

Swiss medical device tour

Medartis sees low profile as route to a high profile future

By MARK MCCARTY

Medical Device Daily Washington Editor

The big names in the orthopedic sector in the U.S. are familiar and many are clustered in Warsaw, Indiana, but Switzerland has its own cluster of firms working this space. Among these is **Medartis** (Basel), which has zeroed in on innovative devices used to fix broken joints in the hands and feet and nearby anatomical locations. While the company is interested in building a reputation, its plan is to use a series of low-profile devices to build a high-profile brand.

Medartis, whose U.S. subsidiary is in Kennett Square, Pennsylvania, designs and manufactures its inventory from traditional but expensive materials and innovative designs the firm's leadership believes give it a leg up, so to speak, on the competition. The company's decision to make most

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Tryton releases interim data for branch stent system

By OMAR FORD

Medical Device Daily Staff Writer

Tryton Medical (Durham, North Carolina), a developer of stents designed to definitively treat bifurcation lesions, reported favorable results from recent studies evaluating its Tryton Side Branch Stent System.

Results from 253 patients in the E-Tryton registry show low rates of target lesion revascularization (TLR) and side branch failure (3.6% and 12%, respectively), with no incidences of stent thromboses.

"The results are remarkable and show a very low complication rate and a very high success rate," Aaron Kaplan, MD, Tryton co-founder told *Medical Device Daily*.

In addition, nine-month angiographic and IVUS follow-up results from the IUVANT study demonstrated a 3.2% rate of TLR, and no stent thromboses.

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International report

St. Jude wins approval for Eon Mini in Japan

A *Medical Device Daily* Staff Report

St. Jude Medical (St. Paul, Minnesota) has won regulatory approval from the Japanese Ministry of Health, Labor and Welfare for the Eon Mini spinal cord stimulation (SCS) system.

According to St. Jude, the device is the world's smallest, longest-lasting rechargeable neurostimulator, and it is the first rechargeable spinal cord stimulator to be approved for use in Japan. The Eon Mini is slightly larger than a typical man's watch, St. Jude said. The small size of the device allows for a smaller incision, which gives physicians more flexibility in selecting the implant location, the company noted.

Spinal cord stimulators manage chronic pain of the trunk or limbs and pain from failed back surgery by delivering

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CARISMA reveals insight into post-AMI arrhythmias

By AMANDA PEDERSEN

Medical Device Daily Senior Staff Writer

Continuous heart monitoring can be a valuable tool for physicians in detecting arrhythmias in patients who have suffered an acute myocardial infarction (AMI), according to a new study published recently in *Circulation*.

Medtronic (Minneapolis) said the results of the CARISMA (Cardiac Arrhythmias and Risk Stratification after Myocardial Infarction) trial demonstrate the benefits of continuous long-term monitoring of patients who have suffered an AMI. The multicenter, prospective study demonstrated that Medtronic's Reveal Plus implantable cardiac monitor recorded arrhythmias in 46% of patients with ejection fractions less than or equal to 40% and who had previously suffered an AMI.

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Tryton

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"That's really the strength of our product," Kaplan said. "We're able to get drug eluting-stent (DES) like results and not worry about thrombosis because our product is a bare metal stent."

The stent system is designed to treat atherosclerotic lesions in the side branch at the site of a bifurcation. Tryton's highly deliverable cobalt chromium stent is deployed in the side branch artery using a standard single-wire balloon-expandable stent delivery system. A conventional DES is then placed in the main vessel.

"It will provide, for the first time, the ability to treat the bifurcation in a way that we haven't been able to treat it before," Kaplan said. "Right now when someone comes in with bifurcation there are really two choices. Send them for bypass surgery . . . or simply treat the side branch with a balloon."

The issue with treating the side branch with a balloon is that often times cardiologists have to worry about the side branch collapsing.

One of the benefits of the system is that it is simple to use and is implanted just like any other stent, Tryton said. It also builds upon established skills and there are no new implant techniques required by the cardiologist.

That ease of use has helped its adoption rate in Europe and has led to more than 2000 of the systems implanted in patients, according to the company.

The stent system has received CE mark and has been commercially available in 21 countries throughout Europe and the Middle East since May. The device has not yet been approved in the U.S.

But the company has plans to start a clinical trial in the U.S. in the near future and hopes to have enough data to be able to successfully file for a PMA in the early part of 2013. The randomized trial will compare Tryton's application against surgeons treating bifurcation with a balloon placed in a side branch.

But while that might be a ways off, the company said that it was extremely happy with the fact that it has such strong data already from its European studies.

"We're pleased that these results confirm positive outcomes seen in earlier studies, including excellent six-month clinical and angiographic results in our first-in-man study and excellent six-month clinical results from four different registries. All of these studies show a low rate of TLR," said Greg Davis, president/CEO of Tryton.

September has been a banner month for the small med-tech company. Earlier this month the company said it closed a \$20 million Series D round of financing. Arnerich Massena led the round, which also included current investors PTV Sciences, RiverVest Venture Partners and Spray Venture Partners (*Medical Device Daily*, Sept. 15, 2010).

Davis said Tryton was fortunate to get such funding, but added that investors were attracted to it because the

company was frugal with its spending and still managed to achieve good quality results.

"There has been a significant amount of momentum and we're very happy about that," Davis told *MDD*. "We're using the funds in two ways. First we're going to fund our clinical trials and then we're going to continue funding adoption of our device in Europe." ■

Omar Ford, 404-262-5546;
omar.ford@ahcmedia.com

Product Briefs

• **American Medical Systems** (AMS; Minnetonka, Minnesota) reported the launch of its MoXy Liquid Cooled Fiber for laser treatment of benign prostatic hyperplasia, or enlarged prostate. Designed to be used with the recently launched GreenLight XPS (Xcelerated Performance System) 180 Watt laser, the MoXy fiber, with its Active Cooling Cap technology, uses 360-degree saline flow to maintain the temperature of the fiber tip for increased fiber longevity. The new system maintains the same safety profile as the GreenLight HPS and PV systems.

• **Hill-Rom** (Batesville, Indiana) reported the introduction of the Hill-Rom P500 Therapy Surface with new treatment features and added versatility, now making it compatible with most flat deck bed systems. Hill Rom says the P500 Therapy Surface offers a mix of key features, including: Weight-based pressure redistribution supporting patients up to 500 pounds; Advanced Microclimate Technology, which is the most advanced low air loss system available; Turn Assist with "confirm rails up" feature to aid the caregiver in turning the patient left or right; Audible and visual Bed Exit, 30-degree Head-of-Bed and RemindMe alarms to help reduce the risk of caregiver and patient injury; and Shear-resistant material and a real-time pressure redistribution algorithm that offers shear and friction management, protecting the skin.

• **RepRegen** (London) reported that three- and six-month data from an *in vivo* study of its CE-marked StronBone bone graft substitute with strontium demonstrated by analytical testing that it can generate bone quality in, and around, bone defects that is significantly superior to a standard bone void filler (TCP-CaSO₄) in the control defect. Specifically, the study demonstrated: The bone in the defect was significantly stiffer (stronger) at three months (69%) in the StronBone bone graft than in the control (it took six months for the control to achieve a comparable stiffness); and, the bone in the defect was significantly denser at three months (41%) and six months (62%) in the StronBone bone graft than in the control.