

INSTRUCTIONS FOR USE FOR:



VIABAHN®

ENDOPROSTHESIS



VIABAHN®
ENDOPROSTHESIS

HEPARIN
BIOACTIVE SURFACE

en

English

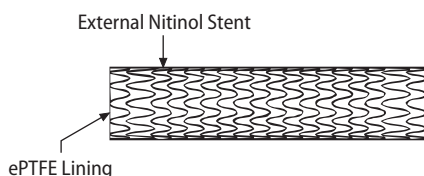
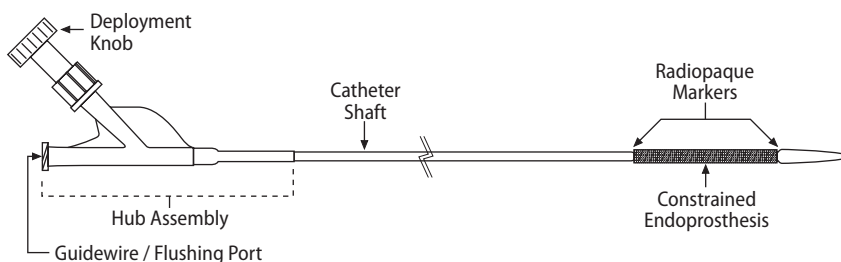
INSTRUCTIONS FOR USE FOR

GORE® VIABAHN® Endoprosthesis**GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface**

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 device is also available with the Heparin Bioactive Surface, where the surface of the endoprosthesis is modified with covalently bound, bioactive heparin. 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. The GORE® VIABAHN® Endoprosthesis should not be resterilized.

FIGURE 1: GORE® VIABAHN® ENDOPROSTHESIS**FIGURE 2: GORE® VIABAHN® ENDOPROSTHESIS DELIVERY SYSTEM****INTENDED USE / INDICATIONS**

The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery lesions with reference vessel diameters ranging from 4.0 – 7.5 mm.

The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions with reference vessel diameters ranging from 4.0 – 12 mm.

CONTRAINDICATIONS

The GORE® VIABAHN® Endoprosthesis is contraindicated for 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.

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

TABLE 1: SIZING TABLE

Device Sizing		Introducer Sheath Size (Fr) Guidewire Diameter 0.035" (0.889 mm)	Introducer Sheath Size (Fr) Guidewire Diameter 0.018" (0.460 mm)	Available Device Lengths' (cm)	Recommended Balloon Diameter for Device Touch-up (mm) ²
Labeled Device Diameter (mm)	Recommended Vessel Diameter (mm)				
5	4.0 – 4.7	7	6	2.5, 5, 10, 15	5.0
6	4.8 – 5.5	7	6	2.5, 5, 10, 15	6.0
7	5.6 – 6.5	8	7	2.5, 5, 10, 15	7.0
8	6.6 – 7.5	8	7	2.5, 5, 10, 15	8.0
9	7.6 – 8.5	9	-	5, 10, 15	9.0
10	8.6 – 9.5	11 ¹	-	2.5, 5, 10, 15	10.0
11	9.6 – 10.5	11	-	2.5, 5, 10	12.0
13	10.6 – 12.0	12	-	2.5, 5, 10	14.0

¹ Labeled device lengths are nominal.

² For the 11 and 13 mm diameter devices, balloon inflation pressure should not exceed 8 atm.

³ 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. The foil pouch for the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is both a moisture barrier and a sterile barrier. DO NOT use or store the device if the foil pouch has been compromised.

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. The presence of heparin on the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is not intended to serve as an alternative to the physician's chosen intraoperative or postoperative anticoagulation regimens.
- 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).

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 superficial femoral or iliac arteries.
- 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.
- 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.
- Do not use in patients with a history of intolerance or adverse reaction to antiplatelet and / or anticoagulation therapies, bleeding diathesis, severe hypertension or renal failure.

- Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of HIT type II. There is no data to demonstrate that the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface causes, or contributes to, the condition of HIT. The incidence of HIT type II is extremely low in vascular bypass 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. If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures, including removal of the endoprosthesis, 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 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) and 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® VIABAHN® Endoprosthesis is designed for single use only.
- 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 endovascular techniques. The implantation procedure should be performed only at facilities where surgical expertise is available.
- 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.
- Antiplatelet 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. The presence of heparin on the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is not intended to serve as an alternative to the physician’s chosen intraoperative or postoperative anticoagulation regimens.
- 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 MR Conditional

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 bodied 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 bodied 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 T1 – 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, 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.

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 aneurysms; infection; inflammation; fever and / or pain in the absence of infection; deployment failure; migration; and device failure.

Tables 7-11, 17, and 18 reflect a complete description of adverse events observed in the clinical studies of the GORE® VIABAHN® Endoprosthesis.

CLINICAL STUDIES FOR SFA AND ILIAC ARTERIES

SUMMARY OF SFA CLINICAL STUDIES

The results of two separate studies support the safety and efficacy of the GORE® VIABAHN® Endoprosthesis. NOTE: These clinical findings are for the GORE® VIABAHN® Endoprosthesis without Heparin Bioactive Surface.

PMA Trial (P040037)

A total of 244 cases were treated at 25 US investigational sites. The purpose of the study was to compare the safety and effectiveness of the GORE® VIABAHN® Endoprosthesis to percutaneous transluminal angioplasty (PTA) in patients with chronic lower limb ischemia or chronic lifestyle altering claudication due to superficial femoral artery (SFA) atherosclerotic disease. A total of 241 patients or 244 cases (limbs) were treated in the study. Each site was permitted up to two training cases. A total of 47 training cases were performed; 197 cases were randomized with 100 assigned to PTA and 97 to the GORE® VIABAHN® Device.

Study Endpoints: The primary endpoint was primary patency of the treated vessel at 12 months. Secondary endpoints included clinical success, the adverse event rate, as well as changes in the Ankle-Brachial Index (ABI), clinical success, and limb ischemia score. For purposes of analysis, patency of the treated vessel and technical success were redefined to more accurately reflect current clinical practices. The original endpoint definition of patency included the composite variables of technical success and treatment success of the treated vessel. Based on current clinical practices, the definition of patency was redefined as “no target revascularization procedure and no evidence of restenosis or occlusion within the originally treated vessel based on a centrally-read CFDU.” Definitions are provided below Table 3. Endpoints were analyzed on an intent-to-treat (ITT) and per protocol (PP) basis.

