Together, improving life

GORE GAINS FDA APPROVAL FOR FIRST DEEP VENOUS STENT INDICATED FOR THE IVC AND ILIOFEMORAL VEINS

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

FLAGSTAFF, Ariz. (January 6, 2026) — W. L. Gore & Associates' medical business (Gore) has announced the FDA approval of the GORE® VIABAHN® FORTEGRA Venous Stent — previously known as the GORE® VIAFORT Vascular Stent — the first device for the treatment of deep venous disease in the inferior vena cava (IVC), iliac and iliofemoral veins.

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 an expanded polytetrafluoroethylene (ePTFE) 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, iliac veins and inflow femoral veins.

Patients will benefit from a device that is designed specifically for this disease and its unique anatomic and physiologic challenges, including preservation of optimal flow dynamics through iliocaval confluence and side branch preservation,” says Kush Desai, MD, and National Primary Investigator.

Study design and outcomes

Gore received Breakthrough Device designation from the FDA for the FORTEGRA Venous Stent. This program helps expedite the development and FDA review of medical devices that offer more effective treatment for life-threatening or irreversibly debilitating diseases or conditions.

The international clinical trial was the first prospective trial of its kind to include IVC, iliac and iliofemoral veins. The device was demonstrated to be both safe and effective for its indicated use in 89 patients treated with deep venous disease. The study included a patient population with extensive disease burden: all were treated for thrombotic disease (acute, subacute and post-thrombotic syndrome), 94.3% of patients had lesions that span three vessel regions (IVC + bilateral iliofemoral veins) and 68.5% required stents that extended below the inguinal ligament into the common femoral vein.

Key data endpoints

Despite the study consisting of patients with extensive disease burden, 12-month primary patency was achieved in 83.4% of patients. Further, results demonstrated 96.5%, 88.9% and 89.8% primary patency in the IVC, left iliofemoral and right iliofemoral vessel regions, respectively. There were no stent embolizations/migrations, fractures, vascular injuries or clinically significant pulmonary embolisms through 12 months.

There were also no device-related deaths or major bleeding through 30 days.[1] Overall, the study met its 12-month composite efficacy and safety primary endpoint.

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.

Reference:
1. GORE® VIABAHN® FORTEGRA Venous Stent [Instructions for Use] W. L. Gore & Associates, Inc; 2025. MD205743. Rev. 2.

For complete indications and other important safety information for Gore commercial products referenced herein, refer to the applicable Instructions for Use (IFU). R_{XOnly}

INDICATIONS FOR USE IN THE U.S.: The GORE® VIABAHN® FORTEGRA Venous Stent is indicated for use in the treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.

CONTRAINDICATIONS: The GORE® VIABAHN® FORTEGRA Venous Stent is contraindicated for use in patients with lesions where expansion of an angioplasty balloon catheter to minimum GORE® VIABAHN® FORTEGRA Venous Stent recommended vessel diameters was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system.

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 billion.
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