

FOR IMMEDIATE RELEASE

GORE ANNOUNCES POSITIVE CLINICAL TRIAL RESULTS OF THE INVESTIGATIONAL GORE® VIABAHN® FORTEGRA VENOUS STENT FOR TREATMENT OF PATIENTS WITH DEEP VENOUS ILIOCAVAL OBSTRUCTION

The investigational device evaluated in the trial, previously known as the GORE® VIAFORT Vascular Stent, will now be referred to as the GORE® VIABAHN® FORTEGRA Venous Stent.

CAUTION: Investigational device. Limited by United States law to investigational use.

LAS VEGAS/FLAGSTAFF, Ariz. (November 7, 2025) — W. L. Gore & Associates' medical business (Gore) today announced trial results evaluating the investigational GORE® VIABAHN® FORTEGRA Venous Stent (VIABAHN® FORTEGRA Venous Stent) for the treatment of deep venous ilio caval obstruction. The trial met its primary endpoint, which evaluated device performance through 12 months in patients with symptomatic deep venous disease.

Co-primary trial investigator Stephen Black, MD, presented the late-breaking clinical trial data at the VEINS Conference in Las Vegas. The findings reflect Gore's commitment to advancing solutions for patients with complex venous disease.

"These trial results demonstrate promising outcomes for patients with significant ilio caval disease," said Black, Chief of Surgery with St. Thomas' Hospital in London. "This is an important step forward in establishing additional treatment options for patients with deep venous obstruction, particularly those with complex anatomy or advanced disease."

About the GORE® VIABAHN® FORTEGRA Venous Stent Trial

The GORE® VIABAHN® FORTEGRA Venous Stent Trial is an international, multicenter, prospective, non-randomized, single-arm clinical trial featuring 89 patients with deep venous disease. It was the first prospective trial of its kind to include the inferior vena cava (IVC), iliac and femoral veins. All treated patients had thrombotic disease (acute, subacute, or chronic/post thrombotic syndrome), of which 94.3% had lesions spanning three vessel regions (IVC + bilateral iliofemoral veins), and 68.5% required stents that extended below the inguinal ligament into the common femoral vein.

The results reported were:

- 12-month primary patency was achieved in 83.4% of patients
- 96.5% primary patency in the IVC
- 88.9% primary patency in the left iliofemoral vessel region
- 89.8% primary patency in the right iliofemoral vessel region
- No stent embolizations/migrations, fractures, vascular injuries or clinically significant pulmonary embolisms through 12 months
- No device-related deaths or major bleeding through 30 days

About the Investigational VIABAHN® FORTEGRA Venous Stent

The VIABAHN® FORTEGRA Venous Stent is a self-expanding nitinol venous stent engineered to restore and maintain patency in the IVC and iliofemoral veins. The VIABAHN® FORTEGRA Venous Stent is not yet approved for commercial use and is under premarket approval review by the U.S. Food and Drug Administration.

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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.

goremedical.com

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. gore.com

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