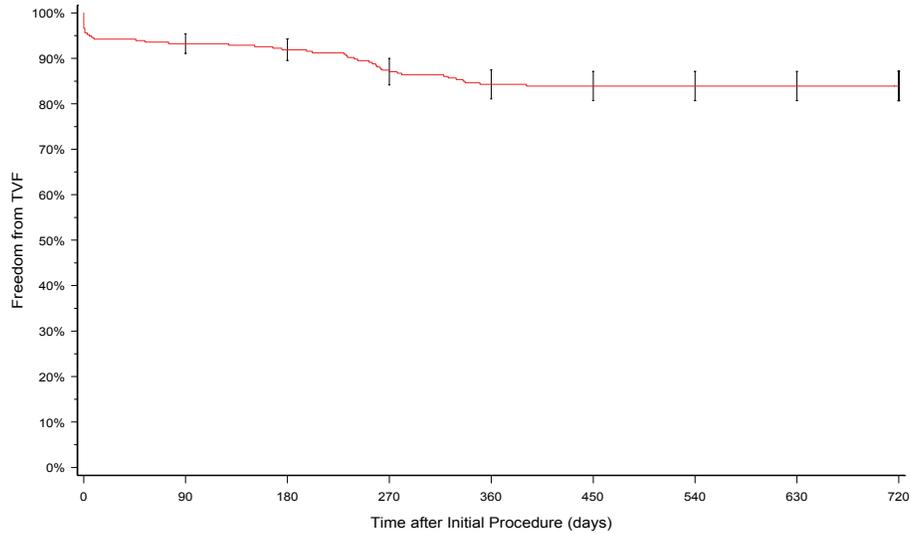
ENDEAVOR II -CA Study
720-Day Clinical Study Report

**Figure 8. Survival Free from Target Vessel Revascularization (at 720 days)
Event-free Survival + 1.5SE – ITT Set**



Day	0	90	180	270	360	450	540	630	720
Endeavor OUS									
#at risk	296	296	289	281	262	252	243	243	243
#censored	0	0	4	4	2	7	0	0	99
#event	0	7	4	15	8	2	0	0	0
%survived	100.0%	97.6%	96.3%	91.1%	88.3%	87.6%	87.6%	87.6%	87.6%
se	0.0%	0.9%	1.1%	1.7%	1.9%	1.9%	1.9%	1.9%	1.9%

**Figure 9. Survival Free from Target Vessel Failure (at 720 days)
Event-free Survival + 1.5SE – ITT Set**



Day	0	90	180	270	360	450	540	630	720
Endeavor OUS									
#at risk	296	286	276	269	251	242	235	235	235
#censored	0	0	3	4	1	6	0	0	96
#event	10	10	4	14	8	1	0	0	0
%survived	96.6%	93.2%	91.9%	87.1%	84.3%	83.9%	83.9%	83.9%	83.9%
se	1.1%	1.5%	1.6%	2.0%	2.1%	2.1%	2.1%	2.1%	2.1%

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 18. Total Stent Length Implanted Per Patient

	Endeavor Continued Access (N=296)
Number of Stent Implanted	
1	236/294(80.3%)
2	54/294(18.4%)
3	4/294(1.4%)
4	0/294(0%)
Total Study Stent Length Implanted (mm)	
n	294
Mean	25.02
SD	9.04
Median	24
1 st quartile	18
3 rd quartile	30
Min-Max	9- 66

Page 1 of 1

N = Total number of patients enrolled
n = Number of patients with evaluable data

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10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 19. Quantitative Intravascular Ultrasound Analysis (Post-Stent Implantation) – IVUS Subset

Endeavor Continued Access			
Measure	Baseline	Eight-Month Follow-up	Difference between Baseline and Eight Month Follow-up
EEM Area (mm²)			
n	35	30	25
Mean	14.18	13.79	0.6
SD	3.6	5.3	2.38
Median	13.62	13.31	0.19
1st quartile	11.72	10.9	-0.29
3rd quartile	16.89	15.45	0.98
Min-Max	6.3- 21.35	6.2- 32.01	-2.36- 10.92
EEM Volumn (mm³)			
n	17	20	16
Mean	314.44	315.73	6.23
SD	113.03	123.91	33.74
Median	307.86	292.15	4.08
1st quartile	239.65	235.52	-11.35
3rd quartile	373.15	393.46	15.95
Min-Max	51.18- 504.1	50.44- 592.01	-46.47- 110.94
Mean Stent Area (mm²)			
n	57	43	41
Mean	6.24	6.47	0.29
SD	1.95	1.97	0.67
Median	6.21	6.74	0.16
1st quartile	4.62	4.8	-0.03
3rd quartile	7.3	7.65	0.46
Min-Max	2.69- 11.18	2.77- 10.73	-0.96- 3.05
Stent Volume (mm³)			
n	24	30	22
Mean	173.73	172.1	3.01
SD	50.94	65.48	21.09
Median	165.34	155	1.31
1st quartile	144.68	138.48	-10.24
3rd quartile	212.94	208.71	7.57
Min-Max	31.5- 259.45	32.83- 331.04	-24.95- 81.21
Mean Lumen Area (mm²)			
n	57	43	41
Mean	6.22	5.34	-0.82
SD	2.01	1.84	1.05
Median	6.21	5.29	-0.86
1st quartile	4.62	3.6	-1.33
3rd quartile	7.26	6.82	-0.2
Min-Max	2.69- 12.44	2.49- 10.1	-4.11- 3.05

Page 1 of 3

N = Total number of patients selected for IVUS
n = Number of patients with evaluable data

Table 19. Quantitative Intravascular Ultrasound Analysis (Post-Stent Implantation) – IVUS Subset (Continued)

Endeavor Continued Access			
Measure	Baseline	Eight-Month Follow-up	Difference between Baseline and Eight Month Follow-up
Minimal Lumen Area (mm²)			
n	57	43	41
Mean	5.78	4.58	-1.01
SD	1.89	1.73	1.08
Median	5.59	4.38	-1.01
1st quartile	4.44	3.27	-1.52
3rd quartile	6.92	5.59	-0.3
Min-Max	2.54- 10.29	2.24- 10.1	-4.11- 3.05
Lumen Volume (mm³)			
n	24	30	22
Mean	172.69	142.44	-27.34
SD	50.01	53.93	18.86
Median	163.98	135.14	-24.27
1st quartile	142.18	112.02	-39.54
3rd quartile	212.14	173.12	-14.81
Min-Max	31.5- 259.44	23.28- 287.54	-69- -2.52
Mean NIH Area (mm²)			
n	NA	42	NA
Mean		1.11	
SD		0.88	
Median		1.01	
1st quartile		0.48	
3rd quartile		1.52	
Min-Max		0- 4.11	
NIH Volume (mm³)			
n	NA	30	NA
Mean		29.66	
SD		22.17	
Median		23.74	
1st quartile		13.16	
3rd quartile		39.57	
Min-Max		2.2- 108.61	
Plaque Volume (mm³)			
n	17	20	16
Mean	156.25	187.74	36.34
SD	71.42	90.4	35.26
Median	146.68	159.21	27.98
1st quartile	97.95	121.7	12.16
3rd quartile	195.49	247.84	55.76
Min-Max	19.68- 315.27	27.16- 370.13	-14.93- 131.15

Page 2 of 3

N = Total number of patients selected for IVUS
n = Number of patients with evaluable data

**Table 19. Quantitative Intravascular Ultrasound Analysis (Post-Stent Implantation) –
IVUS Subset (Continued)**

Measure	Endeavor Continued Access (N=92)		
	Baseline	Eight-Month Follow-up	Difference between Baseline and Eight Month Follow-up
Volume Obstruction (%)			
n	NA	30	NA
Mean		0.17	
SD		0.09	
Median		0.16	
1st quartile		0.11	
3rd quartile		0.23	
Min-Max		0.03- 0.35	

Page 3 of 3

N = Total number of patients selected for IVUS
n = Number of patients with evaluable data

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 20. Frequency of Incomplete Stent Apposition

Measures	Endeavor Continued Access
Incomplete Stent Apposition at Post Procedure	5/56(8.9%)
Incomplete Stent Apposition at 8 Month Follow-up	3/44(6.8%)
Resolved	0/42(0%)
Persistent	3/42(7.1%)
Late Acquired	0/42(0%)

Numbers are % (Count/Sample Size).

IA =Incomplete Apposition, BL = Baseline, FU = Follow-up

Resolved = # patients with BL IA and without FU IA ÷ # patients evaluable at baseline and follow-up.

Persistent = # patients with BL IA and with FU IA ÷ # patients evaluable at baseline and follow-up.

Late Acquired = # patients without BL IA and with FU IA ÷ # patients evaluable at baseline and follow-up.

Incomplete Apposition variables are from assessment by IVUS core laboratory

Table 21.a. Major Protocol Deviation by Type

Type of Deviation	Endeavor Continued Access
Inclusion criteria 1 not met	0
Inclusion criteria 2 not met	0
Inclusion criteria 3 not met	4
Inclusion criteria 4 not met	7
Inclusion criteria 5A not met	5
Inclusion criteria 5B not met	0
Inclusion criteria 5C not met	2
Inclusion criteria 5D not met	0
Inclusion criteria 6 not met	2
Inclusion criteria 7 not met	0
Inclusion criteria 8 not met	1
Exclusion criteria 1 not met	0
Exclusion criteria 2 not met	0
Exclusion criteria 4 not met	0
Exclusion criteria 5 not met	1
Exclusion criteria 6 not met	0
Exclusion criteria 7 not met	1
Exclusion criteria 8 not met	1
Exclusion criteria 9 not met	0
Exclusion criteria 10 not met	5
Exclusion criteria 11 not met	1
Exclusion criteria 12 not met	2
Exclusion criteria 13 not met	1
Exclusion criteria 14 not met	0
Exclusion criteria 15 not met	0
Exclusion criteria 16 not met	0
Exclusion criteria 17 not met	0
Exclusion criteria 18 not met	0
Exclusion criteria 19 not met	0
Exclusion criteria 20 not met	2
Exclusion criteria 21 not met	1
Consent signed after pre-procedure sedation given	0
Consent signed by relative who is not legal guardian	0
Consent signed post-procedure	1
Consent documented in chart, but not found	0
No consent documented or found	0

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 21.b. Minor Protocol Deviation by Type

Type of Deviation	Endeavor Continued Access
Incorrect ASA dose given	0
Incorrect Ticlid/Plavix dose given	1
Water soluble ASA not given	0
Patient discharged on incorrect ASA dose	1
Patient discharged on incorrect Ticlid/Plavix dose	0
Ticlid/Plavix not given	4
ASA not given	9
NTG not given pre-stent	4
NTG not given post-stent	4
Patient did not take required ASA	3
Patient did not take required Ticlid/Plavix	5
Incorrect medication given	2
WBC with diff. not drawn	64
CK/MB not drawn	52
Pre-procedure CK not drawn	8
Post-procedure CK not drawn	182
CK isoenzymes not analyzed (if indicated)	0
Diff. not analyzed (if indicated)	54
Pre-procedure ECG not done	19
Pre-procedure ECG done outside protocol specifications	1
Post procedure/discharge ECG not done	22
Lab value not obtained	45
Stent deployed above nominal pressure	2
Follow-up phone call/visit not made	68
Follow-up phone call/visit outside protocol time frame	165
Follow-up labs not done	30
Follow-up labs drawn outside protocol time frame	60
Follow-up angiogram not done for pt in angio subset	29
Other	258

Table 22.a. Major Protocol Deviation by Site

Site	Endeavor Continued Access
601	5
602	0
603	12
604	0
605	1
606	0
607	0
608	2
609	6
610	3
611	0
612	1
613	0
614	4
615	3
Total	37

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 22.b. Minor Protocol Deviation by Site

Site	Endeavor Continued Access
601	143
602	54
603	156
604	73
605	17
606	43
607	35
608	54
609	219
610	74
611	10
612	16
613	32
614	96
615	70
Total	1092

Table 23a. Adverse Events (to 720 days)

Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (to 720 days)	ENDEAVOR DES ENDEAVOR II (N=296 patients)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2(0.7%)
ANAEMIA	1(0.3%)
LYMPHADENOPATHY MEDISTINAL	1(0.3%)
	132(44.6%)
CARDIAC DISORDERS)
ACUTE MYOCARDIAL INFARCTION	5(1.7%)
ANGINA PECTORIS	73(24.7%)
ANGINA UNSTABLE	14(4.7%)
AORTIC VALVE INCOMPETENCE	1(0.3%)
ARRHYTHMIA	5(1.7%)
ATRIAL FIBRILLATION	3(1.0%)
ATRIAL FLUTTER	1(0.3%)
ATRIAL TACHYCARDIA	1(0.3%)
ATRIOVENTRICULAR BLOCK COMPLETE	1(0.3%)
BRADYCARDIA	5(1.7%)
CARDIAC ARREST	1(0.3%)
CARDIAC FAILURE	4(1.4%)
CARDIAC FAILURE ACUTE	1(0.3%)
CARDIAC FAILURE CONGESTIVE	1(0.3%)
CARDIOMYOPATHY	1(0.3%)
CHEST DISCOMFORT	1(0.3%)
CHEST PAIN	22(7.4%)
CHEST PAIN / ANGINA PECTORIS	3(1.0%)
CORONARY ARTERY DISEASE	3(1.0%)
CORONARY ARTERY STENOSIS	1(0.3%)
CORONARY HEART DISEASE	2(0.7%)
DRESSLER'S SYNDROME	1(0.3%)
DYSPNEA EXERTIONAL	1(0.3%)
DYSPNOEA	11(3.7%)
DYSPNOEA ON EFFORT	3(1.0%)
LEFT VENTRICULAR FAILURE	1(0.3%)
LOW CARDIAC OUTPUT SYNDROME	1(0.3%)
MYOCARDIAL INFARCTION	8(2.7%)
PALPITATIONS	4(1.4%)
SUPRAVENTRICULAR TACHYCARDIA	1(0.3%)
SYNCOPE	2(0.7%)
TACHYARRHYTHMIA	3(1.0%)
TACHYCARDIA	3(1.0%)
UNSTABLE ANGINA PECTORIS	1(0.3%)
VENTRICULAR DYSFUNCTION	1(0.3%)
VENTRICULAR FIBRILLATION	2(0.7%)
VENTRICULAR TACHYCARDIA	1(0.3%)
WOLFF-PARKINSON-WHITE SYNDROME	1(0.3%)
EAR AND LABYRINTH DISORDERS	6(2.0%)
VERTIGO	6(2.0%)

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (to 720 days)	ENDEAVOR DES ENDEAVOR II (N=296 patients)
EYE DISORDERS	2(0.7%)
CATARACT	1(0.3%)
VISUAL ACUITY REDUCED	1(0.3%)
GASTROINTESTINAL DISORDERS	27(9.1%)
ABDOMINAL DISOMFORT	1(0.3%)
ABDOMINAL PAIN	2(0.7%)
ABDOMINAL PAIN UPPER	2(0.7%)
ANAL FISSURE	1(0.3%)
ANASTOMOTIC ULCER HAEMORRHAGE	2(0.7%)
CONSTIPATION	3(1.0%)
DIARRHOEA	1(0.3%)
DYSPHAGIA	1(0.3%)
FLATULESCENCE	1(0.3%)
GASTRIC HAEMORRHAGE	1(0.3%)
GASTRIC ULCER	1(0.3%)
GASTRIC ULCER HAEMORRHAGE	1(0.3%)
GASTROINTESTINAL HAEMORRHAGE	2(0.7%)
GASTROESOPHAGEAL REFLUX DISEASE	1(0.3%)
MELAENA	2(0.7%)
NAUSEA	5(1.7%)
PANCREATITIS ACUTE	1(0.3%)
VOMITING	6(2.0%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	31(10.5%)
CHEST PAIN	3(1.0%)
FATIGUE	2(0.7%)
INJECTION SITE EXTRAVASATION	1(0.3%)
INJECTION SITE HAEMORRHAGE	11(3.7%)
MOUTH HAEMORRHAGE	1(0.3%)
MULTI-ORGAN FAILURE	1(0.3%)
NON-CARDIAC CHEST PAIN	3(1.0%)
OEDEMA	1(0.3%)
OEDEMA PERIPHERAL	2(0.7%)
PAIN	6(2.0%)
PYREXIA	2(0.7%)
SWELLING	1(0.3%)
IMMUNE SYSTEM DISORDERS	4(1.4%)
HYPERSENSITIVITY	4(1.4%)
INFECTIONS AND INFESTATIONS	16(5.4%)
DENTAL ABSCESS	1(0.3%)
INFLUENZA	2(0.7%)
NASOPHARYNGITIS	10(3.4%)
PNEUMONIA	1(0.3%)
SALMONELLOSIS	1(0.3%)
TOOTH ABSCESS	1(0.3%)
TOOTH DISCOLOURATION	1(0.3%)
TOOTHACHE	1(0.3%)

<u>Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (to 720 days)</u>	<u>ENDEAVOR DES ENDEAVOR II (N=296 patients)</u>
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	28(9.5%)
ACCIDENT	1(0.3%)
APPLICATION SITE BLEEDING	7(2.4%)
ARTERIOVENOUS FISTULA SITE HAEMORRHAGE	1(0.3%)
ARTERIOVENOUS GRAFT SITE HAEMORRHAGE	1(0.3%)
CONTUSION	2(0.7%)
DONOR SITE COMPLICATION	1(0.3%)
EXCORIATION	1(0.3%)
GRAFT COMPLICATION	1(0.3%)
JOINT INJURY	2(0.7%)
MEDICAL DEVICE COMPLICATION	2(0.7%)
OPERATIVE HAEMORRHAGE	1(0.3%)
POST PROCEDURAL PAIN	6(2.0%)
STENT OCCLUSION	1(0.3%)
VESSEL PUNCTURE SITE HAEMORRHAGE	3(1.0%)
WOUND DEHISCENCE	1(0.3%)
INVESTIGATIONS	57(19.3%)
ANGIOGRAM	40(13.5%)
BLOOD CREATINE PHOSPHOKINASE	2(0.7%)
BLOOD CREATINE PHOSPHOKINASE INCREASED	9(3.0%)
BLOOD CREATININE INCREASED	1(0.3%)
BLOOD INSULIN ABNORMAL	1(0.3%)
BLOOD PRESSURE INCREASED	1(0.3%)
BLOOD SUGAR INCREASE	1(0.3%)
C-REACTIVE PROTEIN INCREASED	1(0.3%)
CATHETERIZATION CARDIAC	1(0.3%)
CATHETERIZATION, CARDIAC	1(0.3%)
COLONOSCOPY	1(0.3%)
ENDOSCOPY LARGE BOWEL, ABNORMAL	1(0.3%)
FAECAL OCCULT BLOOD POSITIVE	1(0.3%)
HEPATIC ENZYME INCREASED	1(0.3%)
METABOLISM AND NUTRITION DISORDERS	6(2.0%)
DEHYDRATION	2(0.7%)
DIABETES MELLITUS	1(0.3%)
ENDOCRINE DISORDER	1(0.3%)
GOUT	1(0.3%)
HYPERGLYCEMIA	1(0.3%)
HYPERLIPIDAEMIA	1(0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	28(9.5%)
ARTHRALGIA	3(1.0%)
ARTHRITIS	1(0.3%)
BACK PAIN	9(3.0%)
BONE PAIN	1(0.3%)
CLAVICAL FRACTURE	1(0.3%)
GROIN PAIN	1(0.3%)
INTERVERTEBRAL DISCITIS	1(0.3%)

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (to 720 days)	ENDEAVOR DES ENDEAVOR II (N=296 patients)
JOINT SPRAIN	1(0.3%)
MYALGIA	2(0.7%)
OSTEOARTHRITIS	1(0.3%)
PAIN IN EXTREMITY	6(2.0%)
PAIN IN JAW	1(0.3%)
PAINFUL LEFT ARM	1(0.3%)
SPINAL FRACTURE	1(0.3%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5(1.7%)
BASAL CELL CARCINOMA	1(0.3%)
BRONCHIAL CARCINOMA	1(0.3%)
LUNG NEOPLASM MALIGNANT	1(0.3%)
METASTASES TO LIVER	1(0.3%)
PROSTATE CANCER	2(0.7%)
NERVOUS SYSTEM DISORDERS	23(7.8%)
CEREBROVASCULAR ACCIDENT	1(0.3%)
DIZZINESS	5(1.7%)
DYSARTHRIA	2(0.7%)
HEADACHE	8(2.7%)
HYPERTONIA	1(0.3%)
HYPOAESTHESIA	2(0.7%)
HYPOTONIA	2(0.7%)
NERVOUS SYSTEM DISORDER	1(0.3%)
PARASTHESIA	3(1.0%)
PARESIS	1(0.3%)
PSYCHIATRIC DISORDERS	5(1.7%)
AMNESIA	1(0.3%)
DEPRESSION	2(0.7%)
INSOMNIA	1(0.3%)
SLEEP DISORDER	2(0.7%)
RENAL AND URINARY DISORDERS	8(2.7%)
DYSURIA	2(0.7%)
GLOMERULONEPHRITIS	1(0.3%)
HAEMATURIA	2(0.7%)
HAEMOGLOBINURIA	1(0.3%)
RENAL FAILURE, ACUTE	1(0.3%)
RENAL INSUFFICIENCY	1(0.3%)
URINARY RETENTION	1(0.3%)
URINARY TRACT INFECTION	2(0.7%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2(0.7%)
BENIGN PROSTATIC HYPERPLASIA	1(0.3%)
ERECTION DISORDER	1(0.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	14(4.7%)
ACUTE PULMONARY OEDEMA	1(0.3%)
ACUTE SINUSITIS	1(0.3%)
ACUTE TONSILLITIS	1(0.3%)

Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (to 720 days)	ENDEAVOR DES ENDEAVOR II (N=296 patients)
ASTHMA	1(0.3%)
BRONCHITIS	5(1.7%)
CHEST PAIN	1(0.3%)
COUGH	3(1.0%)
PERTUSSIS	2(0.7%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3(1.0%)
EXCORIATION	1(0.3%)
PRURITUS	1(0.3%)
SKIN DISORDER	1(0.3%)
SURGICAL AND MEDICAL PROCEDURES	65(22.0%)
ANGIOPLASTY	7(2.4%)
AORTIC VALVE REPLACEMENT	2(0.7%)
ARTERIAL ANEURYSM REPAIR	1(0.3%)
ARTERIAL BYPASS OPERATION	1(0.3%)
ARTERIAL STENT INSERTION	3(1.0%)
CARDIAC ABLATION	1(0.3%)
CARDIAC PACEMAKER INSERTION	1(0.3%)
CAROTID ENDARTERECTOMY	1(0.3%)
CATARACT EXTRACTION	2(0.7%)
CORONARY ANGIOPLASTY	1(0.3%)
CORONARY ARTERIAL STENT INSERTION	1(0.3%)
CORONARY ARTERY REVASCLARIZATION	1(0.3%)
CORONARY ARTERY SURGERY	9(3.0%)
CORONARY REVASCLARISATION	35(11.8%)
CORONARY REVASCLARIZATION	2(0.7%)
EYE OPERATION	1(0.3%)
HIP ARTHROPLASTY	1(0.3%)
HIP SURGERY	1(0.3%)
KNEE OPERATION	1(0.3%)
PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY	3(1.0%)
PROSTATECTOMY	2(0.7%)
REHABILITATION THERAPY	1(0.3%)
SHOULDER OPERATION	1(0.3%)
TRANSURETHRAL PROSTATECTOMY	2(0.7%)
VASCULAR DISORDERS	44(14.9%)
ABDOMINAL HAEMATOMA	2(0.7%)
ADRENAL HAEMORRHAGE	1(0.3%)
ANEURYSM	4(1.4%)
AORTIC ANEURYSM	2(0.7%)
ARTERIAL OCCLUSIVE DISEASE	1(0.3%)
ARTERIAL RESTENOSIS	3(1.0%)
ARTERIAL STENOSIS	1(0.3%)
CAROTID ARTERY OCCLUSION	1(0.3%)
CAROTID ARTERY STENOSIS	1(0.3%)
CEREBRAL INFARCTION	1(0.3%)
CEREBROVASCULAR ACCIDENT	1(0.3%)

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (to 720 days)	ENDEAVOR DES ENDEAVOR II (N=296 patients)
CORONARY ARTERY OCCLUSION	1(0.3%)
EMBOLISM ARTERIAL	1(0.3%)
EPISTAXIS	3(1.0%)
HAEMATOMA	5(1.7%)
HYPERTENSION	7(2.4%)
HYPOTENSION	5(1.7%)
INTERMITTENT CLAUDICATION	3(1.0%)
PERIPHERAL COLDNESS	1(0.3%)
PERIPHERAL VASCULAR DISEASE	1(0.3%)
SMALL INTESTINAL HAEMORRHAGE	1(0.3%)
SYNCOPE VASOVAGAL	2(0.7%)
TEMPORAL ARTERITIS	1(0.3%)
THROMBOSIS	1(0.3%)
VASCULAR PSEUDOANEURYSM	1(0.3%)

AE data in the table as coded by the coding company Research Point, Austin, Texas, USA

Table 23.b. Adverse Events by Site

Site	Endeavor Continued Access
601	91/ 855
602	16/ 855
603	62/ 855
604	63/ 855
605	154/ 855
606	48/ 855
607	11/ 855
608	38/ 855
609	113/ 855
610	50/ 855
611	37/ 855
612	20/ 855
613	44/ 855
614	52/ 855
615	56/ 855

Denominator is the total number of AEs in each group
Numerators are the total number of AEs in each site.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 24a. Serious Adverse Events (to 720 days)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (to 720 days)	ENDEAVOR DES ENDEAVOR II (N=296 patients)
CARDIAC DISORDERS	78(26.4%)
ACUTE MYOCARDIAL INFARCTION	5(1.7%)
ANGINA PECTORIS	28(9.5%)
ANGINA UNSTABLE	12(4.1%)
AORTIC VALVE INCOMPETENCE	1(0.3%)
ATRIAL FIBRILLATION	1(0.3%)
ATRIAL FLUTTER	1(0.3%)
ATRIAL TACHYCARDIA	1(0.3%)
ATRIOVENTRICULAR BLOCK COMPLETE	1(0.3%)
BRADYCARDIA	1(0.3%)
CARDIAC FAILURE	4(1.4%)
CARDIAC FAILURE ACUTE	1(0.3%)
CARDIAC FAILURE CONGESTIVE	1(0.3%)
CARDIOMYOPATHY	1(0.3%)
CHEST DISCOMFORT	1(0.3%)
CHEST PAIN	12(4.1%)
CHEST PAIN / ANGINA PECTORIS	1(0.3%)
CORONARY ARTERY DISEASE	3(1.0%)
CORONARY ARTERY STENOSIS	1(0.3%)
DRESSLER'S SYNDROME	1(0.3%)
DYSPNEA EXERTIONAL	1(0.3%)
DYSPNOEA	2(0.7%)
LEFT VENTRICULAR FAILURE	1(0.3%)
MYOCARDIAL INFARCTION	8(2.7%)
PALPITATIONS	1(0.3%)
SUPRAVENTRICULAR TACHYCARDIA	1(0.3%)
SYNCOPE	1(0.3%)
TACHYARRHYTHMIA	2(0.7%)
TACHYCARDIA	1(0.3%)
UNSTABLE ANGINA PECTORIS	1(0.3%)
VENTRICULAR DYSFUNCTION	1(0.3%)
VENTRICULAR FIBRILLATION	1(0.3%)
GASTROINTESTINAL DISORDERS	11(3.7%)
ABDOMINAL PAIN	1(0.3%)
ABDOMINAL PAIN UPPER	1(0.3%)
ANAL FISSURE	1(0.3%)
ANASTOMOTIC ULCER HAEMORRHAGE	2(0.7%)
DIARRHOEA	1(0.3%)
DYSPHAGIA	1(0.3%)
GASTRIC HAEMORRHAGE	1(0.3%)
GASTRIC ULCER	1(0.3%)
GASTRIC ULCER HAEMORRHAGE	1(0.3%)
GASTROINTESTINAL HAEMORRHAGE	1(0.3%)
MELAENA	1(0.3%)
PANCREATITIS ACUTE	1(0.3%)
VOMITING	1(0.3%)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (to 720 days)	ENDEAVOR DES ENDEAVOR II (N=296 patients)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1(0.3%)
MULTI-ORGAN FAILURE	1(0.3%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6(2.0%)
ACCIDENT	1(0.3%)
MEDICAL DEVICE COMPLICATION	2(0.7%)
POST PROCEDURAL PAIN	3(1.0%)
INVESTIGATIONS	45(15.2%)
ANGIOGRAM	32(10.8%)
BLOOD CREATINE PHOSPHOKINASE	2(0.7%)
BLOOD CREATINE PHOSPHOKINASE INCREASED	6(2.0%)
BLOOD INSULIN ABNORMAL	1(0.3%)
BLOOD PRESSURE INCREASED	1(0.3%)
CATHETERIZATION CARDIAC	1(0.3%)
COLONOSCOPY	1(0.3%)
ENDOSCOPY LARGE BOWEL, ABNORMAL	1(0.3%)
METABOLISM AND NUTRITION DISORDERS	4(1.4%)
DEHYDRATION	2(0.7%)
DIABETES MELLITUS	1(0.3%)
ENDOCRINE DISORDER	1(0.3%)
HYPERGLYCEMIA	1(0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	5(1.7%)
BACK PAIN	2(0.7%)
CLAVICAL FRACTURE	1(0.3%)
INTERVERTEBRAL DISCITIS	1(0.3%)
PAINFUL LEFT ARM	1(0.3%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4(1.4%)
BASAL CELL CARCINOMA	1(0.3%)
BRONCHIAL CARCINOMA	1(0.3%)
LUNG NEOPLASM MALIGNANT	1(0.3%)
METASTASES TO LIVER	1(0.3%)
PROSTATE CANCER	1(0.3%)
NERVOUS SYSTEM DISORDERS	5(1.7%)
CEREBROVASCULAR ACCIDENT	1(0.3%)
DIZZINESS	1(0.3%)
DYSARTHRIA	1(0.3%)
HEADACHE	1(0.3%)
NERVOUS SYSTEM DISORDER	1(0.3%)
RENAL AND URINARY DISORDERS	4(1.4%)
DYSURIA	1(0.3%)
HAEMATURIA	1(0.3%)
RENAL FAILURE, ACUTE	1(0.3%)
URINARY TRACT INFECTION	1(0.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1(0.3%)
BENIGN PROSTATIC HYPERPLASIA	1(0.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3(1.0%)
ACUTE PULMONARY OEDEMA	1(0.3%)
ASTHMA	1(0.3%)

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (to 720 days)	ENDEAVOR DES ENDEAVOR II (N=296 patients)
CHEST PAIN	1(0.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1(0.3%)
SKIN DISORDER	1(0.3%)
SURGICAL AND MEDICAL PROCEDURES	62(20.9%)
ANGIOPLASTY	6(2.0%)
AORTIC VALVE REPLACEMENT	2(0.7%)
ARTERIAL ANEURYSM REPAIR	1(0.3%)
ARTERIAL BYPASS OPERATION	1(0.3%)
ARTERIAL STENT INSERTION	2(0.7%)
CARDIAC ABLATION	1(0.3%)
CARDIAC PACEMAKER INSERTION	1(0.3%)
CAROTID ENDARTERECTOMY	1(0.3%)
CATARACT EXTRACTION	2(0.7%)
CORONARY ANGIOPLASTY	1(0.3%)
CORONARY ARTERIAL STENT INSERTION	1(0.3%)
CORONARY ARTERY REVASCULARIZATION	1(0.3%)
CORONARY ARTERY SURGERY	8(2.7%)
CORONARY REVASCULARISATION	32(10.8%)
CORONARY REVASCULARIZATION	1(0.3%)
EYE OPERATION	1(0.3%)
HIP ARTHROPLASTY	1(0.3%)
HIP SURGERY	1(0.3%)
KNEE OPERATION	1(0.3%)
PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY	3(1.0%)
PROSTATECTOMY	2(0.7%)
REHABILITATION THERAPY	1(0.3%)
SHOULDER OPERATION	1(0.3%)
TRANSURETHRAL PROSTATECTOMY	2(0.7%)
VASCULAR DISORDERS	19(6.4%)
ADRENAL HAEMORRHAGE	1(0.3%)
ANEURYSM	1(0.3%)
AORTIC ANEURYSM	2(0.7%)
ARTERIAL OCCLUSIVE DISEASE	1(0.3%)
ARTERIAL RESTENOSIS	3(1.0%)
ARTERIAL STENOSIS	1(0.3%)
CAROTID ARTERY STENOSIS	1(0.3%)
CEREBRAL INFARCTION	1(0.3%)
CEREBROVASCULAR ACCIDENT	1(0.3%)
EPISTAXIS	1(0.3%)
HYPERTENSION	2(0.7%)
INTERMITTENT CLAUDICATION	1(0.3%)
PERIPHERAL VASCULAR DISEASE	1(0.3%)
SMALL INTESTINAL HAEMORRHAGE	1(0.3%)
TEMPORAL ARTERITIS	1(0.3%)
THROMBOSIS	1(0.3%)
VASCULAR PSEUDOANEURYSM	1(0.3%)

SAE data in the table as coded by the coding company Research Point, Austin, Texas, USA

Table 24.b. Serious Adverse Events by Site

Site	Endeavor Continued Access
601	28/ 343
602	9/ 343
603	43/ 343
604	20/ 343
605	42/ 343
606	24/ 343
607	10/ 343
608	19/ 343
609	61/ 343
610	24/ 343
611	12/ 343
612	9/ 343
613	16/ 343
614	18/ 343
615	8/ 343

Denominator is the total number of SAEs in each group
Numerators are the total number of SAEs in each site.

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 25. Site Reported Major Adverse Events (to 720 days) – ITT Set

Non-Hierarchical Complications (to 720 days)	Endeavor Continued Access (N=296)	
	Number	%
MACE	45	(15.2%)
Death	4	(1.4%)
MI (Q Wave or Non-Q wave)	18	(6.1%)
Q Wave MI	2	(0.7%)
Non-Q Wave MI	16	(5.4%)
Emergent CABG	5	(1.7%)
Target Lesion Revascularization	28	(9.5%)
TL-CABG	8	(2.7%)
TL-PTCA	21	(7.1%)
Target Vessel Revascularization (non TL)	27	(9.1%)
Target Vessel Failure	42	(14.2%)
Major Bleeding Events	5	(1.7%)
Major Vascular Events	3	(1.0%)

Table 26. Laboratory - Cardiac Enzymes Findings

	Endeavor Continued Access (N=296)
CK (IU/L)	
Pre-Procedure Peak>2 ULN	3/290(1.0%)
Post-Procedure Peak>2 ULN	14/288(4.9%)
Post-Procedure Peak>3 ULN	5/288(1.7%)
CKMB (ng/ml)	
Pre-Procedure Peak>2 ULN	2/168(1.2%)
Post-Procedure Peak>2 ULN	19/192(9.9%)
Post-Procedure Peak>3 ULN	8/192(4.2%)
Pre-Procedure CK>2 ULN and CKMB>1 ULN	0(0%)
Post-Procedure CK>2 ULN and CKMB>1 ULN	12/191(6.3%)*

* In all these cases the CK and CKMB elevations were adjudicated by the CEC as a non Q-wave MI

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 27. Medication - Anti-coagulants Use

Anti-coagulant	Endeavor Continued Access (N=296)
Pre-Procedure	
Aspirin	94.6%(278/294)
Clopidogrel	86.1%(254/295)
Ticlopidine	0%(0/296)
During Procedure	
Clopidogrel	23.0%(68/296)
Ticlopidine	0%(0/296)
IIbIIIa	7.1%(21/296)
Post Procedure	
Aspirin	97.6%(288/295)
Clopidogrel	98.6%(292/296)
Ticlopidine	0%(0/296)
Aspirin and Clopidogrel/Ticlopidine	97.0%(287/296)
At Discharge	
Aspirin	97.3%(288/296)
Clopidogrel	99.7%(295/296)*
Ticlopidine	0%(0/296)
Aspirin and Clopidogrel/Ticlopidine	97.3%(288/296)
At 30-day	
Aspirin	95.9%(282/294)
Clopidogrel	98.3%(289/294)
Ticlopidine	0%(0/295)
Aspirin and Clopidogrel/Ticlopidine	94.2%(278/295)
At 6-Month	
Aspirin	95.1%(272/286)
Clopidogrel	59.4%(170/286)
Ticlopidine	0%(0/287)
Aspirin and Clopidogrel/Ticlopidine	55.9%(161/288)
At 9-Month	
Aspirin	93.0%(264/284)
Clopidogrel	46.6%(132/283)
Ticlopidine	0%(0/284)
Aspirin and Clopidogrel/Ticlopidine	43.0%(122/284)
At 12-Month	
Aspirin	95.2%(275/289)
Clopidogrel	35.3%(102/289)
Ticlopidine	0%(0/287)
Aspirin and Clopidogrel/Ticlopidine	33.9%(98/289)
At 24-Month	
Aspirin	92.8%(257/277)
Clopidogrel	14.4%(40/277)
Ticlopidine	0%(0/277)
Aspirin and Clopidogrel/Ticlopidine	11.6%(32/277)

* One patient not discharged on clopidogrel (see Table 30). Failure to deliver the device and to treat the lesion. CABG planned after procedure. Patient discharged from study and hospitalized at other center. CABG performed after 5 days and clopidogrel administered again after CABG procedure.

Table 28. Summary of Device Performance

Endeavor Continued Access (N=356)		
Performance Malfunction Description	Number	%
Stent Delivery Failure	5	1.4%
Delivery, first attempt only	0	0%
Never delivered	5	1.4%
Other Malfunction	0	0%
Device Failure – Delivery Balloon	0	0%
Device Failure – Stent Misplacement	0	0%
Outcome if Delivery Failure or Device Malfunction	5	1.4%
Associated AE	2	0.5%
Failed Stents All Withdrawn	4	1.1%
Stent Deployed at Unintended Site	0	0%
Stent Embolized	1	0.3%
Treatment if Stent Never Delivered	1	0.3%
Non Study Stent	0	0%
PTCA only	0	0%
CABG	1	0.3%

Note: numbers based on patients reported with device failures by site and, in addition, adjudicated by the CEC as device failures

Table 29. Narrative Summaries of Device Performance

Note: in case CEC result did not match the event indicated by the site: see column 'comments'.

	Case Summary	Comments
	Device delivery failures (2) 0 days post-procedure, no event (no UADE) 0 days post procedure	
	<p>The patient is a 78-year-old female with a history of hyperlipidemia, hypertension and smoking. She presented with a stable angina CCS class IV. On April 23, 2004 two attempts were made to treat the patient with the assigned treatment in the proximal LAD. The lesion was not pre-treated with PTCA. Two stents were used but both deliveries failed. The investigator reported that the first stent was retrieved out of the patient after it detached from the balloon while retracting the device. A second stent was used, which detached from the balloon as well, deploying half in the main left vessel and the other half in the aorta. During an attempt to catch this stent with a lasso the stent got lost in the aorta descendens. Last position of the stent was seen by x-ray control in the region of the pelvis. A final 75% stenosis with TIMI flow III and no dissection was reported. A query confirmed that no revascularization was done. The Angiographic Core Lab reported that the baseline images showed an in-lesion stenosis of 70% and commented that no procedure was done. The patient was discharged on April 28, 2004 on ASA and clopidogrel.</p>	<p>Event on 23 April 2004 reported by site as stent malfunction. Adjudicated by CEC as no event and delivery failure.</p>
	Device delivery failure 0 days post procedure	
	<p>The patient is a 74-year-old male with a history of hypertension and premature CAD in a first-degree relative. The patient presented with stable angina CCS class II. On May 6, 2004 it was attempted to treat the target lesion in the distal CX. It was impossible to pass the proximal CX to reach the target lesion. The cardiac catheter report reported that "it is possible that several aspects combine: relative main trunk quantity, small vessel diameter, calcification." The narrative form commented: "after several manipulations a suspected region in the proximal CX was visible which was protected with a conventional stent at once. Afterwards it was still impossible to reach the target lesion distal CX with the study stent, so the lesion could not be treated. The intervention was stopped and a CABG was planned for the next days." The site reported a 90% final residual stenosis with TIMI flow III and no dissection. The Angiographic Core Lab reported "significant left main disease and distal CX disease left untreated".</p> <p>On May 11, 2004, the patient was successfully resuscitated for bradycardia and hypertonia. On the same day an emergent CABG of the 1st Ob Marg and mid LAD was performed. Postoperative the patient was fully oriented, with no indication of any neurological deficiencies. On May 15, the patient was in a good general condition and with stable circulation and was transferred to another ward. The date of discharge is unknown</p>	<p>Event of 6 May 2004 reported by site as stent malfunction/treatment failure. Adjudicated by CEC as delivery failure</p>

Site	Pt	Case Summary	Comments
		Stent delivery failure 0 days post procedure; no event (no UADE) 0 days post procedure; Dissection grade C 0 days post procedure	
		<p>The patient is a 62-year-old male with a history of hypertension. He presented with an unstable angina CCS class III. On May 21, 2004 he underwent the index procedure with the assigned treatment in the 1st Diag.</p> <p>After pre-dilatation a first stent was implanted. Due to a residual stenosis at the distal end, post-dilatation with a maximum pressure of 16 ATM was performed leading to a distal dissection (Type C) without limiting blood flow. A second study stent could not be advanced through the already implanted stent and was removed. The site reported 0% final residual stenosis with TIMI flow III and a final dissection grade C.</p> <p>The Angiographic Core Lab reported a 33% final residual in-lesion stenosis with dissection grade C, staining and spasm present and TIMI flow III. They noted "residual distal edge dissection at the end of the procedure". The patient was discharged on May 22, 2004 on ASA and clopidogrel.</p>	<p>Event of 21 May 2004 reported by site as stent malfunction. Adjudicated by CEC as stent delivery failure and no UADE.</p>
		Stent delivery/Device failure 0 days post procedure; no event (no acute stent thrombosis) 0 days post procedure; Dissection Grade F 0 days post procedure; Abrupt Closure during index 0 days post procedure	
		<p>The patient is a 62-year-old male with a history of previous MI (1999), hyperlipidemia and premature CAD in a first-degree relative. He presented with stable angina CCS class III. On June 7 he underwent the assigned treatment in the proximal CX. After the placement of the first stent a thrombus closed the vessel, for which another stent was used. After the second study stent was implanted a TIMI flow II was seen, with a non-significant stenosis. In order to improve this, an attempt was made to place a third study stent at the distal lesion. This third stent failed to pass the other stents. The site reported a 0% final residual stenosis with TIMI flow II. Because the patient had a procedural occlusion, he received Abciximab IV during 12 hours post-PCI and blood samples were collected post-procedure. The lab-results showed approx. 12-16 hours post-procedure a peaked CK of 362 (nl <190, ratio 1.9) and CK-MB of 25 (nl <16, ratio 1.6) respectively. The site reported a non Q-wave MI.</p> <p>The ECG core lab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI): persistent anterior ST depression, age recent / acute. No new Q-wave Myocardial Infarction was seen.</p> <p>The Angiographic Core Lab reported a "Type F" dissection after first stent placement without flow. The final result after placement of a second stent was a TIMI 3 flow with a negative (-11%) diameter stenosis.</p> <p>The patient was discharged on June 8 on ASA and clopidogrel.</p>	<p>Event of 7 June 2004: site reported stent malfunction. CEC adjudicated as stent delivery/device failure</p>

Table 30. Narrative Summaries of Major Adverse Cardiac Events

Note: in case CEC result did not match the event indicated by the site: see column 'comments'.

