INSTRUCTIONS FOR USE FOR:

GORE

VIABAHN®
ENDOPROSTHESIS

HEPARIN
BIOACTIVE SURFACE

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English

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INSTRUCTIONS FOR USE FOR

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 with Heparin Bioactive Surface 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 includes 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 with Heparin Bioactive Surface is supplied STERILE. The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface should not be resterilized.

FIGURE 1: *GORE® VIABAHN®* ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE

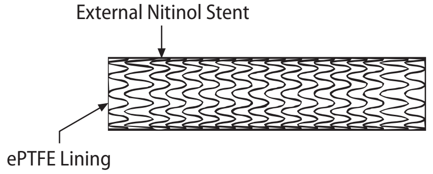
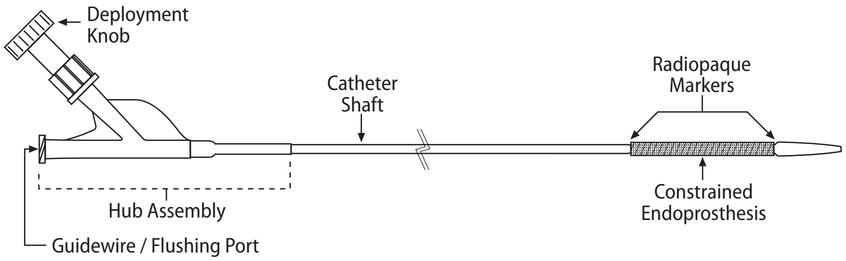


FIGURE 2: *GORE® VIABAHN®* ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE DELIVERY SYSTEM



INTENDED USE / INDICATIONS

The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery lesions up to 230 mm in length with reference vessel diameters ranging from 4.0 – 7.5 mm.

The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0 – 12 mm.

The GORE® VIABAHN® Endoprosthesis is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts.

CONTRAINDICATIONS

The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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)	Available Device Lengths[2] (cm)	Guidewire Diameter	Recommended Balloon Diameter for Device Touch-up (mm)[3]	Deployment Direction
Labeled Device Diameter (mm)	Recommended Vessel Diameter[1] (mm)					
5	4.0 – 4.7	7	2.5, 5, 10, 15, 25	0.035" (0.889 mm)	5.0	Tip to hub
6	4.8 – 5.5	7	2.5, 5, 10, 15, 25	0.035" (0.889 mm)	6.0	Tip to hub
7	5.6 – 6.5	8	2.5, 5, 10, 15, 25	0.035" (0.889 mm)	7.0	Tip to hub
8	6.6 – 7.5	8	2.5, 5, 10, 15, 25	0.035" (0.889 mm)	8.0	Tip to hub
9	7.6 – 8.5	9	5, 10, 15	0.035" (0.889 mm)	9.0	Tip to hub
10	8.6 – 9.5	11[4]	2.5, 5, 10, 15	0.035" (0.889 mm)	10.0	Tip to hub
11	9.6 – 10.5	11	2.5, 5, 10	0.035" (0.889 mm)	12.0	Tip to hub
13	10.6 – 12.0	12	2.5, 5, 10	0.035" (0.889 mm)	14.0	Tip to hub

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

PACKAGE HANDLING

Store in a cool dry place. This product has an expiration date and should be used before the labeled "use by" (expiration) date marked on the box. 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 with Heparin Bioactive Surface 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 with Heparin Bioactive Surface, 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 with Heparin Bioactive Surface 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, iliac arteries or the venous anastomosis of the arteriovenous (AV) access circuit.
- W. L. Gore & Associates has insufficient clinical and experimental data upon which to base any conclusions regarding the effectiveness of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in applications where the device is deployed within stents or stent grafts other than the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface or the GORE® VIABAHN® Endoprosthesis. Other devices may interfere with the deployment of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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 with Heparin Bioactive Surface in applications where the endoprosthesis may experience repeated and extreme flexion, such as across the popliteal fossa. Clinical conditions such as excessive bending, tortuosity, and / or repeated and extreme flexion may result in compromised performance or failure of the endoprosthesis. No device migrations or fractures were detected in 25 devices placed across the antecubital fossa in the AVR 06-01 Clinical Study and patency rates were comparable to those of the entire GORE® VIABAHN® Endoprosthesis cohort.
- Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface for the treatment of lesions that would not allow an operative salvage bypass procedure.
- Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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 with Heparin Bioactive Surface. 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 with Heparin Bioactive Surface back into the introducer sheath once the endoprosthesis is fully introduced. Withdrawing the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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 with Heparin Bioactive Surface to a position close to but not into the introducer sheath. Both the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface and introducer sheath can then be removed in tandem. After removal, do not reuse the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface or introducer sheath.
- Inadvertent, partial, or failed deployment or migration of the endoprosthesis may require surgical intervention.

