INSTRUCTIONS FOR USE FOR:

VIABAHN® VBX

BALLOON EXPANDABLE ENDOPROSTHESIS

en
English

INSTRUCTIONS FOR USE FOR
GORE® VIABAHN® VBX Balloon Expandable 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® VBX Balloon Expandable Endoprosthesis consists of a 316L surgical grade stainless steel balloon expandable stent and a fluoropolymer graft. The CBAS® Heparin Surface on the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis consists of stable, covalent, end-point attached heparin of porcine origin. The endoprosthesis is premounted on a delivery system equipped with a balloon. The delivery system has two radiopaque balloon markers embedded in the shaft (denoting the effective balloon length) to aid in the placement of the endoprosthesis. The delivery system is compatible with 0.035" (0.89 mm) guidewires. The delivery system can be used for initial stent placement and post stent dilatation. The premounted stent system is available in a variety of endoprosthesis lengths from 15 to 79 mm and in a variety of diameters from 5 to 11 mm (See **Table 1**). The premounted endoprosthesis system balloon catheter is also offered in two shaft lengths.

This product is supplied sterile. It should not be resterilized.

Note: The diameter of the endoprosthesis may be increased post-placement beyond the nominal diameter by expanding with a larger diameter balloon. Refer to **Table 1** and **Table 2**.

FIGURE 1: GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

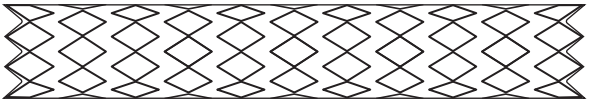
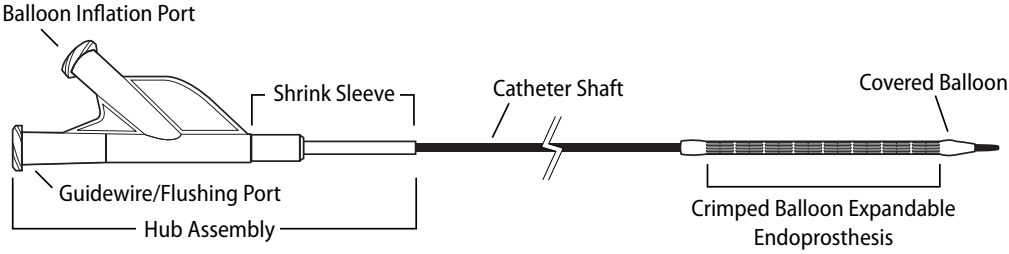


FIGURE 2: GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis Delivery System



INTENDED USE / INDICATIONS

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm - 13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation.

CONTRAINDICATIONS

Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II.

TABLE 1: GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis Sizes

Stent Labeled/ Nominal Diameter (mm)	Crimped Stent Length (mm)	Introducer Sheath Size (Fr)	Guidewire Diameter	Max. Post-Dilated Stent Diameter[1] (mm)	Catheter Length (cm)	RBP[3] (atm / kPa)
5	15, 19, 29, 39, 59, 79	7	0.035" (0.89 mm)	8	80, 135	15 / 1520
6	15, 19, 29, 39, 59, 79	7	0.035" (0.89 mm)	8	80, 135	15 / 1520
7	15, 19, 29, 39, 59, 79	7	0.035" (0.89 mm)	11	80, 135	15 / 1520
8	29, 39, 59	7	0.035" (0.89 mm)	11	80, 135	13 / 1317
	79	8				
8L	29, 39	7	0.035" (0.89 mm)	16[2]	80, 135	13 / 1317
	59, 79	8				
9	29, 39, 59, 79	8	0.035" (0.89 mm)	13	80, 135	13 / 1317
10	29, 39, 59, 79	8	0.035" (0.89 mm)	13	80, 135	13 / 1317
11	29, 39, 59, 79	8	0.035" (0.89 mm)	16[2]	80, 135	12 / 1216

[1] Secondary balloon required to post-dilate the stent beyond its nominal deployed diameter (secondary balloon not included).

[2] Technical limit of the device as determined by in-vitro testing for the indicated use; device expansion beyond 13 mm was not studied as part of the VBX FLEX clinical study.

[3] RBP is Rated Burst Pressure.