Site	Pt	Case Summary	Comments
		Non Target Vessel Revascularization 242 days post-procedure	
		<p>The patient is a 66-year-old male with a history of hypertension and smoking. He presented with stable angina CCS Class 2. On April 2, 2004 he underwent the index procedure with the assigned treatment in the proximal CX, in which two stents were implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiographic Core Lab reported a 50% residual stenosis with no dissection and TIMI flow 3. The patient was discharged April 3, 2004 on ASA and clopidogrel.</p> <p>On November 30, 2004 the 8 months angiography was performed. The patient did not have clinical symptoms. The site reported a 0% diameter stenosis of the target lesion. The Angiographic Core Lab reported a 35% in-lesion stenosis. The site reported that an attempt to revascularize a 'very old' stenosis in the mid-RCA was attempted, but was not successful. No further information is available.</p>	
		Target Lesion Revascularization, Not Clinically Driven 234 days post-procedure; Non Target Vessel Revascularization 436 days post procedure	
		<p>The patient is a 73-year-old male with a history of prior percutaneous coronary revascularization, hyperlipidemia and hypertension. He presented with stable angina class III and a positive stress test. On April 5, 2004 he underwent the index procedure with the assigned treatment in the proximal LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiographic Core Lab reported a 9% residual stenosis, with no dissection and TIMI flow 3. The patient was discharged on April 6, 2004.</p> <p>On November 25, 2004 the 8 months angiography was performed. The patient had no clinical symptoms. The site reported a diameter stenosis of 80% at the target lesion. The Angiographic Core Lab reported a 69% in-lesion with TIMI flow 3. On 25 November 2004 a repeat revascularization of the target lesion was performed. A new drug eluting stent was implanted within the study stent.</p> <p>On June 15, 2005 the patient was hospitalized due to angina pectoris. The ECG corelab reported no significant changes in the ECG of June 13, 2005 as compared to the one of 4 June 2004. No new major ST-T abnormalities and no new Q wave MI was observed. CK and CKMB values were not available. A repeat angiography was performed. The site reported 80% stenosis of the RCA and a patent stent. The angiography corelab reported 14% stenosis of the target lesion. They reported a patent study stent and revascularization of the mid RCA (non target vessel). Two stents were implanted in the mid RCA. The patient was discharged from the hospital on June 16, 2005.</p>	

	Case Summary	Comments
	<p>Non Target Vessel Revascularization 242 days post procedure, Angiographic perforation, not index procedure related 242 days post procedure; Non Target Vessel Revascularization 343 days post procedure</p>	
	<p>The patient is a 46-year-old male with a history of previous MI, prior percutaneous coronary revascularization, hyperlipidemia and hypertension. He presented with stable angina class I. On 5 April 2004 he underwent the index procedure with the assigned treatment in the mid LAD. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported a 16% residual stenosis, with no dissection and TIMI flow 3. The patient was discharged on 6 April 2004 on ASA and clopidogrel.</p> <p>On 3 December 2004 the patient was hospitalized with clinical symptoms. The CK was 174 (nl 171, ratio 1.0) and CKMB was 12 (nl <24, ratio <1). No ECG of this date was available. On the same date, the 8 months angiography was performed. The site reported a 0% stenosis at the target lesion. The Angiography Core Lab reported a 26% stenosis at the target lesion with TIMI flow 3. A revascularization of the distal CX was performed. The procedure was aborted as the guidewire could not pass the vessel and an intramyocardial bleeding (angiographic perforation) occurred. The follow up was uneventful. No further treatment was required.</p> <p>On 14 March 2005 the patient was hospitalized with clinical symptoms. The CK was 147 (nl 171, ratio <1) and CKMB 11 (nl <24, ratio <1). A repeat angiography was performed on 14 March 2005. The site reported 75% stenosis of the target lesion. A repeat revascularization of a non target vessel (mid RCA) was performed.</p>	
	<p>Non Q-wave MI 0 days post-procedure</p> <p>The patient is a 53-year-old male with a history of previous MI (1999), CABG of the target vessel, hyperlipidemia, hypertension and premature CAD in a first-degree relative. The patient was presented with stable angina CCS Class I. On April 7, 2004 he underwent the index procedure with the assigned treatment in the proximal LAD, in which one stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow III.</p> <p>The pre-procedure CK was 156 (nl 171, ratio <1) and CK-MB was 33 (nl <24, ratio 1.4). Approx. 12-16 hours post procedure, the CK peaked at 347 (ratio 2.0) with a CK-MB of 41 (ratio 1.7). The ECG core lab reported no significant changes (no new major ST-T abnormalities and no new Q wave Myocardial Infarction). The patient was discharged on April 8, 2004 on ASA and clopidogrel.</p>	<p>Event of 7 April 2004 reported by site as elevation of CK with no clinical significance. Adjudicated by CEC as non Q wave MI.</p>

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		Non Q-wave MI 1 day post-procedure	
		The patient is a 59-year-old male with a history of hypertension and smoking who presented with unstable angina CCS Class IV. On April 15, 2004 he underwent the index procedure with the assigned treatment in the distal LAD, in which one stent was implanted. No dissection occurred post procedure. The site reported 0% final residual stenosis with TIMI flow III. The pre-procedure CK was 66 (nl 171, ratio <1). The CK-MB was not measured. Approx. 6-8 hours post procedure, the CK peaked at 456 (ratio 2.7) with a CK-MB of 43 (nl 24, ratio 1.8). The ECG core lab reported no new major ST-T abnormalities and no new Q wave Myocardial Infarction. The lab values improved 2 days later. Patient was discharged on April 17, 2004 on ASA and clopidogrel.	
		Target Lesion Revascularization, Clinically Driven 270 days post-procedure; no event (no TVR) 270 days post procedure	
		<p>The patient is a 54-year-old male with a history of hyperlipidemia, hypertension and smoking. He presented with stable angina CCS class 1 and a positive stress test. On 15 April 2004 he underwent the index procedure with the assigned treatment in the distal CX. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported a 7% residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 17 April 2004 on ASA and clopidogrel.</p> <p>On 3 December 2004 the 8 months angiography was performed. The patient did not have clinical symptoms. The site reported 20% stenosis at the target lesion. No revascularization was performed.</p> <p>On 10 January 2005 a repeat angiography was performed. The site reported stable angina CCS class 2 and a positive functional study. No CK/CKMB values were available. According to the site, a plaque was detected which proved to be of hemodynamic significance during the a stress-echocardiography. The Angiography Core Lab reported 68% in stent restenosis and TIMI flow 3. The Angiography Corelab reported a type 2 ISR. They reported that PCI for the in stent restenosis was performed and reported a lateral opening of the OM ostium.</p>	<p>Event of 10 January 2005 reported by site as revascularization of Target Lesion and of Target Vessel at other location than Target Lesion. Adjudicated by CEC as only Target Lesion Revascularization..</p>

Site	Pt	Case Summary	Comments
		No event (no nQMI) 0 days post procedure	
		The patient is a 55-year-old male with a history of diabetes mellitus, hyperlipidemia and hypertension. The patient presented no complaints of angina but had a positive stress test. On April 19, 2004 he underwent the index procedure with the assigned treatment in the proximal CX. One stent was implanted. No dissection occurred post procedure and the site reported a 0% final residual stenosis with TIMI flow III. Pre procedure the CK peaked at 358 (nl 171, ratio 2.1) with a CK-MB of 18 (nl 24, ratio <1). Approx. 6-8 hours post-procedure the CK dropped to 252 (ratio 1.5) and CK-MB was 23 (ratio <1) Approx. 20-24 hours post-procedure the CK was 211 (ratio 1.2) and CK-MB within the normal range. The site reported a non-Q-wave MI. The ECG core lab reported no new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI) and no new Q-wave Myocardial Infarction. The patient was discharged on April 20 on ASA and clopidogrel.	Event of 19 April 2004 reported by site as non Q-wave MI. Adjudicated by CEC as no event.
		No event (no nQMI) 1 day post procedure	
		The patient is a 60-year-old male with a history of MI, hyperlipidemia and premature CAD in a first-degree relative. The patient presented with no complaints of angina and had no positive stress test. On April 26, 2004 he underwent the index procedure with the assigned treatment in the proximal RCA. One stent was implanted. No dissection occurred post procedure. The site reported a 0% final stenosis with a TIMI flow III. The pre-procedure CK was 140 (nl 171, ratio <1) with a CK-MB of 17 (nl 24, ratio <1). Approx. 20-24 hours post procedure, the CK peaked at 200 (ratio 1.2) with a CK-MB of 14 (ratio <1). The site reported a Non-Q-wave MI. The ECG was not interpretable by the ECG Core Lab because of an incomplete pre-procedure ECG. The patient was discharged on April 27, 2004 on ASA and clopidogrel.	Event of 27 April 2004 reported by site as non Q-wave MI. Adjudicated by CEC as no event.

		Case Summary	Comments
		<p>Non Target Vessel Revascularization 245 days post procedure</p> <p>The patient is a 69-year-old male with a history of prior percutaneous coronary revascularization, hyperlipidemia and hypertension. He presented with stable angina CCS class 1. On 11 May 2004 he underwent the assigned treatment in the proximal LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported 17% residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 12 May 2004 on ASA and clopidogrel.</p> <p>On 11 January 2005, the 8 months repeat angiography was performed. The patient had clinical symptoms. No lab values were measured. No ECG was available. The site reported 0% stenosis at the target lesion. The Angiography Core Lab reported 29% stenosis at the target lesion with TIMI flow 3. Revascularization of a non target vessel, the distal CX, was performed.</p>	
		<p>Target Lesion Revascularization, Clinically Driven 197 days post-procedure</p> <p>The patient is a 63-year-old male with a history of hyperlipidemia. He presented with stable angina CCS class 2. On 11 May 2004 he underwent the assigned treatment in the proximal CX. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported 22% residual stenosis at the target lesion with no dissection and TIMI flow 3. The patient was discharged on 12 May 2004 on ASA and clopidogrel.</p> <p>On 18 November 2004 the patient was hospitalized due to angina. On 20 Nov 2004 and on 22 Nov 2004, CK was 50 (nl 171, ratio <1). According to the ECG core lab the ECG of 24 November 2004 was not interpretable as no baseline ECG was available, so there was no reference. However, no major ST-T abnormalities and no abnormal Q-waves were observed. A repeat angiography was performed on 24 November 2004. The patient had clinical symptoms. The site reported 70% stenosis of the target lesion. The Angiography Corelab reported 57% stenosis at the target lesion with TIMI flow 3. A repeat revascularization of the target lesion (proximal CX) was performed.</p>	

	Case Summary	Comments
	<p>Non Q-wave MI 0 days post-procedure, Cardiac Death 123 days post-procedure</p>	
	<p>The patient is a 65-year-old male with a history of previous MI, hypertension and diabetes mellitus. The patient presented with unstable angina CCS Class IV. On 30 May 2004 he underwent the index procedure with the assigned treatment in the proximal CX. One stent was implanted. No dissection occurred post procedure. The site reported a 0% final stenosis with a TIMI flow III. The pre-procedure CK was 122 (nl 171, ratio <1) with a CK-MB of 17 (nl 24, ratio <1). Approx. 6-8 hours post procedure, the CK peaked at 471 (ratio 2.8) with a CK-MB of 61 (ratio 2.5). The ECG core lab reported no new major ST-T abnormalities and no new Q-wave myocardial infarction. Patient was discharged on June 4 on ASA and clopidogrel.</p> <p>On the morning of 30 September 2004, the patient started complaining of chest pain and dyspnea. He went to a pharmacy. The pharmacist called the emergency doctor, but when the physician arrived the patient had already died. Attempts to resuscitate were not successful. An autopsy was not performed. According to the investigator, the official cause of death was left heart failure.</p>	
	<p>No event (no vascular complication) 370-400 days post procedure</p> <p>The patient is a 70-year-old male. He presented with stable angina class 2. On April 26, 2004, he underwent the index procedure with the assigned treatment in the mid LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on April 28, 2004 on ASA and clopidogrel.</p> <p>In May 2005 (the exact date is unknown) the patient was hospitalized due to an abdominal aortic aneurysm. As hospitalization was not at the study site, a surgery report is not available. According to the site, this was not a cardiac event.</p>	

Site	Pt	Case Summary	Comments
		<p>Target Lesion Revascularization, Not Clinically Driven 245 days post-procedure; Non Target Vessel Revascularization 245 days post procedure</p>	
		<p>The patient is a 59-year-old male with a history of diabetes mellitus, hypertension and smoking. He presented with unstable angina CCS class 4. On 25 March 2004 he underwent the index procedure with the assigned treatment in the mid LAD, in which two stents were implanted because of the long lesion. The site reported 10% final residual stenosis with no dissection and TIMI flow 3. The Angiographic Core Lab reported a 45% final residual in-lesion stenosis with no dissection and TIMI flow 3. The patient was discharged on 26 March 2004 on ASA and clopidogrel.</p> <p>On 24 November 2004 the patient was hospitalized for the scheduled 8 months angiography. The patient did not have clinical symptoms. The site reported a 75% stenosis of the target lesion and 80% stenosis in the RCA. The Angiographic Core Lab reported a 67% in-lesion stenosis with TIMI flow 3. On 25 November 2004 a re-PTCA and implantation of a TAXUS stent was performed of the target lesion and non target vessel. The Angiographic Core lab mentioned that a target vessel and a non target vessel revascularization were performed. Target vessel revascularization was performed on the mid LAD (target lesion) and the non target vessel revascularization was performed on the distal RCA.</p>	
		<p>Target Lesion Revascularization, Clinically Driven 239 days post-procedure</p>	
		<p>The patient is a 75-year-old female with a history of hyperlipidemia and hypertension. She presented with stable angina CCS class 1. On 21 April 2004 she underwent the index procedure with the assigned treatment in the mid LAD. Two stents were implanted. After implantation of the first stent, a second stent was placed distally because of a dissection. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiographic Core Lab reported a 30% final residual stenosis, with no dissection and TIMI flow 3. The patient was discharged on 22 April 2004 on ASA and clopidogrel.</p> <p>On 16 December 2004 the 8 months angiography was performed. The patient did not have clinical symptoms. The site reported a 90% stenosis of the target lesion. The Angiographic Core Lab reported a 77% in-lesion stenosis. On the same day, a reintervention of the Mid LAD was performed.</p>	

Site	Pt	Case Summary	Comments
		<p>Target Vessel Revascularization – 329 days post-procedure; Target Vessel Revascularization 555 days post procedure</p>	
		<p>The patient is a 67-year-old male with a history of hyperlipidemia, hypertension, smoking and premature CAD in a first degree relative. He presented with stable angina CCS class 2. On 26 April 2004 he underwent the index procedure with the assigned treatment in the proximal RCA. Two stents were implanted. A second stent was placed proximal of the first stent because of the long lesion. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiographic Core Lab reported a final residual stenosis of 10% with no dissection and TIMI flow 3. The patient was discharged on 26 April 2004 on ASA and Clopidogrel.</p> <p>On 6 December 2004, the 8 months follow up angiography was performed. The patient did not have clinical symptoms. The site reported 0% stenosis of the target lesion. The Angiography Core Lab reported 33% stenosis at the target lesion with TIMI flow 3. They reported that the study stent was patent. No repeat revascularization was performed.</p> <p>In January 2005 the patient started complaining of angina CCS class 2-3. On 20 March 2005 CK and CKMB values were measured. The highest CK measured was 114 (nl 190, ratio <1) and the highest CKMB 13 (nl 24, ratio <1). The ECG Corelab reported no significant changes compared to baseline ECG (no new major ST-T abnormalities, possible myocardial ischemia, injury or NQMI and no new Q wave Myocardial Infarction). On 21 March 2005 a repeat angiography was performed. The site reported 0% stenosis of the target lesion. The Angiography Core Lab reported 29% stenosis at the target lesion with TIMI flow 3. The Angiography Core Lab reported that the study stent was still patent. A revascularization of the target vessel, the distal RCA, was performed on 21 March 2005.</p> <p>In November 2005 the patient started complaining again of chest pain. ECG and blood values are not available. An angiography was performed on November 2, 2005. The site reported a patent stent in the proximal RCA and a restenosis of the stent in the distal RCA. The angiography film is not available. A revascularization of the distal RCA was performed</p>	

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 142 days post procedure</p> <p>The patient is a 48-year-old male with a history of hyperlipidemia, hypertension and smoking. He presented with unstable angina. On 28 April 2004 he underwent the index procedure with the assigned treatment in the mid LAD. One study stent was implanted. The site reported 10% final residual stenosis with no dissection and TIMI flow 3. The angiography Corelab reported 25% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 29 April 2004 on ASA and clopidogrel.</p> <p>On 16 September 2004 the patient was hospitalized because of recurrent angina. The CK was 323 (nl 190, ratio 1.7) and CKMB was 15 (nl 24, ratio <1). The ECG corelab reported no significant changes compared to baseline. No new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI) and no new Q wave myocardial infarction. A repeat angiography was performed on 17 September 2004. The site reported 0% stenosis at the target lesion. The Angiography Corelab reported 28% stenosis at the target lesion with TIMI flow 3. The Angiography Corelab reported that the study stent was patent and a non target vessel revascularization was performed. On 17 September 2004 a revascularization of a non target vessel, the 1st Ob Marg was performed.</p>	
		<p>Target Lesion Revascularization, Clinically Driven 167 days post-procedure</p> <p>The patient is a 74-year-old male with a history of prior CABG, diabetes, hyperlipidemia and hypertension. He presented with stable angina CCS class 2. On 28 April 2004 he underwent the index procedure with the assigned treatment in the 3rd Ob Marg. One stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 15% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 29 April 2004 on ASA and clopidogrel.</p> <p>On 11 October 2004 the patient was hospitalized because of recurrent angina CCS class 3 and a positive functional study. The CK was 116 (nl 190, ratio <1). The CKMB was 16 (nl 24, ratio <1). Compared to the baseline, the ECG Corelab reported a new interval prolongation: PR interval, 260 ms and new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI). They reported persistent inferolateral T- wave inversion, indeterminate age/old. They reported no new Q wave MI.</p> <p>On 12 October 2004, a repeat angiography was performed. The site reported 99% stenosis of the target lesion. The Angiography Corelab reported 97% stenosis of the target lesion with TIMI flow 2. Target lesion revascularization was performed on the 3rd Ob Marg.</p>	

	Case Summary	Comments
	Non Q-wave MI 1 day post-procedure	
	The patient is a 79-year-old female with a history of diabetes mellitus, hyperlipidemia and hypertension. The patient presented with stable angina CCS class II. On 29 April 2004 she underwent the index procedure with the assigned treatment in the proximal CX. One stent was implanted. No dissection occurred post procedure. The site reported a 0% final residual stenosis with TIMI flow III. The pre-procedure CK was 51 (nl 167, ratio <1) with a CK-MB of 19 (nl 24, ratio <1). Approx. 20-24 hours post procedure, the CK peaked at 371 (ratio 2.2) with a CK-MB of 52 (ratio 2.2). The ECG core lab reported no significant changes; no new major ST-T abnormalities and no new Q-waves. Patient was discharged on May 6, 2004 on ASA and clopidogrel.	
	No event 266 days post procedure	
	The patient is a 67-year-old male with a history of hyperlipidemia and hypertension. He presented with stable angina CCS class 2. On 29 April 2004 he underwent the index procedure with the assigned treatment in the proximal RCA. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 1 May 2004 on ASA and clopidogrel. On 19 January 2005 the patient was hospitalized due to peripheral vascular disease. He was discharged on 11 February 2005. On 20 January 2005, a TEA of the Truncus Tibiofibularis was performed, as well as a femoro-popliteal bypass graft and a jump graft. Postoperative a bleeding occurred. The site reported a hematoma of > 5cm and significant blood loss at the cath site. On 21 January 2005 a transfusion was performed. On 24 January 2004, a fasciotomy was performed. The patient was discharged on 11 February 2005.	Site reported bleeding requiring transfusion on 20 January 2005. CEC adjudicated as no event.
	No event (no Non Q wave MI) 727 days post procedure	
	The patient is a 56-year-old male with a history of hyperlipidemia, hypertension and premature CAD in a first degree relative. He presented with stable angina CCS class 2 and a positive stress test. On April 30, 2004, he underwent the index procedure with the assigned treatment in the proximal LAD. Two stents were implanted. A second stent was placed distal of the first stent because of a dissection grade A. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported a final residual stenosis of 30% with no dissection and TIMI flow 3. The patient was discharged on May 1, 2004 on ASA and clopidogrel. The patient was hospitalized on April 27, 2006 because of a positive stress test. The patient did not have anginal complaints. On April 27 the CK value was 466 (nl 24-174 U/l, ratio 2.7) and the CKMB 15 (nl 1-25 U/l, ratio <1). No ECG was available. A repeat angiography was performed on April 28, 2006. The angiography corelab reported 27% residual stenosis at the target lesion. They reported a patent study stent.	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

