GORE® VIABAHN® FORTEGRA

Venous Stent

INSTRUCTIONS FOR USE

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INSTRUCTIONS FOR USE
***GORE® VIABAHN®* FORTEGRA VENOUS STENT**

Carefully read all instructions prior to use. Observe all indications, instructions, warnings, and precautions noted throughout. Failure to do so may result in complications. The GORE® VIABAHN® FORTEGRA Venous Stent should only be used by physicians experienced in interventional techniques.

PRODUCT DESCRIPTION

The GORE® VIABAHN® FORTEGRA Venous Stent is an open-structure, self-expanding, permanently implantable stent constructed of a wire- wound nitinol frame and an FEP-ePTFE (fluorinated ethylene propylene - expanded polytetrafluoroethylene) polymer lattice. Each implant includes radiopaque markers at each end to facilitate fluoroscopic visualization. The intended purpose of the GORE® VIABAHN® FORTEGRA Venous Stent is to serve as a scaffold to maintain an open vessel lumen.

The GORE® VIABAHN® FORTEGRA Venous Stent device is designed to improve blood flow in patients with symptomatic venous outflow obstruction. Potential 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).

The GORE® VIABAHN® FORTEGRA Venous Stent is delivered to the intended treatment site on a flexible delivery catheter of varied length and profile depending on the stent diameter and length. The implant is delivered using established endovascular procedures common to other commercially available stents and stent-grafts.

Accepted procedures require the use of appropriate introducer sheaths, guide catheters and guidewires to gain access to the intended treatment site. In the case of post-thrombotic syndrome, the venous lesion may be pre-dilated using a 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. **Figure 1** displays a representation of the implant.

Delivery System

The delivery system is comprised of the following components: a radiopaque distal tip, a distal catheter, a proximal catheter and a constraining system actuator. The implant is radially constrained on the distal end of the catheter. The profile of the device varies from 10 Fr to 14 Fr, depending on the configuration. **Figure 2** displays a representation of the delivery system with the constrained implant.

Figure 1. GORE® VIABAHN® FORTEGRA Implant (Stent)

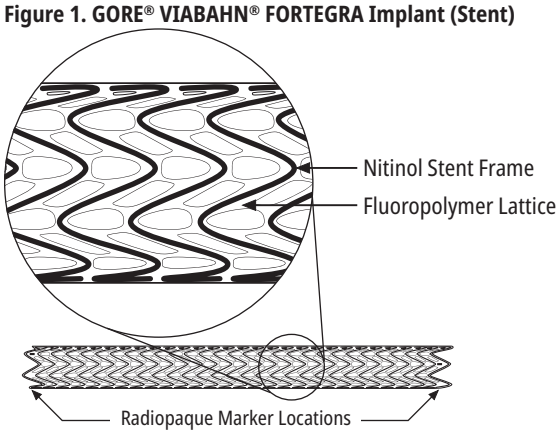


Figure 2. GORE® VIABAHN® FORTEGRA Device

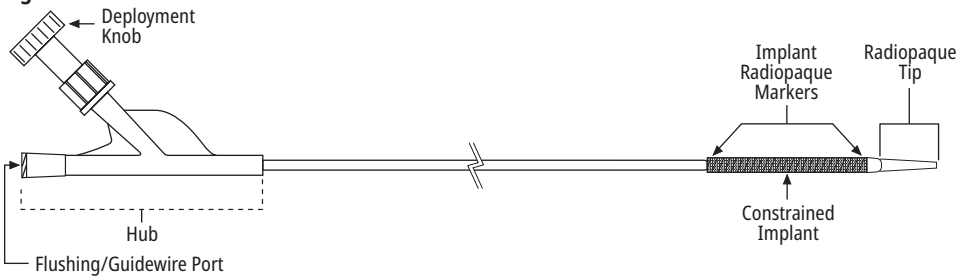


Table 1. GORE® VIABAHN® FORTEGRA Venous Stent

Labeled Device Diameter (mm)	Recommended Vessel Diameter (mm)	Introducer Sheath Size (Fr)*	Recommended Balloon Diameter for Pre- & Post-Dilation (mm)	Available Device Lengths (mm)	Guidewire Diameter (Stiff)	Implant Radiopaque Markers	Deployment Direction
10	7-9	10	10	50, 75, 100, 150	0.035" (0.889 mm)	Yes	Tip to Hub
12	9-11	11	12				
14	11-13	11	14				
16	13-15	11	16				
18	15-17	12	18				
20	17-19	12	20				
24	18-22	14	24**				
28	22-26	14	28**				

* All devices are compatible with the GORE® DrySeal Sheath at the profiles noted in **Table 1**. If necessary, sheaths may be upsized by ≥1 Fr.

- GORE® VIABAHN® FORTEGRA Venous Stent 10-20 mm devices are not compatible with the Cook CHECK-FLO® FLEXOR® sheath or the Abbott FAST-CATH™ Introducer sheath at the profiles noted above.
- The 16 mm diameter device is not compatible with the Cordis AVANTI® Sheath Introducer or the Cordis BRITE TIP® Sheath Introducer at the profile noted above.
- Do not use any introducer sheath that does not have an atraumatic tip (e.g., Inari Protrieve™ Sheath).

** Parallel balloons may be used: two 14-16 mm balloons in a 24 mm GORE® VIABAHN® FORTEGRA Venous Stent, or two 14–18 mm balloons in a 28 mm GORE® VIABAHN® FORTEGRA Venous Stent.

The overall qualitative and quantitative information on the implant materials to which patients are potentially exposed is listed below in **Table 2**.

Table 2. GORE® VIABAHN® FORTEGRA Venous Stent Implant Materials

Material	Approximate Maximum Weight per Implantable Device (mg)
Fluoropolymers (ePTFE, FEP, TFE, PMVE)	600
Nitinol	3825
Gold	30

Note: These values represent the maximum weight of each material per device, across all device sizes. The weight of each material may be less for a given device size.

ePTFE=expanded polytetrafluoroethylene, FEP=fluorinated ethylene propylene, TFE= Tetrafluoroethylene, PMVE= Perfluoromethyl Vinyl Ether, Nitinol=nickel-titanium alloy.

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.

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.

WARNINGS AND PRECAUTIONS

Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient (see *ADVERSE EVENTS*).

WARNINGS

- Stent should be sized and placed in an appropriately sized vessel per **Table 1** by confirming vessel diameter and lesion length via an appropriate imaging modality that can visualize the vessel cross-section (e.g., intravascular ultrasound [IVUS]). Failure to properly size the device and/or the use of short-length, non-overlapped devices (e.g., ≤ 50 mm) may result in stent embolization or migration, malapposition, malposition, interaction with cardiac tissue or vessel wall and related serious harms, including surgical conversion, secondary endovascular procedures, cardiac tamponade, and pericardial effusion.
- If resistance is felt during advancement or withdrawal of the guidewire, sheath, or catheter, stop and assess the cause of resistance. Do not apply excessive or abrupt force to the guidewire, sheath, or catheter. Vessel perforation, dislodgment of previously implanted devices, damage to the implant, delivery catheter damage, or introducer sheath damage and related serious patient harms may occur.
- Exercise caution during the periprocedural period if considering venoplasty and stent placement in patients with prior history of retroperitoneal surgical intervention around the iliocaval vasculature, radiation therapy, or retroperitoneal fibrosis. In these clinical scenarios, patients may be at increased risk for complications such as enteric-caval fistula development and free caval rupture following implant placement, where permanent injury and/or death have been reported in literature.
- Do not use if the package is opened or damaged, or it is suspected that the sterility of the device has been compromised, as infection and related serious potential patient harms could occur.
- Inspect the device once removed from the packaging. Do not use if the GORE® VIABAHN® FORTEGRA Venous Stent is damaged, as deployment difficulties or failure may occur.

- Reuse may result in infection and related serious potential patient harms. Reuse may cause device failure or procedural complications, including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death. See *HOW SUPPLIED*.
- The GORE® VIABAHN® FORTEGRA Venous Stent implant contains ePTFE, FEP, TFE, PMVE, nitinol (nickel-titanium alloy), and gold. Persons with allergic reactions to these materials may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy to the materials.
- Do not use a kinked introducer sheath. A kinked introducer sheath may increase the force necessary to deploy the implant and may cause a deployment failure or catheter breakage on removal and related serious patient harms.
- Do not attempt to deploy the implant or manipulate the delivery system without an appropriately sized guidewire (**Table 1**) and fluoroscopic guidance. Device failure or procedural complications including device damage, vessel damage, displacement of previously implanted devices, or patient serious injury may occur.
- Do not withdraw the GORE® VIABAHN® FORTEGRA Venous Stent back into the introducer sheath once the constrained implant is fully introduced. If removal prior to deployment is necessary, withdraw the constrained device to a position close to, but not into, the introducer sheath. Both the constrained device and introducer sheath can then be removed in tandem. After removal, do not reuse the device or introducer sheath. Withdrawing the GORE® VIABAHN® FORTEGRA Venous Stent back into the sheath, or device use following removal, can cause vessel damage, damage to the implant, premature deployment, deployment failure, and/or catheter separation.
- Inadvertent, partial, or failed deployment or migration of the implant may require surgical intervention.

PRECAUTIONS

The following precautions should be considered to ensure the safe and effective use of the device and protect the safety of the patient.

