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Medtronic receives CE mark for the first balloon expandable covered stent indicated for chimney endovascular aneurysm repair (ChEVAR)

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Medtronic announced today that it recently received CE mark for its Radiant™ balloon-expandable covered stent, the first and currently only covered stent indicated for use in ChEVAR with the Endurant II/IIs stent graft system.

Used together, the Endurant™ II/IIs stent graft and Radiant covered stent offer a standardized, fully on-label, off-the-shelf solution for short-neck, juxtarenal abdominal aortic aneurysms (AAA). This enables safe and effective endovascular repair in both urgent and elective juxtarenal AAA cases, with a proven device combination, backed by clinical outcomes[1].

The Radiant product comes from the long-term collaboration between Medtronic and Getinge, leveraging the proven Advanta V12 design and bringing it to the next level by collecting robust clinical evidence to support the CE mark[2].

ChEVAR is a procedure performed across the globe to treat juxtarenal AAA, yet there remains a lack of standardization on device combination and technique. Medtronic is the only company in the aortic space that has invested the time and resources to empower physicians to perform the ChEVAR procedure in a standardized way that optimizes safety and outcomes for their patients.

The Radiant product's design offers predictable, accurate delivery and deployment, while providing the flexibility and radial strength necessary for a chimney covered stent.3 This is evident in literature, as the Radiant covered stent has been shown to provide significantly better mid-term patency performance in ChEVAR compared to other covered stents[3].

The Radiant™ balloon-expandable covered stent system is intended to maintain perfusion to the renal arteries when used in combination with the Endurant II/IIs stent graft system for AAA patients with inadequate sealing zones.

With this CE mark, Medtronic will roll out a comprehensive training program and continue to invest in clinical data to optimize ChEVAR outcomes for physicians and the patients they treat.

“I can’t wait to get this product into the field and, ultimately, to the physicians and patients we innovate for every day.” says Carolyn Sleeth, Vice President and General Manager of the Aortic operating unit, which is part of the Cardiovascular portfolio at Medtronic. Professor Konstantinos Donas, Head of the Department of Vascular Surgery, Director of the Research Vascular Centre, Asklepios Clinic Langen, University of Frankfurt, Germany declares, “Having a stent-graft specifically approved for ChEVAR reflects a milestone towards standardization of the technique and the materials used. In combination with the strict preoperative protocol regarding planning and sizing, ChEVAR will stabilize its role and approach in the existing endovascular alternatives to treat aneurysms with inadequate infrarenal sealing zones.”

The Radiant balloon expandable covered stent system will be commercially available in Western Europe in November 2022, with other regions that recognize CE mark to follow during 2023.

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[1]Donas KP, Torsello GB, Piccoli G, et al. The PROTAGORAS study to evaluate the performance of the Endurant stent graft for patients with pararenal pathologic processes treated by the chimney/snorkel endovascular technique. J Vasc Surg.2016; 63:1–7.

[2]Endurant ChEVAR New Indication Trial : ENCHANT https://clinicaltrials.gov/ct2/show/NCT03320252

[3] Pitoulias GA, et al. J Vasc Surg. 2021;73:433-442.

https://news.medtronic.com/Medtronic-receives-CE-mark-for-the-first-balloon-expandable-covered-stent-indicated-for-chimney-endovascular-aneurysm-repair-ChEVAR