

## SECTION 10.0 REFERENCES

This section contains a list of peer-reviewed journal articles or presentations related to the SPIRIT family of clinical trials or other relevant publications related to Drug Eluting Stents. The following bibliography is followed by copies of the full articles or presentations.

1. Beijk, M. A., Neumann, F.J., et al. (2007). “Two-year results of a durable polymer everolimus-eluting stent in *de novo* coronary narrowing (The SPIRIT FIRST Trial).” *EuroIntervention* (2007)1: 266-272
2. Beijk MA, Piek JJ. XIENCE V everolimus-eluting coronary stent system: a novel second generation drug-eluting stent. *Expert Rev Med Device* (2007)4:1; 11-21
3. Carrie, D. SPIRIT II: IVUS 6 Months Results. Oral presentation ESC 2006
4. Cutlip, D. E., S. Windecker, et al. (2007). Clinical End Points in Coronary Stent Trials: A Case for Standardized Definitions. *Circulation* (2007)115: 2344-2351
5. Farb A and Boam AB, Stent thrombosis redux—the FDA perspective. *New England Journal of Medicine*. (2007)356:1; 984-7
6. Grines. CL, Bonow, RO, Prevention of Premature Discontinuation of Dual Antiplatelet Therapy in Patients With Coronary Artery Stents: A Science Advisory From the American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association, With Representation From the American College of Physicians. *Circulation* (2007)115: 813-818
7. Grube E, Buellesfeld L. Everolimus for stent-based intracoronary applications. *Rev Cardiovasc Med* (2004)5: Suppl 2; S3-8
8. Khattab, AA, Richardt, G. Differentiated Analysis of an Everolimus-Eluting Stent and a Paclitaxel-Eluting Stent among Higher-Risk Subgroups for Restenosis: Results from the SPIRIT II Trial. Accepted for publication in *EuroIntervention*
9. Krucoff MW, Boam A, Schultz DG. Drug-eluting stents “deliver heartburn”: how do we spell relief going forward? *Circulation*. (2007)115:23; 2990-4. Epub 2007 May 1
10. Laskey WK, Yancy CW, Maisel WH. Thrombosis in coronary drug-eluting stents: report from the meeting of the Circulatory System Medical Devices

- Advisory Panel of the Food and Drug Administration Center for Devices and Radiologic Health, December 7-8, 2006. *Circulation*. (2007)115:17; 2352- 7
11. Maisel WH. Unanswered questions--drug-eluting stents and the risk of late thrombosis. *N Engl J Med*. 2007 Mar 8; 356(10):981-4. Epub 2007 Feb 12
  12. Piek JJ. SPIRIT First: Everolimus Eluting Durable Polymer on the ML VISION Platform. Oral presentation PCR 2004
  13. Piek JJ. SPIRIT First: 12 Months Follow-up Results. Oral presentation AHA 2005
  14. Piek JJ. SPIRIT First: Two Year Follow-up Results. Oral presentation PCR 2006
  15. Pinto Slottow TL, Waksman R. Overview of the 2006 Food and Drug Administration Circulatory System Devices Panel meeting on drug-eluting stent thrombosis. *Catheter Cardiovasc Interv*. (2007)69:7; 1064-74
  16. Pocock, S.; Stone, G. W.; Fahy, M., et al. Relationship between late loss, diameter stenosis and target lesion revascularization after stent implantation: An examination of surrogate endpoints from a pooled analysis of eight large randomized DES trials. *Journal of the American College of Cardiology* (2006) 47(4): 188A-188A
  17. Popma, JJ. Spirit First- Another Hurdle is Cleared. *EuroIntervention* (2005)1:260-263
  18. Ruygrok, P, Desaga, M. One year clinical follow-up of the XIENCE V Everolimus eluting stent system in the treatment of patients with de novo native coronary artery lesions. The SPIRIT II study. Accepted for publication in *EuroIntervention*
  19. Seabra-Gomes, R. Percutaneous coronary interventions with drug eluting stents for diabetic patients, *Heart* (2006)92: 410-419
  20. Serruys, PW, P. Ruygrok, P. A randomized comparison of an everolimus-eluting coronary stent with a paclitaxel-eluting coronary stent: the SPIRIT II trial. *EuroIntervention* (2006)2: 286-294
  21. Serruys, P. W. SPIRIT II- Clinical Study: A Clinical Evaluation of the XIENCE™ V Everolimus Eluting Coronary Stent System in the Treatment of Patients with *de novo* Native Coronary Artery Lesions. Results Update to 9 Months. Oral presentation TCT 2006

22. Serruys PW, Ong A, Piek J. A randomized comparison of a durable polymer everolimus-eluting stent with a bare metal coronary stent: The SPIRIT first trial. *EuroIntervention* (2005)1:58-65
23. Serruys, P. W. SPIRIT II- Clinical, Angiographic and IVUS 6 Months Results. Oral presentation ESC 2006
24. Seth, A. SPIRIT II Clinical study: A clinical evaluation of the XIENCE™ V Everolimus Eluting Coronary Stent System in the Treatment of Patients with *de novo* Native Coronary Artery Lesions- Pharmacokinetics sub-study. Poster presented at ESC 2006
25. Smith, SC, Feldman, TE. ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention--Summary Article: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). *Circulation* (2006)113: 156-175
26. Stone, G.W. XIENCE V: A Next Generation DES. Oral presentation PCR 2006
27. Stone, G.W. Clinical, Angiographic, and IVUS Results from the Pivotal U.S. Randomized Trial of the XIENCE V Everolimus-eluting Coronary Stent System. Oral presentation ACC 2007
28. Stone, G.W. XIENCE™ V Everolimus Eluting Coronary Stent System: SPIRIT FIRST 3 year Results. SPIRIT II and III Meta-Analysis. Oral Presentation PCR 2007
29. Storger, H, Grube, E. Clinical experiences using everolimus-eluting stents in patients with coronary artery disease *J Interv Cardiol* (2004)16: 6; 387-390
30. Tsuchida K, Garcia-Garcia HM, Ong AT, et al. Revisiting late loss and neointimal volumetric measurements in a drug-eluting stent trial: analysis from the SPIRIT FIRST trial. *Catheter Cardiovasc Interv* (2006)67:2; 188-197
31. Tsuchida K, JJ P, FJ N, e a. One - year results of a durable polymer everolimus-eluting stent in *de novo* coronary narrowing (The SPIRIT FIRST Trial). *EuroIntervention* (2005)1:266-272
32. Weimer, M. SPIRIT First: Strength of the long Term Clinical Data. Oral presentation ESC 2005