Endurant AAA Stent Graft System from Medtronic Delivers Consistently Strong Results in Abdominal Aortic Aneurysms with Short and Standard 'Neck' Lengths

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Analysis of ENGAGE Registry Patients Presented at Charing Cross International Symposium

LONDON -- April 29, 2015 -- For endovascular repair of abdominal aortic aneurysms, the Endurant(TM) AAA stent graft system from Medtronic plc (NYSE: MDT) delivered consistently strong results in patients with short and standard neck lengths who were enrolled in the global ENGAGE registry -- the largest contemporary database on the performance of a single company's stent grafts in real-world clinical practice.

Prof. Hence Verhagen, chief of vascular surgery at Erasmus Medical Center in Rotterdam, the Netherlands, presented an analysis of these results today at the Charing Cross International Symposium. His presentation focused on the influence of neck length on patient outcomes through four years of follow up across a variety of measures, including Type 1 endoleaks, secondary procedures, main body migration and aneurysm rupture.

In this context, neck length refers to the span of healthy aortic tissue between the top of the aneurysm and the lowest renal artery. It determines how much of a landing zone is available for the proximal end of the stent graft and is the single anatomical characteristic that most limits patient eligibility for standard endovascular repair of abdominal aortic aneurysms.[i, ii]

"While neck length remains an important consideration for endovascular repair of abdominal aortic aneurysms, data from the ENGAGE registry show that the Endurant AAA stent graft system can address patients with short and standard necks equally well," Prof. Verhagen explained. "In light of these findings, endovascular repair using fenestrated or branched stent graft systems should be limited to patients with especially short necks coupled with other anatomical challenges. The findings also support offering standard endovascular repair with the Endurant system to a broad set of patients with the appropriate anatomy."

The Endurant AAA stent graft system is indicated for endovascular treatment of abdominal aortic aneurysms with neck lengths of at least 10 mm, depending on the device's regional labeling for angulation threshold (60 degrees in the United States; 75 degrees in Europe and other countries that recognize the CE mark).

Prof. Verhagen's analysis included a total of 1,237 patients from the ENGAGE registry -- 137 with a short neck, defined as 8-15 mm in length, and 1,100 patients with a standard neck of 15 mm or greater. While short necks generally make endovascular treatment more challenging, this analysis of ENGAGE registry patients -- all of whom received endovascular treatment with the Endurant AAA stent graft system -- found no significant difference in outcomes between the two groups.

Delivery and deployment was successful in 99.4 percent of the patients with a standard neck and in 100 percent of the patients with a short neck ($p=0.35$). The rate of uncorrected Type 1 endoleak rate was 1.3 percent for patients with a standard neck and 0 percent for patients with a short neck ($p=0.18$). At follow-up, there were no significant differences between the two groups in terms of Type 1 endoleaks and more specifically Type 1a endoleaks. Through four years, the two groups showed similar results in terms of secondary endovascular procedures, ruptures or conversions to open repair, and no main body migrations were reported in any of the patients.

The ENGAGE registry enrolled more than 1,200 patients at 79 sites in 30 countries across six continents, reflecting a challenging, real-world patient population, with 18 percent of the patients being outside the device's approved indications for use (necks shorter than 10mm).

ENGAGE also 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 major adverse events through 30 days and all deaths through five years are adjudicated by an independent clinical events committee.

"The ENGAGE registry demonstrates our unmatched commitment to clinical research on endovascular aortic repair," said Daveen Chopra, vice president and general manager of the Aortic business in Medtronic's Aortic and Peripheral Vascular division. "With 10-year follow-up planned for all enrolled patients, ENGAGE represents the most robust long-term evaluation of any stent graft ever undertaken."

Originally introduced in 2008, the Endurant AAA stent graft system has been used to treat approximately 200,000 patients worldwide. It has been consistently selected for nearly one out of every two endovascular repairs for abdominal aortic aneurysms on a global basis.

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.

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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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[i] *J Vasc Surg*. 2011 Jul;54(1):13-21. doi: 10.1016/j.jvs.2010.12.010

[ii] *J Endovasc Ther*. 2006;13:640-8

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