Patients Studied: Eligible patients were candidates for PTA with de novo or restenotic atherosclerotic or occlusive lesion(s) of the superficial femoral artery causing either chronic lifestyle altering claudication or chronic lower limb ischemia. Stenotic or occlusive lesion(s) originating in the SFA were ≤ 13 cm in length and ranging from 4.5 mm to 12 mm in diameter.

Methods: Patients eligible for the study, who had a percent diameter stenosis of < 50% following the initial PTA, were prospectively randomized to treatment with the GORE® VIABAHN® Endoprosthesis or PTA. Baseline angiography was performed pre-PTA, post-PTA and post-procedure. Duplex Color Flow Doppler Ultrasound (CFDU) and clinical assessments were completed at discharge, and 1, 6 and 12 months post-procedure. For redefined patency of the target vessel, centrally read CFDU videotapes were utilized. Occlusion and restenosis were defined as no color flow or at least a focal doubling of peak systolic velocity (PSVR) respectively. PSVRs were calculated and videos with a PSVR greater than 2.0, as well as indeterminate cases, were identified for further review.

Physician-Sponsored IDE (PS-IDE) Trial Including 5 mm Devices (G030195)

Five vascular surgeons treated a total of 100 limbs at one US investigational site. The purpose of the study was to compare the safety and effectiveness of the GORE® VIABAHN® Endoprosthesis to open surgical bypass in patients requiring invasive treatment for (SFA) occlusive disease. Forty patients (50 limbs) were randomized to treatment with the stent-graft and 46 patients (50 limbs) were randomized to treatment with femoral to above-knee popliteal artery bypass.

Study Endpoints: The primary endpoint was primary patency of the treated vessel at 12 months. Technical success (successful completion of the assigned procedure), symptomatic improvement, limb salvage rates, and length of hospital stay were also measured as part of this study.

Patients Studied: Eligible patients had documented stenotic or occlusive lesions in the SFA or above-knee popliteal artery, had failed conservative treatment, and were in need of invasive treatment.

Methods: Patients eligible for the study were prospectively randomized to treatment with the GORE® VIABAHN® Endoprosthesis or surgical bypass. Duplex Ultrasound and clinical assessments were completed post-operatively and at 3, 6, 9, and 12-months post-procedure.

Study Results for Both Studies: Baseline characteristics of the treatment groups are summarized in Table 2.

TABLE 2: SUMMARY OF PRE-PROCEDURE CHARACTERISTICS FOR SFA STUDIES

Variable	PMA IDE Study (P040037)			PS IDE Study (G030195)	
	PTA (N = 100)	GORE® VIABAHN® Device All Cases (N = 144)	GORE® VIABAHN® Device Randomized Cases (N = 97)	GORE® VIABAHN® Device All Cases (N = 50)	GORE® VIABAHN® Devices 5 mm (N = 21)
Age (years), Mean ± SD	66.9 ± 9.5	66.7 ± 10.1	67.2 ± 9.7	66.9	70.2
Males	70 (70.0%)	114 (79.2%)	80 (82.5%)	33 (66%)	8 (38%)
History of Smoking	51 (51.0%)	73 (50.7%)	45 (46.4%)	26 (54%)	10 (48%)
History of MI	30 (30.0%)	38 (26.4%)	23 (23.7%)	NR*	NR
History of Diabetes Mellitus	34 (34.0%)	49 (34.0%)	36 (37.1%)	22 (44%)	10 (48%)
ABI, Mean ± SD	0.67 ± 0.18	0.73 ± 0.18	0.74 ± 0.17	0.47	0.60
RVD (mm), Mean ± SD	5.6 ± 0.8	5.6 ± 0.6	5.6 ± 0.6	NR	NR
MLD (mm), Mean ± SD	1.1 ± 1.0	1.2 ± 1.0	1.3 ± 1.0	NR	NR
Lesion Length (cm), Mean ± SD	6.7 ± 3.7	7.3 ± 3.6	7.3 ± 3.6	25.6**	23.8**
Percent Diameter Stenosis (%), Mean ± SD	80.9 ± 17.1	77.7 ± 18.2	77.7 ± 17.5	NR	NR
Occlusion	29 (29.0%)	37 (25.7%)	20 (20.6%)	NR	NR

* NR = Not Recorded

** Recorded treatment length

PMA Study Results: The study was originally designed to enroll 415 patients. However, due to clinical study design and endpoint definitions, the Sponsor terminated the study prior to completion of enrollment. Technical success and primary patency were redefined, as described above, to be more clinically relevant. No safety issues were involved in the termination decision. Sites were instructed to follow their patients through the one year exam with optional follow-up at two years. Follow-up compliance through 12 months was 69% (69 / 100) for the PTA group and 79% (114 / 144) for the GORE® VIABAHN® Device group.

As shown in Table 3, there were no differences between the GORE® VIABAHN® Endoprosthesis and PTA groups in the rates of primary patency of the treated vessel or technical success. The GORE® VIABAHN® Device cases showed higher mean rates of treatment success and clinical success at 12 months.

For redefined patency of the target vessel and technical success, the GORE® VIABAHN® Device group had higher mean rates. A further breakdown of redefined patency by lesion length resulted in a benefit for GORE® VIABAHN® Device cases with longer lesions (Table 5). Similarly, redefined technical success for GORE® VIABAHN® Device cases with longer lesions (3 – 12 cm) was better than those in the PTA group (Table 6).

As shown in Table 4, the GORE® VIABAHN® Device group demonstrated a trend toward greater clinical improvement at 6 and 12 months, as assessed with the clinical status score. There were no differences between groups in the mean change from baseline for the resting ABI and limb ischemia scores.

Physician-Sponsored IDE Study Results: One hundred limbs were enrolled in the study. Follow-up compliance at the 12-month visit was 86% (43 / 50) for the GORE® VIABAHN® Device group. The primary patency results and technical success reported for the GORE® VIABAHN® Endoprosthesis in this study are comparable to the results of the PMA Study (Table 3). Clinical Improvement data as collected in the PMA Trial was not available for the PS-IDE Study, and is thus not included in Table 4. Primary patency and technical success by lesion length for the PS-IDE is included in Tables 5 and 6.

