



# Medtronic

NEWS RELEASE

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**FOR IMMEDIATE RELEASE**

**ENDURANT AAA STENT GRAFT MAINTAINS  
DURABLE, CONSISTENT AND PROVEN OUTCOMES FOR  
ABDOMINAL AORTIC ANEURYSM REPAIR IN LONG-TERM FOLLOW-UP**

*Five-Year Results from U.S. IDE Study Presented at Society for Vascular Surgery Meeting*

**CHICAGO – June 20, 2015** – Selected for nearly one of every two endovascular abdominal aortic aneurysm (AAA) repairs globally, the Endurant AAA stent graft system from Medtronic plc (NYSE: MDT) maintained durable, consistent and proven outcomes through five years of follow-up in the company’s U.S. clinical study of the implantable medical device, according to new clinical data presented today at the Society for Vascular Surgery’s “Vascular Annual Meeting.”

The five-year results from the study were presented by Dr. Michael J. Singh, associate professor of surgery at University of Pittsburgh Medical Center, during a late-breaking clinical trial session. The prospective, multi-center, non-randomized bifurcated arm of the study enrolled 150 patients at 26 U.S. medical centers, met its primary safety and effectiveness endpoints and contributed to the device’s approval by the U.S. Food and Drug Administration in December 2010. The study’s primary safety and effectiveness endpoints were major adverse events (MAE) at 30 days and successful aneurysm treatment at 12 months, respectively. Five year follow-up was also conducted.

Significantly for clinical practice, the study included patients with “landing zones,” or healthy aortic neck lengths, as short as 10 mm, whereas most other trials of aortic stent grafts have required neck lengths of at least 15 mm.

“The results of the current study demonstrate the durability of the Endurant system, with very good results up to five years that appear to be better than older generation endografts,” said Dr. Michel Makaroun, professor and chair, division of vascular surgery, University of Pittsburgh School of Medicine and co-director of the UPMC Heart and Vascular Institute and primary investigator of the trial.

Highlights of the findings include 99.2 percent freedom from aneurysm related mortality and 89.0 percent freedom from secondary endovascular interventions through five years. In addition, an independent imaging core laboratory reported 95.2 percent of the patients’ aneurysm sacs remained stable or decreased in diameter by more than 5 mm at five years. Indicative of excellent exclusion of the aneurysm, there were no (0.0%) Type I or III endoleaks at five years and no migrations occurred through the five-year follow-up.

“The five-year results from this study reinforce the long-term durability and consistency of the clinical outcomes that vascular specialists around the world have experienced with the Endurant AAA stent graft system,” Dr. Singh said. “These results add to the growing body of evidence in support of the Endurant platform for endovascular AAA repair.”

The device also achieved excellent procedural performance in the study, with successful delivery and deployment in 99.3 percent of patients and a mean procedure time of 101.5

minutes. Coupled with the long-term clinical outcomes, these performance characteristics support the economic value of the Endurant AAA stent graft system.

“By delivering durable and consistent outcomes for patients with abdominal aortic aneurysms, the Endurant AAA stent graft system has the potential to deliver economic value to hospitals as well,” explained Dr. Edward Woo, director of the MedStar Regional Vascular Program, chairman of vascular surgery at MedStar Washington Hospital Center and professor of surgery at Georgetown University, who previously presented on the clinical and economic effectiveness of the Endurant stent graft at Charing Cross 2015 . “These financial benefits come from reducing operational costs and readmissions.<sup>1</sup>”

Originally introduced in Europe in 2008, the Endurant AAA stent graft system has been used to treat approximately 200,000 patients worldwide — more than any other device of its kind. It has been proven in a variety of clinical studies, including the Endurant U.S. IDE Study, the Endurant Post Approval Study (PAS) and the ENGAGE registry, to offer durable and consistent performance for the endovascular treatment of AAA. With a comprehensive clinical program that includes nearly 2,000 patients, Medtronic continues to study the Endurant Stent Graft 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 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 plc ([www.medtronic.com](http://www.medtronic.com)), headquartered in Dublin, Ireland, 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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<sup>1</sup> Woo, E. "Endurant Stent Graft Has Demonstrated Clinical and Economic Effectiveness At Mid-Term Follow Up." Charing Cross Congress, London. April 29 2015.