

Tryton Medical

Bifurcation lesions treated, definitively

Tryton Medical is the leading developer of stents designed to definitively treat bifurcation lesions. Chief Technical Officer, Mr. Richard Davis, has over 14 years of medical device experience, primarily in the areas of general management, product development, clinical research, and operations. He took some time to talk to Cardiovascular Innovations about Tryton's key product, the Side-Branch Stent and future company developments.

Coronary bifurcation lesions with involvement of a significant side branch are a frequent occurrence. Approximately 540,000 procedures are performed every year to address bifurcation coronary lesions, accounting for 20% of all coronary lesions treated. These lesions are sub-optimally treated with a variety of time consuming and technically challenging procedures. Currently there are no optimised solutions that exist for treating bifurcation lesions, therefore, cardiologists are required to use a provisional strategy which avoids the deployment of a second stent, leaving the un-stented side-branch vulnerable to closure. The ability to definitively treat bifurcation lesions will enable percutaneous coronary intervention (PCI)-stenting to become the new standard of care for the treatment of branch vessels including left main coronary artery disease rather than bypass surgery.

Founded in 2003 by Dr Aaron V Kaplan and Spray Venture Partners (a venture capital firm that has been focused exclusively on early-stage medical technology companies since 1996), Tryton has developed the well-recognised Side-Branch Stent. As Davis explains, "The Tryton Side-Branch Stent is a balloon expandable, 5F guide compatible system that tracks over a single wire. When used in conjunction with a standard workhorse stent for the main vessel, it provides superior scaffolding and radial strength to the side-branch."

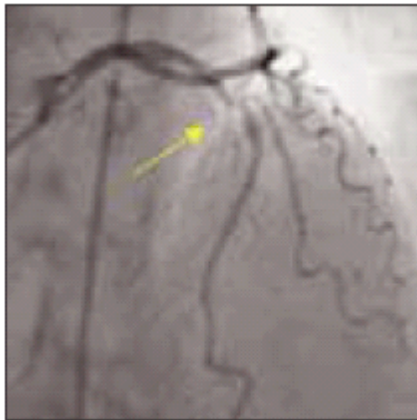
The stent has all the fundamental performance of a state-of-the-art workhorse stent and is delivered using

standard techniques and stent delivery materials. The Tryton Side-Branch Stent provides proven stent coverage to bifurcation lesions while eliminating the need for provisional stenting.

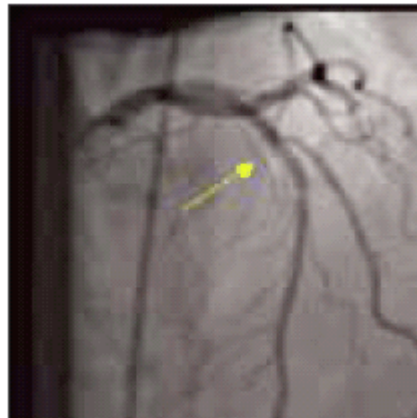
Eliminating the need for provisional stenting

Recently, Tryton announced the successful treatment of the initial ten patients in the company's first-in-man (FIM) multi-centre clinical trial, which demonstrated the clinical feasibility of the Side-Branch Stent. Professor Eberhard Grube, chief of Cardiology/Angiology, and Dr Ralf Muller from the HELIOS Heart Center/Siegburg, Germany, successfully treated patients with coronary blockages involving the side-branch with Tryton's Side-Branch Stent while avoiding major adverse cardiac events. "The Side-Branch Stent was used in conjunction with a standard workhorse stent, achieving excellent angiographic results," said Grube.

During the FIM trial, the Side-Branch Stent was evaluated on two distinct delivery systems. The first was a Step Balloon delivery system and the second was a Standard Balloon. Davis explained that the Step Balloon delivery system has two deployed profiles; a 2.5mm distal profile that deploys the stent portion of the device, and a 3.5mm proximal profile that dilates the main vessel region of the side-branch stent. As a result of this dual profile configuration the ostium of the side branch is flared during stent deployment to better conform to the formation of the origin of the side branch.



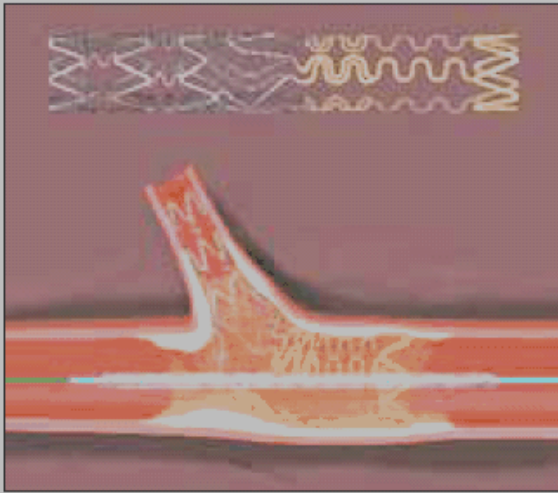
Pre-post comparison — Base



Pre-post comparison — Final

The standard balloon is based on a standard balloon expandable stent delivery system. The balloon is semi-compliant, and has a constant deployed diameter.

Both systems are low profile rapid exchange catheters that allow for 5F Guiding Catheter compatibility. These delivery systems employ a four marker band configuration that denotes the limits of the stent and the location of the transition zone. In addition, both balloons utilise the same semi-compliant balloon material and allow for at least a quarter of a millimetre up-sizing.



Tryton's Side-Branch Stent

Thoraxcenter joins Tryton's FIM Study

Additionally, the Thoraxcenter, Rotterdam joined Tryton Medical's FIM study and has successfully treated two patients with the Tryton's Side-Branch Stent.

"Tryton's Side-Branch Stent eliminates the need for provisional side branch stenting by preserving the side branch without compromising access to the main vessel," said Professor Patrick Serruys, Head of the Department of Interventional Cardiology, Thoraxcenter. "This technology has the capacity to redefine the treatment of bifurcation lesions and resolve a frequent dilemma of the interventional cardiologist," Serruys added.

Tryton's stent uses standard equipment and techniques that enables the interventionalist to remain worry-free about the bifurcation, knowing that the side-branch will stay open allows the implanting physician to focus on the optimal treatment of the main vessel.

Spotlight

FACT FILE

Tryton Medical

US Headquarters

2330 Washington Street
Newton, MA
02462 USA

Phone +1 617 332 6060
Fax +1 617 332 6070
Email info@trytonmedical.com
Web www.trytonmedical.com
CTO Richard Davis

Founded 2003

Focus

Tryton Medical is a privately held company dedicated to develop devices to treat bifurcation lesions within the coronary, cerebral and peripheral circulations.

Potted History

- 2003** Tryton Medical founded
- May 2006** Tryton announces first clinical use of its Side-Branch Stent to treat coronary bifurcation lesions
- October 2006** Tryton announces the successful completion of the company's first ten clinical cases
- October 2006** Dr Patrick W Serruys, Thoraxcenter, Rotterdam, joins Tryton Medical's first-in-man study



Richard Davis

