INSTRUCTIONS FOR USE FOR GORE® VIABAHN® Endoprosthesis

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DESCRIPTION
The GORE® VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal endoprosthesis consisting of an expanded polytetrafluoroethylene (ePTFE) lining with an external nitinol (NiTi = Nickel:Titanium) support extending along its entire length (Figure 1). The endoprosthesis is compressed and attached to a dual lumen delivery catheter (Figure 2). The larger central catheter lumen is used for flushing and guidewire introduction. The smaller lumen contains elements of the deployment mechanism. The delivery catheter hub assembly has one port for the deployment system and one port for flushing and guidewire insertion. To facilitate accurate endoprosthesis placement, two radiopaque metallic bands are attached to the catheter shaft, marking the ends of the compressed endoprosthesis.

The GORE® VIABAHN® Endoprosthesis is supplied STERILE.

FIGURE 1: GORE® VIABAHN® ENDOPROSTHESIS

External Nitinol Stent

ePTFE Lining

FIGURE 2: GORE® VIABAHN® ENDOPROSTHESIS DELIVERY SYSTEM

Catheter Shaft

Guidewire / Flushing Port

Deployment Knob

Hub Assembly

Radopaque Markers

Constrained Endoprosthesis

INTENDED USE / INDICATIONS
The GORE® VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal prosthesis for endovascular grafting of peripheral arteries. The GORE® VIABAHN® Endoprosthesis is also indicated for improving blood flow in symptomatic obstructions of peripheral veins.

CONTRAINDICATIONS
• Non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system.

TABLE 1: SIZING TABLE

<table>
<thead>
<tr>
<th>Device Diameter (mm)</th>
<th>Recommended Vessel Diameter² (mm)</th>
<th>Available Device Length² (cm)</th>
<th>Guidewire Diameter</th>
<th>Recommended Balloon Diameter for Device Touch-up (mm)¹</th>
<th>Deployment Direction</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>4.0 – 4.7</td>
<td>2</td>
<td>2.5, 5, 10, 15</td>
<td>0.035'' (0.889 mm)</td>
<td>Tip to hub</td>
</tr>
<tr>
<td>6</td>
<td>4.8 – 5.5</td>
<td>2</td>
<td>2.5, 5, 10, 15</td>
<td>0.035'' (0.889 mm)</td>
<td>Tip to hub</td>
</tr>
<tr>
<td>7</td>
<td>5.6 – 6.5</td>
<td>2</td>
<td>2.5, 5, 10, 15</td>
<td>0.035'' (0.889 mm)</td>
<td>Tip to hub</td>
</tr>
<tr>
<td>8</td>
<td>6.4 – 7.5</td>
<td>2</td>
<td>2.5, 5, 10, 15</td>
<td>0.035'' (0.889 mm)</td>
<td>Tip to hub</td>
</tr>
<tr>
<td>9</td>
<td>7.2 – 8.5</td>
<td>2</td>
<td>5, 10, 15</td>
<td>0.035'' (0.889 mm)</td>
<td>Tip to hub</td>
</tr>
<tr>
<td>10</td>
<td>8.0 – 9.5</td>
<td>2</td>
<td>5, 10, 15</td>
<td>0.035'' (0.889 mm)</td>
<td>Tip to hub</td>
</tr>
<tr>
<td>11</td>
<td>9.6 – 10.5</td>
<td>2</td>
<td>5, 10</td>
<td>0.035'' (0.889 mm)</td>
<td>Tip to hub</td>
</tr>
<tr>
<td>12</td>
<td>10.6 – 12.0</td>
<td>12</td>
<td>5, 10</td>
<td>0.035'' (0.889 mm)</td>
<td>Tip to hub</td>
</tr>
</tbody>
</table>

¹ Recommended endoprosthesis compression within the vessel is approximately 5 – 20%.
² Labeled device lengths are nominal.
³ For the 11 and 13 mm diameter devices, balloon inflation pressure should not exceed 8 atm.
⁴ The 10 mm diameter device is compatible with the following 10 Fr introducer sheaths: Cordis AVANTI® Sheath Introducer, Boston Scientific SUPER SHEATH Introducer Sheath, B. Braun INTRADYN Tear-Away Introducer Sheath.

PACKAGE HANDLING
• Store in a cool dry place. This product has an expiration date and should be used before the labeled “use by” (expiration) date marked on the box.