TABLE 2: GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis Sizing Table

Stent Labeled/ Nominal Diameter (mm)	Crimped Stent Length (mm)	At Nominal Pressure			At Rated Burst Pressure			At Max. Post-Dilated Stent Diameter[1]	
		Nominal Inflation Pressure (atm / kPa)	Final Stent ID (mm)	Stent Length[3] (mm)	Rated Burst Pressure (atm / kPa)	Final Stent ID (mm)	Stent Length[3] (mm)	Max. Post-Dilated Diameter (mm)	Stent Length at Max. Post-Dilated Stent Diameter[3] (mm)
5	15	14 / 1418	5.0	13.6	15 / 1520	5.1	13.5	8	10.5
	19	12 / 1216	5.0	18.2	15 / 1520	5.3	18.0	8	13.8
	29	12 / 1216	5.0	27.6	15 / 1520	5.3	27.3	8	22.3
	39	11 / 1114	5.0	37.8	15 / 1520	5.4	37.5	8	32.0
	59	11 / 1114	5.0	57.7	15 / 1520	5.3	57.3	8	51.2
	79	12 / 1216	5.0	77.3	15 / 1520	5.3	76.9	8	72.1
6	15	15 / 1520	6.0	13.1	15 / 1520	6.0	13.1	8	10.5
	19	15 / 1520	6.0	17.4	15 / 1520	6.0	17.4	8	14.6
	29	13 / 1317	6.0	27.5	15 / 1520	6.2	27.3	8	24.3
	39	14 / 1418	6.0	37.4	15 / 1520	6.1	37.3	8	33.3
	59	14 / 1418	6.0	57.5	15 / 1520	6.1	57.4	8	52.3
	79	12 / 1216	6.0	77.0	15 / 1520	6.3	76.7	8	73.6
7	15	15 / 1520	6.9	13.4	15 / 1520	6.9	13.4	11	9.5
	19	11 / 1114	6.9	17.7	15 / 1520	7.4	17.3	11	12.6
	29	11 / 1114	7.0	27.3	15 / 1520	7.4	26.8	11	19.4
	39	12 / 1216	7.0	37.0	15 / 1520	7.3	36.5	11	26.6
	59	12 / 1216	7.0	57.1	15 / 1520	7.3	56.7	11	46.9
	79	14 / 1418	7.0	77.3	15 / 1520	7.1	77.2	11	68.1
8	29	12 / 1216	8.0	26.9	13 / 1317	8.1	26.8	11	23.7
	39	12 / 1216	8.0	36.2	13 / 1317	8.1	36.1	11	30.0
	59	12 / 1216	8.0	56.1	13 / 1317	8.1	56.0	11	47.3
	79	11 / 1114	8.0	76.6	13 / 1317	8.3	76.4	11	69.6
8L	29	12 / 1216	8.0	29.0	13 / 1317	8.1	29.0	16[2]	21.8
	39	11 / 1114	8.0	39.0	13 / 1317	8.3	39.2	16[2]	26.8
	59	11 / 1114	8.0	59.4	13 / 1317	8.3	59.7	16[2]	44.1
	79	12 / 1216	8.0	79.3	13 / 1317	8.1	79.4	16[2]	58.6
9	29	11 / 1114	9.0	26.7	13 / 1317	9.3	26.4	13	20.4
	39	12 / 1216	9.0	36.3	13 / 1317	9.1	36.2	13	23.2
	59	11 / 1114	8.9	56.0	13 / 1317	9.2	55.7	13	38.1
	79	10 / 1013	8.9	76.2	13 / 1317	9.4	75.8	13	62.7
10	29	10 / 1013	10.0	25.4	13 / 1317	10.4	25.2	13	19.1
	39	11 / 1114	9.9	35.4	13 / 1317	10.2	35.3	13	31.1
	59	11 / 1114	10.0	55.3	13 / 1317	10.3	55.2	13	44.6
	79	11 / 1114	10.0	76.1	13 / 1317	10.3	76.2	13	68.4
11	29	10 / 1013	10.9	25.7	12 / 1216	11.4	25.4	16[2]	17.8
	39	11 / 1114	11.0	34.7	12 / 1216	11.2	34.6	16[2]	25.8
	59	10 / 1013	11.0	54.9	12 / 1216	11.4	54.5	16[2]	42.8
	79	10 / 1013	11.0	73.9	12 / 1216	11.5	73.7	16[2]	60.6

[1] Secondary balloon required to post-dilate the stent beyond its nominal deployed diameter (secondary balloon not included).
[2] Technical limit of the device as determined by in-vitro testing for the indicated use; device expansion beyond 13 mm was not studied as part of the VBX FLEX clinical study.
[3] Based on idealized in-vitro conditions and provided to be used as a general guide.

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. The foil pouch for the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is both a moisture barrier and a sterile barrier. DO NOT use or store the device if the foil pouch has been compromised.

WARNINGS

- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis for the treatment of lesions that would not allow an operative salvage procedure.
- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of HIT type II. With any vascular procedure, the possibility of HIT may exist. The incidence of HIT type II is extremely low in vascular patients receiving heparin over a period of several days. If HIT type II is diagnosed, established procedures for the treatment of this condition, including immediate cessation of systemic heparin administration, should be followed.[1,2] If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures, including ligation or removal of the device, may be considered at the discretion of the attending physician.
- Special care should be taken to ensure that the appropriate size endoprosthesis, compatible sheath and guidewire are selected prior to introduction. Native vessel dimensions must be accurately measured, not estimated.

- Do not exceed the maximum rated burst pressure. Exceeding this pressure increases the potential for balloon rupture and possible vessel damage.
- Do not exceed the max. post-dilated stent diameter as per **Table 1** and **Table 2**.
- To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis. Overstretching of the artery may result in rupture and life threatening bleeding.
- Use only diluted contrast medium for balloon inflation (typically a 50 / 50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium in the balloon.
- Do not remove the endoprosthesis from the balloon delivery system. The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should not be removed and placed on another balloon catheter for deployment. The endoprosthesis should only be deployed using the supplied delivery system.
- Do not use a kinked introducer sheath. A kinked introducer sheath may increase the force necessary to advance the endoprosthesis to the desired location.
- Do not attempt to deploy the endoprosthesis or manipulate the delivery system without an appropriately sized guidewire (**Table 1**) and fluoroscopic guidance.
- Prior to endoprosthesis deployment, utilize high-resolution fluoroscopy to verify that stent has not been damaged, partially deployed or dislodged during positioning. Do not deploy the endoprosthesis if damaged, partially deployed or dislodged.
- Do not attempt to withdraw or reposition the balloon catheter within the lumen of the deployed endoprosthesis unless the balloon is completely deflated.
- Do not withdraw the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis back into the introducer sheath once the endoprosthesis is fully introduced. Withdrawing the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis back into the sheath can cause dislocation and / or damage to the endoprosthesis, premature deployment, deployment failure, and / or catheter separation. If removal prior to deployment is necessary, withdraw the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis to a position close to but not into the introducer sheath. Both the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis and introducer sheath can then be removed in tandem. After removal, do not reuse the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis or introducer sheath.
- Inadvertent, partial, or failed deployment or migration of the endoprosthesis may require surgical intervention.
- As with any balloon expandable stent, placement of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in vessels susceptible to severe external compression may result in permanent compression of the device.
- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is not indicated for use in the coronary arteries, coronary bypass grafts, coronary sinus or carotid arteries.

