

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Stent, Vena Cava

Device Trade Name: GORE® VIABAHN® FORTEGRA Venous Stent

Device Procode: QTL

Applicant's Name and
Address: W. L. Gore & Associates, Inc.
1505 North Fourth Street
Flagstaff, AZ 86004 U.S.A.

Date(s) of Panel
Recommendation: None

Premarket Approval
Application (PMA) Number: P250017

Date of FDA Notice
of Approval: December 19th, 2025

Breakthrough Device: Granted breakthrough device status on September 18, 2020, because of reasonable expectation that the device can provide for more effective treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction, a life-threatening or irreversibly debilitating disease or condition, as well as due to a lack of approved or cleared endovascular device alternatives.

II. INDICATIONS FOR USE

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.

III. 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.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the GORE® VIABAHN® FORTEGRA Venous Stent labeling.

V. DEVICE DESCRIPTION

The GORE® VIABAHN® FORTEGRA Venous Stent (VIABAHN® FORTEGRA Device) consists of an implant and corresponding delivery system. The VIABAHN® FORTEGRA Device implant is a self-expanding, permanently implantable stent constructed of a wire-wound nitinol frame and a fluorinated ethylene propylene-expanded polytetrafluoroethylene (FEP-ePTFE) fluoropolymer lattice bonded to the nitinol frame. Gold-fluoroelastomer radiopaque markers are included on each end of the implant to facilitate post-deployment visualization (**Figure 1**).

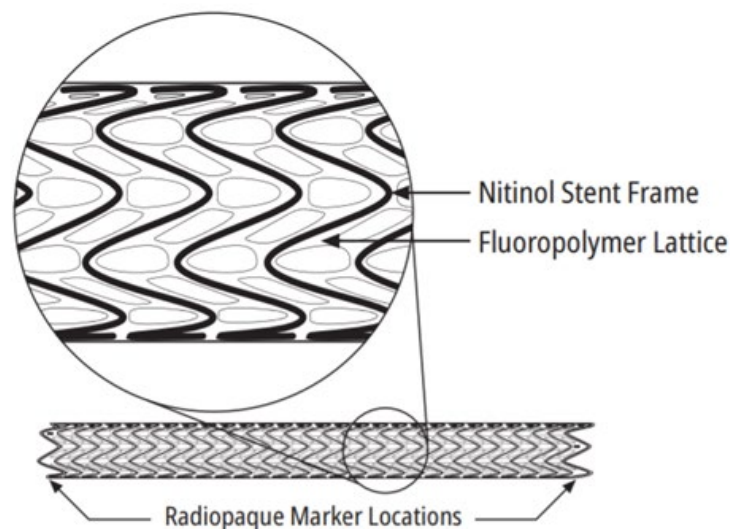


Figure 1. GORE® VIABAHN® FORTEGRA Venous Stent Implant

The VIABAHN® FORTEGRA Device delivery system is composed of a radiopaque tip, a constraining system for the implant, deployment line, catheter assembly, hub, and a deployment knob. The endoprosthesis is radially constrained on the leading end of the catheter assembly (**Figure 2**).

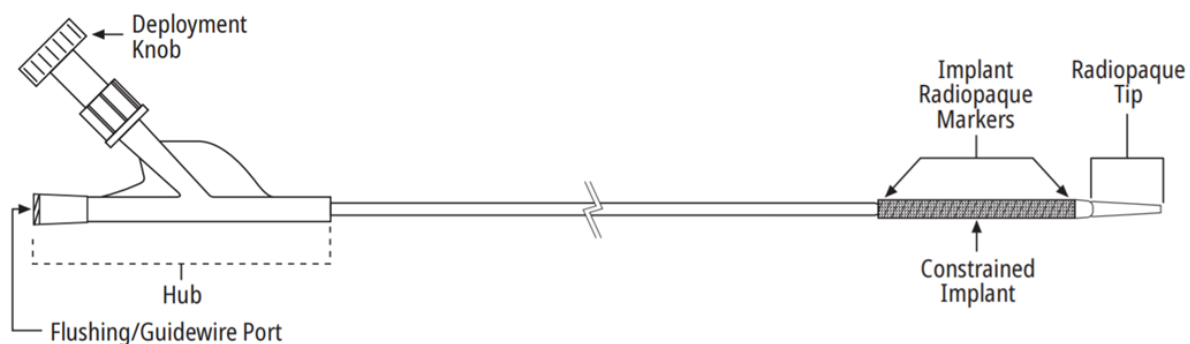


Figure 2. GORE® VIABAHN® FORTEGRA Venous Stent Implant and Delivery System

A dual-lumen catheter (**Figure 3**) forms most of the catheter assembly's working length. The flushing/guidewire lumen is continuous with the lumen of the distal shaft, which is under the constrained implant. The VIABAHN® FORTEGRA Device is compatible with a 0.035" guidewire. The trailing end of the dual-lumen catheter is attached to the hub. The hub includes two ports: a flushing/ guidewire port and a deployment line port. The deployment line is routed from the trailing end of the constrained implant through the deployment line lumen to the deployment line port of the hub, where it is attached to the deployment knob. To deploy the constrained implant, the deployment knob is unlocked by rotating counterclockwise. As the deployment knob and attached deployment line are pulled, the constraining mechanism releases the constrained implant.

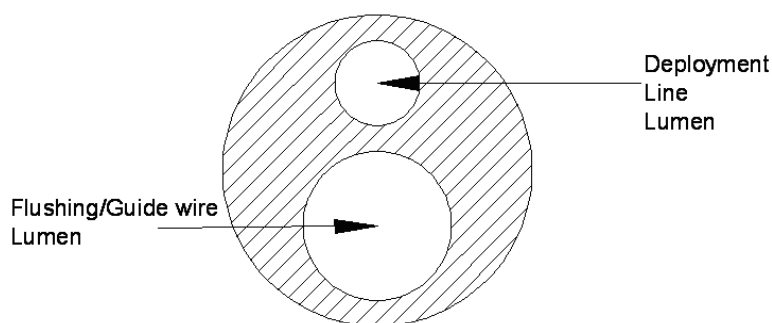


Figure 3. Cross-section of the GORE® VIABAHN® FORTEGRA Venous Stent Dual-Lumen Catheter

The VIABAHN® FORTEGRA Device is delivered using established endovascular procedures common to other commercially available stents and stent-grafts. Device implantation procedures require the use of appropriate introducer sheaths, guide catheters, and guidewires to gain access to the intended treatment site. In most cases, the venous lesion would be pre-dilated using a percutaneous transluminal angioplasty (PTA) balloon. The stent is then advanced and deployed,

the delivery system is removed, and a recommended balloon touch-up may be performed to ensure complete apposition of the stent to the venous wall. Additional details can be found in the VIABAHN® FORTEGRA Device instructions for use (IFU).

The VIABAHN® FORTEGRA Device is offered in a range of device configurations to provide appropriate sizing options accommodating a broad range of ilio caval vessel diameters and lengths, in accordance with its intended use in the treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction (**Table 1**). Available stent lengths range from 50 to 150 mm for each of the available diameters (10, 12, 14, 16, 18, 20, 24, and 28 mm). All configurations are delivered on a 120 cm catheter working length.

Table 1. GORE® VIABAHN® FORTEGRA Venous Stent Configurations

Stent Diameter (mm)	Available Stent Lengths (mm)	Profile (Fr)	Guidewire Diameter	Catheter Length (cm)
10	50, 75, 100, 150	10	0.035” (0.89 mm)	120
12	50, 75, 100, 150	11	0.035” (0.89 mm)	120
14	50, 75, 100, 150	11	0.035” (0.89 mm)	120
16	50, 75, 100, 150	11	0.035” (0.89 mm)	120
18	50, 75, 100, 150	12	0.035” (0.89 mm)	120
20	50, 75, 100, 150	12	0.035” (0.89 mm)	120
24	50, 75, 100, 150	14	0.035” (0.89 mm)	120
28	50, 75, 100, 150	14	0.035” (0.89 mm)	120

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of venous outflow obstruction involving the inferior vena cava, including: noninvasive treatment (e.g., exercise, leg elevation, compression therapy, and drug therapy such as oral anticoagulation); minimally invasive treatment (e.g., thrombectomy, thrombolysis, and balloon angioplasty); and surgical treatment (e.g., endophlebectomy and bypass). Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that

best meets expectations and lifestyle.

VII. MARKETING HISTORY

The GORE® VIABAHN® FORTEGRA Venous Stent has not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below are lists of the potential adverse effects (e.g., complications) associated with the use of the device.

Procedure-related

As with any surgical procedure, there are always risks of complications for vascular interventions, with or without stenting. These may include, but are not limited to, the following potential adverse events (shown in alphabetical order):

- Access failure
- Access site infection
- Allergic reaction to contrast medium or procedure medications
- Arrhythmia
- Bleeding
- Bruising
- Cardiac tamponade
- Constipation
- Death
- Dizziness
- Edema
- Extravascular perforation (e.g., intestinal or structure outside of intended vascular treatment)
- Fever
- Fistula formation (arteriovenous or vessel-gastrointestinal)
- Hematoma
- Hematuria
- Hypertension
- Hypotension, nausea, or other vasovagal response
- Impaired organ function
- Infection
- Inflammation
- Myocardial infarction
- Pain
- Pseudoaneurysm
- Pulmonary embolism
- Radiation injury
- Renal insufficiency/renal failure (new or worsening) – transient or permanent

- Renal toxicity
- Sepsis
- Shock
- Stroke/paradoxical embolism/transient ischemic attack/intracerebral hemorrhage
- Tissue necrosis
- Transfusion reaction following blood transfusion for treatment of major bleeding
- Venous ulceration
- Vessel damage, including dissection, perforation, or rupture
- Vessel thrombosis or occlusion
- Vomiting

Device-related

Possible adverse events and complications that may occur with the use of any implant and may require intervention include, but are not limited to (shown in alphabetical order):

- Allergic reaction to nitinol or other device materials
- Anemia
- Cardiac damage
- Cardiac tamponade
- Death
- Device breakage
- Edema
- Embolism
- Fever
- Fracture
- Hematoma
- Impaired organ function
- Infection
- Inflammation
- Irritation
- Malapposition
- Maldeployment/deployment failure
- Malposition
- Migration or embolization
- Pain, including back pain
- Pericardial effusion
- Pulmonary Embolism
- Side branch occlusion
- Surgical conversion
- Venous stenosis/occlusion/thrombosis, within or outside of stented segment
- Venous ulceration
- Vessel wall trauma and / or rupture

For the specific adverse events that occurred in the clinical study, please see Section X below.

IX. SUMMARY OF NONCLINICAL STUDIES

A series of non-clinical laboratory and animal studies were conducted by the applicant to evaluate the GORE® VIABAHN® FORTEGRA Venous Stent, including: A) bench and analytical testing; B) biocompatibility testing; C) sterilization, packaging, and shelf-life testing; and D) animal studies. This testing is described in the corresponding Sections IX(A) through IX(D) below.