METHOD
• Preparation of patients receiving the GORE® VIABAHN® Endoprosthesis should include initiation of an appropriate dosage of oral antiplatelet medication prior to and following the procedure. Effective anticoagulation therapy should be maintained throughout the procedure and continued into the postoperative period, as deemed appropriate by the treating physician.
• Prior to implantation of the GORE® VIABAHN® Endoprosthesis, the physician should refer to the Sizing Table (Table 1) and read the Directions for Use.
• When used in the treatment of stenotic or occlusive lesions, placement of the GORE® VIABAHN® Endoprosthesis should immediately follow successful transluminal balloon angioplasty confirmed by angiography. The endoprosthesis must be sized in accordance with the Sizing Table (Table 1) using accurate measurement techniques.
• Proper placement of the endoprosthesis should be monitored and confirmed using fluoroscopy.
• Sterile precautions should be the same as for any device implant procedure.
• To ensure an optimal result, the endoprosthesis must be dilated after deployment with an appropriately sized balloon (Table 1). Do not extend balloon dilatation beyond the ends of the device and into healthy vessel.
WARNINGS

• W. L. Gore & Associates has insufficient clinical and experimental data upon which to base any conclusions regarding the effectiveness of the Gore® VIABAHN® Endoprosthesis in applications other than the endovascular grafting of peripheral arteries and improving blood flow in symptomatic obstructions of peripheral veins.

• W. L. Gore & Associates has insufficient clinical and experimental data upon which to base any conclusions regarding the effectiveness of the Gore® VIABAHN® Endoprosthesis in applications where the device is deployed within stents or stent grafts other than the Gore® VIABAHN® Endoprosthesis. Other devices may interfere with the deployment of the Gore® VIABAHN® Endoprosthesis resulting in deployment failure or other device malfunction.

• The Gore® VIABAHN® Endoprosthesis is not indicated for use in the central circulatory system; such as, pulmonary arteries, aorta, coronary arteries, coronary bypass grafts, coronary sinus, carotid arteries, vertebral arteries, brachiocephalic (innominate) arteries, vena cava or pulmonary veins.

• W. L. Gore & Associates has insufficient clinical and experimental data upon which to base any conclusions regarding the effectiveness of the Gore® VIABAHN® Endoprosthesis in applications where the endoprosthesis may experience repeated and extreme flexion, such as across the popliteal fossa and the antecubital fossa. Clinical conditions such as excessive bending, tortuosity, and / or repeated and extreme flexion may result in compromised performance or failure of the endoprosthesis.

• Do not use the Gore® VIABAHN® Endoprosthesis for the treatment of lesions that would not allow an operative salvage bypass procedure.

• Do not use the Gore® VIABAHN® Endoprosthesis for the treatment of ostial lesions or lesions involving a major side branch that may be covered by the endoprosthesis.

• Do not use in patients with less than one distal run-off vessel which has continuous patency to the ankle.

• Special care should be taken to ensure that the appropriate size endoprosthesis, compatible sheath and guidewire are selected prior to insertion. Native vessel dimensions must be accurately measured, not estimated.

• Do not cannulate or puncture the Gore® VIABAHN® Endoprosthesis. Cannulating or puncturing the endoprosthesis may result in damage to the ePTFE lining and / or the external nitinol support, resulting in compromised performance or failure of the endoprosthesis.

• Do not cut the endoprosthesis. The endoprosthesis should only be placed and deployed using the supplied catheter system.

• Do not use a kinked introducer sheath. A kinked introducer sheath may increase the force necessary to deploy the endoprosthesis and may cause a deployment failure or catheter breakage on removal.

• Do not attempt to deploy the endoprosthesis or manipulate the delivery system without an appropriately sized guidewire (Table 1) or fluoroscopic guidance.

• Do not withdraw the Gore® VIABAHN® Endoprosthesis back into the introducer sheath once the endoprosthesis is fully introduced. Withdrawing the Gore® VIABAHN® Endoprosthesis back into the sheath can cause damage to the endoprosthesis, premature deployment, deployment failure, and / or catheter separation. If removal prior to deployment is necessary, withdraw the Gore® VIABAHN® Endoprosthesis to a position close to but not into the introducer sheath. Both the Gore® VIABAHN® Endoprosthesis and introducer sheath can then be removed in tandem. After removal, do not reuse the Gore® VIABAHN® Endoprosthesis or introducer sheath.

• inadvertent, partial, or failed deployment or migration of the endoprosthesis may require surgical intervention.

PRECAUTIONS

• The Gore® Medical Device 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. Reuse may result in infection, serious injury, or patient death.

• W. L. Gore & Associates has insufficient technical information to recommend reuse or reprocessing of the Gore® VIABAHN® Endoprosthesis. However, reasonably foreseeable clinical complications that may result from inappropriate reuse or reprocessing include, but are not limited to: deployment failure, catheter failure, infection, irritation, vessel damage or loss of biocompatibility.

