Medtronic News

Medtronic Starts New U.S. Study of Endurant(R) AAA Stent Graft

Indicated for Endovascular Treatment of Abdominal Aortic Aneurysms, Medical Device Has Been Used to Treat More Than 6,000 Patients in United States Since December FDA Approval

MINNEAPOLIS, Aug 31, 2011 (BUSINESS WIRE) --

Leading the development of endovascular aortic repair (EVAR), Medtronic, Inc. (NYSE: MDT) today announced the start of its U.S. post-approval study of the Endurant(R) AAA Stent Graft System, a medical device used to treat abdominal aortic aneurysms (AAA).

The first patient in the company's Post-Approval Study Evaluating the Long-Term Safety and Effectiveness of the Endurant Stent Graft System (ENGAGE PAS) was enrolled earlier this month at Parkwest Medical Center in Knoxville, Tenn., by the site's principal investigator (PI), vascular surgeon Dr. Christopher Pollock.

The study's national PI is Dr. Marc Schermerhorn, chief of vascular and endovascular surgery at Beth Israel Deaconess Medical Center and associate professor of surgery at Harvard Medical School in Boston.

"The ENGAGE clinical program exemplifies Medtronic's commitment to characterize the real-world, long-term performance of the Endurant AAA Stent Graft," Dr. Schermerhorn said. "The resulting data will help clinicians worldwide improve their minimally invasive treatment of patients with abdominal aortic aneurysms."

ENGAGE PAS is a prospective, multicenter, single-arm study designed to demonstrate the long-term safety and effectiveness of the Endurant AAA Stent Graft in a post-market environment. The study will involve approximately 325 subjects and up to 25 U.S. sites. The primary endpoint of ENGAGE PAS is freedom from aneurysm-related mortality at five years after implantation of the stent graft.

The study augments Medtronic's international ENGAGE Registry, the largest real-world collection of clinical data on a single stent graft ever compiled. Completed in April, the registry enrolled 1,266 patients over two years at 79 sites across 29 countries.

In total, more than 1,800 patients treated with the Endurant AAA Stent Graft System will be followed out to five years as part of Medtronic's global clinical program for the device. The program includes company-sponsored pre- and post-market studies conducted worldwide since November 2007, when the first-in-human implant was performed in the Netherlands.

"From evidence comes confidence," said Tony Semedo, vice president and general manager of the Endovascular Innovations business for Medtronic. "The ENGAGE clinical program has produced a body of evidence on the Endurant AAA Stent Graft System that engenders confidence among physicians performing EVAR worldwide. It stems from an enduring commitment to advancing the standard of care for AAA with innovative technology that reliably and predictably performs its intended function. We believe ENGAGE PAS, the U.S. post-approval study for our next-generation stent graft, will add to this unmatched dataset."

The U.S. Food and Drug Administration (FDA) approved the Endurant AAA Stent Graft System in December 2010. Since then, the device has been used to treat more than 6,000 patients in the United States. It is the market-leading stent graft worldwide.

The Endurant AAA Stent Graft is a flexible wire frame (stent) sewn onto a specially woven fabric tube (graft) that physicians use to create a new path for blood flow in the patient's aorta, reducing pressure on the aneurysm and the risk of rupture. Delivered through catheters inserted into blood vessels in the groin, the device conforms to a broad range of aortic anatomies, enabling physicians to offer EVAR to more AAA patients than ever before.

In the United States, the Endurant AAA Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic and aorto-iliac aneurysms in patients with specific anatomical characteristics, including adequate femoral or iliac artery access, proximal neck length of at least 10 mm, infrarenal neck angulation of no greater than 60 degrees, and aortic neck diameter of 19 mm to 32 mm.

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), 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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