PRECAUTIONS

- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is designed for single use only. 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.
- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if the sterile package is compromised or the endoprosthesis is damaged.
- Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis after the labeled "Use By" (expiration) date.
- Do not resterilize the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis should only be used by physicians trained in endovascular techniques.
- Follow the Directions for Use supplied with all accessories used in conjunction with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
- Antiplatelet medication should be initiated prior to and after placement of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Effective anticoagulation therapy, if needed, should be maintained at a dosage deemed appropriate by the physician. The presence of heparin on the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is not intended to serve as an alternative to the surgeon's chosen intraoperative or postoperative anticoagulation regimens.
- Prep premounted endoprosthesis system per instructions given in Directions For Use. Significant amounts of air in the balloon may cause difficulty in deploying the endoprosthesis and deflation of the balloon.
- Do not attempt to manually remove or adjust the endoprosthesis on the delivery balloon catheter.
- Always manipulate the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis delivery system under fluoroscopy when in the body. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is not designed for use with power injection systems. Inflation at a high rate can cause damage to the balloon catheter. Use of a pressure monitoring device is recommended to prevent over pressurization.

MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing has demonstrated that the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 1000-Gauss / cm or less
- Maximum whole body averaged specific absorption rate (SAR) limited to 2 W / kg (normal operating mode only)

Under the scan conditions defined above, the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is expected to produce a maximum temperature rise of less than 2.1°C after 15 minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by the device extends approximately 15 mm from the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis when imaged using a gradient echo pulse sequence and a 3-Tesla MRI system.

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, 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. A possible complication which may occur in conjunction with the use of systemic heparin: HIT type II.

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. A possible complication which may occur in conjunction with the use of any heparin-containing product: HIT type II (see Warnings).

DIRECTIONS FOR USE

Materials Required For Implantation

- GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis
- Marker guidewire or catheter (for calibrated measurement reference)
- Syringe filled with heparinized saline for prepping the endoprosthesis system
- Introducer sheath of appropriate size (**Table 1**)
- Stiff guidewire: diameter must be 0.035" (0.89 mm)
- Guidewire length should be at least twice the length of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis delivery catheter
- Appropriate diagnostic catheters and accessories
- Inflation device (20 cc or greater) and diluted contrast medium

Treatment of Vessel

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)

1. It is recommended to pre-dilate the lesion to allow for easy passage of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
2. Refer to manufacturer's Directions for Use.
3. 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 GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
4. 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® VBX Balloon Expandable 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.
      Stenotic or occlusive lesions: To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis. To prevent endoprosthesis migration, care should be taken to ensure the device is sufficiently apposed to the vessel wall between initial device deployment and post-dilatation (if performed).
   b. The endoprosthesis lengths of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis listed in **Table 1** are nominal. Wherever appropriate, it is recommended 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. Endoprosthesis foreshortening should be taken into account to achieve the recommended lesion coverage.
   c. Verify that there is sufficient catheter length to access the treatment site.
2. When overlapping (telescoping) multiple devices, the following are suggested:
   - To ensure proper seating, at least 1 cm of overlap between devices is suggested. Endoprosthesis foreshortening should be taken into account to achieve the recommended overlap between devices.
   - Overlapping devices should not differ by more than 1 mm in deployed diameter.
   - When using multiple endoprostheses to treat multiple lesions, it is recommended, wherever appropriate, to first treat the lesion that would obviate the need to cross the first endoprosthesis when placing the second or subsequent endoprosthesis. This would reduce the chance of disrupting or damaging the endoprostheses.
   - Balloon touch-up (post-dilatation) should be performed at the overlap region.
3. When deploying into a tapered vessel, consider the following:
   - To reduce the potential for vessel damage, the final stent inner diameter should approximate both the proximal and distal reference vessel diameters. This is possible when the device is deployed in a tapered configuration.
   - Note the range of diameters that each device configuration can achieve. For achievable diameters using the provided delivery system, refer to the compliance chart. For achievable diameters using a secondary balloon during post-dilatation, refer to **Table 1** and **Table 2** under the max. post-dilated stent diameter.

- Device tapering may be performed by first deploying the device to the smaller of the two reference vessel diameters and subsequently post-dilating the device in the region of the larger reference vessel diameter. To prevent endoprosthesis migration, care should be taken to ensure the device is sufficiently apposed to the vessel wall between initial device deployment and post-dilatation.
- When post-dilating with another balloon, choose a balloon length smaller than the deployed endoprosthesis length. Do not extend balloon dilatation beyond the ends of the endoprosthesis and into healthy vessel as this may also induce restenosis and subsequent failure. Do not expand any portion of the stent beyond the maximum post-dilated diameter as listed in **Table 1** and **Table 2**.
- When post-dilating the 8L device with a larger diameter balloon, do not increase the device diameter by more than 4 mm with a single balloon inflation. For example, to obtain a final diameter >12 mm from the nominal 8 mm diameter, first post-dilate with a 12 mm diameter secondary balloon before post-dilating with a larger diameter (13 - 16 mm) secondary balloon.

