Synergy Everolimus-Eluting Platinum Chromium Coronary Stent System

Boston Scientific Corporation has received US Food and Drug Administration approval of the Synergy Everolimus-Eluting Platinum Chromium Coronary Stent System. The Synergy stent received CE Mark approval in 2012. It is the only bioabsorbable polymer stent available to patients in the United States and features ultra-thin stent struts with an abluminal bioabsorbable drug/polymer coating technology.

The Synergy stent provides synchronized drug and polymer absorption and is designed to enable more rapid and complete arterial healing, thereby reducing the risk of complications associated with long-term polymer exposure compared to currently used drug-eluting stents with permanent polymers.

“The introduction of the first bioabsorbable polymer stent in the United States is a tremendous milestone in the evolution of stent technology,” said Kevin Ballinger, President of Interventional Cardiology, Boston Scientific Corporation. “The Synergy stent is a next-generation therapy designed to improve patient outcomes and ultimately reduce health care costs associated with the treatment of coronary artery disease.”

Cardioband Mitral Reconstruction System

The Valtech Cardioband mitral reconstruction system, an implantable mitral repair device with a transfemoral, transeptal delivery system, received CE Mark approval in September and is available for use in European markets. Results from a multicenter feasibility trial demonstrated that the Cardioband significantly reduced mitral annular size and improved mitral regurgitation (MR). Significant improvement was seen in New York Heart Association classification, quality-of-life score on the Minnesota Living With Heart Failure questionnaire, and in 6-minute walk testing, with positive results on all three extending out through 12 months of follow-up.

The Cardioband delivery system is composed of a delivery system, prosthesis, and adjustment catheter. The prosthesis is attached to the posterior annulus, trigone, via special anchors. The stepwise procedure is performed under real-time beating-heart echocardiography and fluoroscopy. Using the size adjustment catheter, the implant can be adjusted bidirectionally to reshape the annulus, allowing circumferential annular cinching to eliminate MR after full deployment of the implant.
INNOVATIONS

A PREVIEW OF TODAY’S NEW PRODUCTS

NIRxcell CoCr Coronary Stent System

The NIRxcell cobalt chromium (CoCr) coronary stent system has been commercially launched in the United States, having had its premarket approval application approved in December 2013. It is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease associated with stenotic lesions in de novo native coronary arteries (length ≤ 30 mm) with a reference vessel diameter of 2.5 to 4 mm.

In a multicenter, prospective, non-randomized study of 278 patients, NIRxcell demonstrated exceptionally low (5.1%) target lesion revascularization (TLR) rates at 9 months. NIRxcell’s patented WiZeCell stent design combines wide and narrow struts, simultaneously achieving vessel conformability and radial strength. The Flexx catheter technology features a distinctive spring tip, the only tip visible under fluoroscopy, and offers deliverability and crossability even through tortuous and calcified anatomies.

Utilizing a proprietary manufacturing process, NIRxcell stents are produced from flat panels allowing for innovative design and a consistently high-quality end product.

KEY FEATURES
- 5.1%, TLR rate at 9 months
- Vessel conformability and radial strength
- Deliverability and crossability
- Only device with spring tip visible under fluoroscopy

Medinol USA
(800) 477-5801
www.medinol.com

MobiusHD

The MobiusHD device is a novel passive carotid sinus implant designed to amplify signaling from the carotid baroreceptors and consequently lower blood pressure via increased sympathoinhibition and decreased peripheral resistance. The open cell structure of the MobiusHD is designed to increase the differential strain measured by the carotid baroreceptors with every pulsatile wave. The permanent nitinol implant is delivered via a novel rapid exchange catheter and femoral access to the carotid artery, and it is positioned to maximize the windows of the device in the carotid bulb. The MobiusHD recently received CE Mark approval for the treatment of resistant hypertension. The CALM (Controlling and Lowering Blood Pressure with the MobiusHD) clinical studies in the United States and Europe continue to evaluate the safety and performance of the novel device. The MobiusHD is an investigational device in the United States.

KEY FEATURES
- Passive carotid baroreceptor signal amplification
- Permanent self-expanding nitinol implant
- Femoral access, 3 sizes available
- Novel rapid exchange delivery system

Vascular Dynamics, Inc.
(650) 963-9370
www.vasculardynamics.com