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Early cases show success with Tryton's new Side-Branch Stent

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For years, surgeons have attempted to treat Y-shaped bifurcation coronary artery lesions using stents that are designed for straight vessels, the equivalent of trying to cram a square peg into a round hole.

Into this breach comes **Tryton Medical** (Newton, Massachusetts), a developer of stents designed to treat these bifurcation lesions, which last week reported the successful completion of the company's first 10 clinical cases using its Side-Branch Stent.

The company said that all of the patients in the trial had coronary blockages involving a side branch and were successfully treated using the stent without any in-hospital complications.

There are about half a million people that are getting sub-optimal treatment today for bifurcated lesions," Richard Davis, co-founder and chief technical officer of Tryton told *Medical Device Daily*. The company said these bifurcated lesions account for 20% of all coronary lesions treated.

He said the new Side-Branch Stent functions like a standard workhorse stent, but its specific task is to treat bifurcated lesions.

Despite the significant number of bifurcation lesions, the company said that no dedicated solution exists today that fully addresses these lesions.

Davis noted that patients currently undergo complex procedures which are unpredictable and often lead to "suboptimal" results, with greatly increased risk for thrombosis as well as restenosis.

"Currently the stents that are available are approved for straight coronary lesions, and they're great for those types of lesions," he said. "The problem comes in when you have these Y-shaped bifurcation lesions and people are using these straight stents to solve the problem. You end up with a lot of extra material that actually helps increase the clotting of the artery."

The typical way to treat these bifurcated lesions is to "provisionally" span the Y with a straight stent, in the hopes of saving one vessel and, if there is enough blood flow afterwards, attempting to save the second vessel.

The company's mantra has been to save the side branch and the muscle associated with it.

"With our device we're actually saving the side branch, and at the same time we provide flow and we provide access to the main vessel."

Tryton initiated a multi-center clinical trial back in May to demonstrate the clinical feasibility of its new stent to treat coronary bifurcation lesions. The patients were treated by Eberhard Grube, MD, and Ralf Müller, MD, from the **Helios Heart Center** (Siegburg, Germany).

"The Tryton Side-Branch Stent was used in conjunction with a standard workhorse stent to treat a wide spectrum of complex bifurcation lesions, all with excellent angiographic results and without any major adverse cardiac events," said Grube, chief of cardiology/angiology at the Helios Heart Center. "Tryton's dedicated 'save-the-side-branch' strategy removes the uncertainty associated with provisional stenting," he added.

The idea for the device came from co-founder Aaron Kaplan, MD, associate professor from the **Dartmouth-Hitchcock Medial Center** (Lebanon, New Hampshire).

Kaplan has been on the founding team of a number of venture-backed medical device companies including **LocalMed** (Palo Alto, California) and **Perclose** (Redwood City, California). Kaplan has authored more than 18 U.S. Patents.

The beauty of the Kaplan's stent — which is balloon expandable — according to Davis is that it is deployed into the body using the standard stenting technique, including the ability to be tracked in via a single wire. Because of this, he said, "the learning curve with this device is minimal."

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The company believes the ability to definitively treat bifurcation lesions will enable PCI-stenting to become the new standard of care for the treatment of left main coronary artery disease rather than bypass surgery.

The company is currently being privately funded by healthcare venture company Spray Venture Partners (Boston), and Davis said it currently has enough money to get through the development stage.

Davis said the company envisions the device as a platform technology that could be adapted for use in virtually any Y-shaped vessel in the body. And while the company could go

it alone because of this platform potential, he said they are not averse to going the acquisition route if that turns out to be the best pathway for the company.

This stent is not preferential to a specific [company's delivery] device, so it can be used with other devices," he said, adding that larger companies see the bifurcation market as a "growing area."

The company will make several presentations on the Side-Branch Stent later this month at the Transcatheter Cardiovascular Conference in Washington. ■

*For more information visit
www.trytonmedical.com*