A. Bench and Analytical Testing

Comprehensive non-clinical bench and analytical testing was conducted for the GORE® VIABAHN® FORTEGRA Venous Stent; all testing performed met the pre-specified acceptance criteria as summarized in **Table 2**. Non-clinical product bench and analytical testing was developed based on the device risk assessment and is consistent with FDA's Guidance Document *Non-Clinical Tests and Recommended Labeling of Intravascular Stents and Associated Delivery Systems*, April 18, 2010, and its addendum, *Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems*, August 18, 2015. Additional non-clinical testing was conducted to meet the requirements of relevant international standards, including ISO 25539-2, *Cardiovascular implants — Endovascular devices, Part 2: Vascular stents*.

Table 2. Summary of Non-Clinical Bench and Analytical Testing for the GORE® VIABAHN® FORTEGRA Venous Stent

Test Performed	Test Purpose	Acceptance Criteria	Results																		
Implant Only																					
Deployed Diameter	Measure the free diameter of the deployed implant.	Implant deployed outer diameter:	Pass																		
		<table><tr><th>Nominal Implant Diameter (mm)</th><th>Measured Diameter (mm)</th></tr><tr><td>10</td><td>≥ 9.0</td></tr><tr><td>12</td><td>≥ 11.0</td></tr><tr><td>14</td><td>≥ 13.0</td></tr><tr><td>16</td><td>≥ 15.0</td></tr><tr><td>18</td><td>≥ 17.0</td></tr><tr><td>20</td><td>≥ 19.0</td></tr><tr><td>24</td><td>≥ 22.0</td></tr><tr><td>28</td><td>≥ 26.0</td></tr></table>		Nominal Implant Diameter (mm)	Measured Diameter (mm)	10	≥ 9.0	12	≥ 11.0	14	≥ 13.0	16	≥ 15.0	18	≥ 17.0	20	≥ 19.0	24	≥ 22.0	28	≥ 26.0
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		18		≥ 17.0																	
		20		≥ 19.0																	
24	≥ 22.0																				
28	≥ 26.0																				
Deployed Length* ¹	Measure the free length of the deployed implant.	Implant deployed length:	Pass																		
		<table><tr><th>Nominal (mm)</th><th>Min (mm)</th><th>Max (mm)</th></tr><tr><td>50</td><td>43</td><td>57</td></tr></table>		Nominal (mm)	Min (mm)	Max (mm)	50	43	57												
		Nominal (mm)		Min (mm)	Max (mm)																
		50		43	57																

¹ The specific engineering tests completed to support the three-year shelf life for the GORE® VIABAHN® FORTEGRA Venous Stent are denoted in Table 2 by an asterisk (*).

Test Performed	Test Purpose	Acceptance Criteria	Results														
		<table><tr><td>75</td><td>65</td><td>85</td></tr><tr><td>100</td><td>90</td><td>110</td></tr><tr><td>150</td><td>135</td><td>165</td></tr></table>	75	65	85	100	90	110	150	135	165						
75	65	85															
100	90	110															
150	135	165															
Radial Force	Measure the force exerted by the implant when compressed radially through the indicated vessel diameter range.	The implant must meet the following radial force per unit length (N/mm) requirements: <table><tr><th>Implant Diameter (mm)</th><th>Radial Compression Resistance[†] (N/mm)</th></tr><tr><td>10-20</td><td>≥ 0.50</td></tr><tr><td>24</td><td>≥ 0.23</td></tr><tr><td>28</td><td>≥ 0.36</td></tr></table> [†]Upon compression to minimum indicated vessel diameter The Force-Diameter curves from loading and unloading must be characterized. Radial Force (N/mm) must be characterized at the minimum and maximum indicated vessel diameters.	Implant Diameter (mm)	Radial Compression Resistance [†] (N/mm)	10-20	≥ 0.50	24	≥ 0.23	28	≥ 0.36	Pass						
Implant Diameter (mm)	Radial Compression Resistance [†] (N/mm)																
10-20	≥ 0.50																
24	≥ 0.23																
28	≥ 0.36																
Compression Resistance – Iliofemoral Local	Measure the force exerted by the implant when locally compressed by a round bar.	The iliofemoral implant must meet the following minimum local compression resistance (N) requirement: <table><tr><th>Implant Diameter (mm)</th><th>Local Compression Resistance (N)</th></tr><tr><td>10</td><td>≥ 1.89</td></tr><tr><td>12</td><td>≥ 2.13</td></tr><tr><td>14</td><td>≥ 3.61</td></tr><tr><td>16</td><td>≥ 3.99</td></tr><tr><td>18</td><td>≥ 4.15</td></tr><tr><td>20</td><td>≥ 4.56</td></tr></table>	Implant Diameter (mm)	Local Compression Resistance (N)	10	≥ 1.89	12	≥ 2.13	14	≥ 3.61	16	≥ 3.99	18	≥ 4.15	20	≥ 4.56	Pass
Implant Diameter (mm)	Local Compression Resistance (N)																
10	≥ 1.89																
12	≥ 2.13																
14	≥ 3.61																
16	≥ 3.99																
18	≥ 4.15																
20	≥ 4.56																
Compression Resistance – IVC Flat Plate	Measure the force exerted by the implant when globally compressed by a plate.	The IVC implant must meet the following minimum flat plate compression resistance per unit length (N/mm) requirement: <table><tr><th>Implant Diameter (mm)</th><th>Flat Plate Compression Resistance (N/mm)</th></tr><tr><td>24, 28</td><td>≥ 0.05</td></tr></table>	Implant Diameter (mm)	Flat Plate Compression Resistance (N/mm)	24, 28	≥ 0.05	Pass										
Implant Diameter (mm)	Flat Plate Compression Resistance (N/mm)																
24, 28	≥ 0.05																
Conformability to Vessel*	Simulated Use -Evaluate the deployed stent within an anatomical model.	The implant adequately contacts the vessel wall upon deployment.	Pass														
Implant Kink Diameter	Measure the diameter of the inner curve of the implant in a constraining fixture.	The implant must be able to withstand the following bend diameter without kinking or exhibiting a diameter reduction of greater than 50%: <table><tr><th>Implant Diameter (mm)</th><th>Kink Diameter (cm)</th></tr><tr><td>10-20</td><td>≤ 3.18</td></tr><tr><td>24, 28</td><td>≤ 10.80</td></tr></table> The implant must recover from the kink when released from the test fixture.	Implant Diameter (mm)	Kink Diameter (cm)	10-20	≤ 3.18	24, 28	≤ 10.80	Pass								
Implant Diameter (mm)	Kink Diameter (cm)																
10-20	≤ 3.18																
24, 28	≤ 10.80																

Test Performed	Test Purpose	Acceptance Criteria	Results						
Implant Unconstrained Bend Diameter	Measure the diameter of the inner curve of the implant in an unconstrained state.	Determine the smallest bend diameter that the implant can withstand unconstrained without straightening. The diameter must be ≤ the clinically available competitive option (2497mm).	Pass						
Pore Size and Stent-free Surface Area	Measure the average pore size within the lattice using image analysis. Calculate the stent-free surface area at a given recommended vessel diameter by dividing the surface area of the stent by the calculated cylindrical surface area of the recommended vessel diameter and subtracting the result from 1.	The implant must meet the following pore size requirement: <table><tr><th>Implant Diameter (mm)</th><th>Avg. Pore Size (mm²)</th></tr><tr><td>10-20</td><td>≥ 2.81</td></tr><tr><td>24, 28</td><td>≥ 6.75</td></tr></table> Stent-free surface area shall be characterized.	Implant Diameter (mm)	Avg. Pore Size (mm²)	10-20	≥ 2.81	24, 28	≥ 6.75	Pass
Implant Diameter (mm)	Avg. Pore Size (mm²)								
10-20	≥ 2.81								
24, 28	≥ 6.75								
Migration Resistance (Force to Dislodge)	Measure the force required to remove the implant from a mock vessel.	The mean force to dislodge must not be less than that of the clinically available competitive option (3.94 N).	Pass						
MRI Compatibility	A static magnetic field is applied. Resulting displacement and heating are measured, and image artifacts are characterized.	Device must be able to be labeled as MR conditional for 1.5 and 3T static magnetic field strengths and associated radio frequency fields.	Pass						
Durability: Local Compression Fatigue	A cyclic, compressive displacement is locally applied to the cross section of the stent. The stent is observed to determine if its function is compromised.	The implant exhibits acceptable simulated 10-year fatigue durability as evidenced by having no device damage that compromises device functionality.	Pass						
Durability: Multimodal (Axial Compression, Bending, and Torsion Fatigue)	A multimodal test instrument is used to cyclically load test articles. The stent is observed to determine if its function is compromised.	The implant exhibits acceptable simulated 10-year fatigue durability as evidenced by having no device damage that compromises device functionality. Fretting corrosion will be characterized.	Pass						

Test Performed	Test Purpose	Acceptance Criteria	Results
Durability: Axial Compression Fatigue	A cyclic, axial displacement is applied to the body rows of the stent. The stent is observed to determine if its function is compromised.	The implant exhibits acceptable simulated 10-year fatigue durability as evidenced by having no device damage that compromises device functionality.	Pass
Nickel Ion Release – Implant	Samples are immersed in solution and metal ion release over time is assessed.	The nickel leachability must not exceed the acute and chronic limits (≤ 290 ug/day acute and 29 ug/day chronic for an adult patient).	Pass
Pitting and Crevice Corrosion Potential – Implant	Samples are suspended in a test solution and subjected to cyclic potentiodynamic polarized voltages and visually examined for the presence of pitting.	The implant must have a mean E_b that is not statistically lower than an existing commercially approved Gore predicate device.	Pass
Stent Frame Material Characterization	Tests are conducted for stent chemical composition and formulation, stent superelasticity, and stent mechanical (tensile) properties per respective ASTM standards.	The chemical composition of a representative nitinol wire material lot must meet the requirements established in ASTM F2063, "Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants" The mean Austenitic Finish Temperature (A_f) of a representative nitinol wire material lot must be $\leq 35^\circ\text{C}$. Characterize the uniaxial tensile stress-strain behavior of nitinol wire for each of the device sizes.	Pass
Foreshortening	Measure the percent change in device length from the loaded to deployed state.	The percentage decrease in length of the implant from the loaded condition to the deployed condition must be characterized: Foreshortening (%) = $100 \times (\text{Change in Length} \div \text{Loaded Length})$	Complete
Implant and Delivery System			
Radiopacity – Delivery System	Compare the visibility of the delivery system to a clinically acceptable delivery system.	The distal tip of the delivery system includes a radiopaque material component to enable fluoroscopic visualization during withdrawal.	Pass
Radiopacity - Implant	Compare the visibility of the implant to a	Implant enables fluoroscopic visualization during access, deployment, and post-deployment.	Pass