	Case Summary	Comments
<div style="border: 2px solid red; width: 40px; height: 40px; margin: 5px;"></div>	<p>No event (no nQMI) 127 days post procedure; Target Lesion Revascularization, Clinically Driven 128 days post-procedure; Non Target Vessel Revascularization 178 days post procedure; CABG, Target Vessel Revascularization 470 days post procedure</p>	
	<p>The patient is a 51-year-old male with a history of prior percutaneous coronary revascularization, hyperlipidemia, hypertension and smoking. He presented with stable angina CCS class 2. On 3 May 2004 he underwent the index procedure with the assigned treatment in the mid LAD. Two stents were implanted. A second stent was implanted proximally to the first stent due to the long lesion. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 12% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 5 May 2004 on ASA and clopidogrel.</p> <p>On 7 September 2004 the patient presented with clinical symptoms: unstable angina pectoris. The site reported a non Q-wave MI. They also reported a positive Troponin. The CK peaked at 219 (nl < 190, ratio 1.2). CKMB peaked at 32 (nl < 24 ratio 1.3). The ECG Corelab reported new conduction abnormalities (persistent RBBB, incomplete) and new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI). They reported persistent inferior ST elevation, age recent/acute and persistent inferolateral T wave inversion, age recent/acute. They reported no new Q-Wave Myocardial Infarction. An angiography was performed on 8 September 2004 and the site reported 95% stenosis of the target lesion. The Angiography Corelab reported 75% stenosis of the target lesion with TIMI flow 2. A target lesion revascularization was performed of the mid LAD for a type 1B ISR, reported by the Angiography Corelab.</p> <p>On 26 October 2004 the patient presented with clinical symptoms. The chest pain had started on 5 October 2004. An angiography was performed on 28 October 2004 and the site reported 25% stenosis of the target lesion. The Angiography Corelab reported 51% stenosis of the target lesion with TIMI flow 3. Non-target vessel revascularization was performed at the prox CX.</p> <p>On July 27, 2005 the patient was hospitalized because of dyspnea. He did not report symptoms of angina pectoris. Severe aortic valve failure was identified during echocardiography. A repeat angiography was performed which showed aortic insufficiency grade II-III and 50-60% stenosis of the target lesion. The angiography corelab reported 53% stenosis of the target lesion. They reported an unchanged in stent restenosis type 1A. The patient was discharged from the hospital on July 30, 2005.</p> <p>On August 15, 2005, the patient was rehospitalized for a scheduled cardiac surgery. On August 16, 2005, the surgery took place. An aortic valve replacement was performed. The intended grafting of the LAD could not be performed. Therefore, a left mammary artery bypass to the first diagonal was performed. The patient was discharged from the hospital on August 25, 2005.</p>	<p>Site reported non Q wave MI on 7 September 2004. CEC adjudicated this as no event.</p>

Site	Pt	Case Summary	Comments
		Target Lesion Revascularization, Clinically Driven 252 days post-procedure, no event (no UADE) 252 days post procedure	
		<p>The patient is a 76-year-old female with a history of previous MI, hyperlipidemia, hypertension and premature CAD in a first degree relative. She presented with unstable angina. On 5 May 2004 she underwent the index procedure with the assigned treatment in the mid LAD. Two study stents were implanted, both with a diameter of 3.0mm and a length of 18mm. A second stent was implanted proximal of te first stent due to the long lesion. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 6% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 6 May 2004 on ASA and clopidogrel.</p> <p>On 11 January 2005 the patient presented with clinical symptoms. The CK was 85 (nl 167, ratio <1). CKMB was not done. The ECG corelab reported no significant changes compared to baseline. No new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI) and no new Q wave Myocardial Infarction. A repeat angiography was performed on 12 January 2005. The site reported 90% stenosis of the target lesion. The Angiography Corelab reported 61% stenosis of the target lesion with TIMI flow 3. The Angiography Corelab also reported that a Target Lesion Revascularization was performed because of type 1C ISR. They also reported a stent fracture. Target lesion revascularization was performed on the mid LAD.</p>	
		Non Target Vessel Revascularization 249 days post procedure	
		<p>The patient is a 56-year-old female with a history of diabetes, hyperlipidemia, hypertension and premature CAD in a first-degree relative. She presented with stable angina CCS class 3. On 10 May 2004 she underwent the index procedure with the assigned treatment in the mid LAD. A second stent was implanted proximal of the first stent because of the long lesion. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angio Corelab reported 18% residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 11 May 2004 on ASA and clopidogrel.</p> <p>On 14 January 2005 the patient was hospitalized for the scheduled 8 months angiography. She presented with angina pectoris CCS class 1 since 2 months. The CK measured on 13 January 2005 was 106 (nl 167, ratio <1), the CKMB was 15 (nl <24, ratio <1). The site reported 10% stenosis at the target lesion. The Angiographic Core Lab reported 36% stenosis in the target lesion with TIMI flow 3. A non-target vessel revascularization was performed on the prox CX.</p>	

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 244 days post procedure</p> <p>The patient is a 72-year-old male with a history of hyperlipidemia, hypertension and premature CAD in a first-degree relative. He presented with unstable angina. On 14 May 2004 he underwent the index procedure with the assigned treatment in the prox LAD. A second stent was implanted in distally to the first due to the length of the lesion. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angio Corelab reported 37% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 26 May 2004 on ASA and clopidogrel.</p> <p>On 13 January 2005 the patient was hospitalized for the scheduled 8 month angiography. The site reported 0% stenosis at the target lesion. The Angiographic Core Lab reported 40% stenosis in the target lesion and TIMI flow 3. A non-target vessel revascularization was performed on the mid RCA.</p>	
		<p>Non Q-wave MI 0 days post-procedure</p> <p>The patient is a 74-year-old male with a history of hypertension, smoking and pretreatment with PTCA. The patient presented with stable angina CCS class III. On 17 May 2004 he underwent the index procedure with the assigned treatment in the LAD. Initially 2 stents were implanted in the proximal LAD. To cover a distal type B dissection, a third stent was implanted in the mid LAD. The site reported a 0% final residual stenosis with no dissection and TIMI flow III. The pre-procedure CK was 60 (nl 190, ratio <1) with a CKMB of 14 (nl 24, ratio <1). Approx. 12 hours post procedure, the CK peaked at 680 (ratio 3.6) with a CKMB of 118 (ratio 4.9). The ECG core lab reported no new major ST-T abnormalities and no new Q-waves. The patient was discharged on 27 May 2004 on ASA and clopidogrel.</p>	

Site	Pt	Case Summary	Comments
		<p>No event (no non Q-wave MI) 335 days post procedure; CABG, Target Vessel Revascularization – 335 days post procedure</p>	
		<p>The patient is a 71-year-old male with a history of diabetes mellitus, hyperlipidemia, hypertension and smoking. The patient did not present with anginal symptoms. On 18 May 2004 he underwent the index procedure with the assigned treatment in the mid LAD. One study stent was implanted. The site reported 5% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported an 8% final residual stenosis with .no dissection and TIMI flow 3. The patient was discharged on 19 May 2004 on ASA and clopidogrel.</p> <p>On 26 March 2005 the patient was hospitalized due to dyspnea and cardiac failure. The CK value peaked at 929 U/L on 18 April 2005 (normal 0-190 U/L, ratio 4.9), CKMB was 105 (nl <24, ratio 4.4). The ECG Corelab reported new intermittent isolated VPDs, new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI), persistent AL/Apical T wave inversion with indeterminate age and no new Q wave myocardial infarction on the ECG of 8 April 2005 as compared to the ECGs of 11 and 18 May 2004. This was classified by the Clinical Event Committee as no event.</p> <p>A repeat angiography was performed on 11 April 2005. The site reported a severe aortic stenosis and 0% stenosis of the target lesion. The Angiography Corelab reported 9% stenosis of the target lesion with TIMI flow 3. They reported a patent study stent with mild neointimal hyperplasia. On 18 April 2005 an aortic valve replacement and a single bypass to the target vessel were performed. The patient was discharged on 26 April 2005.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 178 days post procedure</p> <p>The patient is a 69-year-old male with a history of hyperlipidemia. He presented with stable angina CCS class 2. On 4 June 2004 he underwent the index procedure with the assigned treatment in the prox RCA. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angio Corelab reported 5% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 5 June 2004 on ASA and clopidogrel.</p> <p>On 19 November 2004 the patient was hospitalized due to recurrent angina. According to the site there were no signs of Myocardial infarction. The CK peaked at 156 (nl 190, ratio <1) and the CKMB peaked at 47 (nl <24, ratio 2.0). The ECG Corelab reported no significant changes (no new ST-T abnormalities and no new Q wave). A repeat angiography was performed on 22 November 2004. The site reported 0% stenosis at the target lesion. The Angio Corelab reported 19% stenosis at the target lesion with TIMI flow 3. The Angio corelab reported that the study stent is patent and no procedure was done. On 2 December 2004 a second scheduled repeat angiography was performed with the purpose to perform a revascularization. The patient did not have clinical symptoms. According to the Angiography Corelab, the target lesion was not adequately shown and, therefore, no analysis is available. A repeat revascularization of the prox LAD (non target vessel) was performed.</p>	
		<p>Stroke 123 days post-procedure</p> <p>The patient is a 76-year-old male with a history of previous MI, hyperlipidemia and hypertension. He presented with unstable angina. On 14 June 2004 he underwent the index procedure with the assigned treatment in the mid RCA. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 15 June 2004 on ASA and clopidogrel.</p> <p>On 15 October 2004 the patient was hospitalized at another hospital than the study site due to apoplexia. This site reported a left hemispherical cardioembolic posterior infarct. The study site reported permanent neurological deficits (decreased consciousness, sensory, coordination, motor and speech deficits, located in the cranial nerves/face). They also reported that the event could be related to anticoagulation. After medical therapy his status improved.</p>	

		Case Summary	Comments
		<p>No event (Revascularization of iliac artery) 40 days post procedure; Target Lesion Revascularization, Clinically Driven 242 days post-procedure</p>	
		<p>The patient is a 52-year old male with a history of hyperlipidemia, hypertension and smoking. He presented with stable angina CCS class 2. On 19 March 2004 he underwent the assigned treatment in the proximal RCA. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported 10% final residual in-lesion stenosis with no dissection and TIMI flow 3. The patient was discharged on 21 March 2004 on ASA and clopidogrel.</p> <p>On 28 April 2004 the patient was hospitalized for planned stenting of the right iliacal artery. During the initial procedure, chronic occlusion of the right iliacal artery had been diagnosed. According to the investigator, this was not stent or procedure related.</p> <p>On 16 November 2004 the 8 months repeat angiography was performed. The patient did not have clinical symptoms. The site reported a diameter stenosis of 95% at the target lesion. The Angiography Core Lab reported a 72% in-lesion stenosis with TIMI flow 3. A repeat revascularization of the target lesion (proximal RCA) was performed.</p>	
		<p>Non Q-wave MI 0 days post-procedure</p>	
		<p>The patient is a 73-year-old male with a history of previous MI, hyperlipidemia and hypertension. He presented with stable angina CCS class II. On March 23, 2004 he underwent the assigned treatment in the proximal RCA. Two stents were implanted. During the index procedure coronary artery spasm occurred. No dissection occurred post procedure. The site reported 0% final stenosis with TIMI flow III. The pre-procedure CK was 132 (nl 174, ratio <1); CK-MB was not measured. Approx. 20-24 hours post procedure, the CK peaked at 403 (ratio 2.3) with a CK-MB of 36.3 (nl <6% of CK, 9%) The ECG Core lab reported no new major ST-T abnormalities and no new Q-waves. The patient was discharged on March 25, 2004 on ASA and clopidogrel. The site reported that the patient was hospitalized in another hospital because of shortness of breath, but he experienced <u>no</u> angina. Acute Coronary Syndrome and MI were ruled out. The reason for his complaint was congestive heart failure due to impaired left ventricular function and atrial fibrillation with tachycardia.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		Non Target Vessel Revascularization 275 days post procedure	
		<p>The patient is a 38-year-old male with a history of hyperlipidemia and smoking. He presented with stable angina CCS class 2. On 14 June 2004 he underwent the assigned treatment in the R-PDA. One study stent was implanted. The site reported a 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported 6% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 15 June 2004 on ASA and clopidogrel.</p> <p>As of January 2005 the patient reported angina pectoris. On 15 March 2005 the patient was hospitalized for a planned revascularization of a non target vessel. CK was 184 (nl 174, ratio 1.06) and CKMB 2.6 (nl <6% of CK). The ECG Core Lab reported no significant changes (no new major ST-T abnormalities and no new Q wave Myocardial Infarction). The site reported a 0% diameter stenosis of the target lesion. The Angiography Core Lab reported 20% diameter stenosis of the target lesion and TIMI flow 3. On 16 March 2005 a repeat revascularization of the 1st LPL (non target vessel) was performed.</p>	

Site	Pt	Case Summary	Comments
		<p>No event 41 days post procedure; Target Vessel Revascularization 54 days post-procedure</p>	
		<p>The patient is a 74-year-old female with a history of hyperlipidemia, hypertension and premature CAD in a first degree relative. She presented with unstable angina CCS class 2. On 24 March 2004 she underwent the index procedure with the assigned treatment in the mid LAD. Two stents were implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 23% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 25 March 2004 on ASA and clopidogrel</p> <p>On 4 May 2004 the patient was hospitalized due to tachyarrhythmia. The site reported ECG changes due to ischemia in the RIVA-region. CK and CKMB values were not available. The ECG corelab reported intermittent atrial fibrillation and persistent sinus rhythm. The ECG corelab also reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI). They reported persistent inferior ST depression, age recent/acute and persistent anterior ST depression, age recent/acute. The ECG corelab reported no new Q wave Myocardial infarction.</p> <p>A repeated angiography was performed on 17 May 2004. The site reported 20% stenosis at the target lesion and a de novo stenosis proximal to the stent. The Angio Corelab reported 22% stenosis at the target lesion with TIMI flow 3. A repeat revascularization of the target vessel was performed. The Angio Corelab reported that the target vessel revascularization was done at the proximal part of the LAD and that the stent was patent.</p> <p>On 17 May 2004 a re-PTCA and implantation of a stent was performed in the prox LAD.</p>	

Site	Pt	Case Summary	Comments
		Target Lesion Revascularization, Clinically Driven 255 days post-procedure, NQMI 256 days post-procedure	
		<p>The patient is a 78-year-old male with a history of a previous MI, hyperlipidemia and hypertension. He presented with angina pectoris CCS class 2 after having suffered from a myocardial infarction. On 30 March 2004 he underwent the index procedure with the assigned treatment in the mid LAD. One study stent was implanted. The site reported 50% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 52% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 31 March 2004 on ASA and clopidogrel</p> <p>On 10 December 2004 the 8 months repeat angiography was performed. The site reported 90% stenosis at the target lesion. The Angiography Corelab reported 77% stenosis at the target lesion with TIMI flow 3. The Angiography Corelab reported type III ISR. A repeat revascularization with stent placement was performed at the target lesion (mid LAD). A new drug eluting stent was implanted. After the procedure the CK level increased. On 11 December 2004 the CK peaked at 568 (nl 171, ratio 3.3) and the CKMB peaked at 56 (nl 28, ratio 2). The ECG corelab reported no significant changes compared to baseline. No new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI) and no new Q wave Myocardial Infarction were reported by the ECG corelab. According to the site, the patient had a non Q-wave MI.</p>	
		Non Target Vessel Revascularization 257 days post procedure	
		<p>The patient is a 62-year-old male with a history of a previous MI, prior percutaneous coronary revascularization, hyperlipidemia and premature CAD in a first-degree relative. He presented with stable angina pectoris CCS class 2. On 6 May 2004 he underwent the index procedure with the assigned treatment in the mid LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 19% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 7 May 2004 on ASA and clopidogrel</p> <p>On 18 January 2005 the 8 months repeat angiography was performed. The patient had no clinical symptoms. The site reported 10% stenosis at the target lesion. The Angiography Corelab reported 5% stenosis at the target lesion with TIMI flow 3. A non-target revascularization was performed at the prox CX.</p>	

Site	Pt	Case Summary	Comments
		NQMI 238 days post-procedure; Non Target Vessel Revascularization 238 days post procedure	
		<p>The patient is a 71-year-old male with a history of diabetes, hyperlipidemia, hypertension and premature CAD in a first-degree relative. On 18 May 2004 he underwent the index procedure with the assigned treatment in the 1st Ob Marg. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 14% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 19 May 2004 on ASA and clopidogrel</p> <p>On 11 January 2005 the patient was hospitalized. The site reported a Q-wave MI. The CK peaked at 1317 (nl 171, ratio 7.7) and the CKMB peaked at 162 (nl 28, ratio 5.8). The ECG Corelab reported new conduction abnormalities (persistent RBBB, incomplete) and new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI). They reported persistent anterior ST elevation, age recent/acute. They reported that interpretation of a new myocardial infarction could not be performed. On the ECGs of 17 and 19 January 2005 they reported no significant changes (no new major ST-T abnormalities and no new Q-wave Myocardial Infarction). On the ECG of 31 January they reported new major ST-T abnormalities (persistent AL/Apical T wave inversion, age recent/acute) and no new Q-wave Myocardial Infarction. On the ECG of 3 February 2005 they reported no significant changes. On 11 January 2005 the 8 months repeat angiography was performed. The site reported 0% stenosis at the target lesion. The Angiography Corelab reported 11% stenosis at the target lesion with TIMI flow 3. A non-target vessel revascularization with stent placement was performed at the prox RCA.</p>	<p>Event of 11 January 2005 reported by site as Q wave MI.</p> <p>Adjudicated by CEC as non Q wave MI.</p>

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		Non Q-wave MI 0 days post-procedure	
		The patient is a 57-year-old male with a history of hyperlipidemia, hypertension and premature CAD in a first-degree relative. He presented with stable angina CCS class III. On 28 May 2004 he underwent the assigned treatment in the Mid LAD. One stent was implanted. The site reported a 0% final residual stenosis with TIMI flow III. The pre-procedure CK was 93 (nl 171, ratio <1) with a CK-MB of 7 (nl 28, ratio <1). Approx. 12-16 hours post procedure, the CK peaked at 481 (ratio 2.8) with a CK-MB of 58 (ratio 2.1). The ECG core lab reported no new major ST-T abnormalities and no new Q-waves. The patient was discharged on May 29, 2004 on ASA and clopidogrel.	
		Non Target Vessel Revascularization 90 days post procedure; CABG, Target Vessel Revascularization 322 days post procedure, Non Target Vessel Revascularization 322 days post procedure	
		<p>The patient is a 68-year-old male with a history of hyperlipidemia, hypertension and premature CAD in a first degree relative. He presented with stable angina CCS class 2. On 28 May 2004 he underwent the index procedure with the assigned treatment in the mid RCA. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 18% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 29 May 2004 on ASA and clopidogrel.</p> <p>On 25 August 2004 the patient was hospitalized for a prognostic angiography. The patient did not have clinical symptoms. The repeat angiography was performed on 26 August 2004. The site reported 0% stenosis at the target lesion. The Angiographic Core Lab reported 23% stenosis in the target lesion with TIMI flow 3. A non target vessel repeat revascularization of the prox CX, the dist CX and 1st Ob Marg was performed.</p> <p>On 5 April 2005 the patient was hospitalized due to progression of cardiovascular disease. The patient suffered from unstable angina pectoris. On 15 April 2005 a CABG was performed at a referring hospital involving the 2nd Diag, mid LAD, 1st Ob Marg and the R-PAV. The operation was performed without complications. The postoperative course was also without complications. The patient was discharged on 29 April 2005.</p>	

Site	Pt	Case Summary	Comments
		<p>No event 127 days post procedure; Target Lesion Revascularization, Clinically Driven 175 days post-procedure</p>	
		<p>The patient is a 43-year-old male with a history of previous MI, prior percutaneous coronary revascularization, hyperlipidemia, smoking and premature CAD in a first-degree relative. He presented with stable angina CCS class 2. On 17 June 2004 he underwent the index procedure with the assigned treatment in the mid RCA. One stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 20% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 18 June 2004 on ASA and clopidogrel.</p> <p>On 22 October 2004 the patient was hospitalized due to a neurological disease. The site reported motor and coordination deficits in the legs that lasted < 24 hours. The discharge letter reported a TIA of the brain stem with giddiness, uncertain gait and visual disturbances. The symptoms lasted a few minutes. Medical therapy was performed.</p> <p>On 8 December 2004 the patient was hospitalized with new onset of angina pectoris. The highest CK value measured on 9 December 2004 was 90 (nl 171, ratio<1). CKMB was not measured. The ECG Corelab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI); persistent AL / apical T wave inversion, age recent / acute and no new Q-wave MI. On 9 December 2004 an angiography was performed. The site reported a restenosis proximal of the target lesion. The Angiography Core Lab reported 73% stenosis in the target lesion with TIMI flow 3. The Angiography Core Lab reported a type 1B ISR and a target vessel revascularization. A target vessel revascularization of the prox RCA was performed.</p>	<p>Event on 22 October 2004 reported by site as TIA. Adjudicated by CEC as no event.</p> <p>Event on 9 December 2004 reported by site as target vessel revascularization. Adjudicated by CEC as target lesion revascularization.</p>

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Target Lesion Revascularization, Clinically Driven 230 days post-procedure; Non Q wave MI 591 days post procedure; CABG, Non Target Vessel Revascularization 591 days post procedure</p>	
		<p>The patient is a 72-year-old female with a history of prior CABG and hypertension. She presented with stable angina CCS class 2. On 30 March 2004 she underwent the assigned treatment in the mid RCA. One stent was implanted. The site reported a 10% final residual stenosis with no dissection and a TIMI flow 3. The Angiography Corelab reported 22% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab also reported that no predilatation was performed and a residual disease was left uncovered proximal and distal of the study stent. On 31 March 2004 the patient was discharged on ASA and clopidogrel.</p> <p>On 15 November 2004 the 8 months repeat angiography was performed. The patient presented with clinical symptoms and a positive functional study. The CK value was 1.36 (nl < 3.17, ratio <1). CKMB was 0.22 (nl <0.41, ratio <1). The site reported a 90% diameter stenosis at the target lesion. The Angiography Corelab reported 80% stenosis at the target lesion with TIMI flow 3. A revascularization of the target lesion (mid RCA) was performed.</p> <p>On November 7, 2005, the patient was hospitalized with angina pectoris symptoms. The ECG corelab reported no significant changes on the ECG of November 7, 2005 as compared to the one of March 31, 2004 (no new major ST-T abnormalities and non new Q wave MI). On November 11, 2005 the CK value was 8.43 (nl < 3.17 $\mu\text{mol/l*s}$, ratio 2.7) and the CKMB value 1.03 (nl < 0.41 $\mu\text{mol/l*s}$, ratio 2.5). On November 12, 2005 the CK peaked at 45.60 (ratio 14.4) and the CKMB at 2.61 (ratio 6.4). A repeat angiography was performed on November 7. The site reported 75% stenosis of the target lesion. The angiography corelab reported also 75% stenosis of the target lesion with TIMI flow 3. They reported repeated diffuse in stent restenosis type 3. On November 11, 2005, a CABG was performed involving the first diagonal of the LAD and not involving the target vessel or target lesion.</p>	<p>Event of 11 November 2005 not reported by site as non Q-wave MI. Adjudicated by CEC as non Q-wave MI</p>

