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Tryton Announces DRG Reimbursement Code For Side Branch Stent in Germany
New Code Signals Growing Market Acceptance for Side Branch Stents

Durham, N.C. – Dec. 20, 2011 – Tryton Medical, Inc., the leading developer of stents designed to definitively treat bifurcation lesions, announced that the German Institute for Medical Documentation and Information (DIMDI, Cologne) has revised the procedure code for the treatment of coronary bifurcations lesions, distinguishing dedicated side branch stent systems from conventional technique and providing for additional reimbursement for use of the Tryton side branch stent.

“This favorable reimbursement decision in Germany is evidence of continued market acceptance of the Tryton stent, which has now been used to treat more than 3,500 patients worldwide,” said Shawn P. McCarthy, president and CEO of Tryton Medical. “The expanded reimbursement validates our commitment to providing data supporting Tryton’s use in this problematic lesion subset.”

“Treating bifurcation lesions is a common, challenging problem for interventional cardiologists,” said Professor Jai-Wun Park of Asklepios Klinik Hamburg, Germany, who received the “Best Challenging Case Award” for a challenging patient case treated with the Tryton stent at the 23rd Annual Transcatheter Therapeutics (TCT) conference last month in San Francisco. “Tryton offers a solution with excellent efficacy and safety in a large and growing body of clinical data. In addition, and just as importantly, Tryton provides me with the confidence to easily treat these difficult lesions with the reliability I associate with more straightforward cases. It has become a mainstay in my clinical practice.”

Clinical data presented on more than 800 patients treated with the Tryton stent has demonstrated consistent target lesion revascularization rates of less than four percent at greater than six months follow up.

In addition, the Tryton stent is also being studied in the first and only randomized IDE clinical trial evaluating dedicated bifurcated stents. More than one-third of the 704 patients have been enrolled to date in the Tryton IDE study. The results of the trial will be submitted to the U.S. Food and Drug Administration (FDA) for approval to market the device in the United States.

About Coronary Bifurcation Disease

Coronary artery disease often results in the buildup of plaque at the site of a bifurcation, where one artery branches from another. Current approaches to treating these lesions are time consuming and technically difficult. As a result, the side branch is often left unstented, leaving it vulnerable to higher rates of restenosis, the re-narrowing of the stented vessel following implantation.¹ In patients undergoing PCI-stenting, approximately one-third has a bifurcation lesion. Left main disease, an accumulation of plaque that narrows the base of the coronary tree, is a persistent challenge in interventional cardiology, as more than 75 percent of left main lesions are bifurcation lesions.

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About the Tryton Side Branch Stent

The Tryton Side Branch Stent System is built for bifurcation using proprietary Tri-zone™ technology to offer a dedicated strategy for treating bifurcation lesions. Tryton's cobalt chromium stent is deployed in the side branch artery using a standard single-wire balloon-expandable stent delivery system. A conventional drug-eluting stent is then placed in the main vessel. The stent system has received CE Mark and is commercially available throughout Europe, Russia and the Middle East. It is approved in the United States for investigational use only.

About the Randomized Tryton IDE Study

More than one third of the patients have been enrolled to date in the landmark Tryton IDE study, a multi-national randomized trial that compares a Tryton stent in the side branch vs. the use of balloon angioplasty in the side branch, with both arms of the trial utilizing a standard drug eluting stent in the main vessel. The study, which is the first and only randomized IDE clinical trial, will enroll 704 patients at up to 75 centers in North America, Europe and Israel. Martin Leon, M.D. (Columbia University, New York) serves as principal investigator for the study and Patrick Serruys (Thoraxcenter, Rotterdam) is leading IVUS and three-dimensional angiographic analysis.

About Tryton Medical, Inc.

Tryton Medical, Inc., located in Durham, N.C., is a leading developer of novel stent systems for the treatment of bifurcation lesions. The company was founded in 2003 by Aaron V. Kaplan, M.D. (professor of medicine at Dartmouth Medical School/Dartmouth- Hitchcock Medical Center) and Dan Cole to develop stents for the definitive treatment of bifurcation lesions. Privately held, Tryton is backed by Arnerich Massena & Associates, Spray Ventures, PTV Sciences, and RiverVest Ventures. For more information please visit www.trytonmedical.com.

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