Gender bias

A higher proportion of males (75%) than females (25%) were included in the PMA trial, which is reflective of the distribution of the disease in the population. Females did not demonstrate as pronounced an advantage as males with respect to treatment success, clinical success, redefined patency and redefined technical success. The early and late adverse event rates for males and females were comparable. It was noted that GORE® VIABAHN® Device male cases had a higher rate of early adverse events (major or minor) than PTA male cases (31.6% GORE® VIABAHN® Endoprosthesis and 15.7% PTA). The difference is a result of a higher proportion of reports of minor pain in the leg, groin or back. The rates of adverse events for all other types of complications are comparable between groups for males.

The overall proportion of males (60%) in the PS-IDE Study was slightly lower than that in the PMA Trial. However, the proportion of males in the 5 mm GORE® VIABAHN® Device cohort was only 38%. This difference is not unexpected given the physiological differences in vessel size between men and women.

TABLE 3: SUMMARY OF EFFECTIVENESS OUTCOMES FOR SFA STUDIES

Effectiveness Measures	PMA IDE Study (P040037)			PS IDE Study (G030195)	
	PTA	GORE® VIABAHN® Device All Cases	GORE® VIABAHN® Device Randomized	GORE® VIABAHN® Device All Cases	GORE® VIABAHN® Device 5 mm
ITT Population	(N = 100)	(N = 144)	(N = 97)	(N = 50)	(N = 21)
12 Month Outcomes					
Primary Patency	45%	51%	50%	73%	63%
Clinical Success	69%	84%	81%	—	—
Treatment Success	84%	94%	94%	—	—
Technical Success	61%	65%	59%	100%	100%
Redefined					
Patency at 12 Months	40%	62%	65%	—	—
Technical Success	66%	94%	95%	—	—

PMA STUDY DEFINITIONS

Primary Patency of the Target Vessel: A composite of treatment success, technical success and freedom from interrupted blood flow or revascularization to the treated vessel.

Treatment Success: Completion of the assigned procedure without an additional recovery procedure or major adverse event, stenosis < 50% and patency by Color Flow Doppler Ultrasound (CFDU).

Technical Success: Treatment success and at 30 days no major adverse event and improvement in segmental limb pressure of 0.15.

Clinical Success: Improvement of at least one category using the Rutherford Clinical Status Scale (1997). Cases with tissue loss must have improved by at least two categories and reach the level of claudication to be considered improved.

Redefined Technical Success: Successful completion of the assigned treatment and post-treatment angiographic results demonstrating less than 30% residual stenosis.

Redefined Patency of the Target Vessel: No target vessel revascularization (TVR) procedure and no evidence of restenosis or occlusion within the originally treated vessel based on a centrally-read CFDU (occlusion and restenosis are defined as no color flow or at least a doubling of focal systolic velocity respectively).

PS-IDE STUDY DEFINITIONS

Primary Patency of the Target Vessel Segment: The percentage of grafts or endoprostheses which are patent without the need for invasive treatment to recover or maintain patency at 12 months.

Technical success: Successful completion of the assigned procedure.

TABLE 4: SUMMARY OF CLINICAL OUTCOMES FOR SFA STUDIES

Clinical Measures	PTA	GORE® VIABAHN® Device All Cases	GORE® VIABAHN® Device Randomized
ITT Population	(N = 100)	(N = 144)	(N = 97)
Clinical Status: Improved			
1 Month	89%	88%	87%
6 Months	72%	84%	85%
12 Months	75%	84%	82%
Change in Limb Ischemia (means)			
1 Month	-1.73	-1.64	-1.61
6 Months	-1.36	-1.55	-1.61
12 Months	-1.45	-1.72	-1.62
Change in ABI (means)			
Discharge	.28	.25	.24
1 Month	.29	.24	.22
6 Months	.18	.22	.19
12 Months	.22	.22	.19

TABLE 5: SUMMARY OF REDEFINED TARGET VESSEL PATENCY BY LESION LENGTH-ITT POPULATION FOR SFA STUDIES

Variable % (N)	PMA IDE Study (P040037)			PS IDE Study (G030195)	
	PTA	GORE® VIABAHN® Device All Cases	GORE® VIABAHN® Device Randomized	GORE® VIABAHN® Device All Cases	GORE® VIABAHN® Device 5 mm
All	40% (100)	62% (144)	65% (97)	73% (50)	63% (21)
Treatment Segment Length					
≤ 3 cm	66% (21)	67% (23)	65% (19)	50% (2)	50% (2)
3 – 6 cm	39% (28)	56% (39)	64% (19)	100% (3)	100% (2)
6 – 9 cm	28% (21)	66% (37)	67% (29)	—	—
9 – 12 cm	38% (24)	67% (29)	68% (21)	75% (5)	50% (2)
> 12 cm	17% (6)	54% (16)	56% (9)	70% (40)	60% (15)

TABLE 6: SUMMARY OF REDEFINED TECHNICAL SUCCESS BY LESION LENGTH-ITT POPULATION FOR SFA STUDIES

Variable % (N)	PMA IDE Study (P040037)			PS IDE Study (G030195)	
	PTA	GORE® VIABAHN® Device All Cases	GORE® VIABAHN® Device Randomized	GORE® VIABAHN® Device All Cases	GORE® VIABAHN® Device 5 mm
All	66.0% (100)	94.4% (144)	94.8% (97)	100% (50)	100% (21)
Treatment Segment Length					
≤ 3 cm	90.5% (21)	91.3% (23)	94.7% (19)	100% (2)	100% (2)
3 – 6 cm	60.7% (28)	94.9% (39)	94.7% (19)	100% (3)	100% (2)
6 – 9 cm	71.4% (21)	94.6% (37)	93.1% (29)	—	—
9 – 12 cm	45.8% (24)	93.1% (29)	95.2% (21)	100% (5)	100% (2)
> 12 cm	66.7% (6)	100% (16)	100.0% (9)	100% (40)	100% (15)

Adverse Events

There was a slight trend toward increased early AE rates in the GORE® VIABAHN® Device groups compared with the control group; the difference in the early AE rates is small and does not raise safety concerns (Table 7). For complications especially pertinent to the procedure and device, the rates of occurrence of major amputation, bleeding events, vascular complications, and distal embolization were clinically indistinguishable. The rate of major device malfunction was low.

The rate of mortality was low in the study. One GORE® VIABAHN® Device patient (0.7%) with significant co-morbidities died during the original hospitalization.

The rate of freedom from TVR was comparable between groups.

No significant differences in adverse events were noted between the PMA Trial and PS-IDE Study.