E. Preparation of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

1. Open the sterile package. Carefully inspect the packaging for damage to the sterile barrier. Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis after the "Use By" (expiration) date. Peel back the outer pouch and remove the sterile inner pouch and coil containing the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Beginning at one corner, peel back the edge of the inner pouch and gently remove the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis.
2. Inspection Prior to Use:
   - Prior to using the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, all materials and equipment to be used for the procedure should be carefully examined for bends, kinks, or other damage.
   - Do not use any damaged or defective equipment and materials.
   - Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if the sterile package is compromised or the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is damaged.
3. The distal end of the delivery catheter with the crimped endoprosthesis may be shaped or formed gently around a radius of about 6 mm or greater, prior to loading the catheter on a guidewire, to assist with trackability of the delivery system. Care should be taken to ensure that the metal stent rings are not deformed, displaced or damaged while shaping or forming.
4. Preparation of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis delivery catheter:
   a. Flush the delivery catheter by attaching a syringe of heparinized saline to the guidewire lumen port on the catheter hub assembly (**Figure 2**). Continue flushing until a steady stream of fluid exits the tip of the catheter.
   b. After flushing the catheter, remove the syringe.
   c. Prepare inflation device / syringe with diluted contrast medium. The standard inflation medium is a 50 / 50 mixture of contrast medium and normal saline or as deemed appropriate by the physician.
   d. Attach inflation device / syringe to stopcock (if needed). Attach to the endoprosthesis system inflation port.
   e. Open stopcock to the endoprosthesis system. With the distal balloon tip pointing down and placed below the level of the inflation device / syringe, pull negative pressure for 20 - 30 seconds. Carefully release to neutral for contrast fill. Do not apply any positive pressure at this time as it may result in partial deployment.
   f. Close stopcock to the endoprosthesis system; purge inflation device / syringe of all air.
   g. Repeat the previous two steps until all air is expelled. If bubbles persist, do not use the endoprosthesis system.
   h. If a syringe was used for preparation, attach a prepared inflation device to stopcock.
   i. Open stopcock between the endoprosthesis system and the inflation device.
5. Do not let the surface of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis dry once it has been wetted.

F. Introduction and Positioning of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

1. Select the compatible size introducer sheath from **Table 1**. Always use an appropriately sized sheath for the implant procedure. It is advisable to use a sheath or guide catheter that is long enough to cross the lesion. Use of a guide sheath or guide catheter minimizes the risk of dislodging the endoprosthesis from the balloon during tracking. Use standard interventional techniques to introduce the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis to the target lesion.
2. Ensure the stiff guidewire is 0.035" (0.89 mm).
3. Be sure to remove the balloon catheter while maintaining the position of the guidewire beyond the target lesion. It is strongly recommended that the guidewire remain across the lesion until the procedure is complete to avoid having to regain access.
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 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® VBX Balloon Expandable Endoprosthesis is introduced through the hemostasis valve, remove and inspect the delivery catheter for damage. Do not reuse the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis if damaged or if the covered stent is fluoroscopically observed to be displaced relative to the radiopaque markers on the delivery catheter. Ensure a compatible introducer sheath size (**Table 1**) is used, and that the introducer sheath is free of kinks. Do not insert the shrink sleeve or the hub assembly into the introducer sheath.
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 sheath together as a unit.
6. Position the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis across the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers (denoting the effective balloon length) as well as the radiopaque endoprosthesis as reference points to position the endoprosthesis in the lesion. **Note:** Upon deployment, the ends of the endoprosthesis will be located inside the effective length of the balloon, away from the radiopaque markers, due to longitudinal foreshortening. Endoprosthesis foreshortening should be taken into account to achieve the desired lesion coverage. During positioning, verify that the endoprosthesis is still centered within the marker bands and has not been dislodged. Do not deploy the endoprosthesis unless it is properly centered on the balloon and properly positioned

within the target lesion. If the position of the endoprosthesis within the lesion is not optimal, it should be carefully repositioned or removed.

Note: If PTA is performed, the endoprosthesis length should cover the entire vessel segment treated with balloon angioplasty. Wherever appropriate, it is recommended that the endoprosthesis extend at least 1 cm proximal and distal to the margins of the lesion.

7. Once the optimal position is verified fluoroscopically, the endoprosthesis is ready to be deployed.
   Note: Should it become necessary to remove either a partially expanded or non-deployed GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis from the vessel, do not withdraw the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis back into the introducer sheath after the endoprosthesis is fully introduced. To remove the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis, it can be withdrawn to a position close to but not into the introducer sheath. Both the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis and introducer sheath can then be removed in tandem. After removal, neither the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis nor the introducer sheath should be reused. Do not attempt to pull an endoprosthesis system that has been either partially expanded or not expanded back into the sheath or guide catheter, as dislodgement of the endoprosthesis from the balloon may occur. Carefully observe the endoprosthesis for stent dislodgement or movement while attempting to withdraw the undeployed stent back through the sheath.

