Medtronic News

Med-Tech Advance for 'Silent Killer': FDA Approves Medtronic Device to Fix Abdominal Aortic Aneurysms

Endurant(R) AAA Stent Graft Expands Patient Access to Minimally Invasive Procedure To Repair Dangerous Bulge in Body's Main Artery Without Major Surgery

MINNEAPOLIS, Dec 21, 2010 (BUSINESS WIRE) --

An estimated 1.2 million people in the United States have an abdominal aortic aneurysm (AAA) - a dangerous bulge or ballooning in their bodies' main artery1 that typically causes no symptoms until it ruptures, which can be deadly - and most of them don't know it. But for those with a known AAA of a certain size, there's a new medical device for a safe and effective treatment option that doesn't require major surgery, an extended hospital stay and a long recovery period.

The U.S. Food and Drug Administration (FDA) today approved the Endurant(R) AAA Stent Graft System from Medtronic, Inc. (NYSE: MDT) for the minimally invasive treatment of this largely unknown, and often fatal, condition.

The Endurant 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 new device is designed to conform to a broad range of aortic anatomies, enabling physicians to offer endovascular aortic repair (EVAR) to more AAA patients than ever before.

"With FDA approval of Medtronic's Endurant stent graft, U.S. physicians now have access to a new-generation device that will allow safe treatment of even more complex AAA patients with EVAR than was feasible with previous devices," said Dr. Michel Makaroun, M.D., professor and chief of vascular surgery at the University of Pittsburgh Medical Center, and the principal investigator for the U.S. clinical study. "With its innovative design and delivery system, the Endurant stent graft represents another significant advance that expands our toolkit for the minimally invasive management of this dangerous, often deadly, condition."

In the study, which supported the device's FDA approval, there were no post-implant aneurysm ruptures or aneurysm-related deaths through one year of patient follow-up, and no patients experienced enlargement of their aneurysms (all remained stable or shrank in size) during this timeframe. Also through one year, there were no device migrations or device-related "endoleaks," which can result in persistent blood flow into the aneurysm sac and enlargement of the aneurysm. The study involved 150 patients and 26 medical centers, and successfully met its primary goals and endpoints for assessing the safety and effectiveness of the Endurant stent graft.

Undetected or untreated, AAAs can burst unexpectedly with often fatal consequences, making this condition the third leading cause of sudden death in men over age 60.2 Approximately 75-90 percent of undiagnosed AAA patients will die if - or when - their aneurysm ruptures3, designating the condition a "silent killer."

AAAs rarely cause symptoms until they rupture, which usually results in death due to rapid and extensive internal bleeding. They are often found coincidentally on X-rays or other medical imaging studies performed for other reasons. Detection and diagnosis of this condition are critical to its effective management. The Society for Vascular Surgery recommends treatment for AAAs that are 5.5 cm or greater in diameter.

Physicians rely primarily on two approaches to treat AAAs: open surgical repair and endovascular repair. Open surgical repair requires a large incision in the abdomen to access the aorta; it involves removal of the aneurysmal segment and replacement with a synthetic graft that is sewn onto healthy aortic tissue. Endovascular repair is a less invasive procedure in which a stent graft - a wire mesh (stent) supporting a fabric tube (graft) - is compressed on a delivery catheter, threaded through an artery in the groin and expanded at the site of the aneurysm; it does not require removal of the aneurysmal segment. EVAR has emerged over the last decade as a viable alternative to open surgery because it significantly reduces the patient's hospital stay and recovery period.

"Offering great therapeutic solutions to the highly skilled clinicians who treat patients with aortic disease is the foundation of our leadership in EVAR," said Tony Semedo, vice president and general manager of Medtronic's Endovascular Innovations business. "In addition to a portfolio of market-leading stent grafts, Medtronic offers a suite of ancillary products and support services that spans the continuum of care for patients with aortic disease. Our leadership also extends to advocacy for screening, diagnosis and management of this highly treatable condition."

Medtronic is committed to advancing the treatment of cardiovascular disease through collaboration with leading clinicians, researchers and scientists 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.

1 Society for Vascular Surgery. Protect Yourself From An AAA Rupture. http://www.vascularweb.org/patients/prevention/aaa_rupture.html. Accessed August 3, 2009.
2 Ohki T, Veith FJ. Endovascular Repair of Ruptured, AAAs In treating AAAs, endovascular repair may hold the key over open repair to lowering mortality. *Endovascular Today*. January 2004;47-51.
3 Earnst, CB Abdominal Aortic Aneurysm. N Engl J Med.1993;328:1167-72.

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