Assurant Cobalt Iliac Balloon-Expandable Stent System

COMPANY	Medtronic, Inc.
PHONE	(888) 283-7868
WEB	www.medtronic.com

KEY FEATURES

- Modular design provides conformability
- Cobalt chromium alloy imparts radial strength
- 6-F sheath compatibility for all configurations
- Immediate postprocedure MRI (MRI conditional)

Medtronic, Inc. (Minneapolis, MN) announced that the US Food and Drug Administration has approved the company's Assurant Cobalt Iliac stent system for the treatment of narrowed iliac arteries. The device features a balloon-expandable stent made from a cobalt chromium alloy. Approval was supported by 9-month results from the ACTIVE trial, which examined the outcomes of 123 patients at 17 sites in the United States. Results from the ACTIVE trial show low major adverse event rates and a 99.2% freedom from target lesion revascularization.

The modular design of Assurant Cobalt Iliac is composed of ultrathin, round, edgeless struts, allowing for smooth delivery to iliac artery lesions and conformability to the vessel wall without sacrificing radial strength. The stent uses a 6-F sheath for the entire size matrix—from the smallest size (6 mm X 20 mm) to the largest size (10 mm X 60 mm).

The company noted that the Assurant Cobalt Iliac stent system complements its self-expanding Complete SE vascular stent system, which has been approved with an iliac indication, to offer the option of a balloon-expandable or self-expanding stent, depending on the lesion location and morphology.

Ovation Abdominal Stent Graft System

COMPANY	TriVascular, Inc.
PHONE	(855) 569-7763
WEB	www.trivascular.com

KEY FEATURES

- Low-profile aortic body and iliac limb delivery system
- Inflatable sealing rings
- Low-viscosity, radiopaque biocompatible fill polymer
- Kink-resistant iliac limbs
- First HDE-approved EVAR stent graft

TriVascular, Inc. (Santa Rosa, CA) announced approval of the Ovation abdominal stent graft system by the US Food and Drug Administration under a humanitarian device exemption. With this approval, Ovation may be used in patients with access vessels < 7 mm in diameter and aortic necks with lengths of at least 7 mm and diameters between 15.5 and 17.4 mm.

The company noted that the approval will provide patients who were previously ineligible for the therapy with access to endovascular aneurysm repair. The low-profile (14-F outer diameter) Ovation system separates and optimizes fixation and seal. It is designed to expand the pool of treatable patients by addressing a wider range of diseased anatomy, the company stated.

To date, more than 500 patients have been treated with TriVascular's Ovation abdominal stent graft. TriVascular advised that the Ovation was launched commercially in Europe in January 2011. In the United States, the pivotal study of the Ovation abdominal stent graft completed enrollment in March 2011. Enrollment in the continued access study is ongoing.

Conformable Gore TAG Thoracic Endoprosthesis

COMPANY	W. L. Gore & Associates, Inc.
PHONE	(800) 437-8181 (928) 779-2771
WEB	www.conformabletag.com

KEY FEATURES

- Designed for flexibility and conformability in tortuous anatomy
- Optimized aortic wall apposition in angulated arch anatomy
- Compression resistant
- Unique 6%–33% oversizing window
- 16–42-mm treatment range with as few as five device sizes

The Conformable Gore TAG Thoracic Endoprosthesis (Gore & Associates, Flagstaff, AZ) is the only FDA-approved ePTFE thoracic endoprosthesis designed for endovascular repair of the descending thoracic aorta that offers conformability and ease of use while accommodating tapered anatomy and resisting compression, according to the company. The broad oversizing window for each device overlaps, allowing physicians to choose from multiple devices with the appropriate radial force for the patient anatomy.

William Jordan, MD, Chief of Vascular Surgery at the University of Alabama, Birmingham, served as national principal investigator for the Conformable Gore TAG Device in the Thoracic Aortic Aneurysm Trial. According to Dr. Jordan, "This new device represents a substantial product improvement brought to us by a company that was already leading the market in aneurysm devices. Gore evaluated the real world results of the first generation endograft and engineered improvements so that the device can be used across a wider range of aortic diameters with stronger radial force to resist compression. These modifications are intended to improve the lives of our patients and provide better outcomes for challenging clinical problems." ■