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 245 days post procedure; Non Target Vessel Revascularization 428 days post procedure</p>	
		<p>The patient is a 64-year-old male with a history of hypertension. He presented with stable angina CCS class 1. On 5 April 2004 he underwent the assigned treatment in the mid LAD. One stent was implanted. The site reported 0% final residual stenosis with no dissection and a TIMI flow 3. The Angiography Core Lab reported a final residual stenosis of 19% with no dissection and TIMI flow 3.</p> <p>On 6 April 2004 the patient was discharged on ASA and Clopidogrel.</p> <p>On 6 December 2004 a repeat angiography was performed as the patient had clinical symptoms. The site reported a 20% diameter stenosis of the target lesion. The Angiography Core Lab reported 17% stenosis at the target lesion with TIMI flow 3. A repeat revascularization of a non target vessel (CX) was performed on 6 December 2004.</p> <p>On June 7, 2005 the patient was hospitalized with angina pectoris. The CK/CKMB values were not available. The ECG corelab reported no new major ST-T abnormalities and no new Q wave Myocardial Infarction. A repeat angiography was performed. The site reported 20% stenosis of the target lesion. The angiography corelab reported 4% stenosis of the target lesion. They reported a patent study stent in the LAD and a patent stent in the CX. They also reported that a non target vessel revascularization of the mid RCA was performed. The site reported a non target vessel revascularization of the mid RCA on June 7, 2005</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
[Redacted]	[Redacted]	<p>Target Lesion Revascularization, Clinically Driven 232 days post-procedure</p>	
		<p>The patient is a 56-year-old male with a history of prior percutaneous coronary revascularization, diabetes, hyperlipidemia and hypertension. The patient presented with stable angina CCS class 2. On 20 April 2004 he underwent the index procedure with the assigned treatment in the mid LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 17% final residual stenosis with no dissection and TMI flow 3. The patient was discharged on 21 April 2004 on ASA and clopidogrel.</p> <p>On 8 December 2004 a repeat angiography was performed. The patient did not have clinical symptoms, but had a positive functional study. The site reported a 20% stenosis of the target lesion and a significant stenosis in the proximal LAD. The Angiography Corelab reported 69% stenosis at the target lesion and TIMI flow 3. On 8 December 2004 a repeat revascularization was performed of the target vessel in the proximal LAD.</p>	<p>Event on 8 December 2004 reported by site as target vessel revascularization. Adjudicated by CEC as target lesion revascularization.</p>

Site	Pt	Case Summary	Comments
		<p>Target Lesion Revascularization, Clinically driven, 9 days post-procedure , Type B dissection 9 days post procedure; No event (no vascular/bleeding complication) 617 days post procedure; Non Cardiac Death 617 days post procedure</p>	
		<p>The patient is a 72-year-old male with a history of hyperlipidemia and hypertension. He presented with unstable angina. On April 21, 2004 he underwent the assigned treatment in the distal CX. One stent was implanted. The site reported a 0% final residual stenosis with TIMI flow III and no dissections were observed post procedure. The Angiographic Core Lab reported a 12% final residual in-lesion stenosis, with no dissection and TIMI flow 3. The patient was discharged on April 22, 2004 on ASA and clopidogrel.</p> <p>On April 29, 2004 the patient was rehospitalized with chest pain. No CK values were drawn. The ECG core lab reported no significant changes (no new major ST-T abnormalities and no new Q wave Myocardial Infarction). On April 30, 2004 a repeat angiography was performed which revealed a dissection distal to the study stent. The distal CX was treated with another Endeavor stent. The Angiographic Core Lab reported a 14% in-lesion stenosis and commented that the study stent was patent and “a new stent was deployed, for type B dissection at the distal end of the study stent”. The patient was discharged on May 1, 2004 without complaints.</p> <p>The patient was admitted to the emergency department on December 29, 2005 because of intense diffuse abdominal pain. The patient’s circulation was stable on admission. An abdominal sonography revealed a covered perforation of the infrarenal aortic aneurysm and an immediate surgery was scheduled. During surgery and after laparotomy, perforation of the aneurysm developed into the abdominal cavity. Despite immediate aortic clamping and volume substitution, the patient died during the surgery of hemorrhagic shock with acute treatment-resistant heart failure</p>	<p>Event of 29 December 2005 reported by site as major bleeding event/ major vascular event. Adjudicated by CEC as no event (no vascular/bleeding event)</p>

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		CABG, Target Lesion Revascularization, Clinically Driven 233 days post-procedure; CABG, Target Vessel Revascularization 233 days post procedure	
		<p>The patient is a 67-year-old male with a history of hyperlipidemia and hypertension. The patient presented with stable angina CCS class 3. On 27 April 2004 he underwent the index procedure with the assigned treatment in the mid LAD. Two stents were implanted. The site reported 5% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported a type 2 dissection after predilatation after deployment of the first stent, distal of the stent. They reported 11% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 28 April 2004 on ASA and clopidogrel.</p> <p>The patient was hospitalized on 14 June 2004 due to persistent angina symptoms. CK and CKMB values were not measured. The ECG was not available. A repeat angiography was performed and the site reported a 20% stenosis in the lumen of the stent, which could not have been the cause for angina. The site reported a subtotal ostial stenosis of the first diagonal as well as non-significant stenosis of the left main and a good ventricular function. The Angiography Corelab reported 27% stenosis at the target lesion with TIMI flow 3. They reported that the study stent was patent and no procedure was done. The patient was discharged on 15 June 2004 without further interventions. On 10 December 2004 the 8 months repeat angiography was performed. The patient had clinical symptoms. The site reported a 50% diameter stenosis of the target lesion. The Angiography Corelab reported 43% stenosis at the target lesion with TIMI flow 3. A CABG was performed on 16 December 2004 involving both the proximal and mid LAD.</p>	
		No event 0 days post procedure	
		<p>The patient is a 61-year-old male with a history of previous MI, hyperlipidemia and hypertension. He presented with stable angina CCS class I. On June 2, 2004 he underwent the assigned treatment in the proximal LAD. One stent was implanted. No dissection occurred post procedure. The site reported a 0% final residual stenosis with TIMI flow III. The pre-procedure CK drawn on June 1 was elevated at 9.78 (nl < 3.17 $\mu\text{mol}/(\text{l}^*\text{s})$, ratio 3.1) with a CKMB of 0.38 (nl < 0.41 $\mu\text{mol}/(\text{l}^*\text{s})$, ratio <1). Approx. 6- 8 hours post procedure the CK and CK-MB was 5.29 (ratio 1.7) and 0.23 (ratio 0.6) respectively. After 12-16 hours post procedure the CK rose again to 7.73 (ratio 2.4) with a CK-MB of 0.32 (ratio 0.8). The site reported a Non-Q-Wave MI. The ECG core lab reported no new major ST-T abnormalities and no new Q wave Myocardial Infarction. On June 4 the CK values were 4.99 (ratio 1.6) and CKMB 0.18 (ratio <1) and the patient was discharged on the same day on ASA and clopidogrel.</p>	<p>Event of 2 June 2004 reported by site as non Q-wave MI. Adjudicated by CEC as no event.</p>

		Case Summary	Comments
		No event 1 day post procedure	
		The patient is an 84-year-old male with a history of previous MI (05-29-2004), hyperlipidemia and hypertension. He presented with stable angina CCS class I. On 2 June 2004 he underwent the assigned treatment in the mid LAD. One stent was implanted. No dissection occurred post procedure. The site reported a 0% final residual stenosis with TIMI flow III. The pre-procedure CK and CK-MB was within normal range. Approx. 12- 16 hours post procedure, the CK and CK-MB rose to 4.09 (nl < 3.17 μmol/ (l*s), ratio 1.3) and 0.50 (nl <0.41 μmol/ (l*s), ratio 1.2) respectively. Approx. 20- 24 hours post procedure the CK peaked at 5.51 (ratio 1.7) and the CK-MB dropped to 0.42 (ratio 1.0).The ECG core lab reported no new ST-T abnormalities and no new Q wave Myocardial Infarction, and a new Rhythm and a new Interval Prolongation (PR) were reported. A repeat Angiography was made on June 4, which according to the site, revealed a restenosis of 20% in the target lesion. No revascularization was performed and the patient was discharged the next day on ASA and clopidogrel.	
		Vascular complication (transfusion) 0 days post procedure	
		The patient is a 71-year-old female with a history of hyperlipidemia and hypertension. She presented with stable angina CCS class II. On 9 June 2004 she underwent the index procedure with the assigned treatment in the mid LAD. One stent was implanted. The site reported a 20% final residual stenosis with no dissection and TIMI flow III. After the procedure a spurious aneurysm of the right AFS was found in de area of the puncture, with major bleeding into the area of the thigh. On June 10, 2 units of packed RBC's were transfused. The aneurysm could not be sealed by thrombin injection and the patient was referred to surgery on June 11. The A. femoralis superficialis lesion was sutured and the hematoma was cleared. Post-operative course was without complications. The patient was discharged on June 21, feeling well.	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>No event (no Non Q-wave MI) 391 days post procedure; Target Lesion Revascularization , Clinically Driven, 391 days post procedure; No event (no Non Q wave MI) 510 days post procedure; Total Occlusion 510 days post procedure; Target Lesion Revascularization, Clinically Driven 510 days post procedure; Total Occlusion 586 days post procedure; Target Lesion Revascularization, Clinically Driven, 586 days post procedure</p>	
		<p>The patient is a 60-year-old male with a history of hyperlipidemia and hypertension. He presented with stable angina CCS class 3 and a positive stress test. On April 21, 2004, he underwent the assigned treatment in the mid RCA. Two study stents were implanted. The second stent was implanted proximal from the first stent because of the long lesion. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The angiography corelab reported a final residual stenosis of 13% with no dissection and TIMI flow 3. The patient was discharged on April 23, 2004 on ASA, clopidogrel, Clexane, and Marcumar.</p> <p>On May 17, 2005 the patient was hospitalized because of unstable angina. The CK value was 138 (nl < 174 U/L, ratio <1) and CKMB 29 (nl <24 U/L, ratio 1.2). The ECG corelab reported for the ECGs of May 17 and 18, 2005 as compared to the ECG of April 22, 2004, new major ST-T abnormalities, possible myocardial ischemia, injury or NQMI (persistent AL/Apical ST depression, age recent/acute). They reported no new Q Wave Myocardial Infarction. A repeat angiography was performed. The site reported 80% stenosis of the target lesion. The angiography corelab reported 82% stenosis of the target lesion. They reported a type 2 in stent restenosis. A repeat revascularization of the mid RCA (target lesion) was performed.</p> <p>On September 13, 2005, the patient was hospitalized again because of unstable angina pectoris. The CK value was 62 (ratio <1). CKMB was not measured. The ECG corelab reported for the ECG of September 9, 2005 as compared to the ECG of May 18, 2005, new major ST-T abnormalities, possible myocardial ischemia, injury or NQMI (persistent Inferior T wave inversion, indeterminate age/old). They reported no new Q Wave Myocardial Infarction. A repeat angiography was performed. The site reported 100% stenosis of the target lesion. The angiography corelab reported also 100% stenosis of the target lesion with TIMI flow 1. According to the angiography corelab, no thrombus was present. They reported a total occlusion of the target lesion (in stent restenosis type 4). A repeat revascularization of the mid RCA (target lesion) was performed.</p> <p>On November 28, 2005, the patient was hospitalized again for unstable angina. The CK value was 122 (ratio <1) and CKMB 14 (ratio <1). The ECG corelab reported for the ECG of November 28, 2005 as compared to the ECG of September 9, 2005, no new major ST-T abnormalities, and no new Q Wave Myocardial Infarction. A repeat angiography was performed. The site reported 100% stenosis of the target lesion. The angiography corelab reported also 100% stenosis of the target lesion with TIMI flow 1. According to the angiography corelab, no thrombus was present. They reported a type 4 in stent restenosis. A revascularization of the RCA, including the mid RCA (target lesion) was performed.</p>	<p>Events of 13 September 2005 and 28 November 2005 not reported by site as total occlusion. Adjudicated by CEC as total occlusion.</p>

Site	Pt	Case Summary	Comments
		<p>Target Lesion Revascularization, Clinically Driven – 318 days post-procedure</p>	
		<p>The patient is a 61-year-old male with a history of hyperlipidemia, hypertension and smoking. The patient presented with stable angina CCS class 2. On 4 June 2004 he underwent the index procedure with the assigned treatment in the mid RCA. Two study stents were implanted. The second stent was implanted proximal of the first stent due to the long lesion. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 6% residual stenosis at the target lesion with no dissection and TIMI flow 3. The patient was discharged on 7 June 2004 on ASA and clopidogrel.</p> <p>On 18 April 2005 the patient was hospitalized with slightly progressive dyspnea and occasional angina pectoris under stress. The patient was transferred from the radiology department, where he had been treated for a stenosis in the renal artery. The ECG Corelab reported no significant changes of the ECG dated 18 April 2005 as compared to the ECG of 6 April 2004.</p> <p>A repeat angiography was performed. The site reported a 70% stenosis of the target lesion. The Angiography Corelab reported 70% stenosis of the target lesion (type 2 in-stent restenosis) and TIMI flow 3. Both the site and the angiography corelab reported that a PCI was performed at the target lesion.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Non Q-wave MI 1 day post-procedure, Non Q-wave MI 118 days post-procedure, Stroke 117 days post-procedure</p>	
		<p>The patient is a 75-year-old male with a history of percutaneous coronary revascularization of a non-target vessel, hyperlipidemia, hypertension, smoking and premature CAD in a first-degree relative. He presented with unstable angina CCS class IV. On 28 April 2004 he underwent the assigned treatment in the proximal LAD. Two stents were implanted. No dissection occurred post procedure. The site reported a 0% final residual stenosis with TIMI flow III. The pre-procedure CK was within normal range. CK-MB was not drawn. Approx. 12-16 hours post procedure CK and CK-MB peaked respectively at 580 (nl <173, ratio 3.4) and 90 (nl <6% of CK, 15.5 %). The ECG core lab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI): persistent AL/ Apical T wave inversion, age recent / acute. No new Q wave myocardial infarction. The site reported a non-Q-wave MI, however no repeat angiography or functional study were performed due to this event. The patient was discharged on April 30 on ASA and clopidogrel.</p> <p>On 23 August 2004, the patient felt down and was hospitalized following cerebral stroke. The hospital diagnosed a major intracerebral bleeding right, with perifocal edema, most likely to be of hypertensive etiology as the patient was known hypertensive. The stroke was confirmed by diagnostic test and is possibly related to anticoagulation. The clopidogrel treatment was stopped, due to continuous intracerebral bleeding. The patient got permanent deficits located on face, arms, legs and trunk: decreased consciousness, altered mentation, sensory, coordination, motor and speech deficits.</p> <p>In a discharge letter it was reported that the patient developed one day after the stroke, 24 August 2004, acute arrhythmia and fluctuations in blood pressure. Enzyme measurements and electrocardiography showed that this was NSTEMI, most probably triggered by the discontinuation of Plavix. On 24 August the CK was 429 (nl <173, ratio 2.48) and the CKMB 52 (nl <6% of CK) and on 25 August 2004 the PK peaked at 532 (nl <173, ratio 3.1) while the CKMB peaked at 64 (nl <6% of CK). The patient was treated with mid-dose heparin through the perfusor (20.000 IU/day) and under these conditions, no new clinical event was observed. Serum troponin was nevertheless still raised on release, with a value of 0.8. CKs values and ECG were not provided from this other hospital. The patient was treated conservatively.</p> <p>The 12 November 2004, the patient's general health condition was stable but did not improve anymore and he was transferred to a nursing home.</p>	

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 30 days post procedure; Non Target Vessel Revascularization 266 days post procedure</p>	
		<p>The patient is a 72-year-old female with a history of hyperlipidemia, hypertension and smoking. She presented with unstable angina CCS class IV. On May 3, 2004 she underwent the assigned treatment in the Mid RCA. One stent was implanted. No dissection occurred post procedure. The site reported a 0% final residual stenosis with TIMI flow III. The Angiographic Core Lab reported an 11% final residual in-lesion stenosis with TIMI flow 3 and commented that the “stenosis was borderline”. The post procedure course was uncomplicated and the patient was discharged on May 4 on ASA and clopidogrel.</p> <p>The patient was rehospitalized on June 2, 2004 for a scheduled PCI procedure. A stent implantation was performed in the mid LAD. Cardiac enzymes were within the normal range. The Angiographic Core Lab report revealed that the target lesion was 35% stenosed. The patient was discharged on June 3.</p> <p>On 24 January 2005 the 8 months scheduled anigography was performed. The patient did not have clinical symptoms. The site reported a 0% stenosis at the target lesion. The Angiography Corelab reported 16% stenosis at the target lesion with TIMI flow 3. A repeat revascularization of a non target vessel, the mid LAD, was performed.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Target Vessel Revascularization 259 days post-procedure</p> <p>The patient is a 54-year-old male with a history of smoking. He presented with stable angina CCS class 2. On 6 May 2004 he underwent the assigned treatment in the prox LAD. One stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 20% final residual stenosis with no dissection and TIMI flow 3. On 7 May 2004 the patient was discharged on ASA and clopidogrel.</p> <p>On 20 January 2005, the patient was hospitalized for the scheduled 8 months angiography. The patient had clinical symptoms. The measured CK was 116 (nl <173, ratio <1). The ECG was not available. The site reported 0% stenosis of the target lesion. The Angiography Corelab reported 19% stenosis of the target lesion with TIMI flow 3. A revascularization with stenting of the mid LAD (target vessel) was performed.</p>	
		<p>Non Q-wave MI 0 days post-procedure; Non Cardiac Death 657 days post procedure</p> <p>The patient is a 75-year-old male with a history of diabetes mellitus, hyperlipidemia and hypertension. He presented with unstable angina class III. On May 11, 2004, he underwent the assigned treatment in the distal CX. One stent was implanted. The site reported a 0% final residual stenosis with no dissection and TIMI flow III. The pre-procedure CK was within normal range. CK-MB was not drawn. Approx. 6-8 hours post procedure CK and CK-MB peaked respectively at 410 (nl <173, ratio 2.4) and 68 (nl <6% of CK, 16.6%). The ECG core lab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI): persistent AL / Apical T wave inversion, age recent / acute. There were no new Q-waves. Despite this event no repeat angiography or functional study were performed. The patient was discharged on May 15, 2004 on ASA and clopidogrel.</p> <p>On January 16, 2006 the patient was hospitalized for acute pancreatitis and the development of pseudocysts. After operative revision of the infected pseudocysts, the patient's condition initially stabilized. However, after some time he developed multiple organ failure requiring both respiratory therapy and hemofiltration. The patient also suffered from gastrointestinal bleeding form a ventricular ulcer. The bleeding affected the hemodynamics. Because of the worsening sepsis and the CT finding of necrosing pancreatitis and marked ascites formation, surgical revision was performed on February 26, 2006. The cardiopulmonary recompensation eventually failed and the patient died on February 27, 2006.</p>	<p>Event of 11 May 2004 reported by site as elevated CK. Adjudicated by CEC as non Q wave MI</p>