G. Deployment of the GORE® VIABAHN® VBX Balloon Expandable 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. To reduce the potential for vessel damage, the final stent inner diameter (as indicated on the compliance chart) should approximate the diameter of the vessel just proximal and distal to the stenosis. To deploy the endoprosthesis, use an inflation device to slowly inflate the endoprosthesis system to the pressure needed for the desired diameter. Maintain the inflation pressure for approximately 15 seconds. Higher pressure may be necessary to overcome any luminal loss due to the lesion or to overcome stent recoil. Balloon pressures must not exceed rated burst pressure (Refer to **Table 1**). Extreme oversizing of the endoprosthesis relative to the vessel diameter may cause vessel damage. Undersizing of the endoprosthesis relative to the vessel diameter may lead to endoprosthesis migration. The compliance charts, provided on the box label, are generated in idealized *in vitro* conditions that do not take into account *in vivo* characteristics of lesions, vessels and patient-to-patient variability. Therefore, the compliance chart should be used as a general guide and user should confirm stent diameter and length angiographically during and after balloon inflation and deflation.
3. After deploying the endoprosthesis, slowly deflate the balloon manually using the inflation device to ensure proper balloon rewrap / refold. Allow adequate time for the balloon to fully deflate prior to removal. Observe fluoroscopically that the balloon is fully deflated prior to removal.
4. Maintaining proper sheath or guide catheter support, very slowly withdraw the balloon. Observe under fluoroscopy to ensure that the balloon disengages from the stent. If resistance is encountered upon attempted removal, do not force removal, use fluoroscopy and conventional techniques to determine and remedy the cause of resistance before proceeding. The balloon needs to be fully deflated to ensure it disengages fully from the endoprosthesis.
5. Confirm endoprosthesis position and deployment using angiographic techniques. For optimal results, the entire lesion should be covered by the stent. Fluoroscopic visualization should be used in order to properly judge the optimum expanded endoprosthesis diameter as compared to the proximal and distal reference vessel diameter.
6. If re-sizing is necessary, re-advance the delivery catheter, or another balloon catheter of appropriate size, to the stented area using standard interventional techniques.
7. While observing under fluoroscopy, inflate the balloon to the desired pressure; do not exceed the rated burst pressure. Do not expand the stent beyond maximum post-dilated stent diameter as shown in **Table 1** and **Table 2**. The maximum post-dilated stent diameter of 16 mm listed in **Table 1** and **Table 2** indicates the technical limit of the device as determined by in vitro testing for the indicated use. Device expansion beyond the diameter noted in the indication statement (13 mm) was not studied as part of the VBX FLEX clinical study. When using another balloon to post-dilate, choose a balloon length smaller than the deployed endoprosthesis length. Do not extend balloon dilatation beyond the ends of the endoprosthesis and into healthy vessel as this may also induce restenosis and subsequent failure. Deflate the balloon and follow the instructions as outlined previously.
8. Reconfirm endoprosthesis position and angiographic result. Repeat inflations until the desired result is achieved.
9. While maintaining negative pressure in the balloon and the guidewire position across the treated lesion, carefully remove the delivery catheter from the body through the sheath or guide catheter. Moderate resistance may be felt when the balloon is withdrawn through the introducer sheath.
   Note: If, during catheter removal, the balloon catches on the leading edge of the introducer sheath, a slight "back and forth" motion of the catheter may aid in release. If needed, the delivery catheter and the sheath or guide catheter may be removed together as a unit. Excessive or abrupt force during catheter removal may damage the delivery catheter, or introducer sheath.
10. A final angiographic run to evaluate vessel patency is recommended.
11. When clinically appropriate, remove the introducer sheath or guide catheter and achieve hemostasis of the puncture site.
12. Deployment of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the kissing stent configuration / technique is recommended when proximal common iliac disease (unilateral or bilateral) cannot be adequately covered without extending into the aortic bifurcation, or when the disease involves the aortic bifurcation. Device selection should be made to ensure that the final stented length properly covers the lesion. The two devices are advanced to the target location and the stent-grafts are deployed simultaneously. Additional devices may be deployed in an overlapping configuration to achieve proper lesion coverage. Any post-dilation in the kissing stent region should be conducted bilaterally and simultaneously to avoid crushing either device.

SUMMARY OF CLINICAL STUDIES

The VBX FLEX clinical study was a prospective, multicenter, single-arm clinical study to evaluate the safety and efficacy of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis for the treatment of arterial occlusive disease in patients with de novo or restenotic lesions in the common and / or external iliac arteries. The primary study endpoint was a composite of major adverse events defined as device- or procedure-related death within 30 days; myocardial infarction (MI) within 30 days; amputation above the metatarsals in the treated leg, resulting from a vascular event, within 9 months; or target lesion revascularization (TLR) within 9 months. The statistical analysis plan prospectively specified that subjects meeting all of the eligibility criteria would be used for analysis of study endpoints. A sensitivity analysis was performed for testing the primary hypothesis in the intent-to-treat (ITT) population, which included all enrolled subjects, as well as the per-protocol (PP) population which included only those subjects who met the study inclusion criteria. The performance goal was met in both analyses with p-values <0.001, providing evidence for similarity of the results between the two populations. All endpoint data reported is based on the PP population, unless otherwise specified.

A. Study Design

The study population included symptomatic (Rutherford Category 2 - 4) patients with angiographic confirmation of either de novo or restenotic unilateral or bilateral occlusive disease in the common and / or external iliac arteries, with a total treated lesion length of ≤110 mm and vessel diameters between approximately 5 mm and 13 mm. Patients were included who presented with up to two discrete lesions requiring treatment, either one lesion per side for patients presenting with bilateral disease, or two lesions on the same side. All subjects could be treated with up to three GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Eligible patients in the study included those presenting with tortuous iliac arteries, severe lesion calcification, total occlusions, and those determined to need direct stenting (pre-dilatation optional) and / or kissing stent treatment at the aortic bifurcation. 134 subjects meeting all eligibility criteria were enrolled across 26 sites in U.S. and 1 site in New Zealand.

