Medtronic Receives First FDA Approval of Cobalt Chromium Balloon-Expandable Stent to Treat Narrowed Iliac Arteries

MINNEAPOLIS –– Oct. 31, 2011 –– Advancing the treatment of peripheral artery disease, Medtronic, Inc. (NYSE: MDT) today announced approval by the U.S. Food and Drug Administration (FDA) of the Assurant® Cobalt Iliac Balloon-Expandable Stent System.
The new medical device features the first balloon-expandable stent made from a cobalt-chromium alloy to be approved by the FDA for the treatment of narrowed iliac arteries. It complements Medtronics self-expanding Complete® SE Vascular Stent, which is already approved with an iliac indication. The iliac arteries branch off the aorta in the abdominal area and carry blood to downstream vessels that perfuse the pelvis, legs and feet.

The new devices FDA approval was supported by the nine-month results from the ACTIVE (Use of the Assurant Cobalt Iliac Stent System in the Treatment of Iliac Vessel Disease) trial, which examined the outcomes of 123 patients at 17 U.S. sites.

The Assurant Cobalt stent demonstrated exceptional technical, procedural and clinical success in the trial and had low rates of major adverse events, target lesion revascularization (TLR) and target vessel revascularization (TVR) –– all at 0.8 percent. In addition, the device also achieved a 99.2 percent primary patency rate, meaning only one of the 123 study patients required a reintervention through nine months of follow-up.

"The Assurant Cobalt stent demonstrated excellent safety and long-term patency in the prospectively conducted and core lab controlled ACTIVE trial, with some of the lowest rates of 9-month TLR ever seen in an iliac interventional trial," said William A. Gray, M.D., of New York Presbyterian Hospital and co-principal investigator of ACTIVE. "The approval of this stent, along with the previous Complete SE self-expanding stent, significantly adds to the armamentarium for interventionalists, and therefore benefits our patients."

The Assurant Cobalt stent leverages the strength of cobalt chromium and a unique modular design to create a device with ultrathin, round, edgeless struts, allowing for smooth delivery to iliac artery lesions and excellent conformability to the vessel wall without sacrificing radial strength. The combination of these design features enables the stent to be the only balloon-expandable device to utilize a 6F sheath for the entire size matrix –– from the smallest (6mm x 20mm) to the largest (10mm x 60mm) size –– for the treatment of iliac arteries.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac

arrhythmias.

ABOUT MEDTRONIC
Medtronic, Inc. (www.medtronic.com [1]), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health and extending life for millions of people around the world.

Links:
[1] http://www.medtronic.com/