Test Performed	Test Purpose	Acceptance Criteria	Results										
	clinically acceptable implant.												
Delivery System Leading End Geometry	Specification review to ensure geometry is compatible with the requirement.	The distal tip shall be smooth, rounded, tapered or similarly finished in order to minimize trauma to vessels during use.	Pass										
Guidewire Compatibility*	Simulated Use - Insert guidewire through the guidewire lumen of the device.	Delivery system must be able to be tracked over a commercially available 0.035” guidewire.	Pass										
Introducer Sheath Compatibility*	Simulated Use - Insert the device through an introducer sheath.	Device must be able to be inserted through a commercially available introducer sheath: <table><tr><th>Implant Diameter (mm)</th><th>Sheath Size (Fr)</th></tr><tr><td>10</td><td>10</td></tr><tr><td>12, 14, 16</td><td>11</td></tr><tr><td>18, 20</td><td>12</td></tr><tr><td>24, 28</td><td>14</td></tr></table>	Implant Diameter (mm)	Sheath Size (Fr)	10	10	12, 14, 16	11	18, 20	12	24, 28	14	Pass
Implant Diameter (mm)	Sheath Size (Fr)												
10	10												
12, 14, 16	11												
18, 20	12												
24, 28	14												
PTA Balloon Compatibility	Simulated Use - Inflate the balloon inside the deployed implant.	The implant must maintain integrity following ballooning with an appropriately sized PTA balloon, and the balloon must be able to be introduced and withdrawn without dislodging the device.	Pass										
Luer Compatibility	Specification review to ensure geometry is compatible with the requirement.	The luer must meet the requirements of BS EN ISO 80369-7.	Pass										
Guidewire Lumen Flushability*	Simulated Use - Use a syringe to flush the lumen with water.	The guidewire lumen must be able to be flushed.	Pass										
Catheter Effective Length*	Measure the length from the device tip to the leading edge of the hub.	Catheter effective length must be 120 cm -2 /+7 cm.	Pass										
Trackability / Pushability / Kink Resistance*	Simulated Use - Track the device through an anatomical model.	Device must be advanced over the guidewire to the target delivery location in a clinically relevant model.	Pass										
Delivery System Kink Resistance*	Determine the diameter at which the catheter lumen becomes non-functional.	The smallest bend diameter that the delivery system can withstand without kinking must be ≤ 120 mm diameter.	Pass										
Delivery System	Determine the peak	The tensile strength of the delivery system must be ≥	Pass										

Test Performed	Test Purpose	Acceptance Criteria	Results
Tensile Strength*	force to separate the components.	38.25 N.	
Deployment Line Tensile Strength*	Determine the peak force that causes component or bond failure.	The tensile strength of the deployment line must be ≥ 2.6 kgf.	Pass
Delivery System Rotations to Failure*	Restrain the tip of the delivery system and rotate the hub until a delivery system component breaks.	With the leading end of the catheter not free to rotate, the number of trailing end rotations until failure must be ≥ 3 rotations.	Pass
Delivery System Ability to Withdraw*	Simulated Use - Remove the delivery system following deployment.	The delivery system must be able to be withdrawn through the introducer sheath in a relevant anatomical model after the device has been deployed.	Pass
Deployment Accuracy*	Simulated Use - Measure the implant location relative to the target following deployment under fluoroscopy.	The nearest stent apex of the implant post-deployment must be ≤ 5 mm from the target location.	Pass
Peak Deployment Force*	Gripping the deployment knob/line, measure the peak force to deploy the device within an anatomical model.	The peak force to deploy the implant under simulated anatomical conditions must be < 2.6 kgf.	Pass
Overlapped Devices Compatibility	Simulated Use - Deploy devices in an overlapped configuration within an anatomical model.	Devices deployed in an overlapped configuration (including confluence stenting) in accordance with IFU overlap instructions must reliably deploy and provide continuous coverage (≥ 0 mm overlap) without adversely affecting previously deployed components. The implant must maintain integrity following ballooning with an appropriately sized PTA balloon, and the balloon must be able to be introduced and withdrawn without dislodging the device.	Pass

B. Biocompatibility Testing

Biocompatibility of the implant and delivery system of the GORE® VIABAHN® FORTEGRA Venous Stent was assessed in accordance with the requirements of ISO 10993-1, *Biological evaluation of medical devices, Part 1: Evaluation and testing within a risk management process*.

The GORE® VIABAHN® FORTEGRA Venous Stent implant is a medical device categorized by ISO 10933-1 as an implant with long-term exposure (>30 days) to circulating blood. The delivery system is categorized by ISO 10993-1 as an externally communicating device with limited exposure (<24 hours) to circulating blood.

All testing performed met the pre-specified acceptance criteria. A summary of the biocompatibility testing conducted for the GORE® VIABAHN® FORTEGRA Venous Stent implant and delivery system is provided in **Table 3**.

Table 3. Summary of Biocompatibility Testing for the GORE® VIABAHN® FORTEGRA Venous Stent Implant and Delivery System

Test Performed	Test Purpose	Acceptance Criteria	Implant	Delivery System	Results
Cytotoxicity: L929 MEM Elution Test	Determine the potential biological reactivity of a mammalian cell culture (L929) in response to the test article extract.	Test article extract cytotoxicity score is ≤ 2 .	X	X	Pass
Sensitization: Kligman Maximization Test	Determine the potential allergenic or sensitizing capacity of the test article.	Less than 10% of animals have a positive sensitization response.	X	X	Pass
Irritation/Intracutaneous Reactivity: Intracutaneous Injection Test	Determine the potential irritation effects of the test article extract as a result of intracutaneous injections.	The difference in the average scores between test and control extracts is ≤ 1 .	X	X	Pass
Acute Systemic Toxicity: Systemic Injection Test	Determine the potential toxic effects of the test article extract as a result of a single-dose systemic injection.	None of the animals treated with test extracts exhibit significantly greater biological reactions than control animals.	X	X	Pass
Material-Mediated Pyrogenicity: Rabbit Pyrogen Study (Material-Mediated)	Determine the potential presence of chemical pyrogens in extracts of solid materials in order to limit to an acceptable level the risks of febrile reaction following administration of the product to the patient.	Temperature increases in individual animals treated with test article extract are each $< 0.5^{\circ}\text{C}$.	X	X	Pass

Test Performed	Test Purpose	Acceptance Criteria	Implant	Delivery System	Results
Implantation: Intramuscular Implantation- 4-Week Implantation in Rabbits	Evaluate the test article for local tissue responses and the potential to induce local toxic effects after implantation in the muscle tissue.	Histological evaluation of implant sites, aided by gross observation at necropsy, indicate that tissue responses surrounding test article implants are not significantly greater than those associated with the negative control article. The Bioreactivity Rating should indicate no significant difference between test and control articles (< 2.9).	X		Pass
Hemocompatibility: Rabbit Blood Hemolysis Test (Complete)	Determine the potential hemolytic activity, via the induction of increased levels of free plasma hemoglobin in blood, in response to the test article and its extract.	Hemolytic index of test article must be < 5 % above the negative control.	X	X	Pass
Hemocompatibility: Partial Thromboplastin Time Test (Direct Contact)	Determine the potential induction of coagulation of human plasma via measurement of the PTT in response to the test article.	No statistically significant difference between the clotting times of the test article and the untreated control or the negative control.	X	X	Pass
Hemocompatibility: SC5b-9 Complement Activation Test (Direct Contact)	Determine the potential activation of the complement system in human plasma in response to the test article.	No statistically significant increase is found between the SC5b-9 concentrations in the plasma exposed to test article and that of plasma exposed to either the negative control or the untreated control.	X	X	Pass

Test Performed	Test Purpose	Acceptance Criteria	Implant	Delivery System	Results
Hemocompatibility: <i>In Vivo</i> Thrombogenicity	Verify that the test article is not thrombogenic.	Thrombus formation involving test and control articles was evaluated by microscopy and SEM in all 30- and 90-day post-operation (DPO) test and control animals.	X	X	Pass
Chemical Characterization: Exhaustive extractables evaluated via GC-MS, LC-MS, ICP-MS, HS-GC-MS	Assess the extractables profile of the test article.	N/A; characterization only	X		Complete
Genotoxicity, Carcinogenicity, Reproductive/ Developmental Toxicity, and Subchronic/Chronic Toxicity: Evaluated via Toxicological Risk Assessment	Determine whether long-term (>30 days) patient exposure to levels of exhaustively extracted chemicals from the test articles could produce unacceptable human health risks; including carcinogenic and systemic non-carcinogenic risks.	Margin of Safety (MOS) values for all identified compounds ≥ 1 .	X		Pass

C. Sterilization, Packaging, and Shelf-life Testing

The GORE® VIABAHN® FORTEGRA Venous Stent is sterilized by ethylene oxide (EO) to provide a Sterility Assurance Level (SAL) of 10^{-6} . The EO sterilization cycles were validated in accordance with ISO 11135, *Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices*. Packaging validation conducted for the device demonstrated the ability of the packaging to protect the product and to maintain a sterile barrier through shipping and shelf life. A shelf life of three years was established for the GORE® VIABAHN® FORTEGRA Venous Stent based on product and package shelf-life testing. The product-specific engineering tests completed to support the three-year shelf life are denoted by an asterisk (*) in **Table 2**.

D. Animal Studies

Three non-clinical chronic *in vivo* animal studies were conducted to evaluate the safety and performance of the GORE® VIABAHN® FORTEGRA Venous Stent in accordance with U.S. Good Laboratory Practice (GLP) regulations (21 CFR Part 58) at AAALAC-accredited facilities. All studies evaluated sterilized VIABAHN® FORTEGRA Devices in an ovine venous model using commercially marketed venous stent devices as controls and in-life periods ranging from 30 to 90 days:

- Study 1 was a 30- and 90-day patency and safety evaluation comparing the GORE® VIABAHN® FORTEGRA Venous Stent and an US-marketed comparator stent in an ovine external iliac vein model. This study evaluated 11 test and 11 control devices in the contralateral iliac veins of 11 sheep.
- Study 2 was a 30- and 90-day patency and safety evaluation comparing overlapping GORE® VIABAHN® FORTEGRA Venous Stents and overlapping an US-marketed comparator stents in an ovine external iliac vein model. This study evaluated six pairs of overlapped devices (12 total test and 12 total control devices) in contralateral iliac veins of six sheep.
- Study 3 was a 30- and 90-day patency and safety evaluation comparing the GORE® VIABAHN® FORTEGRA Venous Stent and an OUS-marketed comparator stent in the ovine inferior vena cava. This study evaluated eight test and six control devices in the inferior vena cava of 14 sheep.

The primary endpoints for each study were device migration and patency. In each study, all VIABAHN® FORTEGRA Devices remained patent at the evaluated 30- and 90-day post-operative periods, and no migrations were observed.

In addition to evaluating the primary endpoints, the studies characterized overall animal health, device delivery and deployment, delivery catheter thrombus formation, stent apposition, device integrity, the tissue healing response of implanted devices, and the presence/absence of device-related thromboembolism.