TABLE 7: SUMMARY OF SAFETY FOR SFA STUDIES

Safety Measures ITT Population	PMA IDE Study (P040037)			PS IDE Study (G030195)	
	PTA (N = 100)	GORE® VIABAHN® Device All Cases (N = 144)	GORE® VIABAHN® Device Randomized (N = 97)	GORE® VIABAHN® Device All Cases (N = 50)	GORE® VIABAHN® Device 5 mm (N = 21)
Major Early Adverse Events					
Any Major Adverse Event	4.0%	7.6%	8.2%	2.0%	4.7%
Amputation	1.0%	0.0%	0.0%	0.0%	0.0%
Bleeding Complications	0.0%	0.0%	0.0%	0.0%	0.0%
Vascular Complications	0.0%	1.4%	1.0%	0.0%	0.0%
Distal Embolization	1.0%	3.5%	4.1%	0.0%	0.0%
Device Malfunction	0.0%	1.4%	2.1%	0.0%	0.0%
Late Adverse Events (any major)	13.0%	12.5%	8.2%	4.0%	4.7%
Mortality within 30 Days	0.0%	0.7%	1.0%	0.0%	0.0%
TVR Free Rate at 12 Months	79%	75%	80%	74%*	67%*

* TLR Free Rate at 12 months

Amputation: Surgical removal of any portion of the involved leg, foot or toes.

Bleeding Complication: Procedural blood loss of more than 1000 ml or post-procedure related bleeding that occurs after the subjects left the OR resulting in need for transfusion.

Vascular Complication: Arterial rupture, artery injury, AV fistula, dissection, erosion through the vessel wall, false aneurysm, or puncture site bleeding.

Distal Embolization: Thrombus or embolism distal to the original treatment site.

TVR: Target vessel revascularization.

TLR: Target lesion revascularization.

Tables 8 – 11 reflect a more detailed description of AEs observed in the clinical studies of the GORE® VIABAHN® Endoprosthesis.

TABLE 8: COMPARISON OF EARLY MAJOR ADVERSE EVENTS (≤ 30 Days) FOR SFA STUDIES

Adverse Event Category ITT Population N (%)	PMA IDE Study (P040037)			PS IDE Study (G030195)	
	PTA (N = 100)	GORE® VIABAHN® Device All Cases (N = 144)	GORE® VIABAHN® Device Randomized (N = 97)	GORE® VIABAHN® Device All Cases (N = 50)	GORE® VIABAHN® Device 5 mm (N = 21)
Any Major Event*	4 (4.0)	11 (7.6)	8 (8.2)	1 (2.0)	1 (4.7)
Amputation	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bowel Ischemia / Obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contrast / Medication Reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac	3 (3.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Distal Embolization	1 (1.0)	5 (3.5)	4 (4.1)	0 (0.0)	0 (0.0)
Hematoma	1 (1.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Infection	0 (0.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Neurovascular	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain (leg / groin / back)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.0)	1 (4.7)
Paraparesis / Paraplegia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Post Implant Syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary	0 (0.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Renal Failure	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stroke / TIA	0 (0.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Vascular	0 (0.0)	2 (1.4)	1 (1.0)	0 (0.0)	0 (0.0)
Deep Venous Thrombosis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

- * Any Major Event includes the following: a) requires therapy, minor hospitalization (< 48 hours),
b) requires major therapy, unplanned increase in level of care, prolonged hospitalization,
c) permanent adverse sequelae or d) death. Cases may have had multiple events.

TABLE 9: COMPARISON OF LATE MAJOR ADVERSE EVENTS (30 Days to 12 Months) FOR SFA STUDIES

Adverse Event Category ITT Population N (%)	PMA IDE Study (P040037)			PS IDE Study (G030195)	
	PTA (N = 100)	GORE® VIABAHN® Device All Cases (N = 144)	GORE® VIABAHN® Device Randomized (N = 97)	GORE® VIABAHN® Device All Cases (N = 50)	GORE® VIABAHN® Device 5 mm (N = 21)
Any Major Event*	13 (13.0)	18 (12.5)	8 (8.2)	2 (4.0)	1 (4.7)
Amputation	1 (1.0)	2 (1.4)	1 (1.0)	1 (2.0)**	1 (4.7)**
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bowel Ischemia / Obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contrast / Medication Reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac	8 (8.0)	11 (7.6)	4 (4.1)	0 (0.0)	0 (0.0)
Distal Embolization	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hematoma	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infection	1 (1.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
Neurovascular	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
Pain (leg / groin / back)	0 (0.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Paraparesis / Paraplegia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Post Implant Syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal Failure	0 (0.0)	2 (1.4)	2 (2.1)	0 (0.0)	0 (0.0)
Stroke / TIA	1 (1.0)	4 (2.8)	1 (1.0)	0 (0.0)	0 (0.0)
Vascular	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deep Vein Thrombosis	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

- * Any Major Event includes the following: a) requires therapy, minor hospitalization (< 48 hours),
b) requires major therapy, unplanned increase in level of care, prolonged hospitalization,
c) permanent adverse sequelae or d) death. Cases may have had multiple events.

** This subject was enrolled into the GORE® VIABAHN® Device arm of the study and failed at 52 days. He was diagnosed with Heparin Induced Thrombocytopenia (HIT). He was then enrolled into the fem-pop arm of the study and failed at 10 days. He subsequently required an above-knee amputation.

TABLE 10: COMPARISON OF EARLY MINOR ADVERSE EVENTS (≤ 30 Days) FOR SFA STUDIES

Adverse Event Category ITT Population N (%)	PMA IDE Study (P040037)			PS IDE Study (G030195)	
	PTA (N = 100)	GORE® VIABAHN® Device All Cases (N = 144)	GORE® VIABAHN® Device Randomized (N = 97)	GORE® VIABAHN® Device All Cases (N = 50)	GORE® VIABAHN® Device 5 mm (N = 21)
Any Minor Event*	17 (17.0)	33 (22.9)	24 (24.7)	6 (12.0)	2 (9.4)
Amputation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bowel Ischemia / Obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contrast / Medication Reaction	4 (4.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Cardiac	2 (2.0)	4 (2.8)	3 (3.1)	0 (0.0)	0 (0.0)
Distal Embolization	2 (2.0)	6 (4.2)	4 (4.1)	0 (0.0)	0 (0.0)
Hematoma	7 (7.0)	13 (9.0)	12 (12.4)	1 (2.0)	0 (0.0)
Infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurovascular	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain (leg / groin / back)	3 (3.0)	14 (9.7)	10 (10.3)	0 (0.0)	0 (0.0)
Paraparesis / Paraplegia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Post Implant Syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal Failure	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stroke / TIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular	3 (3.0)	7 (4.9)	6 (6.2)	2 (4.0)	2 (9.4)
Other**	1 (1.0)	4 (2.8)	3 (3.1)	3 (6.0)	0 (0.0)

* A Minor Adverse Event is an adverse event that does not meet the definition of a Major Adverse Event. See Table 8.

