

Endurant AAA Stent Graft from Medtronic Continues Exceptional Long-Term Performance in Observational Studies

*New Clinical Data from PANDORA and ENGAGE Affirm
Market-Leading Medical Device's Durable, Consistent and Proven Outcomes
In Endovascular Treatment of Abdominal Aortic Aneurysms*

MINNEAPOLIS -- April 18, 2014 -- The Endurant AAA stent graft system from Medtronic, Inc. (NYSE: MDT) continues to demonstrate exceptional long-term performance in the endovascular treatment of abdominal aortic aneurysms, according to new clinical data presented for the first time at the 2014 Charing Cross international symposium in London.

The new data on the world's long-standing market-leader in its product category come from two separate observational studies -- PANDORA, independently conducted at two sites in Germany; and ENGAGE, sponsored by Medtronic and involving 79 sites worldwide. While distinct and different from one another in size, scale and scope, these two datasets affirm the Endurant stent graft's durable, consistent and proven outcomes across a broad spectrum of patient types and anatomical features. Highlights include low rates of aneurysm-related mortality and reintervention, stent graft migration and conversion to open surgery through three to five years of follow-up.

PANDORA

Designed to evaluate the long-term clinical performance of the Endurant stent graft in an all-comer patient population, PANDORA (Prospective evAluation of the eNDurant endOprosthesis for the treatment of abdominal aoRtic Aneurysms) prospectively enrolled 277 consecutive AAA patients, with no exclusion criteria, from November 2007 to December 2010. It is the first independent study of the Endurant stent graft to report long-term results.

Baseline characteristics included short (10mm to less than 15mm) neck lengths (49%), symptomatic aneurysms (7%) and ruptured aneurysms (2%). Follow-up compliance approached 99 percent, with four patients lost to follow-up; 273 patients were included in the analysis.

Despite the complexity of the patients enrolled, PANDORA met its primary endpoint, with a 9.5 percent AAA-related reintervention rate during follow-up (median 42.1 months). Kaplan-Meier estimates demonstrated 87 percent freedom from secondary intervention at five years. On the secondary endpoints, the results were equally compelling, with no (0%) proximal migration of the stent graft, a 2 percent rate of Type I/III endoleaks, and one AAA-related death (0.3%).

The PANDORA results were presented at Charing Cross by Prof. Giovanni Torsello from St. Franziskus Hospital in Meunster. "The findings of this independently executed study are consistent with those published from ENGAGE, the largest contemporary postmarket study on a single stent graft," Prof. Torsello said. "The long-term data reinforce the clinical leadership of the Endurant stent graft in an all-comer patient population."

ENGAGE

The ENdurant Stent Graft NATural Selection Global Postmarket REGistry (ENGAGE) demonstrates Medtronic's unmatched commitment to clinical research on endovascular aortic repair (EVAR). It has enrolled more than 1,200 patients at 79 sites across six continents since the Endurant AAA stent graft system received the CE (*Conformité Européenne*) mark in June 2008. With 10-year follow-up now planned for all enrolled patients, ENGAGE represents the most robust long-term study of any stent graft ever initiated.

The latest subset analysis of data from ENGAGE compared the influence of neck length on patient outcomes at three years of follow-up. In this context, neck length is the span of healthy aortic tissue between the top of the aneurysm and the lowest renal

artery, which cannot be safely occluded. The single anatomical characteristic that most limits patient eligibility for EVAR, neck length determines how much of a landing zone is available for the proximal end of the stent graft.

The three-year data from ENGAGE demonstrated similarly strong outcomes in patients with neck lengths of 10mm to less than 15mm (short) and 15mm or greater (standard). Historically, shorter neck lengths have been associated with limited eligibility for EVAR and higher rates of adverse events. The Endurant stent graft is approved for use in patients with neck lengths of 10mm or greater, depending on the device's regional labeling for angulation (60 degrees in the United States; 75 degrees in Europe and other countries that recognize the CE mark).

The analysis included 48 patients with neck lengths of 10mm to less than 15mm, 79 patients with neck lengths of 15mm to less than 20mm, and 364 patients with neck lengths of greater than or equal to 20mm.

The three-year results demonstrated no statistically significant differences across these three groups -- 10mm to <15mm, 15mm to <20mm, and ≥20mm -- on any of the following outcomes:

- aneurysm rupture (0.0%, 0.0%, 0.3%)
- conversion to open surgery (0.0%, 0.0%, 1.1%)
- secondary endovascular procedure (4.2%, 10.1%, 8.5%)
- secondary endovascular procedure to correct Type I/III endoleak (0.0%, 1.3%, 3.0%)
- stent graft migration (0.0%, 0.0%, 0.0%)

The ENGAGE neck-length analysis was presented at Charing Cross by Prof. Hence Verhagen from Erasmus Medical Center in Rotterdam, the Netherlands. "The Endurant stent graft has opened up standard EVAR to patients who were previously considered ineligible, and the ENGAGE results support the usage of this device in patients with short necks (10mm and up)," Prof. Verhagen said. "The data also show that the Endurant stent graft successfully broadens patient eligibility for standard EVAR."

ENGAGE employs a high degree of clinical rigor for a postmarket study. For example, all data undergoes independent review and verification by investigators, routine site monitoring ensures data quality and consistency, protocol endpoints are 100 percent monitored, and all deaths through five years and major adverse events through 30 days are adjudicated by an independent clinical events committee.

Originally introduced in 2008 and already implanted in nearly 150,000 patients worldwide, the Endurant system has consistently been selected for nearly one out of every two endovascular repairs for abdominal aortic aneurysms on a global basis. The next-generation Endurant II AAA stent graft received the CE mark in December 2011 and approval from the U.S. Food and Drug Administration in May 2012.

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 disease 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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