PRECAUTIONS

- The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is designed for single use only.
- Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface if the sterile package is compromised or the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is damaged.
- Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface after the labeled "use by" (expiration) date.
- Do not resterilize the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface.

- The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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 with Heparin Bioactive Surface.
- 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 with Heparin Bioactive Surface. 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 with Heparin Bioactive Surface 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 MR Conditional

Non-clinical testing has demonstrated that the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is MR Conditional for lengths up to 490mm. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 3000-Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 4.0W/kg in the First Level Controlled Mode for 15 minutes of scanning

3.0 Tesla Temperature Rise:

In non-clinical testing, the GORE® VIABAHN® Endoprosthesis is expected to produce a temperature rise of 3.3°C at an MR system reported maximum whole bodied averaged specific absorption rate (SAR) of 4.0W/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.

1.5 Tesla Temperature Rise:

In non-clinical testing, the GORE® VIABAHN® Endoprosthesis is expected to produce a temperature rise of 3.4°C at an MR system reported maximum whole bodied averaged specific absorption rate (SAR) of 4.0W/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.

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 with Heparin Bioactive Surface. 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 aneurysm; 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.

SUMMARY OF 25 CM *GORE® VIABAHN®* STUDY

NOTE: These clinical findings are for the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface.

The purpose of this study was to confirm the performance and safety of the 25 cm GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface when used in the treatment of de novo and/or restenotic lesions of the superficial femoral artery.

71 patients were enrolled at 7 investigational sites in the European Union.

Study Endpoints: The primary performance endpoint was defined as successful completion of the assigned treatment and post-deployment stent length being within 10% of pre-deployment stent length determined angiographically. Successful completion of the assigned treatment was defined as the Investigator's ability to successfully cover the target lesion, and result in a post-deployment residual stenosis of <30% within the treated arterial lesion. The primary safety endpoint was defined as device and procedure related serious adverse events occurring within 30 days of the procedure. Secondary endpoints were primary patency, primary assisted patency, secondary patency, freedom from target lesion revascularization (TLR), freedom from composite of death, target vessel revasculaization (TVR), and amputation, clinical success, freedom from device fracture, and freedom from adverse events. Secondary endpoints were evaluated at 30 days and 12 months.

Patients Studied: Eligible patients had lifestyle-limiting claudication from de novo or restenotic atherosclerotic or occlusive lesions of the superficial femoral artery. Stenotic or occlusive lesions were ≥ 20 cm in length.

Methods: All enrolled patients were treated with at least one 25 cm length GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface; patients may have been treated with one additional overlapping VIABAHN® Endoprosthesis in order to adequately cover the target lesion. The primary performance endpoint was assessed angiographically. The primary safety endpoint was assessed during the 30-day follow-up period.

Study Results: Baseline characteristics of the study population are summarized in Table 12. A total of 71 patients were enrolled. 5 patients withdrew from the study during the 30-day follow-up window. 61 patients attended the 30-day follow-up visit. Pre- and post-deployment angiography was available for analysis in 60 patients to determine the primary performance endpoint. 46 (76.7%) patients met the primary performance endpoint. 14 (23.3%) failed the primary performance endpoint. All 14 of these patients met the primary performance endpoint of post deployment stent length being within 10% of the pre deployment stent length, but had a residual stenosis >30%. A summary of the study endpoints at 30 days and 12 months is shown in Table 13. Patient follow-up out to 36 months is ongoing.

TABLE 12: SUMMARY OF BASELINE CHARACTERISTICS

Variable	25 cm GORE® VIABAHN® Device (n=71)
Age (years), Mean ± SD	66.7 ± 8.34
Males	50 (70.4%)
History of Smoking	58 (81.7%)
History of MI	11 (15.5%)
History of Diabetes Mellitus	23 (32.4%)
RVD (mm), Mean ± SD	5.3 ± 0.96
ABI, Mean ± SD	0.53 ± 0.19
Lesion Length (cm), Mean ± SD (range)	26.5 ± 5.31 (20.0 - 40.0)
Percent Diameter Stenosis (%), Mean ± SD	74.8 ± 11.30
Chronic Total Occlusion	65 (92.9%)