** Other includes the following: PMA GORE® VIABAHN® Device: Thigh pain; focal slight intimal defect distal to the stent graft; nausea; generalized pruritus without rash. PS-IDE GORE® VIABAHN® Device: Mild edema, intraoperative sheath placement. PTA: After femoral compression was applied to right groin, patient experienced vasovagal reaction without hypotension.

TABLE 11: COMPARISON OF LATE MINOR ADVERSE EVENTS (30 Days to 12 Months) FOR SFA STUDIES

Adverse Event Category ITT Population	PMA IDE Study (P040037)			PS IDE Study (G030195)	
	PTA (N = 100)	GORE® VIABAHN® Device All Cases (N = 144)	GORE® VIABAHN® Device Randomized (N = 97)	GORE® VIABAHN® Device All Cases (N = 50)	GORE® VIABAHN® Device 5 mm (N = 21)
Any Minor Event*	2 (2.0)	6 (4.2)	5 (5.2)	0 (0.0)	0 (0.0)
Amputation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bowel Ischemia / Obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contrast / Medication Reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac	0 (0.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Distal Embolization	0 (0.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Hematoma	0 (0.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurovascular	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain (leg / groin / back)	3 (3.0)	3 (2.1)	1 (1.0)	0 (0.0)	0 (0.0)
Paraparesis / Paraplegia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Post Implant Syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal Failure	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stroke / TIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular	0 (0.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

* A Minor Adverse Event is an adverse event that does not meet the definition of a Major Adverse Event. See Table 8.

PATIENT DEATH SUMMARY FOR SFA STUDIES

One GORE® VIABAHN® Device subject died 16 days after the procedure. This subject had significant co-morbidities and sepsis was reported as the cause of death.

One GORE® VIABAHN® Device subject and three PTA subjects died more than 30 days but less than 12 months post-procedure. The GORE® VIABAHN® Device patient died approximately six months post-procedure. The exact date and cause are unknown. Two PTA subjects died due to a myocardial infarction (MI) and the third due to a pulmonary embolus and MI.

In the second year of follow-up, two GORE® VIABAHN® Device subjects died. One died with secondary heart failure due to chemotherapy and radiation therapy for lung cancer. The other subject had a history of coronary artery disease (CAD), congestive heart failure (CHF), MI and diabetes. This subject developed gangrene and had an above-knee amputation; the patient expired several days later.

In the PS-IDE Study, three patients in the GORE® VIABAHN® Device test group died during the study period from conditions unrelated to infrainguinal disease.

OBSERVED DEVICE MALFUNCTIONS FOR SFA STUDIES

Device malfunctions were observed in eight cases (ten incidents). Those involving the delivery catheter included four attributed to difficulty removing the delivery device and two catheter tip breakage.

One involved a deployment failure or malfunctioning stent, one introduction with device kinking, one balloon catheter rupture during post-dilation and one guidewire tip breakage.

No device malfunctions were noted in the PS-IDE study.

SELECTED SFA PUBLICATIONS

Additional clinical experiences using the GORE® VIABAHN® Endoprosthesis in the superficial femoral artery have been reported in the literature. These reports provide additional long-term performance information regarding the safety and effectiveness of the device for the superficial femoral artery indication. Selections from that literature are included below (See Tables 12 and 13) and the literature citations are provided at the end of this section. These studies report patency rates comparable to those reported in the PMA. Technical success that was reported was 100%. Adverse events reported in the literature were minor and occurred acutely. The rate of distal embolization reported in the clinical trials in Table 7 are comparable to the range of rates reported in the literature.

TABLE 12: SUMMARY OF EFFECTIVENESS (PATENCY) FROM SELECTED SFA GORE® VIABAHN® ENDOPROSTHESIS LITERATURE

Author Yr. Tx. Seg.	N (Limbs) / Avg. Length (cm)	Primary Patency (years)						Patency Definition
		0.5	1	2	3	4	5	
Bley 2004 SFA	67 / 14.3	84%	82%	73%	68%	54%	47%	Patent by duplex ultrasound
Saxon 2004 SFA	42 / > 10	90%	86%	79%	79%	70%	—	No occlusion and absence of 50% restenosis as determined by duplex ultrasound (PSVR < 2.0)
Bauermeister 2001 SFA	35 / 22	79%	73%	—	—	—	—	No occlusion and absence of 50% restenosis as determined by duplex ultrasound
Lammer 2000 SFA	80 / 13.8	90%	79%	—	—	—	—	No occlusion and absence of 50% restenosis as determined by duplex ultrasound (PSVR < 2.5)
Average	224 / 15.0	86%	80%	76%	73.5%			

TABLE 13: SUMMARY OF SAFETY (ADVERSE EVENTS) FROM SELECTED SFA GORE® VIABAHN® ENDOPROSTHESIS LITERATURE

Author Yr. Tx. Seg*	N (Limbs) / Avg. Length (cm)	Distal Embolization	Hematoma	Post-Implant Syndrome [†]	Acute Thrombosis	Infection	Conversion	Amputation	Death
Tarantini 2004 SFA	28 / 29	NR**	NR	NR	NR	NR	NR	11% ¹	0%
Saxon 2004 SFA	42 / > 10	7% ² (minor) 7% (req. tx.)	NR	15% ³	5%	NR	NR	NR	NR
Bleyn 2004 / 2002 SFA	67 / 14.3	27% ⁴	9% ⁵	NR	— ⁴	NR	NR	1%	1% ⁶
Jahnke 2003 SFA Fem Pop	52 / 8.5	7.7% ⁷	13.5%	5.8% ⁸	2%	NR	0% in first 30 days	NR	NR
Bauermeister 2001 SFA	35 / 22	NR	NR	NR	3%	NR	NR	NR	NR
Lammer 2000 SFA	80 / 13.8	3%	2%	NR	4%	0%	0%	0%	0%
Total	304 / 16.2								

* Treated Segment. SFA refers to superficial femoral artery; Fem-Pop refers to Femoropopliteal artery.

