Medtronic News

Medtronic Adds to Endurant 'AAA' Stent Graft System

New Bifurcated Component Leverages Proven Design of Predicate Device and Expands Anatomical Customization Options for Endovascular Repair of Abdominal Aortic Aneurysms

MINNEAPOLIS -- Nov. 12, 2014 -- The global leader in medical technology for endovascular aortic repair (EVAR), Medtronic, Inc. (NYSE: MDT) today announced the launch in Europe and the United States of the Endurant IIs AAA stent graft, which recently received the CE *(Conformité Européene)* mark and U.S. Food and Drug Administration (FDA) approval to be used in the minimally invasive treatment of abdominal aortic aneurysms.

The new device joins the Endurant family of products, which have been used to treat more than 160,000 patients worldwide since they were first introduced in Europe in 2008. The Endurant AAA stent graft system has been used more than any other, being selected for nearly one of every two endovascular procedures to repair abdominal aortic aneurysms around the world.

The Endurant IIs stent graft is a new bifurcated component for the system that leverages the proven design of the predicate device and expands the system's anatomical customization options. The new device is designed to be used as part of a three-piece configuration.

The Endurant IIs stent graft:

- features equal leg diameters to allow limbs to be used on either side
- offers a shorter (50mm) ipsilateral leg for more flexible targeted limb placement
- enables *in situ* sizing with select ipsilateral limbs, allowing a 3-5 stent overlap for adjustment during the implant procedure
- provides up to a 20 percent reduction in distal diameter compared to select Endurant II stent grafts
- allows easier pre-case planning by simplifying sizing decisions

The new device complements the existing Endurant II stent graft, which remains an integral part of the product portfolio and already accommodates a wide range of anatomies. The Endurant II and Endurant IIs stent grafts use the same delivery system, which allows for accurate placement and controlled deployment of the device within the aorta.

"Every AAA patient has different anatomical features, which is why it's so important for a stent graft system to provide for a wide variety of anatomical customization options," explained Dr. William Jordan Jr., professor of surgery and chief of vascular surgery and endovascular therapy at the University of Alabama Birmingham. "The Endurant stent graft system sets the standard for configuration possibilities, and the addition of the Endurant IIs stent graft expands the possibilities even further."

"The new Endurant IIs stent graft gives a winning idea new legs," added Prof. Hence Verhagen, chief of vascular surgery at the Erasmus Medical Center in Rotterdam, the Netherlands. "It stands to broaden the already broad appeal of the Endurant system, especially for physicians who prefer a three-piece configuration for EVAR."

Both Prof. Verhagen and Dr. Jordan have played important roles in studying the Endurant AAA stent graft system -- Prof. Verhagen as a principal investigator in the European study that supported the CE mark and Dr. Jordan as an investigator in the U.S. study for FDA approval.

Affecting an estimated 2.5 million people in the United States and Western Europe, an abdominal aortic aneurysm, or AAA, is a potentially dangerous bulge in the body's main artery where it traverses the mid-section. Those with a diameter of 5.5 centimeters, or twice the diameter of the patient's normal abdominal aorta, typically warrant treatment. Outside a hospital setting, a ruptured AAA usually results in death.

A stent graft is a tubular medical device that creates a new path for blood flow through the diseased segment of the aorta,

thereby reducing pressure on the aneurysm and the risk of rupture. It consists of a wire frame (stent) that is sewn onto a specially woven fabric (graft).

The bifurcated component in a stent graft system for AAA repair resembles a pair of pants with uneven legs. The top of the bifur fits the inner diameter of the aorta, while the "legs" fit the inner diameter of the iliac arteries, which branch off from the lower end of the aorta. The legs are different lengths to facilitate the implant procedure. They accommodate "limbs" that extend into the iliac arteries. The limbs are extensions of the legs.

The Endurant AAA stent graft system is the global leader in its product category. It has been proven in a variety of clinical studies to offer durable and consistent performance for the endovascular treatment of AAA. The Endurant system is the subject of the most robust long-term study of any stent graft ever initiated, called the ENGAGE registry.

The ENGAGE registry is a rigorously designed post-market study of the Endurant AAA stent graft system. It has enrolled more than 1,200 patients at 79 sites across six continents.

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

ABOUT MEDTRONIC

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

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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