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10-Year Data from the Medtronic ENGAGE OUS Registry is the First and Only Prospective, Industry Sponsored Global EVAR Registry to Demonstrate a Decade of Durable Outcomes in Real-World Setting

Presented at Charing Cross, 10-Year Clinical Data from Global ENGAGE OUS Registry Support Endurant Stent Graft System's AAA Market-Leading Position Worldwide

Medtronic today announced its Endurant™ abdominal aortic aneurysm (AAA) stent graft system continues to demonstrate long-term durability through proven outcomes in a real-world setting¹. The 10-year Endurant Stent Graft Natural Selection Global post-market registry (ENGAGE) data were presented at the 2023 Charing Cross Symposium in London, marking the completion of the study.

The ENGAGE registry evaluated more than 1,200 patients¹. The 10-year data, which included follow-up from approximately 400 of these patients, showed a 94.7 percent freedom from aneurysm-related mortality (ARM)[†] and 64.1 percent sac regression (or decreased AAA sac diameter)[‡] at 10 years¹.



“Today with the release of the ENGAGE 10-year data, we have achieved a major milestone in EVAR therapy,” said ENGAGE investigator Hence Verhagen, M.D., professor and chief of vascular surgery, Erasmus University Medical Center in Rotterdam, The Netherlands, who presented the data. “There is now strong and robust evidence that patients treated with the Endurant stent graft system are reaching long-term durable outcomes. We can continue to offer the Endurant stent graft system to any of our patients suitable for endovascular repair as the only graft with global, robust, real-world clinical data to 10 years with consistent sac regression and low aneurysm-related mortality.”

At the completion of the study, the ENGAGE registry included patients across 49 sites in 21 countries². The ENGAGE registry was initiated less than one year post CE mark, further demonstrating the Medtronic confidence in the design of the company's Endurant system and commitment to long-term clinical excellence. The goal of ENGAGE was to gather evidence in a real-world patient population, including patients with challenging anatomy who have historically been difficult to treat and are associated with limited eligibility for endovascular repair and higher rates of secondary interventions. A thorough monitoring protocol resulted in a clinical follow-up compliance of 89.7 percent and imaging compliance of 68.3 percent at 10-years¹.

"As Medtronic works to increase access to treatment for patients with Aortic disease, the 10-year results of the ENGAGE registry demonstrate a critical achievement in the commitment we have made to leading the advancement of EVAR," said Carolyn Sleeth, vice president and general manager of the Aortic business in Medtronic's Cardiac and Vascular Group. "These data add to the current evidence showing that the Endurant stent graft system has a decade of proven long-term durable outcomes and allows physicians the opportunity to treat their patients with the most reliable device."

About the Endurant Stent Graft System

Chosen for more than half a million patients with abdominal aortic aneurysm (AAA) globally³, the Endurant stent graft system is approved outside of the U.S. for use in patients with AAA proximal neck lengths ≥ 10 mm, $\leq 60^\circ$ infra-renal angulation, and $\leq 45^\circ$ supra-renal angulation. It is also approved for use in proximal neck lengths ≥ 15 mm, $\leq 75^\circ$ infra-renal angulation, and $\leq 60^\circ$ supra-renal angulation. In the U.S., the Endurant stent graft system is indicated for proximal neck length of ≥ 10 mm and $\leq 60^\circ$ infra-renal angulation.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission – to alleviate pain, restore health, and extend life – unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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† Data reported through ten-year time frame with full +extended cohort, determined by Clinical Event Committee.

‡ Data reported at ten-year time frame with extended cohort.

References

¹ Verhagen et al. The ENGAGE Registry: Ten-Year Outcomes with the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair. Presented at: Charing Cross 2023 International Symposium; April 26, 2023; London, UK.

² ENGAGE 10-year data. Data on file at Medtronic

³ Data on file at Medtronic. Data current as of April 2023

<https://news.medtronic.com/10-Year-Data-from-the-Medtronic-ENGAGE-OUS-Registry-is-the-First-and-Only-Prospective.-Industry-Sponsored-Global-EVAR-Registry-to-Demonstrate-a-Decade-of-Durable-Outcomes-in-Real-World-Setting>