Medtronic News

Endurant 'AAA' Stent Graft from Medtronic Continues to Deliver Durable, Consistent and Proven Outcomes

Latest Results from Two Clinical Studies Show Strong Mid-Term Performance of Leading Medical Device for Endovascular Repair of Abdominal Aortic Aneurysms

MINNEAPOLIS -- Dec. 9, 2014 -- For endovascular repair of abdominal aortic aneurysms, the Endurant AAA stent graft system from Medtronic, Inc. (NYSE: MDT) continues to deliver durable, consistent and proven outcomes, according to the latest results from two clinical studies.

The Endurant AAA stent graft system has been used to treat more than 165,000 patients worldwide since it was initially introduced in Europe in 2008 -- more than any other device of its kind, being selected for nearly one of every two endovascular procedures to repair abdominal aortic aneurysms around the world.

The latest results on the Endurant AAA stent graft system's mid-term performance come from a U.S. investigational device exemption (IDE) study that led to the device's approval by the U.S. Food and Drug Administration in 2011 and an international study, called the ENGAGE registry, that was initiated after receipt of the CE *(Conformité Européene)* mark in 2008.

The U.S. IDE study enrolled 150 patients at 26 centers with strict eligibility criteria compared to the international ENGAGE registry, which has enrolled more than 1,200 patients at 79 sites across six continents with very few exclusion criteria -- and, as a result, more complex baseline characteristics, including 17.8 percent whose AAA features placed them outside the device's instructions for use.

Four-year follow-up for all 150 patients enrolled in the U.S. IDE study and for the first 500 patients enrolled in the international ENGAGE registry has been completed. Three-year follow-up for all 1,263 patients in the ENGAGE registry has been completed. Outcomes for these three patient cohorts were presented in November at two different medical meetings -- VIVA (in Las Vegas) and VEITH symposium (in New York):

- Four-year results for all 150 patients in the U.S. IDE study include a 99.2 percent rate of freedom from aneurysm-related mortality and a 90.0 percent rate of freedom from secondary intervention. In addition, 98.0 percent of the patients' aneurysm sacs were stable or had decreased in diameter by more than 5 mm at four years of follow-up. At four years, none of the patients (0 percent) had experienced a type I/III endoleak or a main body migration.
- Four-year results for the first 500 patients in the ENGAGE registry are remarkably consistent with those for all patients in the U.S. IDE study, despite the differences in eligibility criteria and baseline characteristics. They include a 98.4 percent rate of freedom from aneurysm-related mortality, and an 87.3 percent rate of freedom from secondary intervention.
- Similarly, three-year results for all 1,263 patients in the ENGAGE registry include a 98.5 percent rate of freedom from aneurysm-related mortality and an 89.5 percent rate of freedom from secondary intervention. In addition, 91.0 percent of the patients' aneurysm sacs were stable or had decreased in diameter by more than 5 mm at three years of follow-up. At three years, type I/III endoleaks had occurred in 1.5 percent of the patients; and main body migration, in none (0 percent).

"Aneurysm-related mortality, secondary interventions and changes in sac diameter are three critically important measures of stent graft performance," said Dr. Edward Woo, director of the MedStar Regional Vascular Program, and chairman of vascular surgery and professor of surgery at Georgetown University in Washington, D.C. "Judging from the latest results from two high-quality studies, the impressive performance of the Endurant stent graft system has proven to be remarkably durable and consistent on these and other important measures across a wide range of patients and operators."

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 ENGAGE registry is the most robust long-term study of any stent graft ever initiated. With follow-up now planned for 10 years, it also promises to be first in providing the longest-term performance data on a single stent graft.

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 cm, 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.

Stent grafts are tubular medical devices that create a new path for blood flow through the diseased segment of the aorta, thereby reducing pressure on the aneurysm and the risk of rupture.

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.

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Contacts:
Joe McGrath
Public Relations
+1-707-591-7367

Jeff Warren
Investor Relations
+1-763-505-2696

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