• Do not use the Gore® VIABAHN® Endoprosthesis if the sterile package is compromised or the Gore® VIABAHN® Endoprosthesis is damaged.

• Do not use the Gore® VIABAHN® Endoprosthesis after the labeled "use by" (expiration) date.

• Do not resterilize the Gore® VIABAHN® Endoprosthesis.

• The Gore® VIABAHN® Endoprosthesis should only be used by physicians trained in its use.

• Follow the Directions for Use supplied with all accessories used in conjunction with the Gore® VIABAHN® Endoprosthesis.

• Once deployment is started, repositioning the endoprosthesis should not be attempted.

• Do not dilate the endoprosthesis with a balloon longer than the labeled endoprosthesis length (Table 1). Refer to Sizing Table (Table 1) for selection of appropriate balloon diameter.

• Do not attempt to withdraw or reposition a balloon catheter within the lumen of the deployed endoprosthesis unless the balloon is completely deflated.

• Antiplatlet medication should be initiated prior to placement of the Gore® VIABAHN® Endoprosthesis. Effective anticoagulation therapy should be maintained at a dosage deemed appropriate by the physician.

• No clinical events related to heating effects of Gore® VIABAHN® Endoprostheses in the MRI environment have been reported. The effect of heating in the MRI environment for devices with fractured stent struts is not known.

MRI Safety and Compatibility

Non-clinical testing has demonstrated that the Gore® VIABAHN® Endoprosthesis is MR Conditional. It can be scanned safely under the following conditions:

• Static magnetic field of 1.5 or 3.0 Tesla
• Spatial gradient field of ≤720 Gauss/cm
• Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0W/kg for 15 minutes of scanning.

3.0 Tesla Temperature Rise:

In non-clinical testing, the Gore® VIABAHN® Endoprosthesis produced a temperature rise of 2.5°C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 3.0W/kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 2.8 W/kg.

1.5 Tesla Temperature Rise:

In non-clinical testing, the Gore® VIABAHN® Endoprosthesis produced a temperature rise of 2.4°C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 2.8W/kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris/4 Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 1.5 W/kg.

Image Artifact:

The image artifact extends approximately 2 – 4 mm from the device, both inside and outside the device lumen when scanned in non-clinical testing using sequence: T1 – weighted, spin echo and gradient echo pulse sequences in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR system with a send-receive RF body coil.
For each vascular device and assembly, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were minor in size relative to the size and shape of these implants. The gradient echo pulse sequence produced larger artifacts than the TI – weighted, spin echo pulse sequence for the Gore® VIABAHN® Endoprosthesis. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Gore® VIABAHN® Endoprosthesis. Therefore, it may be necessary to optimize the MR imaging parameters to compensate for the presence of this implant.

HAZARDS AND ADVERSE EVENTS

Procedure Related: As with all procedures that utilize techniques for introducing a catheter into a vessel, complications may be expected. These complications include: access site infection; entry site bleeding and / or hematoma; vessel thrombosis, occlusion, pseudoaneurysm, and trauma to the vessel wall (including rupture or dissection); distal embolization; arteriovenous fistula formation; transient or permanent contrast induced renal failure; renal toxicity; sepsis; shock; radiation injury; myocardial infarction; fever; pain; malposition; malapposition; inflammation; and / or death.

Device Related: Complications and adverse events can occur when using any endovascular device. These complications include, but are not limited to: hematoma; stenosis, thrombosis or occlusion; distal embolism; side branch occlusion; vessel wall trauma and / or rupture; false aneurysm; infection; inflammation; fever and / or pain in the absence of infection; deployment failure; migration; and device failure.

Complications and adverse events can occur when using any endovascular device. These complications include, but are not limited to: access site infection; entry site bleeding and / or hematoma; vessel thrombosis, occlusion, pseudoaneurysm, and trauma to the vessel wall (including rupture or dissection); distal embolization; arteriovenous fistula formation; transient or permanent contrast induced renal failure; renal toxicity; sepsis; shock; radiation injury; myocardial infarction; fever; pain; malposition; malapposition; inflammation; and / or death.