- Do not use the GORE® VIABAHN® FORTEGRA Venous Stent in patients unable to undergo, or who will not be compliant with, the necessary pre- and post-operative imaging, medication, and follow-up.
- Do not bend, kink, or otherwise alter the delivery system prior to implantation because it may cause deployment difficulties.
- Patients should receive an antithrombotic regimen pre-, peri-, and post-procedure, as deemed appropriate by the treating physician.
- Systemic anticoagulation based on hospital- and physician-preferred protocol should be used during the implantation procedure to prevent thrombotic complications. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Use caution in patients with a history of intolerance or adverse reaction to antiplatelet and/or anticoagulation therapies, bleeding diathesis, severe hypertension, or renal failure.
- Inadequate inflow feeding the target vessel is a known predictor of stent patency loss. Consider alternative or additional treatments to ensure adequate inflow.
- Safety and effectiveness of the use of GORE® VIABAHN® FORTEGRA Venous Stent within an IVC filter have not been established. Removal of an IVC filter should be considered prior to stent implantation when clinical benefits outweigh procedural risks (e.g., IVC tear/rupture due to embedded filter removal and related potential serious harms). Risks associated with implantation within an IVC filter include potential complications due to interaction of the IVC filter with adjacent structures, such as the aorta or duodenum, or embolization of portions of the IVC filter and related potential serious harms.
- Safety and effectiveness of stenting with contralateral access has not been established. Utilizing the device with contralateral access may lead to deployment inaccuracy.
- Do not use an introducer sheath that does not have an atraumatic tip or a sheath that is incompatible with the GORE® VIABAHN® FORTEGRA Venous Stent. Inability to pass the delivery system, sheath damage, or delivery catheter damage may occur. See **Table 1** for sheath compatibility.
- Do not attempt to reposition the GORE® VIABAHN® FORTEGRA Venous Stent after vessel wall apposition has occurred, as vessel wall damage or device misplacement may result.
- *In situ* catheter component separation, which is possible with any endovascular device, could result in patient harm, particularly if the detached component is not detected. If catheter separation occurs, use best medical judgment to determine the appropriate course of action for the patient (e.g., use interventional techniques to snare and safely remove the separated component).
- Failure to post-dilate along the entire length of the implant may lead to restenosis and implant failure.
- Do not overinflate the balloon. Balloon over-inflation may result in balloon or vessel rupture, implant damage, and associated patient harms.
- Ensure complete deflation of the balloon prior to removal of the balloon catheter to prevent implant displacement.
- Do not extend balloon dilatation beyond the ends of the device and into healthy vessel, as this may also induce restenosis and subsequent implant failure.
- Stent patency should be evaluated and monitored early and regularly during follow-up. If reduced blood flow through any device or occlusion of a device is observed, a secondary intervention or surgical procedure may be required to re-establish flow if clinically necessary.

MR SAFETY

Nonclinical testing has demonstrated that the GORE® VIABAHN® FORTEGRA Venous Stent is MR Conditional. A patient with this device can be scanned under the conditions detailed in the *MRI SAFETY INFORMATION* section.

ADVERSE EVENTS

POTENTIAL DEVICE AND PROCEDURE-RELATED ADVERSE EVENTS

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

Refer to IFU Section *WARNINGS AND PRECAUTIONS* for any additional information regarding adverse events and any steps that should be taken to avoid them, as well as information about other warnings and precautions.

CLINICAL AND DEVICE ADVERSE EVENT REPORTING

Any adverse event involving the GORE® VIABAHN® FORTEGRA Venous Stent should be reported to the manufacturer and the country-specific regulatory authorities immediately. To report an event to W. L. Gore & Associates, email: medcomplaints@wlgore.com or contact (as applicable)

US: Phone: +1 800 528 1866 or +1 928 864 4922

China: Phone: +86 21 5172 8299

Japan: Phone: +81 3 6746 2562

Brazil: Phone: +55 11 5502-7953

EMEA: Phone: +49 89 4612 3440

For patients in Australia: Report any serious incident in relation to this device to the Therapeutic Goods Administration: https://www.tga.gov.au/reporting-problems.

To report an adverse event to W. L. Gore & Associates in all other markets, please use the email above (medcomplaints@wlgore.com) or call the US phone number (+1 800 528 1866 or +1 928 864 4922).

HOW SUPPLIED

CONTENTS

The GORE® VIABAHN® FORTEGRA Venous Stent is preloaded on a delivery catheter.

STERILITY

- The GORE® VIABAHN® FORTEGRA Venous Stent is provided STERILE and non-pyrogenic, and is sterilized by ethylene oxide (EtO) sterilization. Do not resterilize.
- Do not use after the "Use By" (expiration) date printed on the label.
- The GORE® VIABAHN® FORTEGRA Venous Stent is designed for single use only; do not reuse device. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination that may lead to patient harms (See *WARNINGS*).

STORAGE AND HANDLING

- Keep dry and store at 15°C to 30°C.
- Do not use the GORE® VIABAHN® FORTEGRA Venous Stent if the pouch is compromised or if the device is damaged.
- To open the package, remove the pouch from the carton. Beginning at one corner, peel back the edge of the inner pouch and gently remove the sterile GORE® VIABAHN® FORTEGRA Venous Stent.
- Use clean sterile gloves or atraumatic sterile instruments when handling the GORE® VIABAHN® FORTEGRA Venous Stent.
- Handle and dispose of the device and packaging, taking into account any infectious or microbial hazard risks, with the necessary precautionary measures in accordance with acceptable medical practice and with applicable local, state, and federal laws and regulations.
- See *WARNINGS AND PRECAUTIONS* for additional considerations specific to storage and handling.

For additional Storage and Handling information, see *HOW SUPPLIED*.

DIRECTIONS FOR USE

PHYSICIAN TRAINING REQUIREMENTS

The GORE® VIABAHN® FORTEGRA Venous Stent should only be used by physicians experienced in interventional techniques, and who have successfully completed the appropriate physician training program (e.g., board certification).

MATERIALS

The following are required accessories for use with GORE® VIABAHN® FORTEGRA Venous Stent:

- Stiff guidewire: diameter must be 0.035" (0.889 mm) and length at least twice the length of the GORE® VIABAHN® FORTEGRA Venous Stent delivery catheter
- Introducer sheath of appropriate size (**Table 1**)

- Appropriate anticoagulation drugs
- Syringe filled with heparinized saline
- Appropriate high-pressure angioplasty balloon catheters and accessories (**Table 1**)
- Appropriate diagnostic catheters and accessories
- Intravascular ultrasound (IVUS) catheters, equipment, and accessories

The following are optional accessories for use with GORE® VIABAHN® FORTEGRA Venous Stent:

- Marker guidewire or catheter (for calibrated measurement reference)

Accessory, auxiliary, and ancillary materials (equipment and tools) should be used in accordance with the manufacturer's instructions for use. Reference the manufacturer's instructions for use and any supporting clinical literature regarding any potential warnings, precautions, and adverse reactions related to materials listed above.

PATIENT SELECTION AND RECOMMENDED DEVICE SIZING

A physician should determine if a particular patient and anatomy is suitable for proper use of the GORE® VIABAHN® FORTEGRA Venous Stent. See *WARNINGS AND PRECAUTIONS* for additional considerations specific to the procedure.

The device should be properly sized by the physician to fit the patient's anatomy (see **Table 1**). Failure to implant a device within the sizing matrix could lead to harms such as those listed in this IFU (see *WARNINGS AND PRECAUTIONS*).

IMPLANT PROCEDURE

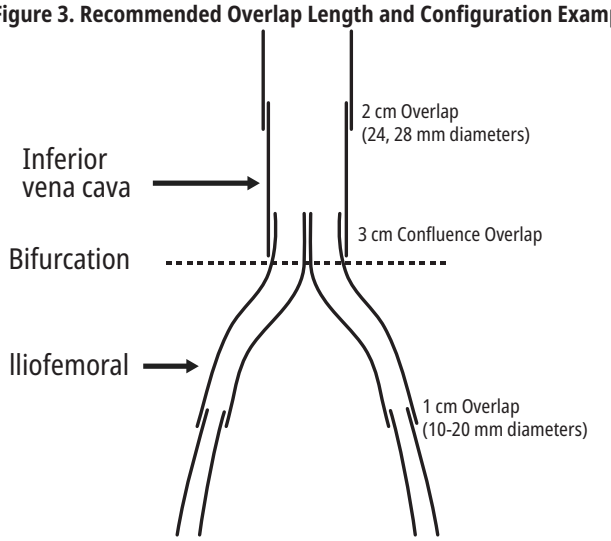
Required materials and accessory devices should be used in accordance with the manufacturer's instructions for use. Reference the manufacturer's instructions for use and any supporting clinical literature regarding any potential warnings, precautions, and adverse reactions related to required materials and accessory devices.

See *WARNINGS AND PRECAUTIONS* for additional considerations specific to the procedure.

1. **Access**
   a. Using appropriate anesthesia, access is achieved using the appropriate vessel. When possible, a percutaneous Seldinger vascular access technique is preferred for vascular access. A cutdown may be performed.
   b. Using standard technique, insert the appropriately sized vascular introducer sheath into the vessel and intraluminally traverse the lesion.
2. **Imaging and Measurement**
   a. To achieve accurate vessel measurement, correctly identify diseased and healthy vessel segments, and to ensure precise sizing and placement of the implant per **Table 1**, use intravascular ultrasound (IVUS) to augment image-centered, magnified-view contrast angiography, including a marker guidewire or catheter.
3. **Percutaneous Transluminal Angioplasty (PTA)**
   a. Pre-dilate the target vessel to the reference vein diameter prior to stent implantation to ensure that the implant is not deployed into a lesion that cannot be ballooned to recommended minimum vessel diameters (see **Table 1**).
   b. Refer to PTA manufacturer's Directions for Use.
   c. Inflate the angioplasty balloon to its nominal pressure according to manufacturer's Directions for Use. Ensure adequate expansion of the balloon within the lesion.
   Note: Carefully mark the margins of the angioplasty treatment segment in order to ensure the implant completely covers the entire vessel segment treated with balloon angioplasty.
   d. Be sure to remove the balloon catheter while maintaining the position of the guidewire beyond the target lesion.
4. **Sizing and Selection of the GORE® VIABAHN® FORTEGRA Venous Stent**
   a. Following deflation of the angioplasty balloon, evaluate the results angiographically and measure with IVUS. For reference, measure the native vessel diameter, lesion length, and residual percent stenosis, ensuring the entire diseased vessel segment(s) will be treated.
   b. Prior to opening the sterile package, check that the diameter and length of the implant are correct before removing from the packaging.
      i. In selecting the appropriate size implant, a careful assessment of the vessel is necessary. To assure adequate anchoring, the diameter of the GORE® VIABAHN® FORTEGRA Venous Stent implant should be approximately 1-3 mm larger (10-20 mm nominal diameter implants) or 2-6 mm larger (24, 28 mm nominal diameter implants) than the healthy vessel diameter immediately adjacent to the lesion.
      ii. The implant lengths of the GORE® VIABAHN® FORTEGRA Venous Stent listed in **Table 1** are nominal. Therefore, it is suggested that the implant overlap the native vessel at least 1 cm (10-20 mm nominal diameter implants) or 2 cm (24, 28 mm nominal diameter implants) beyond the proximal and distal margins of the lesion.
      iii. Verify that there is sufficient catheter length to access the treatment site.
   c. When overlapping multiple devices, the following are suggested:
      i. If vessel recoil or visual malapposition is present after stent deployment, balloon touch-up (post-dilatation) of the first device prior to placing a second device is recommended. Otherwise, balloon touch-up (post-dilatation) may be performed after multiple stents are deployed, if appropriate.
      ii. If the diameters of the overlapping devices are not equal, the larger device should be placed first, and the smaller device should be placed inside of the larger device.
      iii. 10-20 mm nominal diameter implants: Overlapping devices should not differ by more than 2 mm in diameter. To ensure proper seating, at least 1 cm of overlap between devices is suggested.
      iv. 24, 28 mm nominal diameter implants: To ensure proper seating, at least 2 cm overlap between devices is suggested.
      v. Confluence stenting:
         - When two smaller vessels join to form a larger vessel (e.g., the iliac-inferior vena cava confluence), place the larger device first followed by deployments of smaller devices. If bilateral access is obtained, consider retracting the second wire from the deployment location of the larger device to prevent capturing the wire between the implant and the native vessel.
         - Once the larger implant is deployed, ensure intraluminal traversal of the wire that was just retracted to facilitate placement of confluence implants. Take care to avoid any length of guidewire on the outside of the stent lumen (e.g., the guidewire can traverse the stent lumen outside of one or multiple stent struts when intraluminal stent cannulation is not confirmed).