** NR = None Reported for a particular adverse event, although adverse events are discussed within the publication. Fields with — reflect papers without any discussion of adverse events generally.

- 1 "There were three amputations: one for graft failure and two for progressive gangrene despite graft patency."
- 2 "Angiography detectable embolization was seen in 14% (6 / 42) of treated limbs in our series. However three of these cases were felt to be clinically insignificant small vessel occlusions, they caused no adverse event clinical sequelae and one resolved spontaneously. Clinically significant embolization occurred in 7% (3 / 42) of treated limbs. The majority of embolizations were detected in patients who had an endograft placed following catheter-directed thrombolysis for acute arterial occlusions. Further lysis or suction embolectomy has been universally successful in severe / symptomatic cases."
- 3 Post Implantation Syndrome is described as localized thigh pain occurring for one to two weeks following device placement and appears to be related to excessive oversizing of touch-up ballooning of the GORE® VIABAHN® Endoprosthesis. "The pain started immediately after placement and lasted 1 to 2 weeks, occasionally requiring narcotic analgesia..." "We suspect the pain is because of over-expansion of the vessel by the endoprosthesis at initial dilation. We now dilate the device to the size of the normal vessel... Since we have stopped substantially over-dilating the vessel, pain postprocedure has been much less of an issue."
- 4 Distal embolization and acute thrombosis are reported together. "Peripheral emboli or postoperative thrombosis was diagnosed in 18 (26.9%) patients, but only one was resistant to immediate thrombolysis." "The Hemobahn endoprosthesis was implanted percutaneously without systemic heparinization."
- 5 "Conservatively treated hematoma."
- 6 "Death due to a retroperitoneal hematoma in combination with poor cardiopulmonary function."
- 7 "All successfully treated by aspiration thrombectomy and / or short-term local fibrinolysis..." "All cases of distal embolization occurred in patients who initially presented with total occlusions..." "were without clinical sequelae."
- 8 "Minor groin hematoma in seven patients..." "were without clinical sequelae."

LITERATURE CITATIONS FOR SELECTED SFA PUBLICATIONS

Tarantini FA, Smeraldi AG, Naar D, *et al.* Use of expanded polytetrafluoroethylene covered endoprosthesis for the treatment of infrainguinal arterial occlusive disease. Abstract presented at the Eastern Vascular Society (EVS) 18th Annual Meeting. April 29 – May 2, 2004. Philadelphia, PA.

Bleyn J, Schol F, Vamnhandenhove I, Vercaeren P, Marien C. Endovascular reconstruction of the superficial femoral artery. In: Becquemini JP, Alimi YS, Watelet J, Loisanne D, eds. *Controversies and Updates in Vascular & Cardiac Surgery*. Torino, Italy. Edizioni Minerva Medica 2004;14:87-91.

Bleyn J, Goverde P. Hemobahn in superficial femoral artery occlusive disease: long-term results. Abstract presented at the 15th Annual International Congress. February 10-14, 2002. Scottsdale, AZ Page X-7.

Saxon RR, Coffman JM, Gooding JM, Ponec DJ. Stent-graft use in the femoral and popliteal arteries. *Techniques in Vascular and Interventional Radiology* 2004;7(1):6-15.

Jahnke T, Andresen R, Müller-Hülsbeck S, *et al.* Hemobahn stent-grafts for treatment of femoropopliteal arterial obstructions: midterm results of a prospective trial. *Journal of Vascular & Interventional Radiology* 2003;14:41-51.

Bauermeister G. Endovascular stent-grafting in the treatment of superficial femoral artery occlusive disease. *Journal of Endovascular Therapy* 2001;8:315-320.

Lammer J, Dake MD, Bleyn J, *et al.* Peripheral arterial obstruction: Prospective study of treatment with a transluminally placed self-expanding stent graft. *Radiology* 2000;217:95-104.

CONCLUSIONS DRAWN FROM THE SFA STUDIES

The randomized clinical trial results, and information drawn from the published literature, provide reasonable assurance that the GORE® VIABAHN® Endoprosthesis is safe and effective when used in accordance with its labeling. Multicenter, randomized clinical study results demonstrated that the GORE® VIABAHN® Device when compared to PTA resulted in higher rates of treatment success, technical success, and 12-month patency as defined by current clinical standards. Likewise, the GORE® VIABAHN® Device cases demonstrated a trend toward greater improvement for clinical success and clinical status scores. Other primary efficacy parameters were comparable between the GORE® VIABAHN® Endoprosthesis and PTA groups. Multicenter clinical data show that the rates of adverse events for the GORE® VIABAHN® Endoprosthesis group were comparable to the PTA group.

The preclinical testing information and the randomized clinical trial results provide valid scientific evidence and reasonable assurance that the GORE® VIABAHN® Endoprosthesis is safe and effective when used in accordance with its labeling.

SUMMARY OF ILIAC CLINICAL DATA

NOTE: These clinical findings are for the GORE® VIABAHN® Endoprosthesis without Heparin Bioactive Surface.

GORE® VIABAHN® Endoprosthesis Case Review for the Iliac Arteries

Case Report Form (CRF) records were reviewed for 42 subjects with 45 limbs treated for iliac arterial occlusive disease with the GORE® VIABAHN® Endoprosthesis. These records were initially collected as part of the GORE® VIABAHN® Endoprosthesis Feasibility Studies that were conducted in the US (IDE G960121) and Europe from 1996 to 1999. The purpose of the study was to evaluate the safety and effectiveness of the GORE® VIABAHN® Endoprosthesis in patients with documented atherosclerotic stenotic or occlusive lesion(s) of the iliac arteries causing either chronic life-style altering claudication or chronic critical lower-limb ischemia.

Case Review Assessments: The primary assessment was primary patency of the treated lesion at 12 months. Technical success, procedural success, clinical improvement, and device-related AEs were also measured.

Patients Studied: Eligible patients had documented atherosclerotic stenotic or occlusive lesion(s) of the iliac arteries causing either chronic life-style altering claudication or chronic critical lower-limb ischemia.

