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Medtronic Endurant™ stent graft system first and only to receive CE-mark for updated rupture labeling

Following recent U.S. Food and Drug Administration (FDA) labeling approval, European label milestone reinforces Medtronic leadership in advancing aortic care based on clinical evidence supporting the treatment of ruptured abdominal aortic aneurysms (rAAA).

Medtronic plc, a global leader in healthcare technology, today announced it has received Conformité Européenne (CE) approval[1] for the Medtronic Endurant™ stent graft system to remove the rAAA treatment warning. The CE Mark labeling update follows the U.S. FDA labeling approval received in October 2025 and extends updated Endurant rAAA labeling to support expanded training and educational opportunities in Europe.

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. In vascular care, this condition is a time-critical medical emergency, in which 50% of patients die before reaching the hospital, and can carry an overall mortality rate of 80-90%. [2] [3]

"When a patient presents with a ruptured abdominal aortic aneurysm, every minute counts," shares Felice Pecoraro, MD - Professor of Vascular Surgery at University of Palermo and Director of the Vascular Surgery Unit at A.O. Universitaria Policlinico P. Giaccone, Palermo, Italy. "For physicians, this update provides greater clarity and supports confident decision-making while evaluating treatment options for their patients. In an emergency where time is critical, having this change to the IFU is a meaningful step forward."

"The significance of this approval extends beyond the individual procedure. By aligning labeling with the clinical evidence and current practice, hospitals and vascular teams can build more standardized protocols, training programs, and treatment pathways around a platform they know well. This can also help expand access to

minimally invasive care while supporting more consistent delivery of urgent aortic care for patients facing this life-threatening condition," says Konstantinos Spanos, Associate Professor of Vascular Surgery, University Hospital of Larissa, University of Thessaly, Greece.

For over a decade, the Endurant stent graft system has been chosen by physicians to treat more than half a million patients worldwide.[4]

“This milestone represents an important advancement in helping care teams act with clarity and decisiveness when minutes matter most,” said Nicolas Berney - Vice President, Western Europe CardioVascular Surgery. “As we bring this labeling update to Europe, we remain committed to pairing strong clinical evidence with the education and support care teams need when making time-critical treatment decisions.

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.[5] 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).[5] Risks associated with EVAR procedures may include rupture, conversion to open repair, or secondary procedures.

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.

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Contacts:

Emily Niles
Public Relations
+1-612-296-9429

Kiran Kurian
Investor Relations

[1] Endurant stent graft system IFU M997551A001 Rev D, 2026; Endurant II/IIs stent graft system IFU M985265A001 Rev. D, 2026

[2] ReimerinkJJ, et al. Br J Surg. 2013;100:1405–1413

[3] Wise ES, Hocking KM, Brophy CM. Prediction of in-hospital mortality after ruptured abdominal aortic aneurysm repair using an artificial neural network.

[4] Based on internal Endurant™ patient implant tracking at Medtronic. Data current as of April 2026.

[5] 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.

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