- Extend the smaller devices 3 cm into the larger device to ensure continuous lesion coverage.
- To ensure apposition and proper oversizing during and after deployment, the diameter of the smaller diameter devices should be greater than ½ the diameter of the larger devices, e.g., two ≥14 mm iliac devices used with a 24 mm IVC device, or two ≥16 mm iliac devices used with a 28 mm IVC device.

Figure 3. Recommended Overlap Length and Configuration Example for Iliocaval Confluence Stenting (Subject to Anatomical Considerations)



5. Preparation of the GORE® VIABAHN® FORTEGRA Venous Stent

a. Open the carton and remove the pouch (sterile barrier). Carefully inspect the packaging for damage to the sterile barrier. **Do not use the GORE® VIABAHN® FORTEGRA Venous Stent after the "Use By" (expiration) date**. Beginning at one corner, peel back the edge of the inner pouch and gently remove the sterile coil containing the GORE® VIABAHN® FORTEGRA Venous Stent.

b. Inspection prior to use:

i. Prior to using the GORE® VIABAHN® FORTEGRA Venous Stent, all materials and equipment to be used for the procedure should be carefully examined for bends, kinks, or other damage.

ii. Do not use any defective equipment.

iii. **Do not use the GORE® VIABAHN® FORTEGRA Venous Stent if the sterile package is compromised or the GORE® VIABAHN® FORTEGRA Venous Stent is damaged.**

c. Preparation of the GORE® VIABAHN® FORTEGRA Venous Stent delivery catheter:

i. Flush the delivery catheter by attaching a syringe of heparinized saline to the flushing port on the catheter hub assembly (**Figure 2**). Continue flushing until a steady stream of fluid exits the tip of the catheter.

ii. After flushing the catheter, remove the syringe.

6. Introduction and Positioning of the GORE® VIABAHN® FORTEGRA Venous Stent

a. Select the compatible size introducer sheath from **Table 1**.

b. Ensure the stiff guidewire is 0.035" (0.889 mm).

c. With the delivery catheter as straight as possible, insert the guidewire into the tip of the delivery catheter while supporting the delivery catheter and the constrained implant. Carefully advance the implant in small increments (approximately 0.5 cm) over the guidewire, through the hemostasis valve and introducer sheath, and into the access vessel.
Note: If excessive resistance is felt as the GORE® VIABAHN® FORTEGRA Venous Stent is introduced through the hemostasis valve and/or introducer sheath, remove and inspect the delivery system for damage. Do not reuse the GORE® VIABAHN® FORTEGRA Venous Stent if damaged. Confirm that the introducer sheath size is compatible (**Table 1**), and that the introducer sheath is free of kinks.

d. Using fluoroscopic guidance, advance the delivery catheter over the guidewire via the introducer sheath. Advance cautiously, especially if resistance is felt. If excessive resistance is felt, remove the delivery catheter and introducer sheath together while maintaining guidewire access.

e. Position the GORE® VIABAHN® FORTEGRA Venous Stent across the target lesion using fluoroscopic guidance.
Note: If PTA is performed, the implant length should cover the entire vessel segment treated with balloon angioplasty. To optimize accurate device placement, advance the constrained device slightly beyond the delivery target landing zone to align the leading end implant radiopaque markers with the target deployment location. For larger vessels or deployments where leading end device struts do not contact the vessel wall immediately upon expansion of stent (e.g., at the ostium of the common iliac vein at the iliocaval confluence), consider advancing the constrained device further to accommodate potential device pullback.

f. Once the optimal position is verified fluoroscopically, the implant is ready to be deployed.
Note: Should it become necessary to remove the GORE® VIABAHN® FORTEGRA Venous Stent from the vessel prior to deployment, do not withdraw the GORE® VIABAHN® FORTEGRA Venous Stent back into the introducer sheath after the implant is fully introduced. To remove the GORE® VIABAHN® FORTEGRA Venous Stent prior to deployment, the GORE® VIABAHN® FORTEGRA Venous Stent can be withdrawn to a position close to, but not into, the introducer sheath. Both the GORE® VIABAHN® FORTEGRA Venous Stent and introducer sheath can then be removed in tandem. After removal, neither the GORE® VIABAHN® FORTEGRA Venous Stent nor the introducer sheath should be reused.

7. Deployment of the GORE® VIABAHN® FORTEGRA Venous Stent

a. Stabilize the delivery catheter at the hemostasis valve of the introducer sheath. It is also important to stabilize the delivery catheter and introducer sheath relative to the patient. This will minimize catheter movement during deployment and ensure accurate implant positioning. Consider pausing respiration during deployments in the abdominal/thoracic cavity to optimize deployment accuracy.

b. Untwist the screw-connector at the base of the deployment knob. While keeping the extracorporeal segment of the catheter as straight as possible, pull the deployment knob away from the adapter using a steady and continuous motion until the entire length of the stent is deployed. Prior to achieving vessel apposition, the stent may be repositioned.

c. Combined deployment/KD technique: For placement of confluence stents, position the two smaller diameter device markers with sufficient overlap into a larger implant, as noted above. The smaller diameter device markers should be at equal position fluoroscopically. Untwist the screw connector of both implants and simultaneously pull both deployment knobs using a steady and continuous pull. Ensure both devices are fully deployed prior to withdrawal of either delivery system.
Note: to ensure parallel devices open simultaneously, the same diameter and length devices should be used. Unequal length/diameters may be used, but devices will not open simultaneously.

d. **Deployment of the implant will occur from the tip of the delivery catheter toward the hub.**
Note: Once the implant is apposed to the vessel wall, repositioning of the implant could result in vessel wall damage.

e. While maintaining the position of the guidewire across the treated lesion, carefully withdraw the delivery catheter through the lumen of the implant and remove it via the introducer sheath. Moderate resistance may be felt when the distal tip is withdrawn through the introducer sheath.
Note: If, during catheter removal, the tip catches on the implant or introducer sheath, a slight "back and forth" motion, removing guidewire bias against the vessel wall by rotating of the delivery catheter or use of PTA balloons, or repositioning of the introducer sheath may aid in release. Excessive or abrupt force during catheter removal may damage the implant, delivery catheter, or introducer sheath.

f. Verify all catheter components are intact, and discard the used delivery system per applicable hospital procedures.

g. After deployment, the implant must be smoothed and seated against the vessel wall by inflating an angioplasty balloon within it. Touch-up balloon diameter(s), including the use of double barrel balloons, should be selected according to **Table 1**. Angioplasty balloon should be inflated to the desired diameter along the entire length of the implant. If the implant length exceeds that of the balloon, multiple inflations may be needed. If vessel recoil or visual malapposition is present, post-dilate following each deployment. Failure to post-dilate along the entire length of the implant may lead to restenosis and implant failure.

h. After the balloon is inflated throughout the implant, attention is required to ensure complete deflation of the balloon prior to cautious removal of the balloon catheter to prevent implant displacement. Do not extend balloon dilatation beyond the ends of the device and into healthy vessel, as this may induce restenosis and subsequent implant failure.

i. If multiple overlapping devices are utilized, see Sizing and Selection of the GORE® VIABAHN® FORTEGRA Venous Stent section above.

8. COMPLETION OF PROCEDURE

a. Using IVUS and contrast angiography, evaluate the treated segment prior to completing the procedure. Further balloon inflations may be necessary if residual implant folds or invaginations are visualized. A final angiographic run to evaluate vessel inflow and outflow patency is recommended.

b. Prior to removing wires and sheaths, verify all catheter components have been withdrawn from the patient.

c. When clinically appropriate, remove the introducer sheath and achieve hemostasis of the puncture site.

d. Administer/prescribe postoperative drug therapies.

e. Inform patient of any required/desired appropriate postoperative care (e.g., when and which type of physician to follow- up with, what to do/not to do during recovery period, etc.).

See *WARNINGS AND PRECAUTIONS* for additional considerations specific to the procedure.

CLINICAL INVESTIGATIONS

PIVOTAL CLINICAL INVESTIGATION – IDE Number G220109

Study Design

This study is a prospective, multicenter, non-randomized, single-arm study to evaluate the performance, safety, and effectiveness of the GORE® VIABAHN® FORTEGRA Venous Stent for treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction in adult patients (at least 18 years of age).