Methods: Patients eligible for the study, with a percent diameter stenosis of < 30% following the initial PTA, were treated with the GORE® VIABAHN® Endoprosthesis. Blood flow, as defined by non-invasive methods, and clinical assessments were completed post-operatively and at 1, 3, 6, and 12-months post-procedure.

Case Review Results: Baseline characteristics of the treatment groups are summarized in Table 14.

TABLE 14: SUMMARY OF PRE-PROCEDURE CHARACTERISTICS FOR ILIAC ARTERY CASE REVIEW

Variable	GORE® VIABAHN® Device (N = 42)
Age (years), Mean ± SD	59.6 ± 10.6
Males	30 (71.4%)
History of Nicotine Use	37 (90.2%)
History of Coronary Arterial Disease	10 (25.0%)
History of Diabetes Mellitus	9 (21.4%)
ABI, Mean ± SD	0.58 ± 0.17
RVD (mm), Mean ± SD	7.8 ± 1.8
MLD (mm), Mean ± SD	2.3 ± 2.1
Lesion Length (cm), Mean ± SD	4.2 ± 2.6
Percent Diameter Stenosis (%), Mean ± SD	67.1 ± 29.9

CRF records were reviewed for 42 subjects with 45 limbs enrolled. Follow-up compliance at the 12-month visit was 90.5% (38 / 42). The primary patency results and technical success for the GORE® VIABAHN® Endoprosthesis are reported in Table 15. Of the 45 limbs in the analysis, 86.1% maintained primary patency through 12 months. Only one limb (2.3%) occluded within the first 30 days. The 44 limbs with device placement data were considered technical successes (100%); of these, 41 limbs were procedural successes (93.2%). The three limbs in two subjects that did not achieve procedural success experienced serious AEs during the procedure (two embolisms and one “lost guidewire”). All three of these events were resolved at the time of procedure with no clinical sequelae (the embolisms were treated with aspiration thrombectomy and fibrinolysis; the lost guidewire in the contralateral limb was treated with exposure of common femoral artery). Clinical Improvement data is presented in Table 16. ABI, clinical category (Rutherford), and limb ischemia score all showed improvement at 12 months compared to baseline.

TABLE 15: SUMMARY OF EFFECTIVENESS OUTCOMES FOR ILIAC ARTERY CASE REVIEW

Effectiveness Measures	GORE® VIABAHN® Device
12-Month Primary Patency	86.1%
Technical Success	100%
Procedural Success	93.2%

CASE REVIEW STUDY DEFINITIONS

Primary Patency: Primary patency was defined as uninterrupted blood flow through an unrevised device.

Technical Success: Technical success was defined as; a) correct placement of the device and, b) no interventions to restore blood flow at time of procedure after device placement.

Procedural Success: Procedural success was defined as achieving Technical Success and reporting no serious adverse events at the time of procedure.

TABLE 16: SUMMARY OF CLINICAL OUTCOMES FOR ILIAC ARTERY STUDY

Clinical Measures	GORE® VIABAHN® Device — All Cases
Rutherford Clinical Category (12 Months)	
0 (Asymptomatic)	67.5%
1 (Mild Claudication)	12.5%
2 (Moderate Claudication)	15%
3 (Severe Claudication)	5%
4 – 6 (Ischemic Rest Pain to Major Tissue Loss)	0%
Limb Ischemia Change (12 Months)	
Mean Change	1.5
Improved at Least One Category	95%
Improved at Least Two Categories	87.5%
Ankle Brachial Index (Mean)	
Baseline	0.58
1 Month	0.91
6 Months	0.88
12 Months	0.85

Device-Related Adverse Events

No serious device-related events were reported (Table 17). Three non-serious deployment-related events were reported: “distal olive caught by sheath”, “rupture of carrier catheter”, and “prosthesis caught on guidewire”. In all cases the GORE® VIABAHN® Device was deployed successfully and there were no clinical sequelae.

TABLE 17: SUMMARY OF DEVICE-RELATED ADVERSE EVENTS FOR ILIAC ARTERY CASE REVIEW

ADVERSE EVENTS	Serious Adverse Events		All Adverse Events	
	Early (≤ 30 days)	All (≤ 365 days)	Early (≤ 30 days)	All (≤ 365 days)
N (Data Available)	45	45	45	45
All Adverse Events	0 (0.0%) [0]	0 (0.0%) [0]	3 (6.7%) [3]	3 (6.7%) [3]
Access Site Complications	—	—	—	—
Amputation	—	—	—	—
Arterial Aneurysm	—	—	—	—
Bleeding, Significant	—	—	—	—
Cardiac – Myocardial Infarction	—	—	—	—
Cardiac – Other	—	—	—	—
Device Deployment Failure	—	—	—	—
Device Deployment Issue	—	—	3 (6.7%) [3]	3 (6.7%) [3]
Device Infection	—	—	—	—
Device Leak	—	—	—	—
Device Migration	—	—	—	—
Embolism	—	—	—	—
Gastrointestinal	—	—	—	—
Infection – Systemic	—	—	—	—
Neurologic – Stroke	—	—	—	—
Neurologic – Other	—	—	—	—
Pulmonary	—	—	—	—
Renal	—	—	—	—
Vascular Event without Device Revision	—	—	—	—
Vessel Disruption or Dissection	—	—	—	—
Other	—	—	—	—

Serious adverse events were defined as: death; life-threatening events; events which result in permanent impairment of a body function or permanent damage to body structure; events which necessitate medical or surgical intervention by a health care professional to 1) preclude permanent impairment of a body function or permanent damage to body structure, or 2) to relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure.

Number reflects the number of limbs reporting at least one adverse event.

Percentage reflects the percentage of limbs reporting at least one adverse event.

Number in brackets reflects the total number of adverse events reported.

All Adverse Events

A total of 11 subjects (26.2%) experienced a serious AE throughout the course of the study; of these, six subjects (seven limbs) experienced early serious AEs (Table 18). These events were Access Site Complications (1), Cardiac-MI (1), Embolism (1), Vascular Event without Device Revision (2), and Other (1). The two Vascular Events without Device Revision were occlusions of the non-study limb. The Other event was a "lost guidewire" in the left (contralateral) groin that required exposure of the left common femoral artery.

A total of 23 subjects (54.8%) experienced an AE through the course of the study, with 17 of these subjects experiencing an event within 30 days post-procedure (Table 18). The most frequently reported adverse event was Vascular Event without Device Revision, all but one of which occurred in non-study limbs (e.g., contralateral) and non-study lesions (e.g., SFA). The one iliac study limb event was stenosis above and below the GORE® VIABAHN® Device that was attributed to disease progression and was not considered to be device-related.