All VIABAHN® FORTEGRA Devices in all three studies were able to be delivered and deployed at the intended site. All VIABAHN® FORTEGRA Devices in all three studies were observed to be apposed to the vessel wall post-implantation, and no stent fractures were observed in post-explant examinations of device integrity. No thrombus was observed on any VIABAHN® FORTEGRA Device delivery systems upon gross examination after withdrawal.

In all three studies, microscopic observations of vessel injury were similar between test and control devices, and most injury observations for both test and control devices were characterized as superficial. Similarly, the degree of intimal/medial inflammation was similar between test and control devices and was generally characterized as light (i.e., mild). Luminal surfaces of both the test and control devices trended toward becoming fully endothelialized over time. Device-related thromboembolism was not observed in any of the studies.

The results of these animal studies provide evidence of GORE® VIABAHN® FORTEGRA Venous Stent safety and performance, supporting the conclusion that the device meets the design intent and associated user needs and minimizes associated risk.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the GORE® VIABAHN® FORTEGRA Venous Stent for the treatment of

symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction in the US under IDE #G220109, as well as in Europe, Australia, and New Zealand. Data from this global pivotal clinical study, referred to hereafter as the VNS 21-05 study, were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

The VNS 21-05 study was a prospective, single-arm, non-randomized, multicenter, pivotal clinical study. Patients were treated between 26 October 2022 and 30 April 2024. The database for this PMA reflected data collected through 27 May 2025 and included 89 subjects meeting the clinical inclusion and exclusion criteria described below. Twenty-four investigators, across 17 investigational sites globally, treated subjects with the GORE® VIABAHN® FORTEGRA Venous Stent. The primary endpoint for this study is a composite of both safety and effectiveness. The primary endpoint utilized a performance goal derived from a meta-analysis of relevant inferior vena cava stenting literature in combination with clinical trial results for iliofemoral venous stents. The final study sample size was based on the number required to test the primary effectiveness endpoint. To account for a 10% attrition rate, it was calculated that 89 subjects should be enrolled such that 80 subjects were expected to provide evaluable data for the 12-month patency component of the primary endpoint.

Independent evaluations were provided by a study Data and Safety Monitoring Board (DSMB), Clinical Events Committee (CEC), and Core Laboratory, all of which operated under pre-specified procedures. The study DSMB reviewed the data at specified intervals to monitor the study for subject safety and for continuing scientific validity. The CEC, consisting of appropriately trained physicians independent of the study and with relevant clinical experience, adjudicated candidate adverse events related to primary and secondary endpoints using a copy of all applicable source documents obtained from sites. The CEC was also responsible for deciding on the exclusion of treated subjects from the analysis due to eligibility violations. A Core Laboratory was used to perform independent assessments of computed tomography venography (CTV), venogram, X-Ray, and duplex ultrasound (DUS) imaging submitted by clinical sites. The Core Laboratory assessments were used in final analyses.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the VNS 21-05 study was limited to patients who met the following inclusion criteria:

Preoperative Inclusion Criteria:

1. Patient is at least 18 years of age.
2. Patient is willing and able to comply with all follow-up evaluations as well as any required medication or compression regimen.
3. Patient is able to provide informed consent.
4. One of the following: Clinical severity class of CEAP 'C' classification ≥ 3 or rVCSS pain score ≥ 2 .
5. Intention to treat the target areas with only the GORE® VIABAHN® FORTEGRA Venous Stent.

6. Estimated life expectancy ≥ 1 year.
7. Patient is ambulatory (use of assistive walking device such as a cane or walker is acceptable).
8. Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein.

Intraoperative Inclusion Criteria:

1. Presence of non-malignant obstruction of the inferior vena cava defined as occlusion or at least 50% reduction in target vessel lumen as measured by procedural IVUS and venogram, with or without non-malignant obstruction of the common femoral vein, external iliac vein, and/or common iliac vein.
2. Patient can accommodate an appropriately sized GORE® VIABAHN® FORTEGRA Venous Stent as per reference vessel diameter (see IFU), as determined by intraoperative IVUS post pre-dilation.
3. Patient must have appropriate access vessels to accommodate the delivery sheath for the selected device size.
4. Patient has adequate landing zones free from significant disease requiring treatment within the native vessels beyond the proximal and distal margins of the lesion.
5. Patient has adequate inflow to the target lesion(s), per investigator/sub-investigator discretion, involving at least a patent femoral or deep femoral vein.
6. Lesion can be traversed with a guidewire.
7. Disease involves the inferior vena cava and may include iliofemoral segments with intent to stent all affected iliofemoral and caval segments.
8. Patient does not have significant (i.e., $>20\%$ residual thrombosis) acute thrombus within the target stent area at the time of investigational device placement. Patients with acute thrombus within the target stent area must have thrombus successfully treated prior to investigational device placement. Successful thrombus treatment is defined as reestablishment of antegrade flow with $\leq 20\%$ residual thrombosis as confirmed by IVUS and venogram, AND freedom from bleeding, vascular injury, or hemodynamically significant pulmonary embolism. After successful thrombus treatment, investigational device placement can occur within the same procedure.
9. Patient does not have an inferior vena cava filter present within the target stent area at the time of investigational device placement. Patients with an inferior vena cava filter present within the target stent area must have the filter successfully removed prior to investigational device placement. Successful removal is defined as removal of the main body of the filter and intra-luminal fragments such that there is minimal risk to luminal integrity per investigator/sub-investigator discretion AND freedom from bleeding, vascular injury, or hemodynamically significant pulmonary embolism. After successful filter removal, investigational device placement can occur within the same procedure.

Patients were not permitted to enroll in the VNS 21-05 study if they met any of the following exclusion criteria:

Preoperative Exclusion Criteria:

1. Patient is a pregnant or breastfeeding woman, a woman planning to become pregnant through the 12-month visit, or a woman who is unwilling to practice an acceptable method of preventing pregnancy through the 12-month visit.
2. Patient has clinically significant (e.g., symptoms of chest pain, hemoptysis, dyspnea, hypoxia, etc.) pulmonary embolism (confirmed via Computed Tomography Angiography) at the time of enrollment.
3. Patient has a known uncorrectable bleeding diathesis or active coagulopathy meeting the following definitions: uncorrected INR >2 (not as a result of warfarin or DOAC therapy), OR platelet count <50,000 or >1,000,000 cells/mm³, OR white blood cell count <3,000 or >12,500 cells/mm³.
4. Patient has impaired renal function (eGFR <30 mL/min/1.73m²) or is currently on dialysis.
5. Patient has uncorrected hemoglobin of <9 g/dL.
6. Patient has known history of antiphospholipid syndrome (APS) or patients with hypercoagulable states that are unwilling to take anticoagulant medications on a long-term basis.
7. Patient has known homozygous inherited coagulation defect or Protein C/S deficiency.
8. Patient has a planned surgical intervention (other than pre-stenting procedures such as thrombolysis or thrombectomy) within 30 days prior to or within 30 days after the planned study procedure.
9. Patient is currently participating in another investigational drug or device study that has not completed the primary endpoint or that clinically interferes with the endpoints of this treatment, in the opinion of the investigator/sub-investigator. Observational studies are permitted.
10. Patient has had a previous major (i.e., above the ankle) amputation of the target lower limb.
11. Patient has known sensitivity to device materials or contraindication to antiplatelets, thrombolytics, anticoagulants (including patients with known prior instances of Heparin Induced Thrombocytopenia type 2 [HIT-2]), or iodinated contrast.
12. Patient has had prior stenting or grafts in the target vessels.
13. Patient has a known or suspected active systemic infection at the time of the index procedure. Patients with a chronic infection (e.g., HIV, hepatitis C) that is well controlled under their current treatment regimen may be eligible.
14. Patient has known history of intravenous drug abuse within one year of treatment.
15. Patient has significant peripheral arterial disease (chronic Rutherford Type 2 or greater, acute Rutherford Type IIa or greater).
16. Patient has a BMI >40.
17. Patient is actively undergoing or plans to begin cancer treatment.

2. Follow-up Schedule

All subjects were scheduled to return for follow-up examinations at 1 month (± 7 days), 6 months (± 30 days), 12 months (± 30 days), 24 months (± 60 days), 36 months (± 60 days), 48 months (± 60 days), and 60 months (± 60 days). **Table 4** outlines the required screening evaluations and follow-up visit procedures. Adverse events and complications were recorded

at all visits.

Table 4. Study Evaluations and Post-Treatment Follow-Up Schedule

	Screening	Procedure	Discharge	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Unsched.
Informed Consent	X										
Inclusion / Exclusion Criteria	X	X									
Demographics and Medical History	X										
Pregnancy Test (if applicable)	X										
Concomitant Medications	X		X	X	X	X	X	X	X	X	X
Physical Exam	X		X	X	X	X	X	X	X	X	X ⁶
Clinical Scoring ¹	X		X	X	X	X	X	X	X	X	X ⁶
Quality of Life Assessments ¹	X			X	X	X	X	X	X	X	X ⁶
Adverse Events	X	X	X	X	X	X	X	X	X	X	X
DUS ²	X ³			X	X	X	X	X	X	X	X ⁶
CTV				X ⁵	X ⁵	X	X ⁵	X ⁵	X ⁵	X ⁵	X ^{5,6}
Screening CTV or MRV	X ³										
IVUS & Venogram		X ^{3,4}		X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ^{5,6}
X-Ray						X		X		X	X ⁶

¹ Clinical scoring includes the rVCSS, Villalta, and CEAP scales; CEAP scoring ('C' classification only) is only required during screening. Quality of life assessments include VEINES and EQ-5D-5L scales.

² DUS may be inconclusive in the IVC segment; investigators/sub-investigators should assess DUS imaging quality based on iliofemoral segment.

³ Must include attention to inflow vessels (i.e., common femoral vein, deep femoral vein, and femoral vein) to support investigational device patency (see Inclusion Criteria).

⁴ Imaging to be taken of vessels intended for implant both prior to and after device implant.

⁵ CTV, IVUS, or venogram only required when DUS is inconclusive (non-diagnostic or suboptimal in the stented segment) or CTV, IVUS, or venogram is clinically required (subject has symptoms of venous stasis requiring imaging). Imaging modalities used (CTV, IVUS, and/or venogram) are at the discretion of the investigator/sub-investigator.

⁶ Evaluation to be performed as needed.

3. Clinical Endpoints

The primary safety and effectiveness endpoint was a composite endpoint consisting of freedom from the following:

- Loss of primary patency through 12-month follow-up
- Stent embolization through 12-month follow-up
- Device- or procedure-related death through 30 days
- Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days
- Device- or procedure-related vascular injury through 30 days requiring surgical or endovascular intervention
- Device- or procedure-related major bleeding events through 30 days

The VNS 21-05 study was designed to test the null hypothesis that percentage of freedom from the composite primary safety and effectiveness endpoint, when using the GORE® VIABAHN® FORTEGRA Venous Stent, is equal to or lower than a performance goal of 58% established from literature sources based on historical outcomes for the endpoint components listed above in patients with IVC stenosis and patients studied within iliofemoral device trials. The performance goal of 58% was based on an expected loss of primary patency of 18%, an expected combined safety event rate of 10%, and a 14% margin. Endpoint definitions are provided in **Table 5** below. A two-sided 90% exact confidence interval (CI) was constructed ($\alpha = 0.05$). A statistical analysis plan was followed for the study.