The primary endpoint for this study is a composite of both safety and effectiveness. A performance goal was derived from a meta-analysis of relevant inferior vena cava stenting literature in combination with iliofemoral device trial results. All subjects were scheduled to return for follow-up examinations at 1 month, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months.

Imaging is analyzed by an independent Core Laboratory. Endpoints are evaluated using a combination of site reported events, Core Lab Evaluation, and Clinical Events Committee (CEC) adjudication. An independent Data Safety Monitoring Board (DSMB) monitors study safety.

Study Objective

Establish the safety and effectiveness of the GORE® VIABAHN® FORTEGRA Venous Stent for treatment of symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.

Primary Study Endpoint

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 below 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 3** below. A two-sided 90% exact confidence interval (CI) was constructed (α = 0.05). A statistical analysis plan was followed for the study.

The primary endpoint was assessed through a composite primary 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 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.

Secondary Study Endpoints

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 3. 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 ≥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 ≤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.

Patient Population

Eighty-nine (89) adult patients with symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction received implants in 17 total centers located in the United States, Europe, Australia, and New Zealand. Twenty-four investigators treated patients from October 2022 through April 2024.

Key Inclusion/Exclusion Criteria

Enrollment in the Pivotal Study was limited to patients who:

- had a non-malignant obstruction of the inferior vena cava and may include common femoral vein, external iliac vein, and/or common iliac vein
- were at least 18 years of age
- had a CEAP 'C' clinical severity classification ≥3 or rVCSS pain score ≥2
- were ambulatory, and
- had adequate inflow to the target lesion(s) (per investigator discretion).

Patients were excluded who:

- were pregnant or breastfeeding, planned to become pregnant through the 12-month visit
- had a clinically significant PE at the time of enrollment
- had a known history of antiphospholipid syndrome
- had a known homozygous inherited coagulation defect or Protein C/S deficiency
- had a previous major amputation of the target lower limb
- had significant peripheral arterial disease
- had a BMI >40
- was actively undergoing or planned to begin cancer treatment
- had significant acute thrombus within the target stent area at the time of investigational device placement, or had an inferior vena cava filter present within the target stent area; patients with an inferior vena cava filter present within the target stent area were required to have the filter successfully removed prior to investigational device placement.

Demographics and Clinical Characteristics for Treated Subjects

Subject baseline demographic information is displayed in **Table 4**. Medical History and Risk Factors are displayed in **Table 5**. Data may not be available for all 89 patients (e.g., ethnicity and race were not collected for the treated European subjects in accordance with regional requirements, and procedural images failed to save for one patient and were not available for evaluation).

Table 4. Subject Baseline Demographic Information

Sex at birth	
Female	34/89 (38.2%)
Male	55/89 (61.8%)
Age (years)	
Mean (Std Dev)	50.9 (16.81)
Min - Max	18 - 94
Ethnicity	
Hispanic	4/61 (6.6%)
Non-Hispanic	57/61 (93.4%)
Race	
American Indian or Alaska Native	0/61 (0.0%)
Asian	0/61 (0.0%)
Black	16/61 (26.2%)
Pacific Islander	0/61 (0.0%)
White	44/61 (72.1%)
Maori	1/61 (1.6%)

Table 5. Medical History and Risk Factors

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%)
Upper extremity DVT	3/89 (3.4%)
Lower extremity DVT	72/87 (82.8%)
Venous thrombectomy	17/88 (19.3%)
IVC filter placement	37/89 (41.6%)
IVC atresia	18/88 (20.5%)
Pulmonary embolism	31/88 (35.2%)
Orthopedic surgery	15/89 (16.9%)
Superficial venous disease	46/88 (52.3%)
Varicose veins	43/89 (48.3%)
Varicose vein treatment	5/88 (5.7%)
Saphenous vein stripping/occlusion	3/89 (3.4%)
Factor V Leiden	10/86 (11.6%)
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%)
Most Severe Clinical C Classification[1]	
C0	1/89 (1.1%)

C1	0/89 (0.0%)
C2	2/89 (2.2%)
C3	41/89 (46.1%)
C4	13/89 (14.6%)
C5	5/89 (5.6%)
C6	9/89 (10.1%)
Oral contraceptive use	
Current	2/28 (7.1%)
Former	16/28 (57.1%)
Never	10/28 (35.7%)
Cancer	
Ongoing	1/88 (1.1%)
Resolved	12/88 (13.6%)
No	75/88 (85.2%)
Nicotine/Tobacco use	
Never	52/89 (58.4%)
Current	10/89 (11.2%)
Former	27/89 (30.3%)
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%)
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%)
Stroke	11/89 (12.4%)

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

Procedure and lesion characteristics for treated subjects are summarized in **Table 6**. The mean procedure time was 193.1 (96.41) 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 below.

Table 6. Procedure and Lesion Characteristics[2]

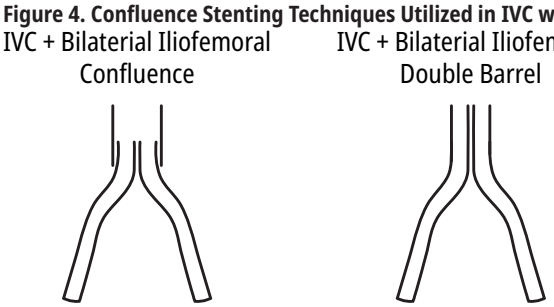
Procedure duration (minutes): Incision to access closure[1]	
Mean (Std Dev)	193.1 (96.41)
Number of devices implanted per subject	
Mean (Std Dev)	5.3 (1.68)
Anesthesia method	
General	85/89 (95.5%)
Local	4/89 (4.5%)
Estimated blood loss (mL)	
Mean (Std Dev)	104.5 (185.48)
Study device placed across inguinal ligament	61/89 (68.5%)
Lesion location (multiple lesions per subject possible)	

Supra-renal IVC	31/86 (36.0%)
Infra-renal IVC	86/88 (97.7%)
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	
Isolated IVC	4/88 (4.5%)
IVC + Unilateral Iliofemoral	1/88 (1.1%)
IVC + Bilateral Iliofemoral	83/88 (94.3%)
IVC + Bilateral Iliofemoral Technique (see **Figure 4**)	
Confluence	80/83 (96.4%)
Double Barrel	3/83 (3.6%)
Stented length - total (cm)	
Mean (Std Dev)	41.2 (13.13)
Min - Max	6.1-72.9

[1] Procedure duration includes adjunct procedures such as IVC filter retrieval and thrombectomy.

[2] Lesion characteristics (lesion location and stented length) are based on venographic Core Lab measurements, and 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.

Figure 4. Confluence Stenting Techniques Utilized in IVC with Bilaterial Iliofemoral Disease Patients



RESULTS

Composite Primary Safety and Effectiveness Endpoint Results

The primary endpoint for the VNS 21-05 study included both safety and effectiveness components as presented in **Table 7**. 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 performance goal (PG) for freedom from primary endpoint events 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% (see **Table 7**). 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.

Table 7. Hypothesis Testing of Composite Primary Endpoint

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 ≤ 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 loss of 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%)

[1] Of 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 8**, nine of the 10 excluded subjects could have failed while still rejecting the null hypothesis.

Table 8. 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

[1] Composite 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.

Secondary Endpoints

See **Table 9** for primary patency, secondary patency, and clinically driven target lesion revascularization (CD-TLR) secondary endpoint analysis performed by subject and by vessel region (up to 3 per patient - inferior vena cava (IVC), left iliofemoral (IF) veins, and right iliofemoral (IF) veins, and all regions, which is the combination of all three regions).

Table 9. Primary Patency, Secondary Patency, & CD-TLR results through 12 months[1]

Endpoint	Subject	Vessel Region			
		All Regions n = 255	IVC n = 88	Left IF n = 83	Right IF n = 84
Primary Patency	83.4%	91.8%	96.5%	88.9%	89.8%
Secondary patency	95.1%	97.5%	98.8%	97.5%	96.1%
Freedom from CD-TLR	89.7%	94.8%	97.7%	91.4%	95.1%

[1] Calculated using Kaplan-Meier Estimation through 365 days. N listed is at the start of interval

One secondary endpoint, mean improvement in rVCSS pain measurement of -1 at 12 months from baseline, was evaluated using a one-sample Wilcoxon signed rank test as shown in **Table 10**. 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. The 63 evaluable subjects presented with a baseline rVCSS pain score of at least 1 and were therefore eligible for improvement. The rVCSS pain score improved by a mean of 1.4, meeting the secondary endpoint ($p<0.001$). Additionally, of the 13 subjects presenting with a baseline rVCSS pain score of 0, none had worsening of pain at the 12-month visit.

Table 10. rVCSS Pain Measurements Hypothesis Test at 12 months

Subjects Available for rVCSS Pain Score Assessment	63
Mean difference in rVCSS pain score (Std Dev)	-1.4 (1.03)
Median difference in rVCSS Pain Score	-2.0
p-Value for testing the null hypothesis that the improvement in rVCSS pain score < -1	<0.001

Table 11 describes other key secondary endpoints through 12 months. There have been no device fractures observed in the study. 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 GORE® VIABAHN® FORTEGRA Venous Stents during the procedural period in all subjects.

Table 11. Secondary endpoint results not already described above through 12 months

Freedom from device fracture	72/72 (100%)
Lesion Success	88/88 (100%)
Procedural Success	79/80 (98.8%)
Technical Success	85/89 (95.5%)
Change in rVCSS score (baseline mean, 12 months mean)[1]	5.5 (9.9, 4.4)
Change in Villalta score (baseline mean, 12 months mean)[1]	7.9 (11.9, 4.0)
Change in VEINES-QOL score (baseline mean, 12 months mean)[1]	30.8 (44.6, 75.4)
Change in EQ-5D-5L Index score (baseline mean, 12 months mean)[1]	0.1 (0.69, 0.79)
EQ-5D-5L Change in Functional Status - Baseline to 12 months[2]	Improved/No Change/Worsened
Mobility	28 (36.4%) / 37 (48.1%) / 12 (15.6%)
Self-Care	12 (15.6%) / 60 (77.9%) / 5 (6.5%)
Usual Activities	31 (40.3%) / 39 (50.6%) / 7 (9.1%)
Pain/Discomfort	40 (51.9%) / 29 (37.7%) / 8 (10.4%)
Anxiety/Depression	17 (22.1%) / 44 (57.1%) / 16 (20.8%)

[1] The difference between baseline and 12-month means showed improvement for each attribute.

