Medtronic News

Endurant II AAA Stent Graft from Medtronic Delivers Durable, Consistent and Proven Outcomes in Real-World Setting

Thomson Reuters ONE via COMTEX) --Presented at VEITH, Three-Year Clinical Data from Global ENGAGE Registry

Supports Innovative Device's Market-Leading Position Worldwide

MINNEAPOLIS -- Nov. 25, 2013 -- Chosen for nearly one out of every two endovascular abdominal aortic aneurysm (AAA) repairs worldwide, the Endurant II AAA stent graft system from Medtronic, Inc. (NYSE: MDT) continues to demonstrate long-term durability and consistent outcomes at three years in a real-world setting.

The latest data on the market-leading stent graft were presented on Friday at the VEITHsymposium(TM) in New York City.

The global ENGAGE registry demonstrates Medtronic's unmatched commitment to clinical research on endovascular aortic repair (EVAR). Its investigators have enrolled more than 1,200 patients at 79 sites across six continents since the Endurant system received the CE (Conformite Europeenne) mark in June 2008. With five-year follow-up planned for all patients, the ENGAGE registry represents the most robust post-market registry ever initiated for a newer generation stent graft.

Results for the 500 registry patients evaluated out to three years show that graft-related complications were very low, with a 0 percent (n=490)* migration rate and a Type I/III endoleak rate of 1.5 percent (n=333)*. Additionally, they show 90.7 percent (n=388)* freedom from secondary endovascular procedures and 98.4 percent (n=417)* freedom from aneurysm-related mortality. Positive results were also presented for the full 1,263 patient cohort evaluated at two years of follow-up.

A rigorous monitoring protocol has resulted in follow-up compliance of more than 90 percent in the ENGAGE registry, which is unprecedented for any registry and improves the reliability of the data.

"The size and scope of the ENGAGE registry distinguish Medtronic among stent graft makers as a committed partner in building the clinical evidence portfolio for EVAR worldwide," said ENGAGE investigator Dittmar Bockler, MD, PhD, from the University Hospital of Heidelberg in Germany, who presented the data. "It is especially compelling to see that at three years the Endurant system has maintained durable, long-term outcomes in treating abdominal aortic aneurysms in a real-world cohort that represents the types of challenging anatomies physicians encounter in daily clinical practice."

Overall, durable results were sustained across a range of patient anatomies, including patients with more hostile aortic necks, which have historically been associated with limited eligibility for endovascular repair and higher rates of adverse events. The Endurant system is approved for use in patients with neck lengths of 10mm or greater.

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* The n-value in parentheses represents the number of patients at risk for the event at three years.

Global ENGAGE Registry:

Three-Year Outcomes with Endurant AAA Stent Graft

Notable Clinical Endpoints

Whole Body Migration (n=490)	0%
Type I/III Endoleak (n=333)	1.5%
Freedom from Secondary Procedure	90.7%

(n=388)
Freedom from Aneurysm-Related Mortality 98.4%
(n=417)

Additional analysis of the patient cohort revealed that 18 percent of patients enrolled had anatomical characteristics that did not fall within the current instructions for use (IFU), further suggesting that the findings are relevant and applicable to current clinical practice. In addition, 16 percent of patients had symptomatic abdominal aortic aneurysms and 10.5 percent were female, representing the single largest cohort of females in any EVAR trial (n=133).

The Endurant II AAA stent graft system sets the standard for EVAR, with proven performance in more than 100,000 patients worldwide. With a comprehensive clinical program that includes nearly 2,000 patients, Medtronic is continuing to grow the body of clinical evidence for the Endurant II system in both controlled settings and real-world practice.

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.

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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Outcomes-in-Real-World-Setting