The analysis populations for the study were defined as the Per Protocol (PP) population, which consisted of all subjects where an investigational device was introduced into the vasculature and were not determined to be ineligible for the study by the CEC, and the Intent to Treat (ITT) population, which consisted of all subjects where an investigational device was introduced into the vasculature.

One secondary endpoint, improvement in rVCSS pain measurement at 12 months, was evaluated using a formal hypothesis test against a performance goal of mean improvement of -1. This goal represents a decrease in the categorization of a patient's pain from severe to moderate, moderate to mild, or mild to absent, signifying a clinically meaningful difference.

The following secondary endpoints were evaluated using descriptive statistics:

- All individual safety components of the primary endpoint
- Primary patency, secondary patency, clinically driven target lesion revascularization (CD-TLR), and device fracture through 60-month follow-up
- Improvement in rVCSS, rVCSS Pain, VEINES, Villalta, and EQ-5D-5L Measurements through 60-month follow-up compared to pre-treatment baseline
- Technical, lesion, and procedural success

Table 5. Study Endpoint Definitions

Term	Study Definition
Primary patency	Freedom from both: -stent occlusion due to restenosis or thrombosis as confirmed with imaging, and -clinically driven target lesion revascularization
Stent embolization	Major dislodgement of an entire stent due to normal blood flow with no overlap within the procedural stent margins.
Device- or procedure-related death	Death related to investigational device or implantation procedure.
Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography	Clinically significant new pulmonary embolism that is symptomatic (e.g., chest pain, hemoptysis, dyspnea, hypoxia, etc.) AND confirmed via Computed Tomography Angiography.

Device- or procedure-related vascular injury	Device- or procedure-related arterial or venous injury occurring in the target vessel or at the access site requiring surgical or endovascular intervention in addition to the planned endovascular treatment.
Device- or procedure-related major bleeding	Device- or procedure-related bleeding at the target lesion or at the access site requiring blood transfusion ≥ 2 units.
Secondary patency	Freedom from permanent loss of blood flow through the device, regardless of reintervention.
Clinically driven target lesion revascularization (CD-TLR)	Repeat endovascular procedures (e.g., PTA, stenting, thrombectomy/thrombolysis) to restore flow, performed within the margins of the investigational devices due to $\geq 50\%$ restenosis of the target lesion as measured via imaging AND the failure to improve or recurrence of venous origin leg pain or venous edema related to the target lesion present at baseline, or the onset of new symptoms including venous origin pain and venous edema related to the target lesion.
Technical success	Successful delivery and deployment of the stent to the intended location, and removal of delivery system.
Lesion success	Evidence of $\leq 50\%$ residual stenosis at the conclusion of the index procedure as measured by IVUS or venogram.
Procedural success	Lesion success with the absence of major adverse events (MAEs) prior to discharge.

B. Accountability of PMA Cohort

Between 26 October 2022 and 30 April 2024, 89 study subjects were treated with the GORE® VIABAHN® FORTEGRA Venous Stent at 17 sites. A flowchart of subject accountability is provided in **Figure 4**, which summarizes how many subjects progressed to each time point in the study before being discontinued and how many subjects completed or missed each visit. A subject has progressed if they were active in the study at the start of the visit window and is considered to have completed the visit if they had at least one evaluation completed after the start of that visit window.

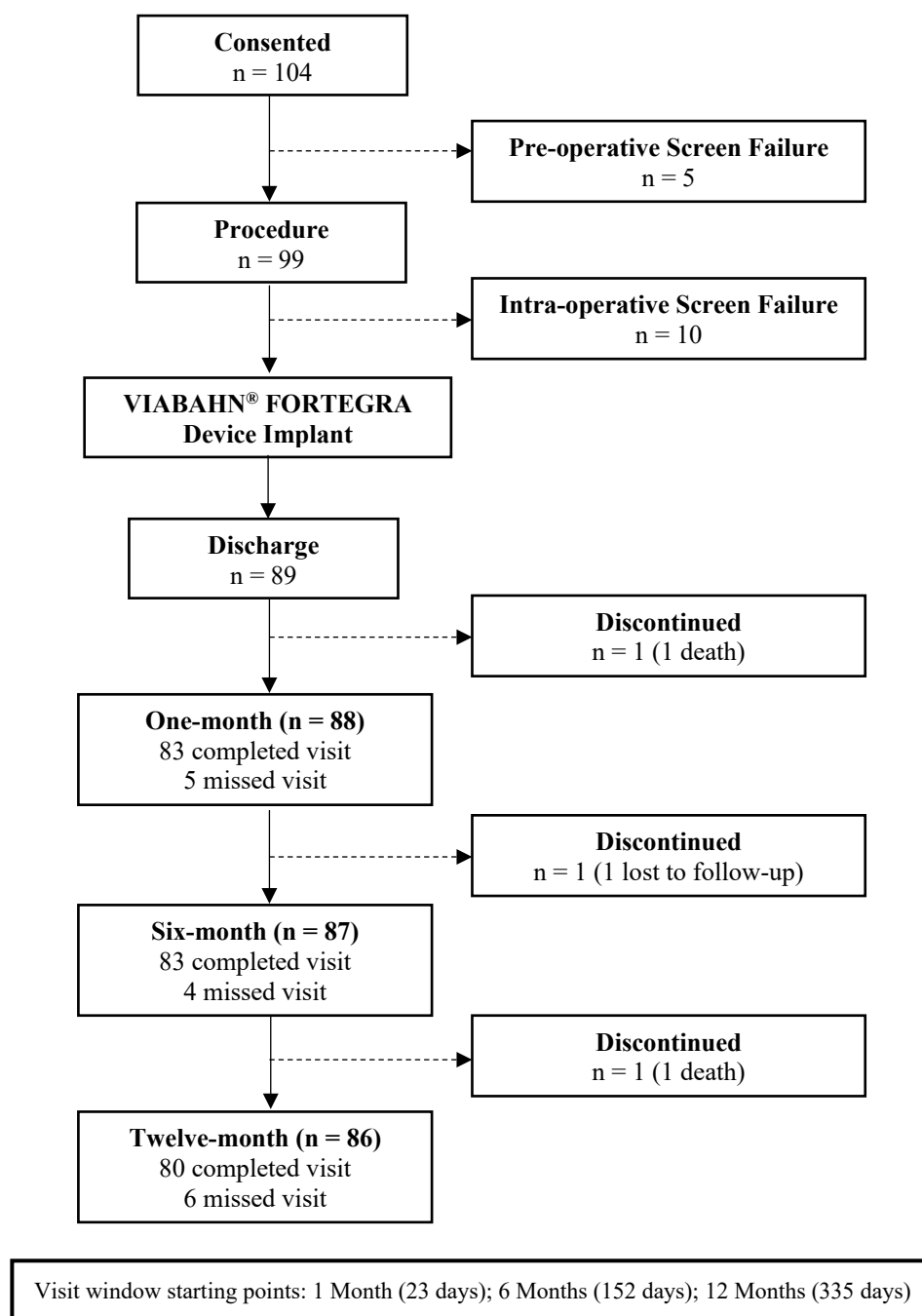


Figure 4. VNS 21-05 Study Subject Accountability

C. Study Population Demographics and Baseline Parameters

1. Demographics

The demographics of the VNS 21-05 study population are typical for a venous stenting study

performed in the US, Europe, Australia, and New Zealand. A summary of subject demographics for treated subjects can be found in **Table 6**. In accordance with European General Data Protection Regulation (GDPR) requirements, ethnicity and race were not collected for the 28 study subjects enrolled at sites in Europe.

Table 6. Subject Demographics

	Total
Subjects Treated	89
Sex at birth	89
Male	55 (61.8%)
Female	34 (38.2%)
Gender	89
Male	55 (61.8%)
Female	34 (38.2%)
Other	0 (0.0%)
Ethnicity¹	61
Hispanic	4 (6.6%)
Non-Hispanic	57 (93.4%)
Race¹	61
American Indian or Alaska Native	0 (0.0%)
Asian	0 (0.0%)
Black	16 (26.2%)
Pacific Islander	0 (0.0%)
White	44 (72.1%)
Other ²	1 (1.6%)
Age (years)	89
Mean (Std Dev)	50.9 (16.81)
Median	51
Min - Max	18 - 94

¹Race and Ethnicity data not collected from study subjects Outside the US (OUS).

²One subject was reported as Maori.

2. Baseline Parameters

Medical history for treated subjects is summarized in **Table 7**. Baseline clinical characteristics, including screening CEAP “C” classifications, procedural details, and lesion characteristics, are provided in **Table 8**, **Table 9**, and **Table 10**, respectively.

The mean procedure time was 193.1 (96.41 Std Dev) minutes. The most common lesion locations were the infra-renal IVC (97.7% of subjects), left common iliac vein (95.5% of subjects), and right common iliac vein (95.5% of subjects). The mean blood loss reported during treatment was 104.5 mL; this measurement included blood loss due to adjunct procedures performed at the same time as the index procedure (e.g., thrombectomy). Three subjects required transfusion, two of which were reported to be related to a planned

thrombectomy procedure. Device deployment was not initially successful in four subjects; these cases are described as part of the technical success secondary endpoint results presented in Section D-2.

Table 7. Subject Medical History

	Total
Subjects Treated	89
Time from onset of venous disease symptoms to treatment	
<= 14 Days	4 / 89 (4.5%)
>14 Days and <= 90 Days	15 / 89 (16.9%)
>90 Days	70 / 89 (78.7%)
Nicotine Use	
Nicotine/Tobacco use	
Never	52 / 89 (58.4%)
Current	10 / 89 (11.2%)
Former	27 / 89 (30.3%)
General Conditions	
Hypercholesterolemia	26 / 87 (29.9%)
Hypertension	28 / 89 (31.5%)
Diabetes mellitus	10 / 89 (11.2%)
Chronic obstructive pulmonary disease	7 / 89 (7.9%)
Renal Insufficiency	3 / 89 (3.4%)
Cancer	
Ongoing	1 / 88 (1.1%)
Resolved	12 / 88 (13.6%)
No	75 / 88 (85.2%)
Cardiovascular Disease	
Myocardial infarction	4 / 89 (4.5%)
Coronary artery disease	6 / 88 (6.8%)
Congestive heart failure	6 / 89 (6.7%)
Peripheral arterial disease	4 / 89 (4.5%)
Upper extremity DVT	3 / 89 (3.4%)
Lower extremity DVT	72 / 87 (82.8%)
Pulmonary embolism	31 / 88 (35.2%)
Stroke	11 / 89 (12.4%)
Other cardiovascular disease	6 / 89 (6.7%)
Previous Surgeries and Interventions	
Orthopedic surgery	15 / 89 (16.9%)
Varicose vein treatment	5 / 88 (5.7%)
Saphenous vein stripping/occlusion	3 / 89 (3.4%)
Venous thrombectomy	17 / 88 (19.3%)

	Total
IVC filter placement	37 / 89 (41.6%)
Thrombophilic Risk Factors	
Varicose veins	43 / 89 (48.3%)
Superficial venous disease	46 / 88 (52.3%)
Oral contraceptive use	
Current	2 / 28 (7.1%)
Former	16 / 28 (57.1%)
Never	10 / 28 (35.7%)
Factor V Leiden	10 / 86 (11.6%)
IVC atresia	18 / 88 (20.5%)
Prolonged immobility	2 / 88 (2.3%)
May-Thurner syndrome	10 / 88 (11.4%)
Increased factor VIII	1 / 87 (1.1%)
Other hypercoagulable disorder	3 / 88 (3.4%)

Table 8. Screening CEAP “C” Classifications

	Total
Subjects Treated	89
Most Severe Clinical C Classification¹	
C0	1 (1.1%)
C1	0 (0.0%)
C2	2 (2.2%)
C2r	0 (0.0%)
C3	41 (46.1%)
C4	13 (14.6%)
C4a	10 (11.2%)
C4b	2 (2.2%)
C4c	1 (1.1%)
C5	5 (5.6%)
C6	9 (10.1%)
C6r	5 (5.6%)

¹Subjects with C0-C2 classification had rVCSS pain scores of 2 or greater.

