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Medtronic Endurant™ stent graft system first and only to receive FDA labeling approval to remove rAAA treatment warning

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Medtronic plc, a global leader in healthcare technology, today announced it has received U.S. Food and Drug Administration (FDA) labeling approval¹ for the Medtronic Endurant™ stent graft system, by adding ruptured abdominal aortic aneurysm (rAAA) clinical evidence and removing the rAAA treatment warning. This FDA labeling approval makes Medtronic the first and only company to remove the rAAA warning from its stent graft system Instructions for Use (IFU), aligning innovation with real-world practices and training to empower physicians to act confidently in emergency cases.

A ruptured AAA is a critical condition in which the main artery in the abdomen bursts, causing severe internal bleeding and requiring emergency surgical intervention. The mortality rate from a ruptured abdominal aortic aneurysm is extremely high, exceeding 80%.²

“This landmark effort harnessed international, real-world data to evaluate the performance of endovascular devices in the treatment of ruptured abdominal aortic aneurysms (rAAA). The recent FDA labeling approval provides physicians with confidence in an endovascular treatment option for rAAA patients for the first time.” said Dr. Adam Beck, MD, FACS, director of the division of Vascular Surgery and Endovascular Therapy at the University of Alabama. “This milestone validates the importance of rAAA, enabling continued medical education and support



for physicians to safely treat these complex, high-acuity cases.”



For over a decade, the Endurant stent graft system has been chosen by physicians to treat more than half a million patients worldwide.³

“This important FDA labeling approval is a testament to the innovation, durability, and effectiveness behind the Endurant stent graft system,” said Simona Zannetti, MD, vice president and general manager of Aortic, part of the Cardiovascular Portfolio at Medtronic. “We are proud to be the first company in the industry with the labeling approval to support treatment of rAAA, strengthening our ability to support physicians in confidently treating patients during critical emergencies.”

About the Endurant™ Stent Graft System

Endurant™ stent graft system is backed by over a decade of robust clinical evidence from the ENGAGE 10-year global registry to demonstrate safe and effective use.⁴

Endurant stent graft system is designed to treat abdominal aortic aneurysms (AAA) using a minimally invasive endovascular aneurysm repair (EVAR). As the first and only EVAR system with a decade of global registry outcomes, Endurant systems continue to prove durability and strength in evidence with consistently high rates of sac regression and low aneurysm-related mortality (ARM).⁴

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, 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 95,000+ passionate people across more than 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, visit www.Medtronic.com and follow Medtronic on [LinkedIn](https://www.linkedin.com/company/medtronic).

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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Risks associated with EVAR procedures may include rupture, conversion to open repair, or secondary procedures.

¹ Endurant stent graft system IFU M720548B001 Rev AB, 2025; Endurant II/IIIs stent graft system IFU M052195T001 Rev. AB, 2025

² Mortality rates of ruptured abdominal aortic aneurysm repair have not changed despite increasing utilisation of EVAR. Vascular News. Available at: <https://vascularnews.com/mortality-rates-of-ruptured-abdominal-aortic-aneurysm-repair-have-not-changed-despite-increasing-utilisation-of-evar/> Accessed September, 18, 2025

³ Based on internal Endurant™ patient implant tracking at Medtronic. Data current as of September 2023.

⁴ 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.

<https://news.medtronic.com/Medtronic-Endurant-TM-stent-graft-system-first-and-only-to-receive-FDA-labeling-approval-to-remove-rAAA-treatment-warning>