

## Press release

Gothenburg, Sweden, on October 13, 2025

## Getinge's Advanta V12 receives CE Mark for major bridging indications

Getinge's Advanta™ V12 is now approved for major bridging indications, marking a milestone in complex aortic aneurysm treatment.

Today, Getinge announces that its Advanta™ V12 Covered Stent System has received CE Mark approval under the European Union Medical Device Regulation (EU MDR) for use as a bridging stent in fenestrated endovascular aneurysm repair (FEVAR), branched endovascular aneurysm repair (BEVAR), and iliac branch device (IBD) aneurysmal repair. This landmark approval offers physicians a trusted, on-label solution backed by over two decades of clinical use.

Advanta V12 has long been a cornerstone in advanced aortic procedures, with nearly one million devices implanted globally and more than 100 peer-reviewed publications supporting its performance. Its stainless-steel design with full ePTFE encapsulation ensures excellent radial support and dependable sealing, while its open cell architecture provides the flexibility needed to adapt to complex anatomies. The system's low-profile, flexible delivery and consistent deployment enable precise placement and optimal seal integrity, even in challenging cases.

"This CE Mark reflects our long-standing commitment to physicians and patients facing advanced stage vascular disease," says Chad Carlton, Vice President Endovascular Solutions at Getinge. "Advanta V12 has earned its place in complex repair strategies through dependable, proven performance. Today, that performance is officially recognized for FEVAR, BEVAR, and IBD bridging — all in one device."

The CE Mark approval adds to Advanta V12's existing indications for renal and AIOD, reinforcing its versatility across a wide spectrum of aortic and peripheral anatomies. With this expanded approval, physicians can now rely on a single, proven platform to treat both complex aneurysmal and occlusive disease with confidence and precision.

"We've used Advanta V12 for years in advanced aortic procedures, and this CE Mark finally matches the evidence we've seen in practice," says Prof. Tilo Kölbel, Vascular Surgeon at University Hospital Hamburg-Eppendorf, Germany. "To now have a single, proven device that's approved for bridging in FEVAR, BEVAR, and IBD aneurysmal repair is a huge step forward, not just in regulatory clarity, but in simplifying and optimizing patient care."

Advanta V12 is marketed as the iCast® covered stent system in the United States, where it received FDA Premarket Approval (PMA) for bridging stent use in aneurysmal disease in July 2025, further strengthening its global regulatory alignment.

Find out more about Getinge's Advanta V12 >>

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## **About Getinge**

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs approximately 12,000 people worldwide and the products are sold in more than 135 countries.