B. Clinical Endpoints

1. Primary Endpoint

   The primary study endpoint was a composite of major adverse events (MAE) defined as device- or procedure-related death within 30 days; MI within 30 days; amputation above the metatarsals in the treated leg, resulting from a vascular event, within 9 months; or TLR within 9 months. The objective of the VBX FLEX clinical study was to demonstrate that the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is safe and effective for treatment of iliac artery disease by comparing the composite primary endpoint result to a pre-specified Performance Goal of 17.0%.

2. Secondary Endpoints

   The secondary endpoints in this study included acute procedural success, 30-day clinical success, primary patency, primary assisted patency, secondary patency, freedom from TLR, freedom from clinically-driven TLR, freedom from target vessel revascularization (TVR), freedom from clinically-driven TVR, change in Rutherford category, change in ankle-brachial index (ABI), and change in functional status (based on subject questionnaires). All of these secondary outcomes were evaluated descriptively without any pre-specified performance criteria.

C. Demographics and Clinical Characteristics

Table 3 reports the baseline demographics and clinical characteristics for all 134 subjects.

TABLE 3: Baseline Demographics and Clinical Characteristics

	N=134 subjects
Gender at Birth	
Male	79 (59.0%)
Age	
Mean (Std Dev)	66 (9.5)
Race	
American Indian or Alaskan Native	3 (2.2%)
Asian	2 (1.5%)
Black or African American	4 (3.0%)
Native Hawaiian or Pacific Islander	0 (0.0%)
White	123 (91.8%)
Other Race	3 (2.2%)
Medical History and Risk Factors	
Smoking History	
Never Smoked	7 (5.2%)
Quit ≤ 1 Year Ago	18 (13.4%)
Quit 1 - 5 Years Ago	8 (6.0%)
Quit > 5 Years Ago	43 (32.1%)
Current User	58 (43.3%)
Diabetes	38 (28.4%)
Hypertension	113 (84.3%)
Hyperlipidemia	104 (77.6%)
Hypercholesterolemia	64 (47.8%)
Coronary Artery Disease	56 (41.8%)
Previous Myocardial Infarction	25 (18.7%)
Prior Treatment on Study Limb	22 (16.4%)
Prior Treatment on Non-Study Limb	13 (9.7%)
Rutherford	
Category 2 - Moderate Claudication	26 (19.4%)
Category 3 - Severe Claudication	101 (75.4%)

Category 4 - Ischemic Rest Pain	7 (5.2%)
TASC II Classification	
Type A	50 (37.3%)
Type B	41 (30.6%)
Type C	32 (23.9%)
Type D	11 (8.2%)

Table 4 reports the baseline anatomic and lesion characteristics for all 134 subjects.

TABLE 4: Baseline Anatomic and Lesion Characteristics

BY SUBJECT	
Access Approach[1]	**N=134**
Ipsilateral	27 (20.1%)
Contralateral	24 (17.9%)
Bilateral	83 (61.9%)
Treated Segments[1]	**N=134**
1	59 (44.0%)
2	71 (53.0%)
3	4 (3.0%)
Treated Limb(s)[1]	**N=134**
Right	29 (21.6%)
Left	38 (28.4%)
Bilateral	67 (50.0%)
Kissing Stent Procedure	57 (42.5%)
Total Lesion Length per Subject (mm)[2]	**N=132**
Mean (Std Dev)	42.08 (23.98)
Total Stented Length per Subject (mm)[2]	**N=133**
Mean (Std Dev)	72.09 (29.39)
Number of Devices per Subject[2]	**N=134**
1	51 (38.1%)
2	69 (51.5%)
3	12 (9.0%)
4	1 (0.7%)
5	1 (0.7%)
BY LIMB	
Resting ABI[1]	**N=199**
Mean (Std Dev)	0.77 (0.22)
Treated Vessel(s)[1]	**N=201**
CIA	154 (76.6%)
EIA	31 (15.4%)
CIA and EIA	16 (8.0%)
Device(s) Successfully Delivered[1]	**N=201** 100%
Max Post-Procedure Residual Stenosis <= 30%[1]	**N=201** 100%
BY LESION	
Disease Characterization[2]	**N=210**
Stenosis	182 (86.7%)
Occlusion	28 (13.3%)
Maximum Stenosis (%)[2]	**N=182**
Mean (Std Dev)	62.1 (15.9)
Lesion Length (mm)[2]	**N=209**
Mean (Std Dev)	26.6 (16.3)
Stented Length (mm)[2]	**N=212**
Mean (Std Dev)	45.2 (14.4)

[1] Site reported.
[2] Core lab determination.

D. Methods

Following enrollment at the index procedure, all evaluable subjects were assessed at 1 month (± 7 days) and 9 months (± 30 days) post-index procedure. The severity of adverse events was determined by the site investigator based on the ISO 14155 definition of serious and non-serious adverse events. All adverse events were reviewed and adjudicated by the Clinical Events Committee. The Clinical Events Committee determined the final relationship of each adverse event and categorized each adverse event as device-related, index procedure-related, disease-related, unrelated to device, procedure, or disease, or unknown relationship. The Data Safety and Monitoring Board provided oversight of safety trends and reviewed site reported protocol deviations and source data related to subject eligibility. Independent core laboratories evaluated angiographic and ultrasound imaging obtained during the study procedure and at follow-up visits.

E. Safety and Effectiveness Results

1. Primary Endpoint

The primary endpoint result consisted of a composite of Major Adverse Events **(Table 5)**. No device- or procedure- related deaths and no myocardial infarctions for any subjects were reported within 30 days of the study procedure. No major amputations for any subjects were reported within 9 months of the study procedure. TLR was reported for 3 subjects within the 9 month follow-up interval. The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis demonstrated safety and effectiveness since the composite MAE of 2.3%, with the upper limit of the 95% confidence interval at 6.5%, was less than the performance goal of 17.0% (p<0.001).

