



THE GORE® VIABAHN® FORTEGRA VENOUS STENT RECEIVES MDR APPROVAL

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

The FORTEGRA Venous Stent is engineered to offer an optimal balance of conformability and compression resistance for treating a broad range of patients.

PUTZBRUNN, Germany, June 9, 2026 /PRNewswire/ - W. L. Gore & Associates Medical Products (Gore) announced today CE Mark approval for the GORE® VIABAHN® FORTEGRA Venous Stent, indicated for use in the treatment of symptomatic inferior vena cava (IVC) and iliofemoral venous outflow obstruction. Building on the recent U.S. FDA approval, this milestone reflects Gore's commitment to expanding access to a purpose-built treatment option for physicians and patients worldwide.

The FORTEGRA Venous Stent, the newest addition to the VIABAHN® Device family, is specifically engineered to treat patients with deep venous disease. It consists of an open-structure, self-expanding wire-wound nitinol frame and a polymer lattice, which is designed for conformability, strength and fracture resistance.

This novel technology helps provide an optimal balance and unique combination of allowing the stent to conform to the natural anatomy while providing compression resistance throughout the entire device. Featuring a wide range of sizes, the FORTEGRA Venous Stent is appropriate for a wide range of patient anatomies.

The FORTEGRA Venous Stent represents a significant advancement in the treatment of patients with the most difficult-to-treat venous obstructive pathology; occlusion of the inferior vena cava and iliac veins. Patients will benefit from a device that is specifically designed for this pathology and its unique anatomic and physiologic challenges, including preservation of optimal flow dynamics through reconstruction of the ilio caval confluence and the unique properties of physiological movement in the inferior vena cava, says Prof. Stephen Black, Professor of Venous Surgery at Guy's and St Thomas Hospital London and Global Primary Investigator.

The FORTEGRA Venous Stent was evaluated in a prospective trial – the first of its kind to include the IVC, iliac and iliofemoral veins. The results demonstrated the device to be both safe and effective for its indicated use in patients with deep venous disease. Among patients that experienced pain at baseline, 81% showed improvement in pain at 12 months, with a median reduction in the pain score of -2.0 ($p < 0.001$). Significant improvements were demonstrated across validated quality-of-life measures (VEINES-QOL, EQ-5D-5L), and improvements were observed in clinical severity measures, including edema and ulcer-related outcomes. Primary patency remained high at 12 months (83.4% overall), with no device-related safety concerns observed.

“What is particularly important about this evidence is that it reflects the full thrombotic spectrum we treat in practice – acute, subacute, and post-thrombotic syndrome,” said Prof Gerry O’Sullivan, Interventional Radiologist, Galway University Hospital, Ireland.

“This prospective study demonstrated conclusively that patients benefitted from a device that is specifically designed for patients with complex cases involving the inferior vena cava, iliac veins and inflow veins. Results showed clinically meaningful benefits, alongside improvements in patient quality of life and clinical severity measures.”

A legacy of transformative medical technologies

The FORTEGRA Venous Stent from Gore is backed by the legacy of over 55 million medical devices implanted over the course of 50 years, building on a reputation of transforming medical technologies through research, education and quality initiatives. The product performance, ease of use and quality of service Gore provides offer long-term value for physicians, hospitals and insurers.

To learn more about the FORTEGRA Venous Stent visit [goremedical.com/en-emea/products/fortegra](https://www.goremedical.com/en-emea/products/fortegra)

Medical Products

Gore engineers medical devices that treat a range of cardiovascular and other health conditions. With more than 55 million medical devices implanted over the course of more than 45 years, Gore builds on its legacy of improving patient outcomes through research, education and quality initiatives. Product performance, ease of use and quality of service provide sustainable cost savings for physicians, hospitals and insurers. Gore is joined in service with clinicians and through this collaboration we are improving lives. For more information, visit <https://www.goremedical.com/en-emea>

About Gore

W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Since 1958, Gore has solved complex technical challenges in demanding environments – from outer space to the world’s highest peaks to the inner workings of the human body. With approximately 13,000 Associates and a strong, team-oriented culture, Gore generates annual revenues of \$5.3 billion. [gore.com](https://www.gore.com)

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