



TRYTON Side Branch Stent Built For Bifurcation

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Tryton Medical, Inc., is a privately-held medical device company leading the development of novel stent systems enabling physicians to predictably treat significant bifurcation lesions with durable results. The company is headquartered in the Research Triangle Park area in Durham, NC.

Tryton was founded in 2003 by Aaron V. Kaplan, M.D., professor of medicine at the Geisel School of Medicine/Dartmouth-Hitchcock Medical Center, and H. Richard Davis, Chief Executive Officer. Investors in Tryton include RiverVest Venture Partners, 3x5 Special Opportunity Fund, Canepa Advanced Healthcare, and an unnamed investor.

The Unmet Need in Treatment of Bifurcation Lesions

More than 3 million people¹ develop coronary artery disease (CAD) each year in the U.S. Treatment often involves use of stents in an angioplasty procedure to open blocked arteries. Among patients with CAD, an estimated one-third have a bifurcation lesion, or a lesion at the site where an artery branches off.

Treatment of a bifurcation lesion can require additional time and be technically difficult. As a result, in many cases the side branch is not stented, leaving it vulnerable to higher rates of complications like restenosis. A definite solution, specifically designed to address the unique challenges in treating a bifurcation lesion, represents an important option for interventional cardiologists and their patients.

Tryton Side Branch Stent

For interventionalists seeking to treat significant bifurcation lesions predictably, the Tryton Side Branch Stent with Tri-ZONE[®] technology is designed to provide complete lesion coverage accommodating all vessel types with procedural control and superior outcomes. Made of cobalt chromium, the Tryton Side Branch 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 Tryton Side Branch Stent has now been used to treat more than 12,000 patients worldwide. It is commercially available in multiple countries within Europe, the Middle East and Africa, and is approved for use in the U.S. Tryton Medical entered into long-term strategic agreement with Cardinal Health to enable Cordis, its interventional vascular business, to be the exclusive distributor of the Tryton Side Branch Stent in the U.S.

The pivotal Tryton Randomized Clinical Trial (RCT), the largest coronary bifurcation study ever conducted, compared the Tryton Side Branch Stent to conventional provisional treatment with balloon angioplasty in the side branch. The intended treatment population of patients with side branch vessels of 2.25 mm diameter or greater showed reductions in target vessel failure and side branch percent diameter stenosis with the Tryton stent^{2,3}. Both the Tryton and provisional treatment strategies were shown to have similarly low rates of stent thrombosis and no cardiac deaths reported at nine months. The Tryton Confirmatory Study, a single-arm study of the Tryton stent confirms the excellent results in significant bifurcations from the pivotal Tryton Randomized Clinical Trial.⁴

Tryton Milestones

- 2003** Tryton founded
- 2008** Earned CE-mark for Tryton Side Branch Stent, company established headquarters in Durham, NC
- 2009** U.S. patent awarded for Side Branch Stent System
- 2010** First patient enrolled in pivotal Tryton Randomized Clinical Trial (RCT)
- 2012** Completed enrollment in Tryton Randomized Trial (RCT)
- 2013** Earned CE-mark and initiated European launch of next-generation Tryton Side Branch SHORT Stent
- 2015** Tryton Medical pivotal study meets primary endpoint, submit PMA for FDA approval
- 2016** Tryton Medical enters into long-term strategic agreement with Cardinal Health for U.S. distribution
- 2017** FDA approval, Tryton Side Branch Stent is the first dedicated bifurcation device to treat significant coronary bifurcation lesions

“With this first-of-its-kind approval in the U.S., interventional cardiologists now have access to a stent that is specifically engineered to provide the complete lesion coverage and more predictable patient outcomes needed for the challenging anatomy of coronary bifurcation lesions.”

– H.Richard Davis
Co-Founder, CEO, COO

Management

H. Richard Davis, Co-Founder, Chief Executive Officer, Chief Operating Officer

Aaron V. Kaplan, M.D., F.A.C.C., Founder & Chief Medical Officer

Brett Farabaugh, Chief Financial Officer

Douglas Ferguson, Vice President, Regulatory and Quality

Michael Healy, QA/QC Director

Pieter Buyl, International Sales & Marketing Manager

Judy Gonzalez, Sr. Marketing and Communications Manager

Board of Directors

Aaron V. Kaplan, M.D., F.A.C.C., Founder & Chief Medical Officer

Russell J. Rottiers, Arnerich Massena, Inc.

Alejandro Sanchez, Canepa Healthcare Fund

Jay Schmelter, RiverVest Venture Partners

1. Google Health Info – https://www.gstatic.com/healthricherkp/pdf/coronary_artery_disease.pdf 2. Outcomes of a Dedicated Stent in Coronary Bifurcations with Large Side Branches: A Subanalysis of the Randomized TRYTON Bifurcation Study – CCI 2015, Généreux et al. 3. RCT post-hoc intended cohort analysis (SB RVD 2.25mm QCA), Study was not designed to demonstrate statistical differences in secondary endpoints or endpoints in sub-populations. 4. Outcomes From the Tryton Confirmatory Study - JACC Interv. 2016 Généreux et al.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. For healthcare professionals only. Prior to use, refer to the instruction for use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions. WARNINGS: Use of the Tryton Side Branch Stent in appropriately sized main vessels and side branches is required for safe and effective performance of the device. Do not use the Tryton Stent in small side branches [<2.50 mm in diameter by visual assessment or <2.25 mm in diameter by quantitative coronary angiography (QCA)], as its use may lead to an increased risk of adverse cardiac events such as myocardial infarction and the need for repeat revascularization. To confirm appropriately-sized side branch diameters, the diameter of the pre-dilation balloon inflated to nominal pressure may be used as a reference. Alternatively, the use of quantitative imaging methods such as on-line quantitative coronary angiography, intravascular ultrasound or optimal coherence tomography should be considered. Use of the Tryton Side Branch Stent, as with percutaneous coronary stent implantation procedures in general, is known to be associated with the following risks: Vessel thrombosis. Increased length of hospital stay relative to those of coronary balloon angioplasty alone. Judicious selection of patients to receive this device rather than balloon angioplasty alone is strongly advised. Infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture. The stent may cause spasm, distal embolization, thrombus, or could migrate from the site of implantation. Excessive dilatation of the artery may cause vessel rupture and life-threatening bleeding. Stents may not be fully expanded during deployment, particularly in resistant lesions. Stent dislodgment from the balloon surface during deployment and/or dislodgment from the target site post-deployment can occur. Major bleeding.

Tryton is manufactured by Tryton Medical and distributed by Cordis.

TRYTON[®]
Medical

BUILT FOR BIFURCATION

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