TABLE 5: Primary Endpoint

Primary Endpoint	Number (Fraction) [95% CI]
Subjects Available for Assessment	N=132
Composite MAE	3 (2.3%) [0.5%, 6.5%]
P-Value	<0.001
Device or Procedure Related Death Within 30 Days	0 (0.0%) [0%, 2.3%]
MI Within 30 Days	0 (0.0%) [0%, 2.3%]
TLR Within 9 Months	3 (2.3%) [0.5%, 6.5%]
Major Amputation Within 9 Months	0 (0.0%) [0%, 2.3%]

2. Secondary Endpoints and additional analyses

Acute Procedural Success was defined as ≤ 30% residual stenosis prior to procedure completion and no device- or procedure-related serious adverse events (SAEs) before discharge. Thirty-day Clinical Success was defined as an improvement of at least one Rutherford Category at the 30-day visit as compared to pre-procedure and no device- or procedure-related SAEs within 30 days of the index procedure. Primary patency was defined as blood flow in the treated segment(s), without reintervention. Acute procedural success was 97.0% (N=134 subjects). Results of all other secondary endpoints at the pre-determined follow-up are summarized in **Table 6**. Kaplan-Meier estimates of survival probability at 1 month and 9 months are shown for primary patency, primary assisted patency, secondary patency, freedom from TLR, freedom from clinically-driven TLR, freedom from TVR, and freedom from clinically-driven TVR.

Upon discharge, there were no instances of residual stenosis greater than 30% **(Table 4)**. Four subjects experienced 5 SAEs before discharge, resulting in a 97.0% acute procedural success rate. One subject did not show evidence of blood flow through the treated segment at 1 month follow-up yet no treatment was attempted, therefore resulting in 99.2% primary patency, primary assisted patency, and secondary patency at 30 days but 100% freedom from TLR at 30 days.

TABLE 6: Secondary Endpoints, by subject[1]

ENDPOINT	1 MONTH	9 MONTHS
30-Day Clinical Success	90.8% (N=119)	N/A
Primary Patency	99.2% (N=128)	96.7% (N=98)
Primary Assisted Patency	99.2% (N=128)	99.2% (N=101)
Secondary Patency	99.2% (N=128)	99.2% (N=101)
fTLR	100% (N=133)	97.7% (N=109)
fCD-TLR	100% (N=133)	98.4% (N=110)
fTVR	100% (N=133)	97.7% (N=109)
fCD-TVR	100% (N=133)	97.7% (N=109)
Change in Rutherford From Pre-Procedure	Worsened / Maintained / Improved 0.8% / 5.1% / 94.1% (N=118)	Worsened / Maintained / Improved 0.0% / 5.4% / 94.6% (N=112)
Change in ABI From Pre-Procedure[1] Mean (Std Dev)	0.19 (0.22) (N=172)	0.19 (0.22) (N=168)
Change in Functional Status From Pre-Procedure		
EQ-5D	Worsened / Maintained / Improved	Worsened / Maintained / Improved
Mobility	6.1% / 49.6% / 44.3% (N=115)	3.5% / 54.4% / 42.1% (N=114)
Self-Care	1.7% / 93.9% / 4.3% (N=115)	2.6% / 92.1% / 5.3% (N=114)
Usual Activities	7.0% / 47.8% / 45.2% (N=115)	3.5% / 50.0% / 46.5% (N=114)
Pain / Discomfort	8.7% / 42.6% / 48.7% (N=115)	8.8% / 48.2% / 43.0% (N=114)
Anxiety / Depression	5.2% / 71.3% / 23.5% (N=115)	6.1% / 69.3% / 24.6% (N=114)
Own Health State (1 - 100)	7.0% / 73.7% / 19.3% (N=114)	15.0% / 64.6% / 20.4% (N=113)
WIQ	Median (IQR)[2]	Median (IQR)[2]
Differential Diagnosis	2 (0, 4) (N=115)	1 (0, 4) (N=114)
Walking Distance	10 (3, 19) (N=115)	10 (3, 18) (N=114)
Walking Speed	5 (1, 8) (N=114)	5 (0, 9) (N=114)
Stair Climbing	4 (1, 8) (N=107)	4 (0, 7) (N=110)

[1] ABI reported on per-limb basis.
[2] Higher scores indicate a healthier state.

Since a significant fraction of the overall population received kissing stents (42.5%, **Table 4**), additional analysis of the composite primary endpoint was conducted for this subgroup **(Table 7)**.

TABLE 7: Primary endpoint for the kissing stent subgroup

Primary Endpoint - Kissing Stent Subgroup	Number (Fraction) [95% CI]
Subjects Available for Assessment	N=57
Composite MAE	2 (3.5%) [0.4%, 12.1%]
Device or Procedure Related Death Within 30 Days	0 (0.0%) [0%, 5.3%]
MI Within 30 Days	0 (0.0%) [0%, 5.3%]
TLR Within 9 Months	2 (3.5%) [0.4%, 12.1%]
Major Amputation Within 9 Months	0 (0.0%) [0%, 5.3%]

A description of all adjudicated/unrefuted SAEs through 9 months is provided in **Table 8**. Two (2) patients were censored from the primary endpoint analysis. The reasons for discontinuation (missing data) were lost to follow-up and death. This death occurred on Day 187 and was not associated with the study device or procedure. This death was related to subject co-morbidities that resulted in cardiac arrest. No subjects experienced a SAE related to the study device within 9 months. There were no unanticipated device-related events reported in the study within 9 months.

