BIOTRONIK Launches Pulsar-35 Self-Expanding Stent and Passeo-14 PTA Balloon Catheter

The Associated Press

Following the success of BIOTRONIK's Pulsar-18 0.018"/4F-platform self-expanding stent system, the company has now introduced its Pulsar stent technology in a 0.035"/6F platform. With this, BIOTRONIK is offering even more physicians its high qualitative stent technology with its high technical success and encouraging clinical performance.

Pulsar stent technology was proven effective during the 4EVER clinical study, with six-month clinical patency rates of 90%. Results were presented in January 2012 at The Leipzig Interventional Course (LINC), Germany, by principal investigator Dr. Marc Bosiers, Chief of Surgery, AZ Sint Blasius, Dendermonde, Belgium.

The 4EVER study is a prospective, nonrandomized, multicenter, 120-patient clinical investigation that evaluates the safety and efficacy of Pulsar stents in the superficial femoral artery (SFA). It examines both the acute and long-term performance of 4F-compatible devices. The primary endpoint is primary patency at 12 months, with secondary endpoints being technical success, time to hemostasis and wound complication rate.

Six-month highlights from 4EVER study data include: primary patency, 90%; freedom from target lesion revascularization (TLR), 95.4%; technical success, 100%; and mean manual compression time, 8.12 minutes (no vascular closure devices used).

The promising 4EVER study data demonstrate the high technical success possible with 4F intervention and the encouraging clinical performance of BIOTRONIK's Pulsar stent systems. Full 12-month data from the 4EVER study will be announced at the CIRSE Annual Congress and Postgraduate Course (CIRSE 2012) in Lisbon, Portugal, in September 2012.

The addition of the Pulsar-35 self-expanding stent system will make BIOTRONIK's proven stent technology available to even more clinicians offering a convenient platform. The Pulsar-35 features a triaxial delivery system designed to provide precise implantation accuracy, and the system benefits from the same outstanding stent design as the Pulsar-18 -- including features such as high multiaxis flexibility and optimized radial force specifically designed for the challenges of SFA stenting. Available in lengths from 30 mm to 200 mm and diameters of 5 mm to 7 mm, this stent will provide an additional treatment option with promising clinical data.

BIOTRONIK Passeo-14 balloon catheter may shorten procedure time Joining the Pulsar-35 in BIOTRONIK's evolving lower limb portfolio is the Passeo-14 balloon catheter, a dedicated 0.014" infrapopliteal percutaneous transluminal angioplasty (PTA) catheter. Developed in collaboration with infrapopliteal experts, the device's unique features are designed to address weaknesses common to infrapopliteal PTA catheters. Key features include a stiffened proximal catheter shaft and hydrophilic coating for excellent push transmission and crossability -- plus a balloon-diameter-specific distal shaft length that provides optimized flexibility in tortuous pedal anatomy. Available in balloon lengths of up to 220 mm, this device may shorten procedure times and could reduce the need for multiple inflations.

"The Pulsar-35 self-expanding Stent and Passeo-14 PTA balloon catheter greatly improve BIOTRONIK's ability to meet physician needs and deliver best-in-class technology with flexibility for different treatment options," said Alain Aimonetti, Vice President of Sales and Marketing, BIOTRONIK Vascular Intervention. "Our robust product and clinical pipeline will continue to make BIOTRONIK a leader in peripheral vascular innovations, and these latest clinical and product developments underscore the strength and performance of BIOTRONIK's unique lower limb portfolio and our continuing commitment to delivering technological excellence backed by scientific evidence."

About BIOTRONIK SE & Co. KGAs one of the world's leading manufacturers of cardiovascular medical devices, with several million devices implanted, BIOTRONIK is represented in over 100 countries by its global workforce of over 5,600 employees. Known for having its finger on the pulse of the medical community, BIOTRONIK assesses the challenges physicians face, and provides the best solutions for all phases of patient care, ranging from diagnosis to treatment to patient management. Quality, innovation and reliability define BIOTRONIK and its growing success, and deliver confidence and peace of mind to physicians and their patients worldwide.

More information: www.biotronik.com

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