TABLE 13: SUMMARY OF STUDY ENDPOINTS

Study Endpoints	30 Days	12 Months
Primary Endpoint		
Primary Performance	76.7% (46/60)	--
Freedom from Device and Procedure Related Adverse Events	79.6%*	--
Secondary Endpoints	**30 Days** **(Subjects at start / Events / Censored)**	**12 Months** **(Subjects at start / Events / Censored)**
Primary Patency	97.0%* (71 / 2 / 7)	67.0%* (62 / 18 / 8)
Primary Assisted Patency	97.0%* (71 / 2 / 7)	73.3%* (62 / 14 /10)
Secondary Patency	98.6%* (71 / 1 / 6)	96.9%* (64 / 1 / 12)
Freedom From TLR	97.1%* (71 / 2 / 5)	78.2%* (64 / 12 / 8)
Freedom From Composite of Death, TVR, and Amputation	94.2%* (71 / 4 / 3)	71.8%* (64 / 15 / 6)
Clinical Success	96.7%* (67 / 2 / 7)	79.2%* (58 / 10 / 8)
Freedom From Device Fracture	100%* (71 / 0 / 11)	100%* (60 / 0 / 17)
Freedom From Adverse Events	48.5%* (71 / 36 / 2)	12.2%* (33 / 24 / 1)

**Kaplan-Meier estimate*

25 CM STUDY DEFINITIONS

Primary Patency: No evidence of restenosis or occlusion within the originally treated lesion without target lesion revascularization.
Primary Assisted Patency: Flow through the treated lesion with or without repeat percutaneous intervention completed prior to complete vessel occlusion.
Secondary Patency: Time to surgical bypass of the study lesion.
Freedom from TLR: Freedom from re-intervention of the treated arterial lesion (including 5mm within healthy vessel at both margins of the treated zone).
Freedom from Composite of Death, TVR, and Amputation: freedom from death, a re-intervention of the treated artery, and amputation (above metatarsals).
Clinical Success: At least a one category improvement of Rutherford clinical category from baseline.
Freedom from Device Fracture: Freedom from device fracture assessed by X-ray
Freedom from Adverse Events: Freedom from any untoward medical occurrence whether device related or not.

Adverse events

A total of 14 device- or procedure-related adverse events were reported on 14 subjects (19.7%) within the first 30 days of the procedure (Table 14). Two patients (2.8%) experienced either a procedure or device related serious adverse event during the 30-day follow up period, all of which were procedure related serious adverse events. Both events were dissections of the SFA that occurred at the time of procedure and were successfully treated with the deployment of an additional VIABAHN® device. There were no device related serious adverse events reported within the first 30 days. Device- or procedure-related adverse events occurring within the first 12 months are also listed in Table 14.

TABLE 14: DEVICE- OR PROCEDURE-RELATED ADVERSE EVENTS

ADVERSE EVENTS		
	30 Days	12 Months
Number of Subjects Available	N=71	N=66
Number experiencing any event(s)	14 (19.7%) [14]	23 (34.8%) [28]
Conjunctival haemorrhage	1 (1.4%) [1]	1 (1.4%) [1]
Vessel puncture site haematoma	2 (2.8%) [2]	2 (2.8%) [2]
Vessel puncture site haemorrhage	1 (1.4%) [1]	1 (1.4%) [1]
Oedema peripheral	4 (5.6%) [4]	5 (7.0%) [5]
Medical device pain	0 (0.0%) [0]	1 (1.4%) [1]
Thrombosis in device	0 (0.0%) [0]	11 (15.5%) [11]
Infection	0 (0.0%) [0]	1 (1.4%) [1]
Vascular pseudoaneurysm	1 (1.4%) [1]	1 (1.4%) [1]
In-stent arterial restenosis	0 (0.0%) [0]	10 (14.1%) [12]
Arterial injury	2 (2.8%) [2]	2 (2.8%) [2]
Pain in extremity	1 (1.4%) [1]	1 (1.4%) [1]
Petechiae	0 (0.0%) [0]	1 (1.4%) [1]
Ecchymosis	1 (1.4%) [1]	1 (1.4%) [1]
Intermittent claudication	0 (0.0%) [0]	1 (1.4%) [1]
Haematoma	1 (1.4%) [1]	1 (1.4%) [1]

Device- or procedure-related adverse events were those that resulted from the design or use of the study device or the index procedure.

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.

Death: A total of 3 patients died within the first 12 months of the study. One patient died 10 days after the index procedure due to influenza, one patient died 146 days after the index procedure due to heart failure, and one patient died 205 days after the index procedure due to respiratory failure.

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 15 and 16) 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 15: 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	
Bleyn 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 16: 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[3]	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 the 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 loca 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: Becquemin JP, Alimi YS, Watelet J, Loisance 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® Endoprosthesis 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® Endoprosthesis 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, the randomized clinical trial results, and the 25cm study 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 17.

TABLE 17: 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 18. 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 19. ABI, clinical category (Rutherford), and limb ischemia score all showed improvement at 12 months compared to baseline.

TABLE 18: 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 19: 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 20). 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® Endoprosthesis was deployed successfully and there were no clinical sequelae.