MATERIALS REQUIRED FOR IMPLANTATION

- Gore® VIABAHN® Endoprosthesis
- Marker guidewire or catheter (for calibrated measurement reference)
- Syringe filled with heparinized saline
- Introducer sheath of appropriate size (Table 1)
- 0.035” (0.889 mm) diameter stiff guidewire
- Guidewire length should be at least twice the length of the Gore® VIABAHN® Endoprosthesis delivery catheter
- Appropriate angioplasty balloon catheters and accessories (Table 1)
- Appropriate diagnostic catheters and accessories

DIRECTIONS FOR USE

Treatment of Vessel Obstruction

A. Access
1. Using appropriate local anesthesia, access is achieved using the appropriate vessel. When possible, a percutaneous Seldinger technique is preferred. A cutdown may be performed when indicated.
2. Using standard technique, insert the appropriately sized angiographic vascular introducer sheath into the vessel.

B. Imaging and Measurement
1. To achieve accurate measurement and ensure precise sizing and placement of the endoprosthesis, use image-centered, magnified-view contrast angiography, including a marker guidewire or catheter.

C. Percutaneous Transluminal Angioplasty (PTA) (if treating stenotic or occlusive lesions)
1. Refer to manufacturer's Directions for Use.
2. Inflate the angioplasty balloon to its nominal pressure according to manufacturer's Directions for Use. Ensure full expansion of the balloon within the lesion.
   Note: Carefully mark the margins of the angioplasty treatment segment in order to ensure complete coverage with the endoprosthesis.
3. Following deflation of the angioplasty balloon, evaluate the results angiographically. For reference, measure the native vessel diameter, lesion length, and residual percent stenosis.

D. Sizing and Selection of the Gore® VIABAHN® Endoprosthesis
1. Prior to opening the sterile package, check that the diameter and length of the endoprosthesis as well as the delivery catheter length are correct before removing from the packaging.
   a. In selecting the appropriate size endoprosthesis, a careful assessment of the vessel is necessary. In general, to assure adequate anchoring, the diameter of the endoprosthesis should be approximately 5 – 20% larger than the healthy vessel diameter immediately proximal and distal to the lesion (Table 1).
   b. The endoprosthesis lengths of the Gore® VIABAHN® Endoprosthesis listed in Table 1 are nominal. It is, therefore, important that the endoprosthesis overlap the native vessel at least 1 cm beyond the proximal and distal margins of the lesion when treating stenotic or occlusive lesions and preferably at least 2 cm beyond the proximal and distal margins of the lesion when treating aneurysmal lesions, creating an arteriovenous graft outflow lesion that starts 30 mm or less from the venous anastomosis, the endoprosthesis should overlap the prosthetic graft by at least 1 cm.
   c. Verify that there is sufficient catheter length to access the treatment site.
2. When overlapping (telescoping) multiple devices, the following are suggested:
   a. Balloon touch-up (post-dilatation) should be performed on the first device prior to placing the second device.
   b. To ensure proper seating, at least 1 cm of overlap between devices is suggested.
   c. If unequal device diameters are used, the smaller device should be placed first and then the larger device should be placed inside of the smaller device.
   d. Overlapping devices should not differ by more than 1 mm in diameter (with the exception that the 13 mm diameter device may be overlapped into the 11 mm diameter device).
   e. When overlapping inside aneurysmal lesions, at least 2 cm of overlap between devices is suggested.

E. Preparation of the Gore® VIABAHN® Endoprosthesis
1. Opening the Sterile Package.
   Carefully inspect the packaging for damage to the sterile barrier. Do not use the Gore® VIABAHN® Endoprosthesis after the "use by" (expiration) date. Peel back the outer pouch and remove the sterile inner pouch and coil containing the Gore® VIABAHN® Endoprosthesis. Beginning at one corner, peel back the edge of the inner pouch and gently remove the Gore® VIABAHN® Endoprosthesis.
2. Inspection Prior to Use.
   a. Prior to using the Gore® VIABAHN® Endoprosthesis, all materials and equipment to be used for the procedure should be carefully examined for bends, kinks, or other damage.
   b. Do not use any defective equipment.
   c. Do not use the Gore® VIABAHN® Endoprosthesis if the sterile package is compromised or the Gore® VIABAHN® Endoprosthesis is damaged.
   a. Flush the delivery catheter by attaching a syringe of sterile saline to the flushing port on the catheter adapter (Figure 2). Continue flushing until a steady stream of fluid exits the tip of the catheter and the deployment lumen at the proximal end of the device.
   b. After flushing the catheter, remove the syringe.

