Synergy Coronary Stent System

Boston Scientific Corporation
Please contact your local Boston Scientific Interventional Cardiology sales representative
www.bostonscientific-international.com/home.bsci

KEY FEATURES

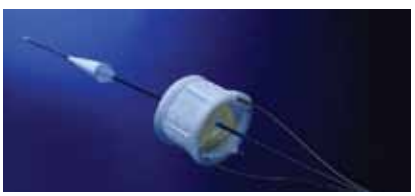
- Ultrathin, abluminal, bioabsorbable polymer coating
- Everolimus-eluting, same dose as Promus Element
- Low polymer weight
- Bioabsorbable coating dispersed at approximately 3 months
- Enhanced platinum-chromium platform

The Synergy stent (Boston Scientific Corporation, Natick, MA) received CE Mark approval in October 2012 and is an everolimus-eluting stent that combines an advanced platinum-chromium stent platform with an ultrathin, bioabsorbable PLGA polymer and everolimus drug coating applied to only the abluminal surface of the stent. Synergy is unique in that the polymer and the drug are designed to absorb and elute in a parallel manner. The polymer is dispersed when it is no longer needed, shortly after drug elution ends at 3 months. This has the potential to improve postimplant vessel healing and to eliminate long-term polymer exposure, a possible cause of late adverse events, said the company.

Synergy was tested in the EVOLVE trial, which randomized Synergy (94 patients) against the Promus Element (98 patients). Results of this first-human-use trial showed 6-month late loss and 12-month target vessel failure rates to be similar between products. There was no stent thrombosis in either group.

The Synergy stent system is not available for sale in the United States and Japan, the company advised.

Direct Flow Medical Transcatheter Aortic Valve System



Direct Flow Medical
(707) 576-0420, ext. 202
www.directflowmedical.com

KEY FEATURES

- Significantly reduces aortic regurgitation
- Double-ring valve design for tight annular seal
- Complete assessment of hemodynamic performance
- Fully repositionable and retrievable
- No rapid pacing or postdilatation required

Direct Flow Medical (Santa Rosa, CA) has received CE Mark approval for its distinctive transcatheter aortic heart valve with a metal-free frame and flexible, low-profile transfemoral delivery system. The Direct Flow Medical Transcatheter Aortic Valve System enables clinicians to optimize hemodynamic outcomes for their patients while significantly reducing aortic regurgitation and reducing procedural risks. Two sizes of valves, 25 mm and 27 mm, will be commercially available in Europe immediately.

"The Direct Flow Medical system is unique in many ways that combine to virtually eliminate aortic regurgitation, creating greater confidence in the outcome," said Professor Joachim Schofer, MD, Coprincipal Investigator for the DISCOVER trial.

The unique, double-ring design of the valve creates a tight and durable annular seal. It also allows complete assessment of hemodynamic performance, as well as repositioning and retrieval after the valve is fully deployed, but before final implantation. Additionally, no rapid pacing or postdilatation is required, reducing hemodynamic stress.

The 30-day DISCOVER trial results, presented at TCT 2012, demonstrated 97% freedom from all-cause mortality and 97% of patients with no or mild aortic regurgitation. ■

R-Band Radial Hemostasis Device

Vascular Solutions, Inc.
(763) 656-4300
www.vasc.com

KEY FEATURES

- Compression band targets hemostasis needs in rapidly growing radial artery access for performing cardiology procedures
- Device comprises soft plastic wrist strap with adjustable hook and loop fasteners, two inflatable compression balloons, and inflation syringe
- Clear plastic strap and compression balloons allow the clinician to visualize the access site

Vascular Solutions, Inc. (Minneapolis, MN) announced the launch of the R-Band radial hemostasis compression device in the United States. The R-Band, which has received 510(k) clearance, is a radial compression device that is used by interventional cardiologists to achieve hemostasis following transradial diagnostic and interventional catheterization procedures. The device consists of a soft plastic wrist strap with adjustable hook and loop fasteners, two inflatable compression balloons, and an inflation syringe with a proprietary connector tip. After applying the strap around the patient's wrist, the physician inflates the compression balloons to apply gentle pressure to the puncture site of the radial artery, while maintaining flow through the ulnar artery. The clear plastic strap and clear compression balloons allow the clinician to visualize the access site during the entire process.

"Radial access is undergoing tremendous expansion in the United States, and we are especially pleased that the addition of the R-Band will allow us to offer a broader range of products for radial hemostasis to fit physician preferences, supplementing our existing Rad-Band and D-Stat Rad-Band products," said Howard Root, Chief Executive Officer of Vascular Solutions. "In addition, the R-Band provides obvious synergies with the Accumed wrist-positioning splint that we acquired in June."

Xience Xpedition

Abbott
(800) 227-9902
www.abbottvascular.com

KEY FEATURES

- New stent-delivery system
- Designed to optimize acute performance in challenging coronary anatomy
- Offers the largest size matrix in the United States market
- First and only drug-eluting stent in the United States proven safe for direct stenting

The Xience Xpedition everolimus-eluting coronary stent system (Abbott, Santa Clara, CA) is now available in the United States for the treatment of coronary artery disease. Xience Xpedition features a new stent-delivery system designed to optimize acute performance, particularly in challenging coronary anatomies. Xience Xpedition will be available in the largest size matrix in the United States market, including a unique 3.25-mm diameter and lengths up to 38 mm.

Abbott's Xience drug-eluting stents, including the newly approved Xience Xpedition, are the first and only drug-eluting stents in the United States market to be proven safe for direct stenting. Direct stenting, a technique in which the stent system is not preceded by another device (such as a balloon-dilatation catheter) to prepare the lesion, has the potential to save time and resources in the catheterization laboratory. The Xience family of stents is supported by robust clinical evidence, with data from more than 45,000 patients across more than 100 studies and long-term outcomes out to 5 years. ■