[2] Improved = number of subjects that improved from baseline to 12-month follow-up visit, No Change = number of subjects that reported no change in score from baseline to 12-month follow-up visit, and Worsened = number of subjects that worsened from baseline to 12-month follow-up visit. Percentages are based on the number of subjects available for assessment.

Adverse Events

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 12** and **Table 13**, respectively. The percentages of subjects, as reported by the investigators, with any AEs 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. Within 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). And within 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 12. All Adverse Events for Treated Subjects through 12 months

	Cumulative Results Through 12 Months[1]
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]

	Cumulative Results Through 12 Months[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]
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]

	Cumulative Results Through 12 Months[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]
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]

	Cumulative Results Through 12 Months[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]
Hypoaesthesia	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]

	Cumulative Results Through 12 Months[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]
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]

[1] Format of 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 13. Serious Adverse Events for Treated Subjects through 12 months

	Cumulative Results Through 12 Months[1]
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]

[1] Format 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.

	Cumulative Results Through 12 Months[1]
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]
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]

[1] Format 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.

	Cumulative Results Through 12 Months[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]
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]

[1] Format 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.

	Cumulative Results Through 12 Months[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]

[1] Format 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.

Subgroup Analyses

Subgroup analysis on the composite primary endpoint was performed by sex (**Table 14**) and by geographical region (**Table 15**), 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 14. 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 15. 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%)	

The GORE® VIABAHN® FORTEGRA Venous Stent pivotal clinical investigation did not evaluate device safety or effectiveness in the pediatric population.

CONCLUSION

The GORE® VIABAHN® FORTEGRA Venous Stent pivotal clinical study evaluated the GORE® VIABAHN® FORTEGRA Venous Stent for treatment of symptomatic inferior vena cava (IVC) obstruction with or without combined iliofemoral obstruction. The 12-month primary endpoint was designed to compare the observed composite percentage of subjects in the study who maintained primary patency and were free from MAEs to the established performance goal, based on comparative literature. The observed endpoint rate was 74.7%, meeting the primary endpoint ($p<0.001$). Kaplan-Meier estimation of primary patency at 12 months was 83.4%, there were no device fractures or stent embolizations through 12 months, there were no clinically significant pulmonary embolisms and no device- or procedure-related vascular injuries through 30 days, 95.4% of subjects were free from device- or procedure-related major bleeding within 30 days, and one subject experienced a device- or procedure-related death (adjudicated as procedure related by the CEC). Kaplan-Meier estimation of patient-level secondary patency and freedom from clinically driven target lesion revascularization (CD-TLR) at 12 months were 96.2% and 89.7%, respectively. Clinically meaningful improvements were observed within venous clinical scoring scales (rVCSS and Villalta) and quality of life questionnaires (EQ-5D-5L and VEINES) between baseline and 12 months, and rVCSS pain measurement demonstrated a statistically significant ($p<0.001$) mean improvement of 1.4 on a scale of 0-3.

These results support that quality of life and clinical symptoms can be improved through stenting of the iliocaval veins with the GORE® VIABAHN® FORTEGRA Venous Stent. The benefits and risks observed within the trial were within performance expectations, supporting an acceptable risk/benefit profile for clinical use of the GORE® VIABAHN® FORTEGRA Venous Stent. Thus, the clinical study supports the conclusion that the GORE® VIABAHN® FORTEGRA Venous Stent is safe and effective in treating subjects with symptomatic inferior vena cava obstruction with or without combined iliofemoral obstruction.

MRI SAFETY INFORMATION

MR Conditional

MRI Safety Information

A patient with the GORE® VIABAHN® FORTEGRA Venous Stent may be safely scanned immediately after placement under the following conditions. Failure to follow these conditions may result in injury.

Device Name	GORE® VIABAHN® FORTEGRA Venous Stent
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	There are no RF excitation restrictions
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body averaged SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact. With a gradient echo pulse sequence in a 3.0T MR System, the artifact may extend up to 5 mm from the implant. Under these conditions, the central portion of the lumen was visible.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

PATIENT COUNSELING INFORMATION

Based on the specific patient condition and comorbidities, the healthcare provider determines the risks and benefits specific to the patient and suggests the most appropriate course of action. The healthcare provider should counsel the patient on the prescribed procedure and its associated devices and can include the following when discussing this device and procedure:

- Information about the device and procedure. See *INDICATIONS*, *PRODUCT DESCRIPTION*, and *DIRECTIONS FOR USE* sections.
- Potential advantages, risks, and differences between treatment options;
- The possibility that subsequent intervention, explant, or additional procedures may be required after initial repair;
- Potential limitation of safety and/or effectiveness data as required by regulatory agencies;
- Potential exposure to materials contained in the device including potential for allergy/hypersensitivity to these materials. See *PRODUCT DESCRIPTION*, *CONTRAINDICATIONS*, *WARNINGS* and *PRECAUTIONS* sections;
- Safety information about the device including potential adverse events and corresponding symptoms and recommended actions for the patient, if any. See *CONTRAINDICATIONS*, *WARNINGS*, *PRECAUTIONS* and *ADVERSE EVENTS* sections.
- The Patient Implant Card, which is provided with the device for you to give to the patient, and the Patient Information Leaflet (PIL), which is available to patients (in applicable regions) through: eifu.goremedical.com.

Patients should be counseled on the need for regular follow-up, even in the absence of obvious signs or symptoms of concern to the healthcare provider.

Healthcare providers should advise all patients on what signs or symptoms would indicate that it is important to seek prompt medical attention.

Clinical data support the safety and performance of the GORE® VIABAHN® FORTEGRA Venous Stent and provides assurance that the benefits outweigh the risks. Laboratory testing conducted by Gore simulates long term use and supports the performance and the safety of the product. While the device materials are intended to remain safe for the patient's lifetime, the *expected device lifetime* per regulatory requirements Regulation (EC) No 2017/745 of the European Parliament and of the Council is limited to 5 years due to factors such as: differing regulatory guidance and standards (Regulation (EC) No 2017/745 of the European Parliament and of the Council), available clinical follow-up data in literature, and clinical study follow-up time periods.

The *expected device lifetime* per regulatory requirements is not meant to be a recommendation or indication for reintervention or removal of the implant except as otherwise determined by the physician and/or per the applicable labeling. The *expected device lifetime* is based on normal conditions of use and is not meant to be a warranty or guarantee as the actual duration of clinical use or implantation of the implant for a particular patient may be shorter or longer than the *expected device lifetime* based on the patient's medical conditions, anatomy, or other medical treatment as well as procedure and clinical factors and decisions.

DEFINITIONS

EC REP Authorised Representative in the European Community

REF Catalogue Number

Caution

℞ Only CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

Consult Instructions for Use

Date of Manufacture

Do Not Resterilize

Do Not Reuse

Do Not Use if Package is Damaged

Importer into the European Community

Keep Dry

Manufacturer

MD Medical Device

MR Conditional

SN Serial Number

Single Sterile Barrier System

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

UDI Unique Device Identifier

Use By

Catheter Working Length

Delivery Profile

Diameter

Guidewire Compatibility

Introducer Sheath

Vessel Diameter

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES
Order Information: Tel.: +1 928 526 3030 • Tel.: +1 800 528 8763
Technical Information: Tel.: +1 928 779 2771 • Tel.: +1 800 437 8181

For international contact and additional product information,
visit goremedical.com

Consult Instructions for Use
eifu.goremedical.com

Together, improving life

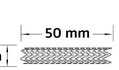
MD Medical Device

GORE® VIABAHN® FORTEGRA
Venous Stent

VS | **10 mm x 50 mm** | **10 Fr**
SELF EXPANDING

0.035”
Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	10 Fr	7-9 mm	10 mm



REF Catalogue Number VNS100502A
SN Serial Number 00000000000A
Use By **0000-00-00**

Do Not Resterilize
Keep Dry
MR Conditional
STERILE EO Sterilized using Ethylene Oxide
Store at 15°C to 30°C

Date of Manufacture
0000-00-00

(01)00733132663682
(17)0000000(21)000000000000A

#1 Contents: One (1) stent and one (1) delivery catheter.

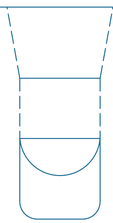
For product patent information, please refer to goremedical.com/patents.

MADE IN USA

VS GORE® VIABAHN® FORTEGRA Venous Stent | 10 mm x 50 mm | 10 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS100502A | SN 00000000000A | Use By 0000-00-00 | UDI (01)00733132663682 (17)0000000(21)000000000000A

20069165

Consult Instructions for Use
eifu.goremedical.com



Caution
Do Not Reuse
Do Not Use if Package is Damaged
℞ Only
Recyclable Packaging Material

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

goremedical.com

EC REP Authorised Representative in the European Community
W. L. GORE & ASSOCIATES B.V.
Ringbaan Oost 152A
5013CE Tilburg
NETHERLANDS

Importer into the European Community

MD Medical Device

GORE® VIABAHN® FORTEGRA
Venous Stent

VS | **10 mm x 50 mm** | **10 Fr**

SELF EXPANDING

REF Catalogue Number VNS100502A

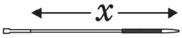
SN Serial Number 00000000000A

Use By 0000-00-00

Date of Manufacture 0000-00-00

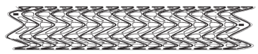
0.035"

Guidewire Compatibility



Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**10 Fr**	**7-9 mm**	**10 mm**

50 mm



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Do Not Use if Package is Damaged
- Rx Only
- Single Sterile Barrier System
- Keep Dry
- Store at 15°C to 30°C
- MR Conditional
- Do Not Resterilize
- Do Not Reuse
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663682

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100502A
SN 00000000000A
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UDI-DI:(01)00733132663682