Site	Pt	Case Summary	Comments
		CABG, Target Lesion Revascularization, Not Clinically Driven 713 days post procedure; CABG, Non Target Vessel Revascularization 713 days post procedure	
		<p>The patient is a 59-year-old male with a history of hypertension and premature CAD in a first degree relative. He presented with unstable angina CCS class 4 and a positive stress test. On May 27, 2004 he underwent the index procedure with the assigned treatment in the 2nd obtuse marginal. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The angiography corelab reported 27% stenosis at the target lesion with no dissection and TIMI flow 3. The patient was discharged on May 28, 2004 on ASA and clopidogrel.</p> <p>On May 10, 2006, the patient was hospitalized. The patient suffered from unstable angina. The CK value on May 10, 2006 was 93U/l (nl 174U/l, ratio <1) and CKMB 12U/l (normal 24U/l, ratio <1). The ECG corelab reported no new major ST-T abnormalities and no new Q Wave MI on the ECG of May 15, 2006 as compared to the ECG of May 28, 2004. A repeat angiography had been performed on May 9, 2006, after which the decision was made for a bypass surgery. The angiography corelab reported a stenosis at the target lesion of 33%. They reported a patent study stent. A CABG was performed on May 10, 2005 because of 3-vessel coronary heart disease. The mid LAD, 2nd obtuse marginal and R-PDA were involved.</p>	
		Non Cardiac Death 728 days post procedure	
		<p>The patient is a 79-year-old male with a history of prior CABG, hyperlipidemia and hypertension. He presented with unstable angina CCS class 4 and a positive stress test. On June 4, 2004, he underwent the index procedure with the assigned treatment in the 1st Obtuse Marginal. One study stent was implanted. The site reported 5% final residual stenosis with no dissection and TIMI flow 3. The angiography corelab reported a final residual stenosis of 18% with no dissection and TIMI flow 3. The patient was discharged on June 5, 2004 on ASA and clopidogrel.</p> <p>On February 22, 2005, the patient was hospitalized for two weeks because of bronchial carcinoma which was inoperable according to the site. A palliative irradiation was performed. On April 19, 2006, the patient was hospitalized again due to increased deterioration in his general condition and pain in the right chest. He was transferred to a hospice on April 27. The patient died on June 2, 2006.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 38 days post procedure</p> <p>The patient is a 49-year-old male with a history of hyperlipidemia, hypertension and premature CAD in a first-degree relative. He presented with unstable angina CCS class 3. On 8 June 2004 he underwent the assigned treatment in the distal RCA. One stent was implanted. The site reported a 5% final residual stenosis with no dissection and TIMI flow 3. The Angiographic Core lab reported a final residual in-lesion stenosis of 28% with no dissection and TIMI flow 3. The pre-procedure CK (8 Jun 2004) peaked at 307 (nl <173, ratio 1.8) with a CK-MB within normal range. The site reported post procedure CK elevation. Post procedure the CK values decreased from 268 (ratio 1.6) after 6-8 hours to 242 (ratio 1.4) after 20-24 hours. CK-MB remained within the normal range. The ECG core lab reported no new major ST-T abnormalities and no new Q waves. No repeat angiography or functional tests were performed. The patient was discharged on 9 June 2004 on ASA and clopidogrel with angina pectoris complaints of a non-severe nature.</p> <p>On 16 July 2004 the patient was rehospitalized for 2 days, because of a revascularization procedure of a non-target vessel. The patient had clinical symptoms. The CK value was 301 (ratio 1.7). CKMB was within normal range. The ECG was not available. An angiography was performed. The site reported 0% stenosis at the target lesion. The Angio Corelab reported 22% stenosis at the target lesion with TIMI flow 3. The site reported a successful PCI of a LAD stenosis. The Angiographic Core lab reported that the "target stent is patent" and that PCI was done to 2nd Ob Marg.</p>	
		<p>Non Target Vessel Revascularization 295 days post procedure; No event (no bleeding/ vascular complication) 615 days post procedure</p> <p>The patient is a 57-year-old male with a history of hypertension and cigarette smoking. He presented with unstable angina CCS class 4. On June 21, 2004 he underwent the index procedure with the assigned treatment in the mid RCA. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on June 22, 2004 on ASA and clopidogrel.</p> <p>On April 9, 2005, the patient was hospitalized because of angina symptoms. ECG and CK/CKMB values were not available. According to the site, an MI could be excluded. A non target vessel revascularization of the first obtuse marginal was performed on April 12, 2005.</p> <p>On February 26, 2006 the patient was hospitalized because of acute abdominal pain. Abdominal sonography revealed an inhomogenous zone in the kidney/liver/vena cava area. A surgery was performed on March 3, 2006, including laparoscopy and adrenalectomy. The histology showed a suprarenal gland with signs of bleeding. The patient was discharged from the hospital in good general condition on March 11, 2006.</p>	<p>Event of 26 February 2006 reported by site as major bleeding event. Adjudicated by CEC as no event.</p>

Site	Pt	Case Summary	Comments
[Redacted]	[Redacted]	<p>Non Target Vessel Revascularization 238 days post procedure; Non Target Vessel Revascularization 280 days post procedure</p>	
		<p>The patient is a 70-year-old male with a history of previous MI, prior percutaneous coronary revascularization, diabetes, hyperlipidemia and hypertension. He presented with stable angina CCS class 2. On 20 April 2004 he underwent the assigned treatment in the 1st Ob Marg. One study stent was implanted. The site reported a 0% final residual stenosis with TIMI flow 3 and no dissection. The Angiographic Core Lab reported a 6% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged 22 April 2004 on ASA and clopidogrel.</p> <p>On 13 December 2004 the patient was hospitalized for the 8 months repeat angiography. The patient had clinical symptoms and a positive functional study. An angiography was performed on 14 December 2004. The Angiography Corelab reported 39% stenosis at the target lesion. They reported that a non target vessel revascularization of the LAD was performed. The site reported revascularization of the prox LAD and the left main.</p> <p>On 24 January 2005, the patient was hospitalized for a planned brachytherapy. The patient did not have clinical symptoms. An angiography was performed on 25 January 2005. The site reported a 30% diameter stenosis of the target lesion. The Angiography Corelab reported a 47% stenosis of the target lesion with TIMI flow 3. They reported moderate hyperplasia inside of the study stent. A repeat revascularization of the prox LAD (non target vessel) was performed.</p>	

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 121 days post procedure; Target Vessel Revascularization 258 days post-procedure</p> <p>The patient is a 64-year-old male with a history of hyperlipidemia and hypertension. He presented with stable angina CCS class 1. On 21 April 2004, he underwent the assigned treatment in the mid LAD. One study stent was implanted. The site reported 0% final residual stenosis with TIMI flow 3 and no dissection. The Angiographic Core Lab reported 24% final residual stenosis with no dissection and TIMI flow 3. They also reported PCI for opening of the diagonal during the index procedure. The patient was discharged 23 April 2004 on ASA and clopidogrel.</p> <p>On 19 August 2004, the patient was hospitalized due to angina pectoris and a positive stress test. A repeat angiography was performed on 20 August 2004. The site reported 0% stenosis at the target lesion and a stenosis in the RCA. The Angiography Corelab reported 18% stenosis at the target lesion with TIMI flow 3. They reported that the study stent was patent. The Angiography Corelab reported a revascularization of the R-PDA.</p> <p>The patient was hospitalized on 29 December 2004 due to dyspnea and a reduced common condition. A repeat angiography was performed on 30 December 2004. The site reported 0% of target lesion restenosis and reported that the angiography showed a non-significant stenosis in the prox LAD and a patent study stent. The Angiography Corelab reported 17% stenosis at the target lesion with TIMI flow 3. No revascularization was performed.</p> <p>On 4 January 2005, the 8 months angiography was performed. The patient did not have clinical symptoms. The site reported 0% stenosis of the target lesion. The Angiography Corelab reported 20% stenosis of the target lesion with TIMI flow 3. A target vessel revascularization was performed in the prox LAD.</p>	
		<p>Non Target Vessel Revascularization 215 days post procedure</p> <p>The patient is a 65-year-old male with a history of prior percutaneous coronary revascularization, hyperlipidemia, hypertension and premature CAD in a first degree relative. He presented with a positive stress test. On 23 April 2004, he underwent the assigned treatment in the prox RCA. Two study stents were implanted. The site reported a 0% final residual stenosis with TIMI flow 3 and no dissection. The Angiography Core Lab reported 14% final residual stenosis with no dissection and TIMI flow 3. They reported a proximal edge dissection after deployment of the study stent. A second stent was deployed to overlap proximal. The patient was discharged 26 April 2004 on ASA and clopidogrel.</p> <p>On 24 November 2004, the 8 months repeat angiography was performed. The patient did not have clinical symptoms. The site reported a stenosis of 0% at the target lesion. The Angiography Core lab reported 15% stenosis at the target lesion with TIMI flow 3. A revascularization of the mid LAD and dist LAD was performed.</p>	

Site	Pt	Case Summary	Comments
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	Target Vessel Revascularization 7 days post-procedure	
	<p>The patient is a 78-year-old female with a history of previous MI (1984), diabetes mellitus, hyperlipidemia, hypertension, smoking and premature CAD in a first-degree relative. She presented with an unstable angina CCS class 4. On April 26, 2004 she underwent the assigned treatment in the mid LAD. One stent was implanted. The Angiographic Core Lab reported a 19% final residual in-lesion stenosis with no dissection and TIMI flow 3.</p> <p>Because of clinical symptoms, a repeat angiography was done on May 3, 2004, which was followed by a revascularization in the 2nd Diagonal. The Angiographic Core Lab reported that the study stent was patent and had a residual stenosis of 19%. The Core lab also reported that a side branch was 80% stenosed at the ostium and PCI was done to the side branch. The patient was discharged on May 15, 2004, on ASA and clopidogrel.</p>	<p>Event of 3 May 2004 reported by site as Non Target Vessel Revascularization. Adjudicated by CEC as Target Vessel Revascularization.</p>
	<p>Non Target Vessel Revascularization 260 days post procedure</p> <p>The patient is a 69-year-old male with a history of prior percutaneous coronary revascularization, prior CABG, hyperlipidemia, hypertension and premature CAD in a first degree relative. He presented with stable angina CCS class 2. On 28 April 2004 he underwent the index procedure in the prox RCA. Two study stents were implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 0% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 6 May 2004 on ASA and clopidogrel.</p> <p>On 12 January 2005 the patient was hospitalized for the 8 months angiography. On 13 January 2005, the angiography was performed. The patient did not have clinical symptoms. The site reported 0% stenosis at the target lesion. The Angiography Corelab reported 5% stenosis at the target lesion with TIMI flow 3 and mentioned that the study stent was patent. A revascularization of the prox LAD was performed.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

	Case Summary	Comments
<div style="border: 1px solid red; width: 80px; height: 20px;"></div>	<p>No event, 73 days post procedure; CABG, Target Vessel Revascularization 75 days post-procedure; Cardiac Death 78 days post-procedure</p>	
	<p>The patient is a 68-year-old female with a history of previous MI, prior percutaneous coronary revascularization, diabetes, hyperlipidemia and hypertension. She presented with stable angina CCS class 1. On 30 April 2004, she underwent the assigned treatment in the dist CX. One study stent was implanted. The site reported 0% final residual stenosis with TIMI flow 3 and no dissection. The Angiography Core Lab reported 4% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 3 May 2004 on ASA and clopidogrel.</p> <p>On 12 July 2004, the patient was hospitalized due to angina pectoris and positive Troponin T. The highest CK value measured on July 12 was 97 (nl <145, ratio <1). The CKMB was not measured. The ECG Corelab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI), persistent high lateral T wave inversion of indeterminate age/old and they reported no new Q Wave Myocardial Infarction.</p> <p>Acute Troponin Coronary Syndrome was diagnosed, according to the clinical site. An angiography was performed and the site reported 0% stenosis at the target lesion. The site reported a high grade stenosis at the ostium of the left main as well as a functional closure of the LAD and an occlusion of the postero-lateral branch of the RCA. The Angiography Corelab reported 16% stenosis at the target lesion with TIMI flow 3. They reported that the study stent was patent.</p> <p>On 12 July 2004 the patient was transferred to the cardiac surgery department at another site. Echocardiography showed an EF of 35% with global hypokinesia and partial akinesia of the basal and apical posterior myocardium. The patient was asymptomatic after treatment with heparin and nitrate. A CABG was performed on 14 July 2004 involving the left main, the RCX, the LAD and the RIVP. The patient was treated with standard surgical techniques. The patient was transferred to ICU after closure of the sternum in good condition.</p> <p>During the stay in the ICU, the patient was treated with epinephrine and extubated on the first post-op day. Intermittent atrial fibrillation was successfully treated with cardioversion. On the third post-operative day, it was necessary to resuscitate the patient who had been completely asymptomatic, had had good respiration and stable hemodynamics. An asystole occurred and, despite continuous manual and medical resuscitation, it was not possible to create sufficient arterial pressure. The patient died on 17 July 2004.</p>	<p>Event of 14 July 2004 reported by site as Emergency Bypass Surgery of Non Target Vessel. Adjudicated by CEC as CABG, Target Vessel.</p>

Site	Pt	Case Summary	Comments
		<p>Target Vessel Revascularization 46 days post-procedure</p> <p>The patient is a 67-year-old man with a history of diabetes, hyperlipidemia and hypertension. He presented with a positive stress test. On 30 April 2004, he underwent the assigned treatment in the 1st Diag. One study stent was implanted. The site reported a 0% final residual stenosis with TIMI flow 3 and no dissection. The Angiography Core Lab reported 23% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 4 May 2004 on ASA and clopidogrel.</p> <p>On 15 June 2004, the patient was hospitalized for a planned PCI as part of a staged procedure. The patient did not have clinical symptoms. The site reported 0% stenosis of the target lesion. The Angiography Corelab reported 24% stenosis at the target lesion with TIMI flow 3. A revascularization of the mid LAD was performed.</p> <p>On 4 August 2004, the patient was hospitalized due to atypical chest pain and dyspnea. A repeat angiography did not show significant stenosis. The site reported a 0% residual stenosis of the target lesion. The Angiographic Core Lab reported 15% stenosis of the target lesion with TIMI flow 3. They reported that the study stent was patent and no PCI was done. No intervention was performed and the patient was discharged on 6 August 2004.</p>	<p>Event of 15 June 2004 reported by site as Non Target Vessel Revascularization. Adjudicated by CEC as Target Vessel Revascularization.</p>
		<p>Target Vessel Revascularization 262 days post-procedure</p> <p>The patient is a 72-year-old male with a history of previous MI, prior percutaneous coronary revascularization, hyperlipidemia and hypertension. On 3 May 2004 he underwent the index procedure in the mid LAD. Two stents were implanted. The site reported 0% stenosis at the target lesion with no dissection and TIMI flow 3. The Angiography Corelab reported a 23% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 10 May 2004 on ASA and clopidogrel.</p> <p>On 18 January 2005 the patient was hospitalized for the 8 months control angiography. The patient did not have clinical symptoms. On 20 January 2005, the angiography was performed. The site reported 0% stenosis at the target lesion. The Angiography Corelab reported 19% stenosis at the target lesion with TIMI flow 3. They reported that the study stent was patent. A target vessel revascularization of the prox LAD was performed.</p>	

		Case Summary	Comments
		Target Lesion Revascularization, Clinically Driven 281 days post-procedure, Target Vessel Revascularization 281 days post-procedure; Non Target Vessel Revascularization 281 days post procedure	
		<p>The patient is a 83-year-old male with a history of hyperlipidemia. He presented with stable angina CCS class 2. On 5 May 2004 he underwent the index procedure with the assigned treatment in the prox LAD. Two stents were implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 16% stenosis at the target lesion with no dissection and TIMI flow 3. The patient was discharged on 12 May 2004 on ASA and clopidogrel.</p> <p>On 9 February 2005 the patient was hospitalized for the control 8 months angiography. The patient did not have clinical symptoms. The angiography was performed on 10 February 2005. The site reported 90% stenosis at the target lesion. The Angiography Corelab reported 85% stenosis at the target lesion with TIMI flow 3. A revascularization was performed involving the prox LAD, mid LAD, 1st Diag and the 1st Ob Marg.</p>	
		Stroke 137 days post-procedure	
		<p>The patient is a 73-year-old male with a history of previous MI, prior percutaneous coronary revascularization, hyperlipidemia, hypertension and premature CAD in a first degree relative. He presented with a positive functional test. On 10 May 2004 he underwent the assigned treatment in the mid RCA. One stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 12 May 2004 on ASA and clopidogrel.</p> <p>On 24 September 2004 the patient was hospitalized. The site reported an ischemic stroke syndrome. A duplex sonography of the carotid artery was performed which showed a stenosis of 70% (right) with a high grade arteriosclerosis. The site reported motor and speech related permanent neurological deficits. Diagnostic testing results and stroke scale scores are not available.</p>	

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 87 days post procedure; Target Lesion Revascularization, Clinically Driven 277 days post-procedure; Non Target Vessel Revascularization 312 days post procedure</p>	
		<p>The patient is a 54-year-old male with a history of hypertension, smoking and premature CAD in a first degree relative. He presented with stable angina CCS class 2. On 10 May 2004 he underwent the assigned treatment in the prox RCA. One stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 10% final residual stenosis with no dissection and TIMI flow 3. The target lesion was prox RCA. On 12 May 2004 the patient was discharged on ASA and clopidogrel.</p> <p>On 4 August 2004 the patient was hospitalized for stenting of a non target vessel which was part of a staged procedure. On 5 August 2004, the angiography was performed. The patient did not have clinical symptoms. The site reported 0% stenosis at the target lesion. The Angiography Corelab reported 48% stenosis at the target lesion with TIMI flow 3. They reported borderline intimal hyperplasia at the proximal edge of the study stent. A Non target vessel revascularization in the prox LAD was performed.</p> <p>On 11 February 2005 the patient was hospitalized for the control 8 months angiography. The patient did not have clinical symptoms. The site reported 90% stenosis at the target lesion. The Angiography Corelab reported 74% stenosis at the target lesion. The target lesion, the prox RCA, was revascularized.</p> <p>On 17 March 2005 the patient was hospitalized for a planned intervention of a known stenosis in the LAD. The patient did not have clinical symptoms. A revascularization involving the prox LAD and the 1st diagonal was performed on 18 March 2005.</p>	
		<p>Other (renal artery PTA) 285 days post procedure</p> <p>The patient is a 68-year-old male known with hyperlipidemia and a history of prior percutaneous coronary revascularization. He presented with a positive exercise test.</p> <p>On 13 May 2004 he underwent the assigned treatment in the 2nd obtuse marginal artery. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. On 15 May 2004 he was uneventfully discharged on ASA and clopidogrel.</p> <p>The patient was hospitalized Feb 22, 2005 for a PTA and stent implantation of the renal artery. According to the investigator, there was no relationship with the stent or ABT-578.</p>	

		Case Summary	Comments
		<p>Non Target Vessel Revascularization 225 days post procedure</p> <p>The patient is a 54-year-old male with a history of previous MI, prior percutaneous coronary revascularization, hyperlipidemia and hypertension. He presented with stable angina CCS class 1. On 18 May 2004 he underwent the assigned treatment in the 1st Ob Marg. One stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 16% final residual stenosis with no dissection and TIMI flow 3. On 29 May 2004 the patient was discharged on ASA and clopidogrel.</p> <p>On 29 December 2004 the patient was hospitalized for angina. A repeat angiography was performed. The Angiography Corelab reported 18% stenosis of the target lesion. The Angiography Corelab reported that the study stent is still patent. They reported that a revascularization for an in-stent restenosis of a non study stent in the LAD (non target vessel) was performed.</p>	<p>Event of 29 December 2004 reported by site as Target Lesion Revascularization and by Angiography Corelab as Non Target Vessel Revascularization. Adjudicated by CEC as Non Target Vessel Revascularization.</p>
		<p>Non Target Vessel Revascularization 231 days post procedure</p> <p>The patient is a 57-year-old male with a history of prior percutaneous coronary revascularization, diabetes, hyperlipidemia, hypertension, smoking and premature CAD in a first degree relative. He presented with stable angina CCS class 2. On 25 May 2004 he underwent the assigned treatment in the prox LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 11% final residual stenosis at the target lesion with no dissection and TIMI flow 3. On 27 May 2004 he was discharged on ASA and clopidogrel.</p> <p>On 10 January 2005 the patient was hospitalized for the scheduled 8 months angiography. The patient did not have clinical symptoms. The Angiography Corelab reported 18% stenosis at the target lesion with TIMI flow 3. The Angiography Corelab reported that the study stent is patent. On 11 January 2005 a repeat revascularization of a non target vessel (1st RPL) was performed.</p>	

Site	Pt	Case Summary	Comments
		<p>Target Lesion Revascularization, Clinically Driven 202 days post-procedure, CABG, Target Lesion Revascularization, Clinically Driven – 285 days post procedure</p>	
		<p>The patient is a 60-year-old male with a history of diabetes, hyperlipidemia, hypertension and premature CAD in a first degree relative. He presented with MI CCS class 3. On 26 May 2004 he underwent the assigned treatment in the prox CX. One study stent was implanted. The site reported 0% stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 10% final residual stenosis with no dissection and TIMI flow 3. On 2 June 2004 the patient was discharged on ASA and clopidogrel.</p> <p>On 14 December 2004 the patient was hospitalized for a planned angiography. The patient had clinical symptoms. The site reported 90% stenosis at the target lesion. The Angiography Corelab reported 72% stenosis at the target lesion with TIMI flow 3. A repeat revascularization of the prox CX (target lesion) was performed.</p> <p>On 1 March 2005, the patient was hospitalized due to progressive stress dyspnea and non-specific chest symptoms. A repeat angiography was performed on 2 March 2005. The site reported 99% stenosis of the target lesion (prox CX), 100% stenosis of the prox RCA, 70% stenosis of the distal LMCA and 70% stenosis of the prox LAD. The Angiography Corelab reported 76% stenosis of the target lesion. They reported a type 1B in stent restenosis. A CABG was performed on 7 March 2005 and involved the proximal RCA, LMCA, proximal CX (target lesion) and the proximal LAD. The patient was discharged on 22 March 2005.</p>	
		<p>Non Target Vessel Revascularization 57 days post procedure</p>	
		<p>The patient is a 39-year-old male with a history of previous MI, prior percutaneous coronary revascularization, prior CABG, diabetes, hyperlipidemia, hypertension, smoking and premature CAD in a first degree relative. He presented with unstable angina CCS class 2. On 2 June 2004 he underwent the assigned treatment in the dist LAD. Two study stents were implanted. The second stent was implanted distally of the first stent because of the long lesion. The site reported a 0% final residual stenosis with no dissection and TIMI flow 3. The Angiographic Core Lab reported 26% final residual stenosis with no dissection and TIMI flow 3. On 8 June 2004 the patient was discharged on ASA and clopidogrel.</p> <p>On 28 July 2004 the patient was hospitalized due to a planned intervention in a non target vessel. The patient did not have clinical symptoms. On 29 July 2004, the angiography was performed. The site reported a 0% stenosis of the target lesion. The Angiography Core Lab reported a -13% stenosis of the target lesion with TIMI flow 3. A repeat revascularization of a non target vessel (2nd Ob Marg) was performed. The patient was discharged on 31 July 2004.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Q-wave MI 0 days post-procedure, Target Vessel Revascularization 253 days post-procedure</p>	
		<p>The patient is a 61-year-old male with a history of smoking, premature CAD in a first-degree relative, a CCS class IV unstable angina with a positive stress test. On June 5, 2004 the patient presented with a MI, which prompted the intervention. On June 7, he underwent the assigned treatment in the proximal LAD. One stent was implanted. The site reported a 0% final residual stenosis with TIMI flow 3 and no dissection occurred post procedure. The Angiography Corelab reported 9% final residual stenosis at the target lesion with no dissection and TIMI flow 3. The pre-procedure CK was within normal range. The CK-MB was not measured. Approx. 6-8 hours post procedure, the CK peaked at 999 (nl ≤ 171, ratio 5.8) with a CK-MB of 114 (nl < 24, ratio 4.8). Approx. 12-16 hours post procedure, the CK and CK-MB were 591 (ratio 3.5) and 64 (ratio 2.7) respectively. Approx. 20-24 hours post procedure the CK was 496 (ratio 2.9) but the CK-MB was elevated again to 119 (ratio 5.0). The ECG Core Lab reported “new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI): persistent evolutionary changes of anterior ST elevation, age recent / acute.” A new Myocardial Infarction (anterior loss R waves) was reported. The patient was discharged on June 15 on ASA and clopidogrel.</p> <p>On 14 February 2005 the patient was hospitalized for a planned angiography. The patient did not have clinical symptoms. On 15 February 2005, the angiography was performed. The Angiography Corelab reported 38% stenosis at the target lesion with TIMI flow 3. The target vessel was revascularized at the 1st Diag.</p>	<p>Event of 7 June 2004 reported by site as rise of CK/CKMB. Adjudicated by CEC as Q wave MI.</p>