Table 9. Index Procedure Details

	Total
Subjects Treated	89
Procedure duration (minutes): Incision to access closure	
Mean (Std Dev)	193.1 (96.41)
Number of devices implanted per subject	
Mean (Std Dev)	5.3 (1.68)

	Total
Anesthesia method	
General	85 (95.5%)
Local	4 (4.5%)
Patient position	
Prone	10 (11.2%)
Supine	79 (88.8%)
Access vessels used for study device (multiple vessels per subject possible)	
Right common femoral vein	36 (40.4%)
Left common femoral vein	28 (31.5%)
Right internal jugular vein	28 (31.5%)
Right femoral vein	21 (23.6%)
Left femoral vein	21 (23.6%)
Left popliteal vein	12 (13.5%)
Left great saphenous vein	11 (12.4%)
Right popliteal vein	10 (11.2%)
Right great saphenous vein	10 (11.2%)
Other	4 (4.5%)
Right tibial vein	3 (3.4%)
Left internal jugular vein	2 (2.2%)
Left tibial vein	2 (2.2%)
Left small saphenous vein	2 (2.2%)
Right small saphenous vein	1 (1.1%)
Study device placed across inguinal ligament	
Yes	61 (68.5%)
No	28 (31.5%)
Fluoroscopy time (minutes)	
Mean (Std Dev)	66.4 (46.41)
Estimated blood loss (mL)	
Mean (Std Dev)	104.5 (185.48)
Heparin administered	
Yes	83 (93.3%)
No	6 (6.7%)
Another anticoagulation used	
Yes	12 (13.5%)
No	77 (86.5%)

Table 10. Core Lab-reported Lesion Characteristics

	Total
Subjects Treated	89 ¹
Lesion location(s)	
Infra-renal IVC	86/88 (97.7%)
Supra-renal IVC	31/86 (36.0%)

	Total
Left common iliac vein	84/88 (95.5%)
Left external iliac vein	54/88 (61.4%)
Left common femoral vein	39/88 (44.3%)
Right common iliac vein	84/88 (95.5%)
Right external iliac vein	59/88 (67.0%)
Right common femoral vein	32/88 (36.4%)
Device Configuration	88
Isolated IVC	4 (4.5%)
IVC + Unilateral Iliofemoral	1 (1.1%)
IVC + Bilateral Iliofemoral	83 (94.3%)
IVC + Bilateral Iliofemoral Technique²	83
Confluence	80 (96.4%)
Double Barrel	3 (3.6%)
Apposition	0 (0.0%)
Stented length - total (cm)	87
Mean (Std Dev)	41.2 (13.13)
Median	41.3
Min - Max	6.1 - 72.9

¹Lesion characteristics (lesion location and stented length) are only reported for subjects with evaluable imaging for the specific lesion characteristic and vessel region, and for the subjects who received treatment in the specified vessel region.

²Graphical representations of each IVC + bilateral iliofemoral technique are provided below:

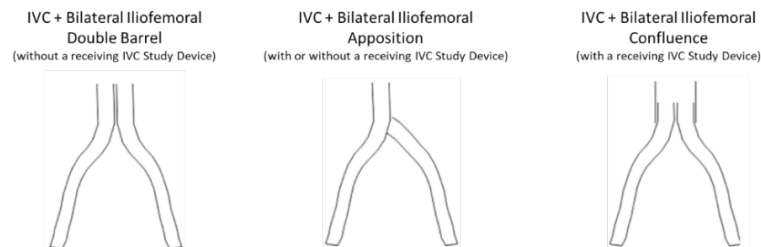


Figure 5. Confluence Stenting Techniques in IVC with Bilateral Iliofemoral Disease Patients

D. Safety and Effectiveness Results

1. Composite Safety and Effectiveness Results

The primary endpoint for the VNS 21-05 study included both safety and effectiveness components, consisting of freedom from the following:

- Loss of primary patency through 12-month follow-up
- Stent embolization through 12-month follow-up
- Device- or procedure-related death through 30 days
- Clinically significant pulmonary embolism confirmed via Computed Tomography Angiography through 30 days
- Device- or procedure-related vascular injury through 30 days requiring surgical or

- endovascular intervention
- Device- or procedure-related major bleeding events through 30 days

Analysis was based on the 79 subjects that were evaluable for the composite endpoint. Of the ten subjects that were not evaluable, six patients did not return for the 12M visit, two patients returned for the visit but did not have evaluable imaging, one patient expired due to unrelated causes prior to the 12M visit, and one withdrew consent prior to the 12M visit. The PP and ITT populations were identical in this study, as no treated subjects were determined to be ineligible by the study CEC. Therefore, the results presented incorporate all available data from all treated subjects.

The key primary endpoint outcomes for this study are presented below in **Table 11**. The performance goal (PG) for freedom from primary endpoint events of 58% was met. The overall rate of freedom from a primary endpoint event was 74.7%, with a 95% one-sided exact lower confidence limit of 66.6%. All observed safety-related primary endpoint events (i.e., related to any endpoint component except primary patency) were adjudicated as procedure-related by the study CEC.

Adverse events that occurred in the VNS 21-05 study are reported in Section X(C)(3) below.

Table 11. Hypothesis Testing of Composite Primary Endpoint

	Results
Subjects Treated	89
Subjects Available for Composite Primary Endpoint Assessment	79
Composite Primary [90% CI]	59 (74.7%) [66.6%, 82.7%]
p-Value for testing the null hypothesis that composite primary $\leq$ PG	<0.001
Components of the Primary Endpoint	
Freedom from loss of primary patency through 12-month follow-up ¹	63 / 79 (79.7%)
Freedom from stent embolization through 12-month follow-up	78 / 78 (100.0%)
Freedom from device- or procedure-related death through 30 days	88 / 89 (98.9%)
Freedom from clinically significant pulmonary embolism through 30 days	87 / 87 (100.0%)
Freedom from device- or procedure-related vascular injury through 30 days	87 / 87 (100.0%)
Freedom from device- or procedure-related major bleeding through 30 days	83 / 87 (95.4%)

¹Of those that lost primary patency, seven were due to device occlusion, two were due to CD-TLR, and seven were due to both device occlusion and CD-TLR.

A tipping point analysis was performed to demonstrate how many of these subjects could have failed the primary endpoint while still rejecting the null hypothesis, therefore meeting the performance goal. Per **Table 12**, nine of the 10 excluded subjects could

have failed while still rejecting the null hypothesis.

Table 12: Primary Endpoint Tipping Point Analysis

Simulated Endpoint Successes (N=10)	Simulated Endpoint Failures (N=10)	Composite Freedom from Endpoint Event ¹ (95% Exact LCL)	Reject Null Hypothesis (LCL > 58% PG)
10 (100.0%)	0 (0.0%)	77.5% (69.1%)	Yes
9 (90.0%)	1 (10.0%)	76.4% (67.8%)	Yes
8 (80.0%)	2 (20.0%)	75.3% (66.6%)	Yes
7 (70.0%)	3 (30.0%)	74.2% (65.4%)	Yes
6 (60.0%)	4 (40.0%)	73.0% (64.2%)	Yes
5 (50.0%)	5 (50.0%)	71.9% (63.0%)	Yes
4 (40.0%)	6 (60.0%)	70.8% (61.9%)	Yes
3 (30.0%)	7 (70.0%)	69.7% (60.7%)	Yes
2 (20.0%)	8 (80.0%)	68.5% (59.5%)	Yes
1 (10.0%)	9 (90.0%)	67.4% (58.3%)	Yes
0 (0.0%)	10 (100.0%)	66.3% (57.2%)	No

¹Composite result calculates combined success rate among observed and simulated successes, N=89; 95% LCL represents one-sided 95% Lower Confidence Limit by exact Clopper-Pearson method.

2. Secondary Endpoint Results

Table 13 provides results for key secondary endpoints that are not already described in **Table 11** above, through 12 months or as otherwise defined. The rVCSS pain measurement at the 12-month follow-up visit was also evaluated using a formal hypothesis test to detect an improvement in rVCSS pain score (a change of -1) as compared to baseline at screening. For the 63 subjects that were evaluable for this endpoint (i.e., subjects presenting with a baseline rVCSS pain score of at least 1 and therefore eligible for improvement), the rVCSS pain score improved by a mean of 1.4 (1.03), meeting the secondary endpoint. Additionally, of the 13 subjects presenting with a baseline rVCSS pain score of 0, none had worsening of pain at the 12-month visit.

Eighty-five (85) of 89 (95.5%) evaluable subjects met the criteria for technical success. Of the four subjects that did not, separation of the delivery catheter occurred in two cases, the stent could not be advanced due to vessel recoil after PTA in one case, and in the final case, there was a failed attempt to deploy the device after it was withdrawn and reinserted into the introducer sheath (which is contrary to a warning in the device IFU). The one subject who failed to meet the procedural success definition had a CEC-adjudicated major bleed during the procedure. Target lesions were ultimately successfully treated with VIABAHN® FORTEGRA Devices during the procedural period in all subjects.