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100502A
SN 00000000000A
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GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100502A
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GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100502A
SN 00000000000A
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UDI-DI:(01)00733132663682

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663682

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663682
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **10 mm x 75 mm** | **10 Fr**

SELF EXPANDING

REF Catalogue Number VNS100702A

SN Serial Number 00000000000A

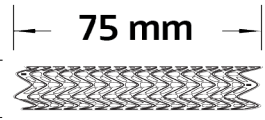
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**10 Fr**	**7-9 mm**	**10 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663996

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663996

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663996

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100702A
SN 00000000000A
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UDI-DI:(01)00733132663996

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663996

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS100702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663996

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663996
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | 10 mm x 100 mm | 10 Fr | SELF EXPANDING

REF Catalogue Number VNS101002A

SN Serial Number 00000000000A

Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035"

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter	Length
120 cm	10 Fr	7-9 mm	10 mm	100 mm

en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663989

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663989

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101002A
SN 00000000000A
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GORE® VIABAHN® FORTEGRA
Venous Stent
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Venous Stent
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GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663989

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663989
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **10 mm x 150 mm** | **10 Fr**

SELF EXPANDING

REF Catalogue Number VNS101502A

SN Serial Number 00000000000A

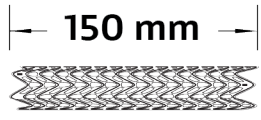
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**10 Fr**	**7-9 mm**	**10 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663972

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663972

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663972

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663972

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663972

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS101502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663972

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663972
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **12 mm x 50 mm** | **11 Fr**

SELF EXPANDING

REF Catalogue Number VNS120502A

SN Serial Number 00000000000A

Use By 0000-00-00

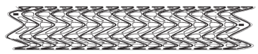
Date of Manufacture 0000-00-00

0.035"

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**9-11 mm**	**12 mm**

50 mm



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Do Not Use if Package is Damaged

Rx Only

Single Sterile Barrier System

Keep Dry

Store at 15°C to 30°C

MR Conditional

Do Not Resterilize

Do Not Reuse

STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663965

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663965

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663965

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663965

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663965

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663965

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663965
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **12 mm x 75 mm** | **11 Fr**

SELF EXPANDING

REF Catalogue Number VNS120702A

SN Serial Number 00000000000A

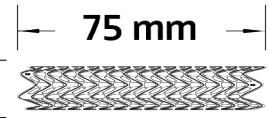
Use By **0000-00-00**

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**9-11 mm**	**12 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663958

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663958

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663958

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663958

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663958

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS120702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663958

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663958
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **12 mm x 100 mm** | **11 Fr**

SELF EXPANDING

REF Catalogue Number VNS121002A

SN Serial Number 00000000000A

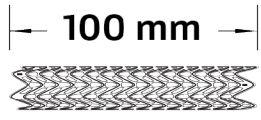
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**9-11 mm**	**12 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663941

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663941

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663941

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663941

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663941

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663941

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663941
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **12 mm x 150 mm** | **11 Fr**

SELF EXPANDING

REF Catalogue Number VNS121502A

SN Serial Number 00000000000A

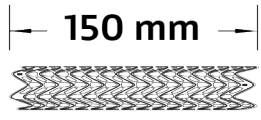
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**9-11 mm**	**12 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663934

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663934

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663934

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663934

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663934

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS121502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663934

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663934
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | 14 mm x 50 mm | 11 Fr

SELF EXPANDING

REF Catalogue Number VNS140502A

SN Serial Number 00000000000A

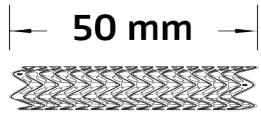
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	11 Fr	11-13 mm	14 mm



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663927

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663927

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663927

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663927

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663927

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663927

Manufacturer

W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI

(01)00733132663927
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA
Venous Stent

VS | **14 mm x 75 mm** | **11 Fr** | **SELF EXPANDING**

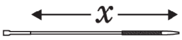
REF Catalogue Number VNS140702A

SN Serial Number 00000000000A

Use By 0000-00-00

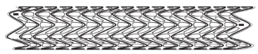
Date of Manufacture 0000-00-00

0.035"
Guidewire Compatibility



Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**11-13 mm**	**14 mm**

75 mm



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663910

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663910

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663910

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663910

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663910

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS140702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663910

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663910
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | 14 mm x 100 mm | 11 Fr

SELF EXPANDING

REF Catalogue Number VNS141002A

SN Serial Number 00000000000A

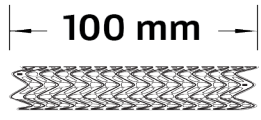
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	11 Fr	11-13 mm	14 mm



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663903

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663903

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663903

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663903

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663903

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663903

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI

(01)00733132663903
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **14 mm x 150 mm** | **11 Fr**

SELF EXPANDING

REF Catalogue Number VNS141502A

SN Serial Number 00000000000A

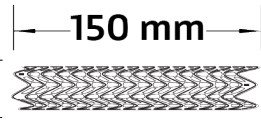
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**11-13 mm**	**14 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663897

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663897

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663897

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663897

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663897

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS141502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663897

Manufacturer

W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI

(01)00733132663897
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **16 mm x 50 mm** | **11 Fr**

SELF EXPANDING

REF Catalogue Number VNS160502A

SN Serial Number 00000000000A

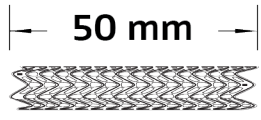
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**13-15 mm**	**16 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663880

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663880

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663880

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663880

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663880

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663880

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663880
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | 16 mm x 75 mm | 11 Fr

SELF EXPANDING

REF Catalogue Number VNS160702A

SN Serial Number 00000000000A

Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	11 Fr	13-15 mm	16 mm

en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663873

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663873

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663873

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663873

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS160702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663873

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663873
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | 16 mm x 100 mm | 11 Fr
SELF EXPANDING

REF Catalogue Number VNS161002A

SN Serial Number 00000000000A

Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035"

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter	
120 cm	11 Fr	13-15 mm	16 mm	100 mm

en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663866

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663866

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663866

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663866

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663866

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663866

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663866
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **18 mm x 75 mm** | **12 Fr**

SELF EXPANDING

REF Catalogue Number VNS180702A

SN Serial Number 00000000000A

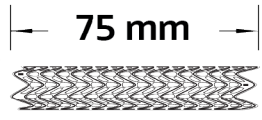
Use By **0000-00-00**

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**15-17 mm**	**18 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663835

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663835

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663835

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663835

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663835

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663835

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663835
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | 18 mm x 100 mm | 12 Fr

SELF EXPANDING

REF Catalogue Number VNS181002A

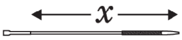
SN Serial Number 00000000000A

Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility



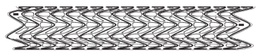
Catheter Working Length
120 cm

Introducer Sheath
12 Fr

Vessel Diameter
15–17 mm

Diameter
18 mm

100 mm



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663828

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663828

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663828

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663828

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663828

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663828

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663828
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **18 mm x 150 mm** | **12 Fr**

SELF EXPANDING

REF Catalogue Number VNS181502A

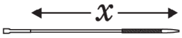
SN Serial Number 00000000000A

Use By 0000-00-00

Date of Manufacture 0000-00-00

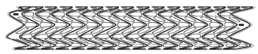
0.035”

Guidewire Compatibility



Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**15–17 mm**	**18 mm**

150 mm



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663811

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663811

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663811

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663811

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663811

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS181502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663811

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663811
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA
Venous Stent

VS | 16 mm x 150 mm | 11 Fr
SELF EXPANDING

REF Catalogue Number VNS161502A
SN Serial Number 00000000000A

Use By 0000-00-00
Date of Manufacture 0000-00-00

0.035"
Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter	
120 cm	11 Fr	13-15 mm	16 mm	150 mm

en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663859

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663859

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663859

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663859

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663859

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS161502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663859

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663859
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **18 mm x 50 mm** | **12 Fr**

SELF EXPANDING

REF Catalogue Number VNS180502A

SN Serial Number 00000000000A

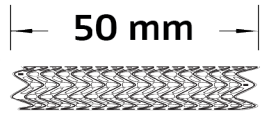
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**15-17 mm**	**18 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663842

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663842

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663842

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663842

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663842

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS180502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663842

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663842
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **20 mm x 50 mm** | **12 Fr**

SELF EXPANDING

REF Catalogue Number VNS200502A

SN Serial Number 00000000000A

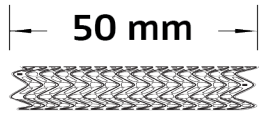
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**17-19 mm**	**20 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663804

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663804

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663804

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663804

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663804

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663804
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | 20 mm x 75 mm | 12 Fr

SELF EXPANDING

REF Catalogue Number VNS200702A

SN Serial Number 00000000000A

Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	12 Fr	17-19 mm	20 mm

en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663798

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663798

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663798

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663798

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663798

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS200702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663798

Manufacturer

W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI

(01)00733132663798
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **20 mm x 100 mm** | **12 Fr**

SELF EXPANDING

REF Catalogue Number VNS201002A

SN Serial Number 00000000000A

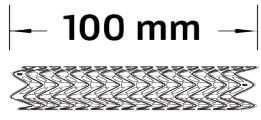
Use By **0000-00-00**

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**17-19 mm**	**20 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663781

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663781

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663781

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663781

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663781

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663781

Manufacturer

W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI

(01)00733132663781
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **20 mm x 150 mm** | **12 Fr**

SELF EXPANDING

REF Catalogue Number VNS201502A

SN Serial Number 00000000000A

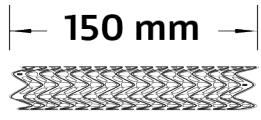
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**17-19 mm**	**20 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663774

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663774

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663774

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663774

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663774

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS201502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663774

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663774
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | 24 mm x 50 mm | 14 Fr

SELF EXPANDING

REF Catalogue Number VNS240502A

SN Serial Number 00000000000A

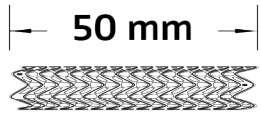
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	14 Fr	18-22 mm	24 mm