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 185 days post procedure</p> <p>The patient is a 55-year-old male with a history of previous MI, prior percutaneous coronary revascularization, hyperlipidemia, hypertension and premature CAD in a first degree relative. The patient presented with a positive stress test. On 8 June 2004 he underwent the assigned treatment in the prox CX. One study stent was implanted. The site reported a 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported 18% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 10 June 2004 on ASA and clopidogrel.</p> <p>On 11 July 2004, the patient was hospitalized due to thoracic pain with radiation in the left arm, which occurred after sporting. A functional study showed a positive result. The site reported that the ECG and lab did not show signs of a myocardial infarction. The highest CK value measured on 11 July 2004 was 158 (nl 171, ratio <1). The ECG was not available. A repeat coronary angiography was performed on 14 July 2004. The site reported 0% stenosis at the target lesion. The site reported that the angiography showed no relevant stenosis. The Angiography Core Lab reported 12% stenosis at the target lesion with TIMI flow 3. They reported that the study stent is still patent and no PCI was done. The patient was discharged on 15 July 2004.</p> <p>On 9 December 2004 the patient was hospitalized again for a planned angiography. The patient did not have clinical symptoms. The angiography was performed on 10 December 2004. The Angiography Core Lab reported 38% stenosis at the target lesion with TIMI flow 3. They reported moderate to severe intimal hyperplasia. They also reported that a non target revascularization was done on the RCA. A revascularization of the distal RCA was performed.</p>	
		<p>Non Target Vessel Revascularization 76 days post procedure, Non Target Vessel Revascularization 321 days post procedure.</p> <p>The patient is a 74-year-old female with a history of hypertension. She presented with symptoms of stable angina pectoris CCS class 2 further confirmed by a positive stress test. On June 9, 2004 she underwent the assigned treatment in the prox LAD. Two study stents were implanted. The site reported a 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported 29% final residual stenosis with no dissection and TIMI flow 3. The hospitalization stay was uneventful. She was discharged June 12, 2004 on clopidogrel and phenprocoumon.</p> <p>On 24 August 2004 a planned repeat angiography was performed. The patient did not have clinical symptoms. The Angiography Corelab reported a 33% stenosis at the target lesion. They reported that the study stent was patent and that a non target vessel revascularization was performed of the 1st Ob Marg.</p> <p>On 25 April 2005 the patient was hospitalized for a planned control angiography. The patient did not have clinical symptoms. A revascularization of the 1st Ob Marg was performed.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Target Lesion Revascularization, Not Clinically Driven 251 days post-procedure</p>	
		<p>The patient is a 60-year-old female with a history of hypertension and smoking. She presented with stable angina CCS class 2. On 15 June 2004 she underwent the assigned treatment in the prox LAD. One stent was implanted. The site reported a 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported 14% final residual stenosis with no dissection and TIMI flow 3. On 17 June 2004 the patient was discharged on ASA and clopidogrel.</p> <p>On 21 February 2005 a planned repeat angiography was performed. The patient did not have clinical symptoms. The Angiography Corelab reported 56% stenosis of the target lesion with TIMI flow 3. They reported a study stent with type 2 ISR. According to the Angiography Corelab, the target lesion (prox LAD) was revascularized.</p>	

Site	Pt	Case Summary	Comments
		<p>Non Q-wave MI 3 days post-procedure, Target Vessel Revascularization 3 days post-procedure; Non Target Vessel Revascularization 41 days post procedure</p>	
		<p>The patient is a 69-year-old male with a history of previous MI (03/14/2004), prior percutaneous coronary revascularization in a non-target vessel, hyperlipidemia and hypertension. On June 16, 2004 he presented with unstable angina CCS class IV that prompted the assigned treatment in the mid RCA. One stent was implanted. No dissection was observed post procedure. The site reported a 0% final residual stenosis with TIMI flow III. The Angiographic Core Lab reported a final in-lesion stenosis of 27%. The pre-procedure CK was within normal range. CK-MB was not drawn. On June 19, 2004 CK and CK-MB peaked at 422 (nl ≤ 171, ratio 2.5) and 57 (nl < 24, ratio 2.4) respectively. The site reported a non-Q-wave MI. The ECG Core Lab reported no new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI), no new Q-wave Myocardial Infarction.</p> <p>On June 19, 2004 a repeat angiography was performed due to the rise of cardiac enzymes and angina pectoris complaints of the patient. It revealed a stenosis in the proximal RCA, which was stented. The Angiographic Core Lab reported the study stent to be patent and that a remote target vessel revascularization was done. The target lesion was reported to be 38% stenosed with TIMI flow 3. The patient was discharged on June 24, 2004 on ASA and clopidogrel.</p> <p>On July 26, 2004 the patient was hospitalized due to a planned intervention in a non target vessel. On 27 July 2004 a repeat angiography was performed which was part of a planned staged procedure. The patient did not have clinical symptoms. The site reported a 0% stenosis of the target lesion. The Angiography Corelab reported 25% stenosis of the target lesion with TIMI flow 3. They reported that the study stent was patent and PCI was done on a non target vessel. A revascularization of the proximal LAD was performed.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		Non Target Vessel Revascularization 237 days post procedure	
		<p>The patient is a 71-year-old male with a history of prior percutaneous coronary revascularization, hypertension and hyperlipidemia. The patient presented with unstable angina CCS class 4 and a positive stress test. On 6 April 2004 he underwent the index procedure with the assigned treatment in the prox CX. One stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported a 17% residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 7 April 2004 on ASA and clopidogrel.</p> <p>On 9 April 2004, the patient was hospitalized for angina pectoris. According to the site, the ECG, blood analysis, CK, Troponin, myoglobin and stress test showed no signs of myocardial ischemia. Lab values were not available. The ECG corelab reported no new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI and no new Q Wave Myocardial Infarction. No diagnostic angiography was performed. After drug treatment, the patient was discharged on 14 April 2004.</p> <p>On 19 April 2004, the patient was hospitalized for a repeat angiography. The patient had clinical symptoms. The site reported 0% stenosis at the target lesion. The site reported that the clinical symptoms reported are untypical for CHD. No changes were found since the last investigation, no restenosis of the stent and no progression of the CHD. The patient exhibited a good exercise tolerance and the symptoms predominantly developed at rest. The Angiography Corelab reported 29% stenosis at the target lesion with TIMI flow 3. On 21 April 2004 the patient was hospitalized again for angina pectoris. Lab values were not available. The ECG corelab reported no new major ST-T abnormalities and no new Q Wave Myocardial Infarction. A repeat angiography was performed. The site reported 0% stenosis at the target lesion. The Angiography Corelab reported 12% stenosis at the target lesion. No revascularization was performed.</p> <p>On 29 November 2004 the 8 months angiography was performed. The patient had clinical symptoms. No lab values were available. The site reported a <30% diameter stenosis of the target lesion. The Angiography Core Lab reported a 22% diameter stenosis of the target lesion with TIMI flow 3. They reported that the study stent was still patent. A lesion in the dist RCA (non target vessel) was treated.</p> <p>On 2 February 2005, the patient was hospitalized due to syncope, nausea, vertigo and light chest pain. According to the site, the blood analysis and ECG results showed no myocardial infarction.</p>	

Site	Pt	Case Summary	Comments
		<p>Target Lesion Revascularization, Clinically Driven 263 days post-procedure</p>	
		<p>The patient is a 55-year-old male know with hypertension as risk factor. The cardiac medical history was blanc. Patient presented with symptoms of unstable angina pectoris confirmed by a positive exercise test. On April 23, 2004 he underwent the index procedure with the assigned treatment in the proximal LAD, in which one stent were implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiographic Core Lab reported a 21% residual stenosis with no dissection and TIMI flow 3. The patient was discharged the next day on April 24, 2004 on ASA and clopidogrel as anti-thrombotic medication</p> <p>On July 28, 2004 the patient was admitted with atypical symptoms. A repeat angiography on July 29 showed a patent coronary stent without any signs of restenosis according to the clinical site. The Angiographic Core Lab reported a 16% in-lesion diameter stenosis with TIMI flow 3. They reported that the study stent was patent and no PCI was done. They also reported mid to moderate intimal hyperplasia of the ostial part of the LAD. No intervention was performed.</p> <p>The patient reported back to the hospital with anginal symptoms for which he was admitted January 10, 2005. A repeat angiogram on Jan 11, 2005 revealed a significant stenosis in the implanted stent of 90% according to the clinical site. The Angiographic Core Lab reported a 64% in-lesion diameter stenosis with TIMI flow 3. An intervention was performed at the target lesion site (prox LAD).</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		Device delivery failures (2) 0 days post-procedure, no event (no UADE) 0 days post procedure, no event 61 days post procedure	
		<p>The patient is a 78-year-old female with a history of hyperlipidemia, hypertension and smoking. She presented with stable angina CCS class 4. On April 23, 2004 two attempts were made to treat the patient with the assigned treatment in the prox LAD. The lesion was not pre-treated with PTCA. Two stents were used but both deliveries failed. The investigator reported that the first stent was retrieved out of the patient after it detached from the balloon while retracting the device. A second stent was used, which detached from the balloon as well, deploying half in the main left vessel and the other half in the aorta. During an attempt to catch this stent with a lasso the stent got lost in the aorta descendens. Last position of the stent was seen by X-ray control in the region of the pelvis. A final 75% stenosis with TIMI flow 3 and no dissection was reported. A query confirmed that no revascularization was done. The Angiography Core Lab reported that the baseline images showed an in-lesion stenosis of 71% and commented that no procedure was done. The patient was discharged on April 28 on ASA and clopidogrel.</p> <p>On 22 June 2004, the patient was hospitalized at another site than the study site. The patient had clinical symptoms. No lab values were available. No angiography was performed. On 23 June 2004, a CABG was performed. A revascularization involving the target lesion (prox LAD) was performed.</p>	<p>Event on 23 April 2004 reported by site as stent malfunction. Adjudicated by CEC as no event.</p> <p>Event on 23 June 2004 reported by site as CABG, Target Lesion Revascularization, clinically driven and Target Vessel Revascularization (after unsuccessful implantation of the study stent at the target lesion during procedure). Adjudicated by CEC as no event.</p>

Site	Pt	Case Summary	Comments
		<p>Non Q-wave MI 0 days post-procedure</p> <p>The patient is a 64-year-old male with a history of smoking. He presented with unstable angina CCS class IV. On May 6, 2004 he underwent the assigned treatment in the proximal LAD. One stent was implanted. No dissection occurred post procedure. The site reported a 0% final residual stenosis with TIMI flow III. The pre procedure cardiac enzymes were above normal limits with CK of 274 (nl <171, ratio 1.6) and CKMB of 51 (nl <24, ratio 2.1). Approx. 6-8 hours post procedure, the CK peaked at 1132 (ratio 6.6) with a CK-MB of 194 (ratio 8.1). Approx. 12-16 hours post procedure the CK and CKMB values were 757 (ratio 4.4) and 103 (ratio 4.3) respectively. On May 9, 2004 the CK value was again within the normal range, although the CKMB was 51 (ratio 2.1). The ECG core lab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI): persistent evolutionary changes of anterior ST elevation, age recent / acute. There were no new Q-waves reported. On May 11, 2004, the patient was discharged on ASA and clopidogrel.</p>	
		<p>Device Delivery Failure 0 days post-procedure, Emergent CABG, Target Vessel Revascularization 5 days post-procedure</p> <p>The patient is a 74-year-old male with a history of hypertension and premature CAD in a first-degree relative. The patient presented with stable angina CCS class II. On May 6, 2004 it was attempted to treat the target lesion in the distal CX. It was impossible to pass the proximal CX to reach the target lesion. The cardiac catheter report reported that "it is possible that several aspects combine: relative main trunk quantity, small vessel diameter, calcification." The narrative form commented: "after several manipulations a suspected region in the proximal CX was visible which was protected with a conventional stent at once. Afterwards it was still impossible to reach the target lesion distal CX with the study stent, so the lesion could not be treated. The intervention was stopped and a CABG was planned for the next days." The site reported a 90% final residual stenosis with TIMI flow III and no dissection. The Angiographic Core Lab reported "significant left main disease and distal CX disease left untreated".</p> <p>On May 11, 2004, the patient was successfully resuscitated for bradycardia and hypertonia. On the same day an emergent CABG of the 1st Ob Marg and mid LAD was performed. Postoperative the patient was fully oriented, with no indication of any neurological deficiencies. On May 15, 2004, the patient was in a good general condition and with stable circulation and was transferred to another ward. The date of discharge is unknown.</p>	<p>Event of 6 May 2004 reported by site as stent malfunction/treatment failure. Adjudicated by CEC as delivery failure</p>

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 80 days post procedure; Target Vessel Revascularization 151 days post-procedure</p> <p>The patient is a 80-year-old female with a history of previous MI, prior percutaneous coronary revascularization, diabetes, hyperlipidemia and hypertension. She presented with stable angina CCS class 1. On 26 April 2004 she underwent the index procedure with the assigned treatment in the mid LAD. Two study stents were implanted. The second stent was implanted proximal of the first stent due to a dissection. The site reported 10% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported a 19% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged 27 April 2004 on ASA and clopidogrel.</p> <p>On 13 July 2004, the patient was hospitalized with thoracic pain, similar to the pain before stent implant. The highest CK value measured on July 13 was 47 (nl <145, ratio <1). The CKMB was 14 (nl <6% of CK). The ECG Corelab reported no significant changes compared to the previous reading, no new major ST-T abnormalities and no new Q wave MI. An angiography was performed on 15 July 2004. The site reported 30% stenosis of the target lesion. The Angiography Corelab reported 28% stenosis of the target lesion with TIMI flow 3. They reported that the study stent was patent and PCI of the CX was performed.</p> <p>On 24 September 2004 the patient was hospitalized with clinical symptoms again. The measured CK was 42 (nl <145, ratio <1). The ECG corelab reported no significant changes compared to the previous reading. No new major ST-T abnormalities and no new Q wave MI. An Angiography was performed the same day. The site reported a 10% diameter stenosis of the target lesion. The Angiography Core Lab reported a 32% stenosis of the target lesion with TIMI flow 3. They reported that the stent was patent and PCI was performed of an intermediate branch. A revascularization of the 1st Diag was performed.</p>	
		<p>No event (no UADE) 0 days post procedure; Stent delivery failure 0 days post-procedure, Dissection grade C 0 days post procedure;</p> <p>The patient is a 62-year-old male with a history of hypertension. He presented with an unstable angina CCS class III. On May 21, 2004 he underwent the index procedure with the assigned treatment in the 1st Diag.</p> <p>After pre-dilatation a first stent was implanted. Due to a residual stenosis at the distal end, post-dilatation with a maximum pressure of 16 ATM was performed leading to a distal dissection (Type C) without limiting blood flow. A second study stent could not be advanced through the already implanted stent and was removed. The site reported 0% final residual stenosis with TIMI flow III and a final dissection grade C. The Angiographic Core Lab reported a 35% final residual in-lesion stenosis with dissection grade C, staining and spasm present and TIMI flow III. They noted "residual distal edge dissection at the end of the procedure". The patient was discharged on May 22, 2004 on ASA and clopidogrel.</p>	<p>Event of 21 May 2004 reported by site as stent malfunction and Unanticipated Adverse Device Effect. Adjudicated by CEC as stent delivery failure and no UADE.</p>

Site	Pt	Case Summary	Comments
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		<p>No event 86 days post procedure; Other, hematuria 146 days post procedure</p>	
		<p>The patient is a 86-year-old male with a history of diabetes, hyperlipidemia and hypertension. He presented with unstable angina CCS Class 2. On 27 May 2004 he underwent the index procedure with the assigned treatment in the mid LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 28 May 2004 on ASA and clopidogrel.</p> <p>On 21 August 2004 the patient fell and a big bleeding occurred at the right knee. The site reported a hematoma > 5cm which required surgery. An ambulant surgery was performed on 1 September 2004.</p> <p>On 20 October 2004 the patient was hospitalized for a hematuria due to prostate hypertrophy and bleeding from vessels in the bladder. According to the site, hematuria had first been found 4 years ago because of prostatic hyperplasia. Urethrocystoscopy was performed and mild bleeding was discovered. On biopsy, malignancy was excluded. Laboratory findings that were outside of the reference range were bicarbonate: 29.3 mmol/l (nl 22-29) , Creatinine: 1.37 mg/dl (nl 0.59-1.24), Glucose: 123 mg/dl (nl 55-115), Ery: 3.82/pl (nl 4.4-5.9), Hb 11.2 g/dl (nl 14-18), Hematocrit: 33.4% (nl 40-52). Other tests gave normal results. The patient complained of giddiness and weakness. There was no evidence for myocardial ischemia. The symptoms improved after transfusion of two erythrocyte concentrates. The patient was discharged on 3 November 2004.</p>	

Site	Pt	Case Summary	Comments
		<p>Non Target Vessel Revascularization 427 days post procedure; Non Target Vessel Revascularization 743 days post procedure</p>	
		<p>The patient is a 63-year-old male with a history of prior percutaneous coronary revascularization, hyperlipidemia and hypertension. He presented with stable angina CCS class 2. On June 1, 2004, he underwent the index procedure with the assigned treatment in the mid LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The angiography corelab reported 19% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on June 4, 2004 on ASA and clopidogrel.</p> <p>On August 2, 2005, the patient was hospitalized with angina symptoms. The patient had stable angina since May 2005. CK/CKMB values and ECG were not available. Coronary angiography showed progression of the coronary artery disease in the RCA (Non Target Vessel). The site reported 40% stenosis of the target lesion. An angiography film was not available. A repeat revascularization of the mid RCA was performed. The patient was discharged on August 4, 2005 without symptoms.</p> <p>On June 14, 2006 the patient was hospitalized due to angina. CK and CKMB values were not available. The ECG corelab reported no new major ST-T abnormalities and no new Q-wave MI for the ECGs of June 12 and June 15, 2006, as compared to the ECG of June 3, 2004. A repeat angiography had been performed on June 1, 2004. The site reported 40% stenosis of the target lesion. The angiography corelab reported 14% stenosis of the target lesion. They reported a patent study stent. A repeat revascularization of a non target vessel (proximal RCA) was performed on June 14, 2006.</p>	

Site	Pt	Case Summary	Comments
		<p data-bbox="435 386 1089 415">Non Target Vessel Revascularization 266 days post procedure</p> <p data-bbox="435 415 1235 611">The patient is a 68-year-old male with a history of hyperlipidemia and hypertension. He presented with stable angina CCS class 2. On 15 June 2004 he underwent the assigned treatment in the dist CX. One stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 15% final residual stenosis with no dissection and TIMI flow 3. On 24 June 2004 the patient was discharged on ASA and clopidogrel.</p> <p data-bbox="435 642 1235 869">On 23 November 2004 the patient was hospitalized for a repeat angiography. The patient had clinical symptoms. No lab values were available. The ECG corelab reported no significant changes compared to the previous ECG. No new major ST-T abnormalities and no new Q wave MI. The angiography was performed on 24 November 2004. The site reported 0% stenosis at the target lesion. The Angiography Corelab reported 27% stenosis at the target lesion with TIMI flow 3. They reported that the study stent was patent. No procedure was performed.</p> <p data-bbox="435 900 1211 1068">On 8 March 2005 the patient was hospitalized with clinical symptoms again. On 9 March 2005 the CK peaked at 156 (nl <190, ratio <1). The ECG corelab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI). They reported intermittent inferolateral ST depression, indeterminate age/old and intermittent inferolateral T wave inversion, indeterminate age/old. They reported no new Q wave MI.</p> <p data-bbox="435 1073 1227 1178">On 8 March 2005 a repeat angiography was performed. The site reported 0% stenosis at the target lesion. The Angiography Corelab reported 22% stenosis at the target lesion with TIMI flow 3. A repeat revascularization of the mid LAD (non target vessel) was performed.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>No event (no Non Q wave M) 520 days post procedure</p> <p>The patient is a 70-year-old male. He presented with stable angina CCS class 2 and a positive stress test. On April 9, 2004, he underwent the index procedure with the assigned treatment in the proximal LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported a final residual stenosis of 21% with no dissection and TIMI flow 3. The patient was discharged on April 10, 2004 on ASA and clopidogrel.</p> <p>The patient was hospitalized on September 11, 2005 with complaints of angina at rest and atrial fibrillation. No CK or CKMB values were available. The Troponin-I value was within normal range (<0.10ng/ml, nl 0.00-0.10). The ECG corelab reported for the ECGs of September 11 and 12 as compared to the ECGs of September 2004, new major ST-T abnormalities (possible MI, injury or NQMI): persistent inferior ST depression, age recent/acute, persistent inferior T wave inversion, age recent/acute and persistent AL/apical T wave inversion, age recent/acute. They reported that they could not interpretate whether there was a new myocardial infarction due to poor quality tracings. According to the site, myocardial infarction could be excluded due to negative troponin. The medication was adapted. The patient was discharged on September 12, 2005.</p>	