Table 13. Secondary Endpoint Results

Secondary Endpoint	Results
Subjects Treated	89
Subjects Available for rVCSS Pain Score Secondary Endpoint Assessment	63

Mean difference in rVCSS pain score (Std Dev)	-1.4 (1.03)
Median difference in rVCSS Pain Score	-2.0
Signed Rank Score	-262.5
p-Value for testing the null hypothesis that the improvement in rVCSS pain score < -1	<0.001
Other Secondary Endpoints (Descriptive Statistics)	
Secondary patency through 365 days ¹	96.2%
Freedom from Clinically Driven Target Lesion Revascularization through 365 days ¹	89.7%
Freedom from device fracture through 12-month follow-up ¹	100%
Change in mean rVCSS score between baseline and 12 months	5.5 (9.9 at baseline to 4.4 at 12 months) ²
Change in mean Villalta score between baseline and 12 months	7.9 (11.9 at baseline to 4.0 at 12 months) ²
Change in mean VEINES-QOL score between baseline and 12 months	30.8 (44.6 at baseline to 75.4 at 12 months) ²
Change in mean EQ-5D-5L score between baseline and 12 months	0.1 (0.69 at baseline to 0.79 at 12 months) ²
Lesion Success	88 / 88 (100%)
Technical Success	85 / 89 (95.5%)
Procedural Success	79 / 80 (98.8%)

¹Calculated using Kaplan-Meier Estimation

²Mean scores for rVCSS, Villalta, VEINES-QOL, and EQ-5D-5L all trended favorably from baseline to 12 months.

3. Adverse Event Summary

Summaries of all coded adverse events (AEs) and serious adverse events (SAEs) for treated subjects through 12 months post-procedure can be found in **Table 14** and **Table 15**, respectively. The percentages of subjects, as reported by the investigators, with any AE was 69.7%, and with SAEs was 40.4%. The one device-related AE was reported by the site as “thrombosis in the device” at 294 days after the index procedure. Among the SAEs, the most reported events per SOC were 1) infections and infestations; and 2) product issues (i.e., device occlusion or thrombosis in device). Among the non-SAEs, the most reported events per SOC were 1) musculoskeletal and connective tissue disorders; 2) gastrointestinal disorders; 3) general disorders and administration site conditions; and 4) injury, poisoning and procedural complications. Although rare, serious adverse events including hemoperitoneum and hepatic rupture have occurred. The types and occurrences of adverse events reported in the VNS 21-05 study are within expected rates for the studied patient population and therapeutic area.

Of the 89 total treated subjects, 18 subjects were diagnosed with IVC atresia at baseline. Of the 18 subjects with atresia, 11 (61.1%) reported procedure-related AEs, while 20 of 70 (28.6%) non-atresia subjects reported procedure-related AEs (one subject's atresia status was not reported at baseline). Note that in post-hoc analysis of the 79 trial subjects that were evaluable for the primary endpoint, 4 of 16 (25.0%) atresia subjects reported one or more

failures of a composite primary endpoint component, while 16 of 63 (25.4%) non-atresia subjects reported one or more of these failures. Although rates of procedure-related AEs for atresia subjects were higher than non-atresia subjects, primary endpoint results are comparable.

Table 14. All Adverse Events Through 12 Months

	Cumulative Results Through 12 Months¹
Subjects Treated	89
Subjects experiencing any adverse event	62 (69.7%) [240]
Site-reported Primary Relationship	
Related to study device	1 (1.1%) [1]
Related to study procedure	31 (34.8%) [81]
Related to disease	32 (36.0%) [56]
Not related to study device, procedure, or disease	35 (39.3%) [88]
Unknown relationship	11 (12.4%) [14]
All Adverse Events Coded Using MedDRA	
Blood and lymphatic system disorders	6 (6.7%) [8]
Anaemia	3 (3.4%) [3]
Blood loss anaemia	1 (1.1%) [1]
Iron deficiency anaemia	1 (1.1%) [1]
Leukocytosis	2 (2.2%) [2]
Thrombocytopenia	1 (1.1%) [1]
Cardiac disorders	4 (4.5%) [4]
Cardiac arrest	1 (1.1%) [1]
Cardiac failure	1 (1.1%) [1]
Palpitations	2 (2.2%) [2]
Ear and labyrinth disorders	1 (1.1%) [1]
Vestibular disorder	1 (1.1%) [1]
Eye disorders	3 (3.4%) [3]
Ocular fistula	1 (1.1%) [1]
Retinal detachment	1 (1.1%) [1]
Vision blurred	1 (1.1%) [1]
Gastrointestinal disorders	19 (21.3%) [28]
Abdominal pain	4 (4.5%) [4]
Abdominal pain lower	1 (1.1%) [1]
Constipation	3 (3.4%) [3]
Diarrhoea	1 (1.1%) [1]
Erosive duodenitis	1 (1.1%) [1]
Gastrointestinal haemorrhage	1 (1.1%) [1]

	Cumulative Results Through 12 Months¹
Haemoperitoneum	1 (1.1%) [1]
Nausea	7 (7.9%) [7]
Retroperitoneal fibrosis	1 (1.1%) [1]
Retroperitoneal haematoma	2 (2.2%) [2]
Small intestinal obstruction	1 (1.1%) [1]
Vomiting	5 (5.6%) [5]
General disorders and administration site conditions	19 (21.3%) [22]
Asthenia	1 (1.1%) [1]
Chest pain	1 (1.1%) [1]
Fatigue	1 (1.1%) [1]
Non-cardiac chest pain	2 (2.2%) [2]
Pain	2 (2.2%) [2]
Peripheral swelling	4 (4.5%) [4]
Puncture site haematoma	1 (1.1%) [2]
Puncture site haemorrhage	1 (1.1%) [1]
Pyrexia	1 (1.1%) [1]
Vascular stent stenosis	6 (6.7%) [7]
Hepatobiliary disorders	1 (1.1%) [1]
Subcapsular hepatic haematoma	1 (1.1%) [1]
Infections and infestations	16 (18.0%) [22]
Acute sinusitis	1 (1.1%) [1]
Arthritis bacterial	1 (1.1%) [1]
COVID-19	1 (1.1%) [1]
Cellulitis	2 (2.2%) [2]
Conjunctivitis	2 (2.2%) [2]
Coronavirus infection	1 (1.1%) [1]
Cystitis	1 (1.1%) [1]
Escherichia urinary tract infection	1 (1.1%) [1]
Pharyngitis	1 (1.1%) [1]
Pneumonia	3 (3.4%) [3]
Sepsis	1 (1.1%) [1]
Staphylococcal bacteraemia	1 (1.1%) [1]
Urinary tract infection	5 (5.6%) [5]
Wound infection	1 (1.1%) [1]
Injury, poisoning and procedural complications	19 (21.3%) [27]
Contusion	1 (1.1%) [1]
Fall	1 (1.1%) [1]
Hepatic rupture	1 (1.1%) [1]
Incision site complication	1 (1.1%) [1]

	Cumulative Results Through 12 Months¹
Incision site inflammation	1 (1.1%) [1]
Lip injury	1 (1.1%) [1]
Procedural pain	1 (1.1%) [1]
Traumatic ulcer	1 (1.1%) [1]
Vascular access site bruising	1 (1.1%) [1]
Vascular access site haematoma	5 (5.6%) [6]
Vascular access site haemorrhage	6 (6.7%) [6]
Vascular access site pain	2 (2.2%) [2]
Wound dehiscence	3 (3.4%) [3]
Wound haemorrhage	1 (1.1%) [1]
Investigations	3 (3.4%) [3]
Gastrointestinal stoma output increased	1 (1.1%) [1]
Ultrasound scan abnormal	2 (2.2%) [2]
Metabolism and nutrition disorders	1 (1.1%) [1]
Hypokalaemia	1 (1.1%) [1]
Musculoskeletal and connective tissue disorders	28 (31.5%) [42]
Arthralgia	2 (2.2%) [2]
Back pain	18 (20.2%) [18]
Flank pain	1 (1.1%) [1]
Foot deformity	1 (1.1%) [1]
Gouty arthritis	1 (1.1%) [1]
Groin pain	3 (3.4%) [3]
Joint effusion	1 (1.1%) [1]
Limb discomfort	1 (1.1%) [1]
Muscle fatigue	1 (1.1%) [1]
Muscle spasms	3 (3.4%) [3]
Musculoskeletal pain	1 (1.1%) [1]
Myalgia	1 (1.1%) [1]
Myositis	1 (1.1%) [1]
Neck pain	1 (1.1%) [1]
Osteoarthritis	1 (1.1%) [1]
Pain in extremity	5 (5.6%) [5]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1.1%) [1]
Bladder cancer recurrent	1 (1.1%) [1]
Nervous system disorders	10 (11.2%) [14]
Complex regional pain syndrome	1 (1.1%) [1]
Dizziness	3 (3.4%) [3]
Headache	2 (2.2%) [2]

	Cumulative Results Through 12 Months¹
Hypoesthesia	2 (2.2%) [3]
Memory impairment	1 (1.1%) [1]
Presyncope	1 (1.1%) [1]
Seizure	1 (1.1%) [1]
Syncope	1 (1.1%) [1]
Toxic encephalopathy	1 (1.1%) [1]
Product issues	14 (15.7%) [18]
Device occlusion	3 (3.4%) [4]
Thrombosis in device	13 (14.6%) [14]
Psychiatric disorders	7 (7.9%) [8]
Anxiety	2 (2.2%) [3]
Delirium	1 (1.1%) [1]
Depression	1 (1.1%) [1]
Irritability	1 (1.1%) [1]
Mental status changes	1 (1.1%) [1]
Panic attack	1 (1.1%) [1]
Renal and urinary disorders	5 (5.6%) [6]
Acute kidney injury	1 (1.1%) [1]
Dysuria	1 (1.1%) [1]
Haematuria	1 (1.1%) [1]
Hydronephrosis	1 (1.1%) [1]
Micturition urgency	1 (1.1%) [1]
Urinary retention	1 (1.1%) [1]
Reproductive system and breast disorders	2 (2.2%) [3]
Pelvic pain	2 (2.2%) [2]
Vaginal haemorrhage	1 (1.1%) [1]
Respiratory, thoracic and mediastinal disorders	6 (6.7%) [6]
Cough	1 (1.1%) [1]
Dyspnoea	2 (2.2%) [2]
Epistaxis	2 (2.2%) [2]
Pulmonary embolism	1 (1.1%) [1]
Skin and subcutaneous tissue disorders	7 (7.9%) [7]
Hyperhidrosis	1 (1.1%) [1]
Rash	1 (1.1%) [1]
Skin discolouration	1 (1.1%) [1]
Skin ulcer	3 (3.4%) [3]
Urticaria	1 (1.1%) [1]

	Cumulative Results Through 12 Months¹
Vascular disorders	11 (12.4%) [15]
Deep vein thrombosis	1 (1.1%) [3]
Haematoma	2 (2.2%) [2]
Hypertension	2 (2.2%) [2]
Hypotension	1 (1.1%) [1]
Phlebitis	1 (1.1%) [1]
Spider vein	1 (1.1%) [1]
Varicose vein	4 (4.5%) [4]
Vein rupture	1 (1.1%) [1]

¹Format of adverse event data is as follows: X (Y%) [Z], where X is the number of subjects with an event, Y is the percentage of subjects with an event, and Z is the total number of events.