F. Introduction and Positioning of the Gore® VIABAHN® Endoprosthesis
1. Select the compatible size introducer sheath from Table 1.
2. Ensure the 0.035” (0.889 mm) diameter stiff guidewire has a length at least twice that of the delivery catheter.
3. Be sure to remove the balloon catheter while maintaining the position of the guidewire beyond the target lesion.
4. 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 compressed endoprosthesis. Carefully advance the endoprosthesis 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® Endoprosthesis is introduced through the hemostasis valve, remove and inspect the delivery system for damage. Do not reuse the Gore® Viabahn® Endoprosthesis if damaged. Ensure a compatible introducer sheath size (Table 1), and that the introducer sheath is free of kinks.
5. Using fluoroscopic guidance, advance the delivery catheter over the guidewire via the angiographic sheath. Advance cautiously, especially if resistance is felt. If excessive resistance is felt, remove the delivery catheter and angiographic sheath together as described in step F. 7.
6. Position the Gore® Viabahn® Endoprosthesis across the target lesion using the radiopaque hub and tip markers on the catheter. These markers identify the proximal and distal ends of the endoprosthesis, respectively. **Note:** If PTA is performed, the endoprosthesis length should cover the entire vessel segment treated with balloon angioplasty. For treatment of stenotic or occlusive lesions, the endoprosthesis should extend at least 1 cm proximal and distal to the margins of the lesion, and at least 2 cm beyond the proximal and distal margins of the lesion when treating aneurysmal lesions. For a lesion that starts within 30 mm of the venous anastomosis of an arteriovenous graft, the endoprosthesis should overlap the prosthetic graft by at least 1 cm.
7. Once the optimal position is verified fluoroscopically, the endoprosthesis is ready to be deployed. **Note:** Should it become necessary to remove the Gore® Viabahn® Endoprosthesis from the vessel prior to deployment, do not withdraw the Gore® Viabahn® Endoprosthesis back into the introducer sheath after the endoprosthesis is fully introduced. To remove the Gore® Viabahn® Endoprosthesis prior to deployment, the Gore® Viabahn® Endoprosthesis can be withdrawn to a position close to but not into the introducer sheath. Both the Gore® Viabahn® Endoprosthesis and introducer sheath can then be removed in tandem. After removal, neither the Gore® Viabahn® Endoprosthesis nor the introducer sheath should be reused.

**G. Deployment of the Gore® Viabahn® Endoprosthesis**

1. 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 endoprosthesis positioning.
2. Untwist the screw-connector at the base of the deployment knob. While keeping the extracorporeal segment of the catheter as straight as possible, slowly pull the deployment knob away from the adapter. **Deployment of the endoprosthesis will occur from the tip of the delivery catheter toward the hub.** If deployed as instructed, the endoprosthesis should not appreciably shorten. **Note:** Once deployment has started, repositioning of the endoprosthesis should not be attempted.
3. While maintaining the position of the guidewire across the treated lesion, carefully withdraw the delivery catheter through the lumen of the endoprosthesis and remove it via the introducer sheath. Moderate resistance may be felt when the distal tip exit of the hemostasis valve of the introducer sheath.

**Note:** If, during catheter removal, the tip olive catches on the leading edge of the endoprosthesis, a slight “back and forth” motion of the catheter may aid in release. Excessive or abrupt force during catheter removal may damage the endoprosthesis or cause separation at the catheter tip.

4. After deployment, the endoprosthesis must be smoothed and seated against the vessel wall by inflating an angioplasty balloon within it. Touch-up balloon diameter should be selected according to Table 1. It should be inflated to the desired diameter along the entire length of the endoprosthesis. If the endoprosthesis length exceeds that of the balloon, multiple inflations may be needed. After the balloon is inflated throughout the endoprosthesis, attention is required to ensure complete deflation of the balloon prior to cautious removal of the balloon catheter to prevent endoprosthesis displacement. Do not extend balloon dilatation beyond the ends of the device and into healthy vessel.
5. Using contrast angiography, evaluate the treated segment prior to completing the procedure. Further balloon inflations may be necessary if residual endoprosthesis folds or invaginations are visualized angiographically. A final angiographic run to evaluate vessel patency to the foot is recommended.
6. When clinically appropriate, remove the introducer sheath and achieve hemostasis of the puncture site.

**DEFINITIONS**

- **Do Not Use By**
- **Keep Dry**
- **Consult Instructions for Use**
- **Do Not Reuse**
- **Catalogue Number**
- **Lot**
- **Serial Number**
- **Authorised Representative in the European Community**
- **MR Conditional**
- **Only**
- **CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.**
- **Sterile**
- **Sterilized using Ethylene Oxide**
- **Do Not Use If Package is Damaged**
- **Store in a Cool Place**
- **Device Deploys from Tip to Hub**
- **Catheter Length**
- **Diameter**
- **Guidewire Compatibility**
- **Vessel Diameter**