TABLE 8: Description of Serious Adverse Events through 9 months

Subjects Enrolled	**134**
Subjects Experiencing Serious Adverse Events	30 (22.4%) [43]
Blood and Lymphatic System Disorders	1 (0.7%) [1]
Haemorrhagic Anaemia	1 (0.7%) [1]
Cardiac Disorders	4 (3.0%) [4]
Acute Myocardial Infarction	1 (0.7%) [1]
Angina Pectoris	1 (0.7%) [1]
Cardiac Failure Congestive	1 (0.7%) [1]
Coronary Artery Disease	1 (0.7%) [1]
Gastrointestinal Disorders	3 (2.2%) [3]
Gastrointestinal Haemorrhage	1 (0.7%) [1]
Rectal Haemorrhage	1 (0.7%) [1]
Umbilical Hernia	1 (0.7%) [1]
General Disorders and Administration Site Conditions	2 (1.5%) [2]
Non-Cardiac Chest Pain	1 (0.7%) [1]
Vascular Stent Occlusion	1 (0.7%) [1]
Infections and Infestations	4 (3.0%) [4]
Clostridium Difficile Infection	1 (0.7%) [1]
Pneumonia	1 (0.7%) [1]
Postoperative Wound Infection	1 (0.7%) [1]
Urinary Tract Infection	1 (0.7%) [1]
Injury, Poisoning, and Procedural Complications	8 (6.0%) [10]
Arterial Restenosis	1 (0.7%) [1]
Humerus Fracture	1 (0.7%) [1]
Incisional Hernia	1 (0.7%) [1]
Joint Dislocation	1 (0.7%) [1]
Post Procedural Haematoma	1 (0.7%) [1]
Postoperative Ileus	1 (0.7%) [1]
Vascular Pseudoaneurysm	2 (1.5%) [2]
Wound Dehiscence	2 (1.5%) [2]
Metabolism and Nutrition Disorders	1 (0.7%) [1]
Hyperkalaemia	1 (0.7%) [1]
Neoplasms Benign, Malignant and Unspecified (including cysts and polyps)	2 (1.5%) [2]
Lung Adenocarcinoma	1 (0.7%) [1]
Prostate Cancer	1 (0.7%) [1]
Nervous System Disorders	2 (1.5%) [2]
Carotid Artery Stenosis	1 (0.7%) [1]
Vascular Dementia	1 (0.7%) [1]
Renal and Urinary Disorders	1 (0.7%) [1]
Acute Kidney Injury	1 (0.7%) [1]
Respiratory, Thoracic, and Mediastinal Disorders	1 (0.7%) [1]
Chronic Obstructive Pulmonary Disease	1 (0.7%) [1]
Vascular Disorders	8 (6.0%) [11]
Femoral Artery Dissection	1 (0.7%) [1]
Haematoma	1 (0.7%) [1]
Hypovolaemic Shock	1 (0.7%) [1]
Intermittent Claudication	2 (1.5%) [3]
Lymphocele	1 (0.7%) [1]
Peripheral Arterial Occlusive Disease	1 (0.7%) [1]
Peripheral Artery Stenosis	1 (0.7%) [1]
Peripheral Ischaemia	1 (0.7%) [1]
Poor Peripheral Circulation	1 (0.7%) [1]

3. Results by Gender
   No statistically significant difference in the primary endpoint was observed based on gender.
4. Applicability to Pediatric Population
   Peripheral artery disease is not typically found in pediatric populations. The VBX FLEX clinical study did not evaluate the safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in the pediatric population.
5. Summary of Results
   The primary endpoint for the VBX FLEX clinical study consisted of a composite of major adverse events to evaluate the safety and effectiveness of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis through 9 months. The composite MAE of 2.3%, with the upper limit of the 95% confidence interval at 6.5%, was less than the performance goal of 17.0% ($p<0.001$). Within 9 months, no subjects experienced a SAE related to the study device and there were no unanticipated device-related events reported. Additionally, secondary endpoints including Rutherford status and functional status improved through 9 months follow-up, providing evidence of relief from clinical symptoms and a corresponding increase in quality of life. In conclusion, the VBX FLEX clinical study demonstrated that the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is safe and effective in treating subjects with de novo or restenotic lesions found in iliac arteries.

REFERENCES

1. Linkins LA, Dans AL, Moores LK, Bona R, Davidson BL, Schulman S, Crowther M; American College of Chest Physicians. Treatment and prevention of heparin-induced thrombocytopenia: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141(2) Supplement:e495S-e530S.
2. Warkentin TE. Heparin-coated intravascular devices and heparin-induced thrombocytopenia. In: Warkentin TE, Greinacher A, eds. *Heparin-Induced Thrombocytopenia.* 5th ed. New York, NY: Informa Healthcare USA; 2012;(20):573-590.

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

Keep Dry

Manufacturer

MR Conditional

SN Serial Number

STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

Store in a Cool Place

Use By

Catheter Working Length

Final Stent ID

Guidewire Compatibility

Inflation Pressure

Introducer Sheath

Max Post-Dilated Stent Diameter

NP Nominal Pressure

Nominal Stent Diameter

RBP Rated Burst Pressure

\+ Second Balloon Required, Not Included

Stent Length

20037751

Manufacturer
W. L. Gore & Associates, Inc.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES
Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763
Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

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

DECEMBER 2016
20037691