Table 15. Serious Adverse Events Through 12 Months

	Cumulative Results Through 12 Months¹
Subjects treated	89
Subjects experiencing serious adverse event	36 (40.4%) [82]
Site-reported Primary Relationship	
Related to study device	1 (1.1%) [1]
Related to study procedure	16 (18.0%) [27]
Related to disease	13 (14.6%) [17]
Not related to study device, procedure, or disease	17 (19.1%) [34]
Unknown relationship	3 (3.4%) [3]
Serious Adverse Events Coded Using MedDRA	
Blood and lymphatic system disorders	3 (3.4%) [3]
Anaemia	2 (2.2%) [2]
Blood loss anaemia	1 (1.1%) [1]
Cardiac disorders	1 (1.1%) [1]
Cardiac arrest	1 (1.1%) [1]
Eye disorders	1 (1.1%) [1]
Ocular fistula	1 (1.1%) [1]
Gastrointestinal disorders	8 (9.0%) [9]
Abdominal pain	1 (1.1%) [1]
Abdominal pain lower	1 (1.1%) [1]
Erosive duodenitis	1 (1.1%) [1]
Gastrointestinal haemorrhage	1 (1.1%) [1]
Haemoperitoneum	1 (1.1%) [1]
Nausea	1 (1.1%) [1]
Retroperitoneal haematoma	2 (2.2%) [2]
Small intestinal obstruction	1 (1.1%) [1]

	Cumulative Results Through 12 Months ¹
General disorders and administration site conditions	8 (9.0%) [10]
Asthenia	1 (1.1%) [1]
Non-cardiac chest pain	1 (1.1%) [1]
Pain	2 (2.2%) [2]
Puncture site haematoma	1 (1.1%) [1]
Vascular stent stenosis	4 (4.5%) [5]
Infections and infestations	10 (11.2%) [12]
Arthritis bacterial	1 (1.1%) [1]
Cellulitis	1 (1.1%) [1]
Coronavirus infection	1 (1.1%) [1]
Escherichia urinary tract infection	1 (1.1%) [1]
Pneumonia	3 (3.4%) [3]
Sepsis	1 (1.1%) [1]
Staphylococcal bacteraemia	1 (1.1%) [1]
Urinary tract infection	2 (2.2%) [2]
Wound infection	1 (1.1%) [1]
Injury, poisoning and procedural complications	7 (7.9%) [8]
Hepatic rupture	1 (1.1%) [1]
Incision site complication	1 (1.1%) [1]
Lip injury	1 (1.1%) [1]
Procedural pain	1 (1.1%) [1]
Vascular access site haematoma	2 (2.2%) [2]
Vascular access site haemorrhage	1 (1.1%) [1]
Wound dehiscence	1 (1.1%) [1]
Investigations	1 (1.1%) [1]
Gastrointestinal stoma output increased	1 (1.1%) [1]
Metabolism and nutrition disorders	1 (1.1%) [1]
Hypokalaemia	1 (1.1%) [1]
Musculoskeletal and connective tissue disorders	7 (7.9%) [9]
Back pain	4 (4.5%) [4]
Gouty arthritis	1 (1.1%) [1]
Groin pain	1 (1.1%) [1]
Myositis	1 (1.1%) [1]
Osteoarthritis	1 (1.1%) [1]
Pain in extremity	1 (1.1%) [1]
Nervous system disorders	3 (3.4%) [4]
Dizziness	1 (1.1%) [1]

	Cumulative Results Through 12 Months ¹
Seizure	1 (1.1%) [1]
Syncope	1 (1.1%) [1]
Toxic encephalopathy	1 (1.1%) [1]
Product issues	9 (10.1%) [11]
Device occlusion	1 (1.1%) [1]
Thrombosis in device	9 (10.1%) [10]
Psychiatric disorders	3 (3.4%) [4]
Anxiety	1 (1.1%) [2]
Delirium	1 (1.1%) [1]
Panic attack	1 (1.1%) [1]
Renal and urinary disorders	2 (2.2%) [2]
Acute kidney injury	1 (1.1%) [1]
Hydronephrosis	1 (1.1%) [1]
Reproductive system and breast disorders	1 (1.1%) [1]
Pelvic pain	1 (1.1%) [1]
Respiratory, thoracic and mediastinal disorders	1 (1.1%) [1]
Pulmonary embolism	1 (1.1%) [1]
Skin and subcutaneous tissue disorders	1 (1.1%) [1]
Skin ulcer	1 (1.1%) [1]
Vascular disorders	3 (3.4%) [3]
Haematoma	1 (1.1%) [1]
Hypertension	1 (1.1%) [1]
Hypotension	1 (1.1%) [1]

¹Format of adverse event data is as follows: X (Y%) [Z], where X is the number of subjects with an event, Y is the percentage of subjects with an event, and Z is the total number of events.

4. Subgroup Analyses

Subgroup analysis on the composite primary endpoint was performed by sex (**Table 16**) and by geographical region (**Table 17**), using a Fisher's Exact Test. The study was not powered for these subgroup analyses; however, there were no significant differences observed in the primary endpoint outcome based on sex or region.

Freedom from a primary endpoint event was observed in 75.5% of male subjects and 73.3% of female subjects.

Freedom from a primary endpoint event was observed in 82.2% of subjects enrolled in the

US, 64.3% of subjects enrolled in Europe, and 66.7% of subjects enrolled in Australia/New Zealand.

Table 16: Primary Endpoint Results by Sex

	Available for Composite Primary Endpoint Assessment	Free from Endpoint Event (%)	P-value
Male	49	37 (75.5%)	1.000
Female	30	22 (73.3%)	

Table 17: Primary Endpoint Results by Region

	Available for Composite Primary Endpoint Assessment	Free from Endpoint Event (%)	P-value
US	45	37 (82.2%)	0.180
Europe	28	18 (64.3%)	
Australia/New Zealand	6	4 (66.7%)	

5. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 90 investigators that were delegated to study activities at any point. Of these 90 investigators, 24 investigators implanted devices, and no investigators were full-time or part-time employees of the sponsor. Three investigators, all at one site, had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0
- Significant payment of other sorts: 3
- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 0

The applicant has adequately disclosed the financial interest/arrangements with clinical

investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety and Effectiveness Conclusions

Bench / analytical, sterilization, packaging, product shelf life, biocompatibility, and *in vivo* animal testing, along with the results of the VNS 21-05 pivotal clinical study, provide reasonable assurance that the GORE® VIABAHN® FORTEGRA Venous Stent is safe and effective for the intended clinical use. All pre-specified acceptance criteria for non-clinical testing were met, confirming that the device met all design requirements.

The primary endpoint for the prospective, single-arm, multicenter VNS 21-05 study was a composite safety and effectiveness endpoint, with a performance goal (PG) established based on previous literature-reported ilio caval and iliac stenting outcomes. The PG for freedom from primary endpoint events of 58% was met, with a p-value <0.001. The overall rate of freedom from a primary endpoint event was 74.7%, with a 95% one-sided exact lower confidence limit of 66.6%. Freedom from loss of primary patency was 79.7 % with no embolization through 12 months, and no pulmonary embolism or vascular injury through 30 days. There were no significant differences observed in the primary endpoint outcome for the analyzed patient subgroups (i.e., sex and geographical region). Safety events were bleeding and vascular access site hematoma, which are common for this patient population and type of procedure. Subjects experienced a significant reduction in rVCSS pain scores and improvements based on Villalta and VEINES-QOL.

B. Benefit-Risk Determination

The probable benefits of the device are based on data collected in a clinical study conducted to support PMA approval as described above. The GORE® VIABAHN® FORTEGRA Venous Stent is intended to improve the serious and potentially debilitating symptoms of ilio caval outflow obstruction by improving venous blood flow in the impacted vessels. The expected benefits of improved venous blood flow include a reduction in patient pain and swelling (venous edema), improvement in skin conditions (e.g., pruritis, induration, inflammation, and/or skin pigmentation), and healing of venous ulcers (e.g., reduce number of active ulcers and/or ulcer size), all of which result in improved day-to-day functioning for treated patients.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The types and occurrences of adverse events reported in the VNS 21-05 study are within expected rates for the studied patient population and therapeutic area. No new risks associated with the GORE® VIABAHN® FORTEGRA Venous Stent were identified as a result of any observed adverse events in the trial.

1. Patient Perspective

Patient perspectives considered during the review included Quality of Life assessments, specifically VEINES and EQ-5D-5L. Scores for treated patients improved from pre-procedure assessments through follow-up. It is expected that patients would place value on this treatment and would be able to understand the probable benefits and risks of treatment with the GORE® VIABAHN® FORTEGRA Venous Stent without difficulty.

In conclusion, given the available information above, the data support that for the treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction, the probable benefits of the GORE® VIABAHN® FORTEGRA Venous Stent outweigh the probable risks.

C. Overall Conclusions

The non-clinical testing performed for the GORE® VIABAHN® FORTEGRA Venous Stent confirmed that the device met all design requirements, and data from the pivotal VNS 21-05 clinical study met the pre-specified performance goal that served as the composite primary safety and effectiveness endpoint for the trial. Therefore, the data in this application demonstrate reasonable assurance that the GORE® VIABAHN® FORTEGRA Venous Stent is safe and effective when used in accordance with the indications for use.

XIII. CDRH DECISION

CDRH issued an approval order on December 19th, 2025. The final conditions of approval cited in the approval order are described below.

1. *VNS 21-05: Continued Follow-up Study.* This study is a prospective, multi-center, single-arm trial (G220109) that treated a total of 89 subjects, with 55 subjects treated at eight US investigational sites and 34 subjects treated at nine OUS investigational sites. The study should be conducted per protocol VNS 21-05 (2 November 2023). The study will evaluate the long-term safety and effectiveness of the GORE® VIABAHN® FORTEGRA Venous Stent. At the time of database export, 85 patients were still active in the study and will continue to be followed through 60 months.

Follow-up at the 24-month, 36-month, 48-month, and 60-month timepoints will include the following assessments:

- Concomitant medications
- Physical exam

- Clinical scoring
- Quality of life assessments
- Adverse events
- Vessel imaging (doppler ultrasound, CTV, IVUS, or venogram) to evaluate device patency and stent embolization, as applicable

Follow-up at the 36-month and 60-month timepoints will include X-ray imaging of the stent to evaluate device fracture and stent embolization.

Post-approval Study (PAS): New Enrollment Study. GORE® VIABAHN® FORTEGRA Venous Stent Post-approval Study: This study is a single-arm, prospective, multi-center, open label study of patients treated with the GORE® VIABAHN® FORTEGRA Venous Stent at a maximum of 35 sites in the United States. The objective of the study is to continue the assessment of device performance and capture outcome data in real-world use of the device. A total of 150 subjects will be enrolled. Follow-up will occur immediately after the initial implant procedure, as well as at one month, six months, 12 months, 24 months, and 36 months post-procedure. Primary endpoints for the study include primary patency through 12 months and freedom from device- or index procedure-related serious adverse events (SAEs) through 30 days.

Follow-up at the one-month, six-month, 12-month, 24-month, and 36-month timepoints will include the following assessments:

- Concomitant medications
- Adverse events
- Quality of life assessment
- Imaging of lesion(s) / stent(s)

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.