Promus Premier Everolimus-Eluting PtCr Stent System

Boston Scientific Corporation
(612) 991-4943
www.bostonscientific.com

KEY FEATURES

- Customized stent architecture
- Outstanding clinical outcomes
- Enhanced stent delivery system
- Available in a broad matrix

Boston Scientific Corporation (Natick, MA) has received CE Mark approval for the Promus Premier everolimus-eluting platinum-chromium (PtCr) stent system, which was developed with input from physicians. According to the company, its customized PtCr stent architecture is designed to provide strength, flexibility, conformability, and fracture resistance, and the enhanced low-profile delivery system is designed to facilitate precise stent delivery across challenging lesions. The everolimus drug and fluorinated-copolymer stent coating have been studied in multiple randomized clinical trials demonstrating long-term safety and efficacy.

The Promus Premier stent system is offered in a matrix of 47 sizes, including diameters from 2.25 to 4 mm and lengths from 8 to 38 mm, on a monorail catheter platform. It is not available for sale in the United States or Japan, the company advised.

Engager Transcatheter Aortic Valve Implantation System

Medtronic, Inc.
(763) 526-2051
www.medtronic.com

KEY FEATURES

- Transcatheter aortic valve with transapical delivery
- Design gives physicians tactile feedback
- Precise valve positioning
- Minimal paravalvular leak
- Excellent procedural success

The Engager transcatheter aortic valve implantation system with transapical delivery catheter from Medtronic, Inc. (Minneapolis, MN) received CE Mark approval in February 2013 to treat patients with severe aortic stenosis who are at high or extreme risk for surgical aortic valve replacement. The new valve demonstrated positive clinical outcomes in its European pivotal trial, the results of which revealed high rates of procedural success, minimal paravalvular leak, and continuing clinical benefits for patients over time.

In the trial, the Engager valve was delivered transapically and had 94.3% overall device success (according to Valve Academic Research Consortium modified definitions). There were no procedures requiring a second valve and no occurrences of valve embolization, coronary obstruction, or device malposition. No patients had moderate or severe paravalvular leak at 6 months, as measured by an independent echocardiography core lab. The Engager system is not available in the United States, the company advised.

Claret Montage 2 Dual Filter System

Claret Medical, Inc.
(707) 528-9300
www.claretmedical.com

KEY FEATURES

- Embolic protection during TAVR
- Right radial or brachial access
- Compatible with 6-F introducer
- Captures and retrieves embolic material
- Simple deployment and retrieval

The Montage 2 Dual Filter System (Claret Medical, Inc, Santa Rosa, CA), a low-profile system for embolic filtration of both carotid arteries during interventional procedures such as transcatheter aortic valve replacement (TAVR), has received CE Mark approval. It is indicated for use as an embolic protection device to capture and remove embolic material, including thrombus or debris that may enter the cerebral vascular system during endovascular procedures.

The 6-F catheter is introduced in the right radial artery and delivered over a standard, 0.014-inch X 190-cm coronary guidewire. Following insertion, the filters are deployed prior to TAVR, and the system remains in place for the duration of the procedure. At the completion of the TAVR procedure, the filters are retrieved along with any captured embolic debris and are removed from the patient. ■