Medtronic Endurant II AAA Stent Graft System Launches Internationally with CE Mark

MINNEAPOLIS –– Medtronic Inc. today announced the CE (Conformité Européenne) mark and international launch of the Endurant® II AAA Stent Graft System, which meaningfully expands the options physicians outside the United States have to treat patients with abdominal aortic aneurysms through a minimally invasive technique called endovascular aortic repair (EVAR).
An abdominal aortic aneurysm (AAA) is a weakening or bulge in the segment of the aorta, the bodys main artery, that crosses through the abdomen. AAA is often called a "silent killer" because it rarely causes apparent symptoms until rupturing, which usually results in the patients death.

Developed in collaboration with more than 250 physicians from around the world, the new system encompasses the proven clinical performance of the market-leading Endurant stent graft platform, while adding advanced design features that enhance the devices ease of use.

Now available in most European counties, the Endurant II AAA Stent Graft System carries forward the proven performance of its predecessor, while adding three distinct enhancements to enable both the most straightforward and challenging cases:

- Beginning at the point of access, the new lower-profile delivery system –– with 35 percent extended hydrophilic coating for enhanced access to challenging anatomies –– allows the 28mm-diameter bifurcated segment (the most commonly used size) to fit inside an 18 French OD (outer diameter) catheter (down from 20 French with the original device).
- Second, the addition of two new contralateral limb lengths (156mm and 199mm) enables more configuration options requiring fewer total pieces.
- Finally, the radiopacity of the distal end of the bifurcated segments contralateral gate has been improved to enhance visibility and aid with limb insertion, placement and deployment.

"The Endurant II AAA Stent Graft System will confer considerable confidence to vascular surgeons who use EVAR to treat even the most complex AAAs," said Prof. Hence Verhagen, chief of vascular surgery at the Erasmus Medical Center in Rotterdam, the Netherlands. "Building on the exceptional clinical outcomes of the original system, which has significantly increased the applicability of EVAR, Endurant II offers an even better user experience which will benefit even more patients whose AAAs are detected before rupturing."

Prof. Verhagen, who led the European clinical trial of the original Endurant Stent Graft that contributed to that devices approval, was the first physician to

successfully use the new system since it received the CE mark.

In countries where the Endurant II Stent Graft is approved with the CE mark, the device is indicated for the endovascular treatment of abdominal aortic aneurysms in patients with a proximal neck ? 10 mm in length with ? 60° infrarenal and ? 45° suprarenal angulation and in patients with a proximal aortic neck ? 15 mm in length with ? 75° infrarenal and ? 60° suprarenal angulation.

In the United States, the Endurant II AAA Stent Graft System is expected to receive approval from the U.S. Food and Drug Administration (FDA) during 2012.

The original Endurant AAA Stent Graft System received FDA approval in December 2010 and quickly became the U.S. market leader.

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.

Posted by Sean Fenske, Editor-in-Chief, MDT

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