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663767

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663767

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663767

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663767

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663767

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663767

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663767
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | 24 mm x 75 mm | 14 Fr

SELF EXPANDING

REF Catalogue Number VNS240702A

SN Serial Number 00000000000A

Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	14 Fr	18-22 mm	24 mm

en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663699

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663699

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663699

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663699

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS240702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663699

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663699
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **24 mm x 100 mm** | **14 Fr**

SELF EXPANDING

REF Catalogue Number VNS241002A

SN Serial Number 00000000000A

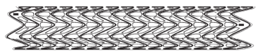
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”
Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**18–22 mm**	**24 mm**

100 mm



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution

Rx Only

Keep Dry

MR Conditional

Do Not Reuse

Do Not Use if Package is Damaged

Single Sterile Barrier System

Store at 15°C to 30°C

Do Not Resterilize

STERILE EO
Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663750

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663750

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663750

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663750

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663750

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663750

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663750
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA
Venous Stent

VS | **24 mm x 150 mm** | **14 Fr** | **SELF EXPANDING**

REF Catalogue Number VNS241502A
SN Serial Number 00000000000A

Use By 0000-00-00
Date of Manufacture 0000-00-00

0.035”
Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter	
120 cm	14 Fr	18-22 mm	24 mm	150 mm

en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

Caution
Rx Only
Keep Dry
MR Conditional
Do Not Reuse
Do Not Use if Package is Damaged
Single Sterile Barrier System
Store at 15°C to 30°C
Do Not Resterilize
STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663743

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663743

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663743

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663743

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663743

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS241502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663743

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663743
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **28 mm x 50 mm** | **14 Fr**

SELF EXPANDING

REF Catalogue Number VNS280502A

SN Serial Number 00000000000A

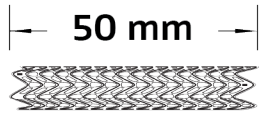
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**22-26 mm**	**28 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO — Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663736

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663736

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663736

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663736

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663736

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663736

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663736
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **28 mm x 75 mm** | **14 Fr**

SELF EXPANDING

REF Catalogue Number VNS280702A

SN Serial Number 00000000000A

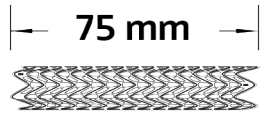
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**22-26 mm**	**28 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663729

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663729

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663729

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663729

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663729

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS280702A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663729

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663729
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **28 mm x 100 mm** | **14 Fr**

SELF EXPANDING

REF Catalogue Number VNS281002A

SN Serial Number 00000000000A

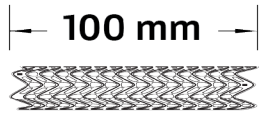
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**22-26 mm**	**28 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663712

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663712

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663712

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663712

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663712

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281002A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663712

Manufacturer
W. L. GORE & ASSOCIATES, INC.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663712
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **28 mm x 150 mm** | **14 Fr**

SELF EXPANDING

REF Catalogue Number VNS281502A

SN Serial Number 00000000000A

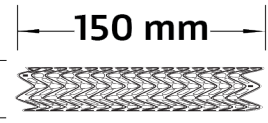
Use By 0000-00-00

Date of Manufacture 0000-00-00

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**22-26 mm**	**28 mm**



en Contents: One (1) stent and one (1) delivery catheter.

Consult Instructions for Use
eifu.goremedical.com

- Caution
- Rx Only
- Keep Dry
- MR Conditional
- Do Not Reuse
- Do Not Use if Package is Damaged
- Single Sterile Barrier System
- Store at 15°C to 30°C
- Do Not Resterilize
- STERILE EO Sterilized using Ethylene Oxide

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663705

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663705

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663705

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663705

GORE® VIABAHN® FORTEGRA
Venous Stent
REF VNS281502A
SN 00000000000A
0000-00-00
UDI-DI:(01)00733132663705

Manufacturer
W. L. Gore & Associates, Inc.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES

UDI
(01)00733132663705
(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

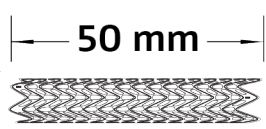
VS | 10 mm x 50 mm | 10 Fr

SELF EXPANDING

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	10 Fr	7-9 mm	10 mm



REF Catalogue Number VNS100502A

SN Serial Number 00000000000A

Use By 0000-00-00

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663682

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 10 mm x 50 mm | 10 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS100502A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663682 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **10 mm x 75 mm** | **10 Fr**

SELF EXPANDING

0.035”

Guidewire Compatibility

REF Catalogue Number VNS100702A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**10 Fr**	**7-9 mm**	**10 mm**

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663996

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 10 mm x 75 mm | 10 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS100702A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663996 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

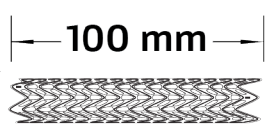
VS | 10 mm x 100 mm | 10 Fr

SELF EXPANDING

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	10 Fr	7-9 mm	10 mm



REF Catalogue Number VNS101002A

SN Serial Number 00000000000A

Use By 0000-00-00

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

MADE IN USA

(01)00733132663989

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 10 mm x 100 mm | 10 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035”

REF VNS101002A SN 00000000000A | 0000-00-00 | UDI (01)00733132663989 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **10 mm x 150 mm** | **10 Fr**

SELF EXPANDING

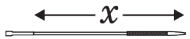
0.035”

Guidewire Compatibility

REF Catalogue Number VNS101502A

SN Serial Number 00000000000A

Use By **0000-00-00**



Catheter Working Length

120 cm

Introducer Sheath

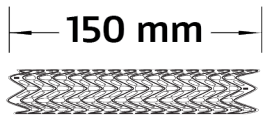
10 Fr

Vessel Diameter

7-9 mm

Diameter

10 mm



en Contents: One (1) stent and one (1) delivery catheter.

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

For product patent information, please refer to goremedical.com/patents.

(01)00733132663972

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 10 mm x 150 mm | 10 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS101502A | SN 00000000000A | **0000-00-00** | UDI (01)00733132663972 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

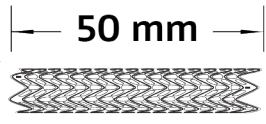
VS 12 mm x 50 mm 11 Fr

SELF EXPANDING

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	11 Fr	9-11 mm	12 mm



REF Catalogue Number VNS120502A

SN Serial Number 00000000000A

Use By 0000-00-00

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663965

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 12 mm x 50 mm 11 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS120502A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663965 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS **12 mm x 75 mm** **11 Fr**

SELF EXPANDING

0.035”

Guidewire Compatibility

REF Catalogue Number VNS120702A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**9-11 mm**	**12 mm**

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663958

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent

12 mm x 75 mm **11 Fr**

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS120702A

SN 00000000000A

0000-00-00

UDI (01)00733132663958 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **12 mm x 100 mm** | **11 Fr**

SELF EXPANDING

0.035”

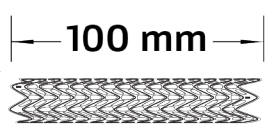
Guidewire Compatibility

REF Catalogue Number VNS121002A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**9-11 mm**	**12 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

MADE IN USA

(01)00733132663941

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | **12 mm x 100 mm** | **11 Fr** | Catheter Working Length **120 cm** | Guidewire Compatibility **0.035”** | REF VNS121002A | SN 00000000000A | **0000-00-00** | UDI (01)00733132663941 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **12 mm x 150 mm** | **11 Fr**

SELF EXPANDING

0.035”

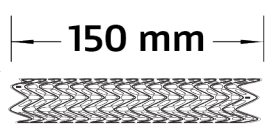
Guidewire Compatibility

REF Catalogue Number VNS121502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**9-11 mm**	**12 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663934

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | **12 mm x 150 mm** | **11 Fr**

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS121502A

SN 00000000000A

0000-00-00

UDI

(01)00733132663934

(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **14 mm x 50 mm** | **11 Fr**

SELF EXPANDING

0.035”

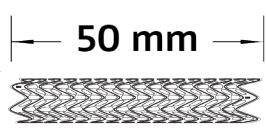
Guidewire Compatibility

REF Catalogue Number VNS140502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**11-13 mm**	**14 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663927

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | **14 mm x 50 mm** | **11 Fr** | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS140502A | SN 00000000000A | **0000-00-00** | UDI (01)00733132663927 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **14 mm x 75 mm** | **11 Fr**

SELF EXPANDING

0.035”

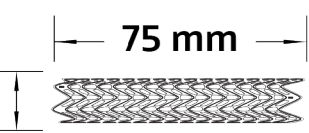
Guidewire Compatibility

REF Catalogue Number VNS140702A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**11-13 mm**	**14 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663910

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | **14 mm x 75 mm** | **11 Fr** | Catheter Working Length **120 cm** | Guidewire Compatibility **0.035”** | REF VNS140702A | SN 00000000000A | **0000-00-00** | UDI (01)00733132663910 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **14 mm x 100 mm** | **11 Fr**

SELF EXPANDING

0.035”

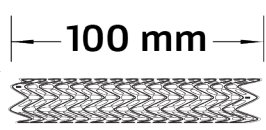
Guidewire Compatibility

REF Catalogue Number VNS141002A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**11-13 mm**	**14 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663903

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | **14 mm x 100 mm** | **11 Fr**

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS141002A

SN 00000000000A

0000-00-00

UDI

(01)00733132663903

(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **14 mm x 150 mm** | **11 Fr**

SELF EXPANDING

0.035”

Guidewire Compatibility

REF Catalogue Number VNS141502A

SN Serial Number 00000000000A

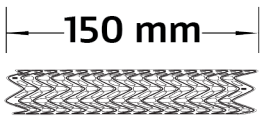
Use By **0000-00-00**

Catheter Working Length
120 cm

Introducer Sheath
11 Fr

Vessel Diameter
11-13 mm

Diameter
14 mm



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture
0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663897

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 14 mm x 150 mm | 11 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS141502A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663897 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **16 mm x 50 mm** | **11 Fr**

SELF EXPANDING

0.035”