TABLE 18: SUMMARY OF ALL ADVERSE EVENTS FOR ILIAC ARTERY CASE REVIEW

ADVERSE EVENTS	Serious Adverse Events		All Adverse Events	
	Early (≤30 days)	All (≤365 days)	Early (≤30 days)	All (≤365 days)
N (Data Available)	42	42	42	42
All Adverse Events	6 (14.3%) [7]	11 (26.2%) [14]	17 (40.5%) [19]	23 (54.8%) [34]
Access Site Complications	1 (2.4%) [1]	1 (2.4%) [1]	2 (4.8%) [2]	3 (7.1%) [3]
Amputation	—	—	—	—
Arterial Aneurysm	—	—	—	—
Bleeding, Significant	—	—	—	—
Cardiac – Myocardial Infarction	1 (2.4%) [1]	1 (2.4%) [1]	1 (2.4%) [1]	1 (2.4%) [1]
Cardiac – Other	—	1 (2.4%) [1]	—	2 (4.8%) [2]
Device Deployment Failure	—	—	—	—
Device Deployment Issue	—	—	3 (7.1%) [3]	3 (7.1%) [3]
Device Infection	—	—	—	—
Device Leak	—	—	—	—
Device Migration	—	—	—	—
Embolism	1 (2.4%) [2]	1 (2.4%) [2]	2 (4.8%) [3]	2 (4.8%) [3]
Gastrointestinal	—	—	1 (2.4%) [1]	2 (4.8%) [2]
Infection – Systemic	—	—	—	—
Neurologic – Stroke	—	1 (2.4%) [1]	—	1 (2.4%) [1]
Neurologic – Other	—	—	—	—
Pulmonary	—	—	—	—
Renal	—	—	2 (4.8%) [2]	3 (7.1%) [3]
Vascular Event without Device Revision	2 (4.8%) [2]	6 (14.3%) [7]	3 (7.1%) [3]	10 (23.8%) [12]
Vessel Disruption or Dissection	—	—	1 (2.4%) [1]	1 (2.4%) [1]
Other	1 (2.4%) [1]	1 (2.4%) [1]	3 (7.1%) [3]	3 (7.1%) [3]

Serious adverse events were defined as: death; life-threatening events; events which result in permanent impairment of a body function or permanent damage to body structure; events which necessitate medical or surgical intervention by a health care professional to; 1) preclude permanent impairment of a body function or permanent damage to body structure, or 2) to relieve unanticipated temporary impairment of a body function or unanticipated temporary damage to body structure.

Number reflects the number of subjects reporting at least one adverse event.

Percentage reflects the percentage of subjects reporting at least one adverse event.

Number in brackets reflects the total number of adverse events reported.

PATIENT DEATH SUMMARY FOR ILIAC ARTERY CASE REVIEW

No patient deaths were reported.

OBSERVED DEVICE MALFUNCTIONS FOR ILIAC CASE REVIEW

Three non-serious deployment-related events were reported: “distal olive caught by sheath”, “rupture of carrier catheter”, and “prosthesis caught on guidewire”. In all cases the GORE® VIABAHN® Device was deployed successfully and there were no clinical sequelae.

CONCLUSIONS DRAWN FROM THE ILIAC ARTERY CASE REVIEW

The pre-clinical testing information and the clinical trial results provide valid scientific evidence and reasonable assurance that the GORE® VIABAHN® Endoprosthesis is safe and effective when used in accordance with its labeling

DIRECTIONS FOR USE

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)
- Appropriate diameter stiff guidewire (Table 1)
- 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

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.

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.
 - c. Verify that there is sufficient catheter length to access the treatment site.
2. When overlapping (telescoping) multiple devices, the following are suggested:
 - Balloon touch-up (post-dilatation) should be performed on the first device prior to placing the second device.
 - To ensure proper seating, at least 1 cm of overlap between devices is suggested.
 - Overlapping devices should not differ by more than 1 mm in diameter.
 - 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.

E. Preparation of the GORE® VIABAHN® Endoprosthesis

1. Open 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.
 - 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.
 - Do not use any defective equipment.
 - Do not use the GORE® VIABAHN® Endoprosthesis if the sterile package is compromised or the GORE® VIABAHN® Endoprosthesis is damaged.
3. Preparation of the GORE® VIABAHN® Endoprosthesis delivery catheter.
 - a. 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 and the deployment lumen at the proximal end of the device.
 - b. After flushing the catheter, remove the syringe.
4. Do not let the surface of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface dry once it has been wetted.

F. Introduction and Positioning of the GORE® VIABAHN® Endoprosthesis

1. Select the compatible size introducer sheath from Table 1.
2. Ensure the stiff guidewire is the appropriate diameter (Table 1)
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 sheath together.

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.
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 is withdrawn through the introducer sheath. Note: If, during catheter removal, the tip catches on the leading edge of the endoprosthesis or introducer sheath, a slight “back and forth” motion of the catheter or repositioning of the sheath may aid in release. Excessive or abrupt force during catheter removal may damage the endoprosthesis, delivery catheter, or introducer sheath.
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. Failure to post-dilate along the entire length of the endoprosthesis may lead to restenosis and graft failure. 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 as this may also induce restenosis and subsequent graft failure.**
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

 Use By

 Caution


 Consult Instructions for Use

 Do Not Resterilize


 Do Not Reuse

 Catalogue Number


 Batch Code

 Authorised Representative in the European Community

 MR Conditional

 **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


 Catheter Working Length

 Delivery Profile

 Do Not Use if Package is Damaged

 Keep Dry

 Store in a Cool Place

 Manufacturer

 Guidewire Compatibility

 Vessel Diameter



AP3360-ML2



 Manufacturer

W. L. GORE & ASSOCIATES, INC.

Flagstaff, Arizona 86004 • USA

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


GORE®, VIABAHN®, and designs are trademarks of W. L. Gore & Associates.

AVANTI® is a trademark of Johnson & Johnson Gateway, LLC.

SUPER SHEATH is a trademark of Boston Scientific Corporation.

INTRADYN is a trademark of B. Braun Medical, Inc.

© 2005, 2007, 2009-2011 W. L. Gore & Associates, Inc.

 Printed on recyclable paper

MARCH 2011