Site	Pt	Case Summary	Comments
		<p>Revascularization Non Target Vessel 21 days post procedure, CABG - Target Vessel Revascularization, Not Clinically Driven 120 days post-procedure</p>	
		<p>The patient is a 70-year-old female with a history of diabetes mellitus, hyperlipidemia, hypertension and smoking. She presented with stable angina CCS class I. On 17 May 2004 she underwent the assigned treatment . According to the center, the target lesion was located in the proximal LAD. One stent was implanted. The site reported a 10% final residual stenosis with no dissection and TIMI flow 3. The Angiographic Core Lab reported a 40% final residual in-lesion stenosis with no dissection and TIMI flow 3 in the mid LAD, the target lesion site according to the Angiography Core lab. Post procedural CK values were within the normal range and the ECG was unchanged as reported by the ECG Core lab. The patient was discharged on the same day on ASA and clopidogrel.</p> <p>3 Days post procedure; the patient started developing angina pectoris. On June 7, 2004, the patient was hospitalized and cardiac enzymes were drawn and found within normal range. CK was 86 (nl <170, ratio <1) and CKMB was 6 (nl <25, ration <1). The ECG was unchanged as reported by the ECG corelab. A repeat angiography revealed a lesion in the proximal CX. This was treated on the same day with PTCA and a stent. The site reported that there were no complications after this intervention. The Angiographic Core Lab reported that the study stent was patent and a non-target vessel revascularization was done.</p> <p>Since July 2004, the patient experienced angina complaints. On September 2, 2004, the patient was hospitalized at a reference hospital for angina pectoris. The ECG was unchanged as reported by the ECG corelab. Coronary angiography was performed. The site reported 50% stenosis at the main stem and a significant stenosis at the proximal CX. The Angiographic Corelab reported 46% final residual in-lesion stenosis in the mid LAD and TIMI flow 3. The Angiography Corelab reported that the stent MLD was decreased, but it was < 50% stenosed. No PCI was done. On September 11, cardiac enzymes were within normal range. One CK value was measured, which was 51 (nl 170, ratio <1). On 13 September 2004, the patient was hospitalized at the study center. A CABG was performed on 14 September 2004, involving the LMCA, proximal LAD and first Obtuse Marginal. There were no postoperative complications. The patient was discharged and sent to the reference hospital on 17 September 2004. The patient was discharged on 24 September 2004.</p>	<p>Event on 14 September 2004 reported by site as CABG, Target Lesion, Target Vessel and Non Target Vessel Revascularization. Adjudicated by CEC as CABG, Target Vessel Revascularization (Note: site reported prox LAD as target lesion, Angiography corelab reported mid LAD as target lesion).</p>

Site	Pt	Case Summary	Comments
		<p>CABG, Target Lesion Revascularization, Clinically Driven – 337 days post-procedure; CABG, Non Target Vessel Revascularization 337 days post procedure</p>	
		<p>The patient is a 60-year-old male with a history of diabetes mellitus, hypertension, smoking and premature CAD in a first degree relative. He presented with stable angina CCS class 3. On 8 June 2004 he underwent the index procedure with the assigned treatment in the mid RCA. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 16% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 9 June 2004 on clopidogrel.</p> <p>On 7 April 2005, the patient was hospitalized at another hospital than the study site due to angina pectoris CCS class 4. The CK peaked at 68 (nl 200, ratio 0.34) on 8 April 2005. The ECG corelab reported no new major ST-T abnormalities and no new Q wave myocardial infarction on the ECG of 8 April 2005 as compared to the ECG of 8 June 2004. A repeat angiography was performed on 11 April 2005, which showed a three vessel disease. The site reported hemodynamically significant stenosis in the right coronary artery just before the stent, hemodynamically significant stenosis in an intermediate branch of the circumflex artery and a proximal LAD stenosis. The Angiography Corelab reported 75% stenosis at the target lesion and a type 3 in stent restenosis. The patient was discharged on 13 April 2005.</p> <p>On 10 May 2005 the patient was hospitalized at the study site for a planned CABG. On 11 May 2005 a CABG was performed involving the prox LAD, prox CX, dist CX and mid RCA.</p>	

Site	Pt	Case Summary	Comments
		<p data-bbox="435 386 1089 415">Non Target Vessel Revascularization 223 days post procedure</p> <p data-bbox="435 422 1203 615">The patient is a 76-year-old male with a history of previous MI and smoking. He presented with stable angina CCS class 4. On 17 June 2004 he underwent the index procedure with the assigned treatment in the mid-RCA. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The Angiography Corelab reported 31% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 18 June 2004 on ASA and clopidogrel.</p> <p data-bbox="435 646 1230 789">On August 5, 2004 a repeat angiography was performed. The patient had clinical symptoms. The ECG was unchanged as reported by the ECG corelab. No new major ST-T abnormalities were reported. The site reported a 30% stenosis in the main stem, an occluded RCX, an 80% stenosis in the RDA in D2 and a good result in the RCA (<40% in-stent stenosis). No action was taken</p> <p data-bbox="435 821 1235 1188">On 6 January 2005 the patient was admitted to the hospital due to a planned PCI of the RCX due to continuous complaints of dyspnea d'effort. The ECG was unchanged as reported by the ECG corelab (no new major ST-T abnormalities). On 7 January 2005 a PCI was attempted, but was without success. No recanalisation was possible. The procedure was complicated because of a dissection in the MO branch, decompensation cordis and VF. The procedure was stopped. The site reported that the adverse events were resolved. On 10 January 2005 the PCI procedure has been repeated without success and a new dissection as complication of the procedure occurred. It was decided to treat the patient with medications only (β-blockers, nitrate and statin). For both angiography films, the Angiography Corelab could not give an analysis, as the films did not show the target lesion. The patient was discharged on 11 January 2005.</p> <p data-bbox="435 1220 1203 1297">On 26 January 2005, a successful PCI of the dist CX was performed. The Angiography Corelab could not analyse the target lesion, as it was not shown on the film.</p>	

Site	Pt	Case Summary	Comments
		<p>Revascularization Non Target Vessel 7 days post procedure</p> <p>The patient is a 59-year-old male with a history of hypertension. He presented with stable angina CCS class III. On April 20, 2004 he underwent the assigned treatment in the mid LAD. Two stents were implanted. The site reported a 0% final residual stenosis with no dissection and a TIMI flow III. The Angiographic Core Lab reported a 15% final residual in-lesion stenosis with TIMI flow III. The pre-procedure CK and CK-MB were within normal range. Approx. 12-16 hours post-procedure the CK and CK-MB values elevated to 253 (nl <190, ratio 1.3) and 27 (nl <16, ratio 1.7). The patient was discharged on April 21 on ASA and clopidogrel.</p> <p>On April 23, 2004 the patient was rehospitalized because of recurrent angina pectoris complaints during mild exercise. The cardiac enzymes were within normal range. On April 27, 2004 a repeat angiography was done and a revascularization was performed in the proximal CX and the 1st LPL. The site reported a significant stenosis in a non-target vessel, which was stented. The angiography showed no stenosis in the target lesion according to the site. The Angiographic Core Lab reported a 17% stenosis in the target lesion. The patient was discharged on April 28.</p>	
		<p>Non Target Vessel Revascularization 103 days post procedure</p> <p>The patient is a 55-year-old male with a history of previous MI, prior percutaneous coronary revascularization and premature CAD in a first degree relative. He presented with stable angina CCS class 3. On 28 April 2004 he underwent the assigned treatment in the mid RCA. One study stent was implanted. The site reported a 0% final residual stenosis with no dissection and TIMI flow 3. The Angio Corelab reported a 25% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 29 April 2004 on ASA and clopidogrel.</p> <p>On 9 August 2004 the patient was hospitalized for anginal complaints which had occurred since the original procedure. The ECG corelab reported no new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI). FFR of the LAD was performed and a lesion in the mid LAD turned out to be haemodynamically significant. On 9 August 2004 the mid LAD was treated with one Cypher and two Driver stents.</p>	

Site	Pt	Case Summary	Comments
		Angiographic perforation 0 days post procedure	
		<p>The patient is a 48-year-old male with a history of previous MI (April 4, 2004). On May 4 he underwent the assigned treatment in the 1st Ob Marg. The investigator reported that during the index procedure it was observed with IVUS that the stent was excentric deployed. A dilatation in the stent followed. The maximum deployment pressure used was 18 ATM with a balloon diameter of 3.5 mm. As a result the stent was oversized and had probably damaged the artery wall. Dye extravasation was seen on the angiography. A second attempt to perform IVUS was unsuccessful because of a defect system. On the next angiogram the dye extravasation already seemed to decrease. The patient was followed clinically by an ultrasound on which no pericard effusion was seen. The Angio core lab reported on a lesion in the 1st Ob Marg a final residual in-lesion stenosis of 31% with no dissection and TIMI flow 3.</p> <p>The patient was discharged on the same day on ASA and clopidogrel.</p>	
		Non Target Vessel Revascularization 730 days post procedure	
		<p>The patient is a 79-year-old female with a history of prior percutaneous coronary revascularization, diabetes mellitus and hypertension. She presented with stable angina CCS class 2. On May 10, 2004, she underwent the index procedure with the assigned treatment in the mid LAD. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The angiography corelab reported 14% final residual stenosis with no dissection and TIMI flow 3. They also reported ` a diffuse proximal LAD disease left untreated at the end of the procedure. The patient was discharged on May 11, 2004 on ASA and clopidogrel.</p> <p>On April 20, 2006 a repeat angiography was performed. The patient had had complaints of angina pectoris since December 2005. The angiography corelab reported 27% stenosis of the target lesion. They reported a patent study stent and diffuse coronary artery disease. On May 6, 2006, the patient was hospitalized for a planned revascularization of a non target vessel. The revascularization was performed on May 10, 2005. The angiography corelab reported 17% stenosis at the target lesion. They reported that the study stent was patent and a non target vessel/ target lesion intervention was performed. A revascularization of the first obtuse marginal was performed.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Abrupt closure during index 0 days post-procedure, Stent delivery/Device failure 0 days post procedure, Dissection grade F 0 days post procedure, no event (no non Q-Wave MI, no stent thrombosis) 0 days post procedure, Total Occlusion 238 days post-procedure, Non Q-Wave MI - 354 days post procedure, CABG, Target Lesion Revascularization, Clinically Driven – 374 days post-procedure; CABG, Non Target Vessel Revascularization – 374 days post procedure</p>	
		<p>The patient is a 62-year-old male with a history of previous MI (1999), hyperlipidemia and premature CAD in a first-degree relative. He presented with stable angina CCS class III. On June 7, 2004 he underwent the assigned treatment in the proximal CX. After the placement of the first stent a thrombus closed the vessel, for which another stent was used. After the second study stent was implanted a TIMI flow II was seen, with a non-significant stenosis. In order to improve this, an attempt was made to place a third study stent at the distal lesion. This third stent failed to pass the other stents. The site reported a 0% final residual stenosis with TIMI flow 2. Because the patient had a procedural occlusion, he received Abciximab IV during 12 hours post-PCI and blood samples were collected post-procedure. The lab-results showed approx. 12-16 hours post-procedure a peaked CK of 362 (nl <190, ratio 1.9) and CK-MB of 25 (nl <16, ratio 1.6) respectively. The site reported a non Q-wave MI.</p> <p>The ECG core lab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI): persistent anterior ST depression, age recent / acute. No new Q-wave Myocardial Infarction was seen. The Angiographic Core Lab reported a "Type F" dissection after first stent placement without flow. The final result after placement of a second stent was a TIMI 3 flow with a negative (-11%) diameter stenosis. The patient was discharged on June 8 on ASA and clopidogrel.</p> <p>On 31 January 2005 the patient returned for the 8 months control angiography. The patient did not have clinical symptoms. The ECG corelab reported no significant changes compared to baseline (no new major ST-T abnormalities and no new Q-wave Myocardial Infarction). The site reported an occluded target lesion/target vessel (CX). The Angio Corelab reported 100% diameter stenosis with TIMI flow 0 and a thrombus at the target lesion. No revascularization was performed.</p> <p>On 23 May 2005 the patient was admitted to the hospital because of ventricle fibrillation due to myocardial infarction. An electrocardioversion was performed several times and atropine, amiodaron and bicarbonate were administered. The CK value peaked at 3919 on 27 May 2005 (nl 10-200 U/l, ratio 19.6) and the CKMB at 97 (nl 0-5 µg/L, ratio 19.4). The site reported a Q-wave MI. The ECG Corelab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI) on the ECG dated 29 May 2005 as compared to the ECG dated 31 January 2005. They reported no new Q wave myocardial infarction.</p> <p>A repeat angiography was performed on 24 May 2005. The site reported a stenosis in the LAD with TIMI flow 3, a proximal occlusion of the RCX with crossfills from the RCA and a diffusely diseased RCA. The Angiography Corelab reported total occlusion of the target lesion (type 4 in stent restenosis). Because of the diffuse three-vessel disease, a PTCA was not performed and a CABG was planned.</p> <p>On 16 June 2005, a CABG was performed involving the prox CX, 1st Diag, R-PDA and 1st RPL. On 21 June 2005 the patient was transferred to the local hospital in good condition.</p>	<p>Event of 7 June 2004: site reported stent malfunction. CEC adjudicated as stent delivery/device failure.</p> <p>Event of 7 June 2004: Site reported non Q-wave MI 0 days post procedure; CEC adjudicated as no event.</p> <p>Event of 23 May 2005 reported by site as Q wave MI. Adjudicated by CEC as non Q wave MI.</p>

Site	Pt	Case Summary	Comments
		<p data-bbox="435 386 1175 415">CABG, Non Target Vessel Revascularization 553 days post procedure</p> <p data-bbox="435 422 1235 615">The patient is a 43-year-old male with a history of previous MI, which had occurred 6 days before the procedure, and hypertension. On June 7, 2004, he underwent the index procedure with the assigned treatment in the proximal CX. One study stent was implanted. The site reported 0% final residual stenosis with no dissection and TIMI flow 3. The angiography corelab reported a final residual stenosis of 16% with no dissection and TIMI flow 3. The patient was discharged on June 7, 2004 on ASA and clopidogrel.</p> <p data-bbox="435 646 1235 1157">On September 28, 2005, the patient was hospitalized at a referring site with unstable angina. The highest CK value which was measured on September 29, 2005, was 150 (nl 200 U/l, ratio <1). The CKMB was not available. An ECG was not available. A repeat angiography was performed. The target lesion was not filmed. The patient was transferred to the study site and a new repeat angiography was performed on October 3, 2005. The site reported a chronic total occlusion of the RCA. The site reported an attempt for revascularization of the RCA which failed because of a dissection. No information of the target lesion was available from the angiography film, as the target vessel was not filmed. On October 25, a repeat angiography was performed again. The angiography corelab reported a stenosis of 21% at the target lesion with TIMI flow 3. They reported a patent study stent and stenting of the RCA (non target vessel) without success. The site reported again a non successful revascularization of the RCA. As the repeat revascularization of the RCA had failed twice, the option of a CABG was discussed. On December 12, 2005, a CABG was performed involving the proximal, mid and distal RCA (non target vessel). On December 15, 2005 the patient was transferred to the referring hospital in good condition.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		<p>Non Q-wave MI 0 days post-procedure, Target Vessel Revascularization – 354 days post-procedure; No event (no non Q wave MI) 354 days post procedure</p>	
		<p>The patient is a 71-year-old male with a history of previous MI (14 June '02) and premature CAD in a first-degree relative. He presented with stable angina CCS class 3. On June 17, 2004, he underwent the assigned treatment in the mid LAD. One stent was implanted. The site reported no dissection post procedure and a 0% final residual stenosis with TIMI flow 3. The pre-procedure CK and CK-MB were within normal range. Approx. 20-24 hours post-procedure the CK and CK-MB peaked at 377 (nl. <190, ratio 2.0) and 46 (nl. <16, ratio 2.9) respectively. The site reported that after the PCI with the Endeavor stent, a small side branch was occluded. The patient was treated with Reopro and nitroglycerin IV. The ECG core lab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI): persistent inferior ST depression, age recent / acute. There were no new Q-waves. The Angiography Corelab reported 14% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged in good condition on June 18, 2004, on ASA and clopidogrel.</p> <p>On 1 June 2005, the patient was hospitalized with angina pectoris complaints at another site than the study site. According to this site, a bicycle test performed on May 17, 2005 was positive for recurrent coronary insufficiency. The results of the test are not available. The ECG corelab reported new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI), persistent anterior ST depression of indeterminate age/old and persistent anterior T wave inversion of indeterminate age/old on the ECG of 6 June 2005 as compared to the ECG of 17 June 2004. They reported no new Q wave myocardial infarction. The site did not measure enzymes, as they excluded an MI. Therefore, CK and CKMB values are not available. A repeat angiography was performed on 6 June 2005. The site reported 90% stenosis at the target lesion and a revascularization of the mid LAD (target lesion). According to the site, an attenuated, very severe lesion was visible from just before up to or possibly continuous right into the stent of the LAD. The Angiography Corelab reported 11% stenosis at the target lesion. They reported that the study stent is patent. They also reported a proximal residual stenosis and that PCI was performed for this lesion. According to the Angiography Corelab the revascularization was a remote Target Vessel Revascularization.</p>	<p>Event of 6 June 2005 reported by site as Target Lesion Revascularization. Adjudicated by CEC as Target Vessel Revascularization.</p>

Site	Pt	Case Summary	Comments
		Non Q-wave MI 0 days post-procedure	
		<p>The patient is a 67-year-old female with a history of hypertension. She presented with stable angina CCS class III. On May 14, 2004 she underwent he assigned treatment in the proximal LAD. One stent was implanted. The investigator reported that the first diagonal vessel was sacrificed. After recrossing and dilation of this side branch there was a TIMI flow I in the diagonal vessel. The Angiographic Core Lab reported a final 34% residual in-lesion stenosis with TIMI flow III. The pre-procedure CK was within normal range. The CK-MB was not drawn. Approx. 20-24 hours post-procedure the CK and CK-MB peaked at 508 (nl. <175, ratio 2.9) and 36 (nl. <15, ratio 2.4) respectively. The site reported a non-Q-wave MI. The ECG core lab reported: "new major ST-T abnormalities (possible myocardial ischemia, injury or NQMI): intermittent high lateral ST elevation, recent / acute. No new Q-wave myocardial infarction."The patient was longer hospitalized on CCU-unit for further evaluation. On May 17, 2004 she was discharged in reasonable good condition on ASA and clopidogrel.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Site	Pt	Case Summary	Comments
		No event (no subacute closure) 0 days post procedure	
		<p>The patient is a 46-year-old female with a history of previous MI, hyperlipidemia and premature CAD in a first degree relative. She presented with stable angina. The CCS class was unknown. On 18 May 2004 she underwent the assigned treatment in the mid RCA. One stent was implanted. The site reported ST-elevation on the ECG and angina due to no reflow during pre-dilatation. The site reported TIMI flow 2, worst dissection grade 0 and 90% diameter stenosis during pre-treatment. They reported a subacute closure of the target vessel. The Angiography Corelab reported an aneurysm both pre and post procedure. They also reported 14% final residual stenosis at the target lesion with no dissection and TIMI flow 3.</p> <p>According to the site, the ECG normalized after intra-coronary injection of Papaverin. The ECG corelab reported no significant changes (no new major ST-T abnormalities, possible myocardial ischemia, injury or NQMI) and no new Q-wave Myocardial Infarction for the ECG of 19 May compared to the one of 17 May. On 18 May 2004, two CK values were measured. At 2:23 pm, the CK value measured at the study site was 69 (nl <175, ratio <1). At 10:03 pm, the CK value measured at the referring hospital was 73 (nl <170, ratio <1). On 19 May 2004 at 8:00 am the CK was 89 (nl <170, ratio <1). No CKMB values were available. The site reported 0% final residual stenosis with no dissection and TIMI flow 3 after the procedure. The patient was discharged on 19 May 2004 on ASA and clopidogrel.</p>	Event of 18 May 2004: site reported abrupt or threatened abrupt closure of the target vessel. CEC adjudicated as no event.
		Other: revascularization, not of coronary artery 122 days post procedure	
		<p>The patient is a 45-year-old male with a history of smoking and premature CAD in a first degree relative. He presented with stable angina CCS class 3. On 1 June 2004 he underwent the assigned treatment in the proximal LAD. One study stent was implanted. The site reported a 0% final residual stenosis with no dissection and TIMI flow 3. The patient was discharged on 2 June 2004 on ASA and clopidogrel.</p> <p>On 1 October 2004 the patient was hospitalized because of a PTA with stent implantation in the right and left arteria iliaca, due to stenosis with significant pressure fall. The complaints existed already before the enrollment. The patient was discharged on 2 October 2004 in good health.</p>	

	t	Case Summary	Comments
		<p>Target Lesion Revascularization, Not Clinically Driven 244 days post-procedure</p>	
		<p>The patient is a 65-year-old male with a history of previous MI and hyperlipidemia. He presented with stable angina CCS class 0. On 8 June 2004 he underwent the assigned treatment in the proximal LAD. Two study stents were implanted because of the long lesion. The site reported a 5% final residual stenosis with no dissection and TIMI flow 3. The Angiography Core Lab reported a 22% residual stenosis with TIMI flow 3 and no dissection. The patient was discharged on 9 June 2004 on ASA and clopidogrel.</p> <p>On 7 February 2005 the 8 months angiography was performed. The patient did not have clinical symptoms. The site reported 50-70% stenosis at the target lesion. The Angiography Core Lab reported 52% stenosis at the target lesion with TIMI flow 3. A repeat revascularization of the target lesion, the proximal LAD, was performed.</p>	

Medtronic Vascular, Inc.
10 November 2006

ENDEAVOR II -CA Study
720-Day Clinical Study Report

Table 31. Detailed Patient Listing
(See Attached Excel Document)

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 \leq 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 \geq 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).