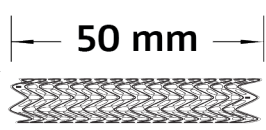
Guidewire Compatibility

REF Catalogue Number VNS160502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**13-15 mm**	**16 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663880

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | **16 mm x 50 mm** | **11 Fr**

Catheter Working Length **120 cm**

Guidewire Compatibility **0.035”**

REF VNS160502A

SN 00000000000A

0000-00-00

UDI

(01)00733132663880

(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **16 mm x 75 mm** | **11 Fr**

SELF EXPANDING

0.035”

Guidewire Compatibility

REF Catalogue Number VNS160702A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**13-15 mm**	**16 mm**

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663873

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 16 mm x 75 mm | 11 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS160702A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663873 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

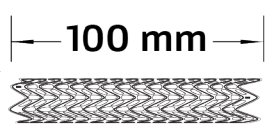
VS 16 mm x 100 mm 11 Fr

SELF EXPANDING

0.035”

Guidewire Compatibility

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	11 Fr	13-15 mm	16 mm



REF Catalogue Number VNS161002A

SN Serial Number 00000000000A

Use By 0000-00-00

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663866

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent

16 mm x 100 mm 11 Fr

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS161002A

SN 00000000000A

0000-00-00

UDI (01)00733132663866 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **16 mm x 150 mm** | **11 Fr**

SELF EXPANDING

0.035”

Guidewire Compatibility

REF Catalogue Number VNS161502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**11 Fr**	**13-15 mm**	**16 mm**

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663859

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 16 mm x 150 mm | 11 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS161502A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663859 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS **18 mm x 50 mm** **12 Fr**

SELF EXPANDING

0.035”

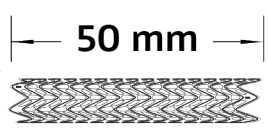
Guidewire Compatibility

REF Catalogue Number VNS180502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**15–17 mm**	**18 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663842

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent

18 mm x 50 mm **12 Fr**

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS180502A

SN 00000000000A

0000-00-00

UDI

(01)00733132663842

(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **18 mm x 75 mm** | **12 Fr**

SELF EXPANDING

0.035”

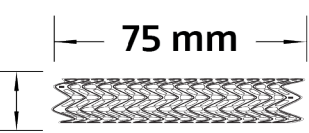
Guidewire Compatibility

REF Catalogue Number VNS180702A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**15–17 mm**	**18 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663835

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 18 mm x 75 mm | 12 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS180702A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663835 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **18 mm x 100 mm** | **12 Fr**

SELF EXPANDING

0.035”

Guidewire Compatibility

REF Catalogue Number VNS181002A

SN Serial Number 00000000000A

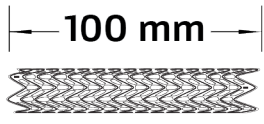
Use By **0000-00-00**

Catheter Working Length
120 cm

Introducer Sheath
12 Fr

Vessel Diameter
15–17 mm

Diameter
18 mm



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture
0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

MADE IN USA

(01)00733132663828

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 18 mm x 100 mm | 12 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS181002A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663828 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **18 mm x 150 mm** | **12 Fr**

SELF EXPANDING

0.035”

Guidewire Compatibility

REF Catalogue Number VNS181502A

SN Serial Number 00000000000A

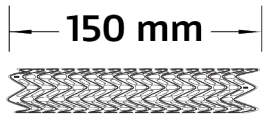
Use By **0000-00-00**

Catheter Working Length
120 cm

Introducer Sheath
12 Fr

Vessel Diameter
15–17 mm

Diameter
18 mm



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture
0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

MADE IN USA

(01)00733132663811

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 18 mm x 150 mm | 12 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS181502A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663811 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **20 mm x 50 mm** | **12 Fr**

SELF EXPANDING

0.035”

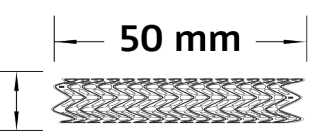
Guidewire Compatibility

REF Catalogue Number VNS200502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**17-19 mm**	**20 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663804

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 20 mm x 50 mm | 12 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS200502A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663804 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **20 mm x 75 mm** | **12 Fr**

SELF EXPANDING

0.035”

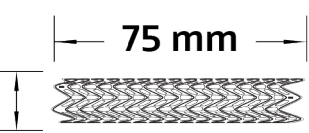
Guidewire Compatibility

REF Catalogue Number VNS200702A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**17-19 mm**	**20 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663798

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 20 mm x 75 mm | 12 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS200702A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663798 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS **20 mm x 100 mm** **12 Fr**

SELF EXPANDING

0.035”

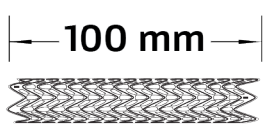
Guidewire Compatibility

REF Catalogue Number VNS201002A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**17-19 mm**	**20 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663781

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent

20 mm x 100 mm **12 Fr**

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS201002A

SN 00000000000A

0000-00-00

UDI (01)00733132663781 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS **20 mm x 150 mm** **12 Fr**

SELF EXPANDING

0.035”

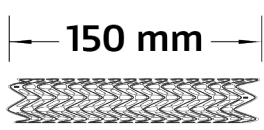
Guidewire Compatibility

REF Catalogue Number VNS201502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**12 Fr**	**17-19 mm**	**20 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture
0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663774

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent
20 mm x 150 mm 12 Fr
Catheter Working Length 120 cm
Guidewire Compatibility 0.035”
REF VNS201502A
SN 00000000000A
0000-00-00
UDI (01)00733132663774 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **24 mm x 50 mm** | **14 Fr**

SELF EXPANDING

0.035”

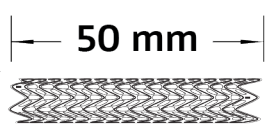
Guidewire Compatibility

REF Catalogue Number VNS240502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**18-22 mm**	**24 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663767

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 24 mm x 50 mm | 14 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS240502A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663767 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS **24 mm x 75 mm** **14 Fr**

SELF EXPANDING

0.035”

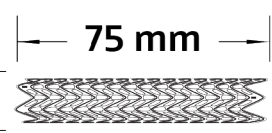
Guidewire Compatibility

REF Catalogue Number VNS240702A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**18-22 mm**	**24 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663699

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent

24 mm x 75 mm **14 Fr**

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS240702A

SN 00000000000A

0000-00-00

UDI (01)00733132663699 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS **24 mm x 100 mm** **14 Fr**

SELF EXPANDING

0.035”

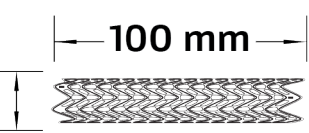
Guidewire Compatibility

REF Catalogue Number VNS241002A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**18-22 mm**	**24 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663750

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent

24 mm x 100 mm **14 Fr**

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS241002A

SN 00000000000A

0000-00-00

UDI (01)00733132663750 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **24 mm x 150 mm** | **14 Fr**

SELF EXPANDING

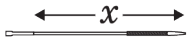
0.035”

Guidewire Compatibility

REF Catalogue Number VNS241502A

SN Serial Number 00000000000A

Use By **0000-00-00**



Catheter Working Length

120 cm

Introducer Sheath

14 Fr

Vessel Diameter

18-22 mm

Diameter

24 mm

en Contents: One (1) stent and one (1) delivery catheter.

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

For product patent information, please refer to goremedical.com/patents.

(01)00733132663743

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | **24 mm x 150 mm** | **14 Fr**

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS241502A

SN 00000000000A

0000-00-00

UDI

(01)00733132663743

(17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **28 mm x 50 mm** | **14 Fr**

SELF EXPANDING

0.035”

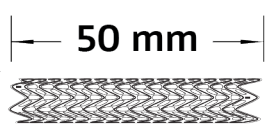
Guidewire Compatibility

REF Catalogue Number VNS280502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**22-26 mm**	**28 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663736

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent

28 mm x 50 mm 14 Fr

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS280502A

SN 00000000000A

0000-00-00

UDI (01)00733132663736 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS | **28 mm x 75 mm** | **14 Fr**

SELF EXPANDING

0.035”

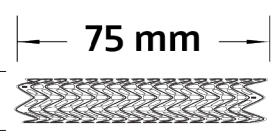
Guidewire Compatibility

REF Catalogue Number VNS280702A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**22-26 mm**	**28 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663729

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent | 28 mm x 75 mm | 14 Fr | Catheter Working Length 120 cm | Guidewire Compatibility 0.035” | REF VNS280702A | SN 00000000000A | 0000-00-00 | UDI (01)00733132663729 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS **28 mm x 100 mm** **14 Fr**

SELF EXPANDING

0.035”

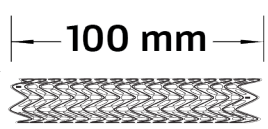
Guidewire Compatibility

REF Catalogue Number VNS281002A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**22-26 mm**	**28 mm**



Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663712

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent

28 mm x 100 mm 14 Fr

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS281002A

SN 00000000000A

0000-00-00

UDI (01)00733132663712 (17)000000(21)00000000000A

MD Medical Device

GORE® VIABAHN® FORTEGRA

Venous Stent

VS **28 mm x 150 mm** **14 Fr**

SELF EXPANDING

0.035”

Guidewire Compatibility

REF Catalogue Number VNS281502A

SN Serial Number 00000000000A

Use By **0000-00-00**

Catheter Working Length	Introducer Sheath	Vessel Diameter	Diameter
120 cm	**14 Fr**	**22-26 mm**	**28 mm**

Do Not Resterilize

Keep Dry

MR Conditional

STERILE EO Sterilized using Ethylene Oxide

Store at 15°C to 30°C

Date of Manufacture

0000-00-00

en Contents: One (1) stent and one (1) delivery catheter.

For product patent information, please refer to goremedical.com/patents.

(01)00733132663705

(17)000000(21)00000000000A

VS GORE® VIABAHN® FORTEGRA Venous Stent

28 mm x 150 mm 14 Fr

Catheter Working Length 120 cm

Guidewire Compatibility 0.035”

REF VNS281502A

SN 00000000000A

0000-00-00

UDI (01)00733132663705 (17)000000(21)00000000000A