TABLE 20: 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 21). 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 21). 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 21: 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® Endoprosthesis 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.

SUMMARY OF AV ACCESS CLINICAL DATA

The results of the AVR 06-01 clinical study support the safety and efficacy of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface for revision of the venous anastomosis of AV access circuits to maintain or re-establish vascular access for hemodialysis. A total of 293 subjects, enrolled from 31 clinical sites, comprised the final cohort of all subjects enrolled, randomized, and treated in the clinical study; 145 subjects randomized to the GORE® VIABAHN® Device group and 148 subjects randomized to the PTA group.

Study Endpoints: The primary effectiveness endpoint for the study was target lesion primary patency defined as the time interval of uninterrupted patency from initial study treatment to the next access thrombosis or intervention performed on the target lesion. The primary safety endpoint is the proportion of subjects remaining free from major device, procedure and treatment site-related adverse events through 30 days.

Additional Assessments: The following assessments were also made:

- Freedom from Major Adverse Events
- Anatomical Success (defined as <30% residual stenosis)
- Clinical Success (defined as resumption of normal dialysis for at least one session),
- Procedural Success (defined as composite of the anatomic and clinical success endpoints),
- Circuit Primary Patency (defined as time to intervention from index procedure to the next access thrombosis or intervention)
- Assisted Primary Patency (defined as time interval from index procedure to access occlusion),
- Access Secondary Patency (defined as time interval from the index procedure to access abandonment),
- Treatment Site Secondary Patency (defined as time interval from index procedure to the elimination of the target lesion from the access circuit),
- Target Lesion Primary Patency Proportions (defined as proportion of subjects who maintained target lesion primary patency).

Patients Studied: Eligible patients were adults (age ≥ 18) receiving hemodialysis treatment via a prosthetic graft located in the upper extremity presenting with clinical or hemodynamic evidence of graft thrombosis or graft dysfunction.

Methods: Patients eligible for the study were prospectively randomized to treatment with the GORE VIABAHN® Endoprosthesis or PTA. Baseline angiography was performed pre-PTA, post-PTA, and post-procedure. Enrolled subjects that experienced an angioplasty induced rupture that was unresponsive to balloon tamponade were eligible for the non-randomized study cohort treating venous ruptures with the VIABAHN® Endoprosthesis. Following the procedure, all study subjects were assessed for the presence of a palpable, continuous thrill. The goal of the study follow-up was to track the natural course of the vascular access as the subject undergoes regular hemodialysis. As such, there were no protocol requirements for additional follow-up imaging such as angiography at pre-specified intervals or the collection of hemodialysis-specific clinical parameters. Site investigators and dialysis centers followed their institutional procedures for hemodialysis access surveillance. Each subject was followed for two years or until study discontinuation.

Subject Characteristics: No differences in demographics, baseline characteristics, medical, or vascular access history except for ethnicity were determined to be statistically significant between treatment groups as described in Table 22. There were no significant differences between treatment groups in relation to subject height, weight, or Body Mass Index (BMI). There were no significant differences between treatment groups in relation to a medical history of diabetes or hypertension. With the exception of one subject, all subjects enrolled in AVR 06-01 presented with diabetes, hypertension, or both.

TABLE 22: SUMMARY OF PRE-PROCEDURE CHARACTERISTICS

	GORE® VIABAHN® Device Treatment Group	PTA Treatment Group	Overall	p-value
Intent-to-Treat Population	145	148	293	
Age (Yrs.)				
N (Data Available)	145	148	293	
Mean	62.2 ± 12.9	61.3 ± 12.9	61.7 ± 14.0	0.545 [1]
Ethnicity				
N (Data Available)	142	144	286	
Hispanic or Latino	16 (11.3%)	30 (20.8%)	46 (16.1%)	0.036 [2]
Race				
N (Data Available)	145	148	293	
American Indian or Alaskan Native	0 (0.0%)	1 (0.7%)	1 (0.3%)	1.000 [2]
Asian	9 (6.2%)	7 (4.8%)	16 (5.5%)	0.617 [2]
Black or African American	74 (51.0%)	80 (54.4%)	154 (52.7%)	0.639 [2]
Native Hawaiian or Pacific Islander	1 (0.7%)	0 (0.0%)	1 (0.3%)	0.497 [2]
White or Caucasian	61 (42.1%)	56 (38.1%)	117 (40.1%)	0.551 [2]
Other	0 (0.0%)	4 (2.7%)	4 (1.4%)	0.122 [2]
Gender				
N (Data Available)	145	148	293	
Female	76 (52.4%)	75 (50.7%)	151 (51.5%)	0.815 [2]
Physical Characteristics				
N (Data Available)	145	148	293	
Height (cm)	167.4 ± 12.2	165.4 ± 12.7	166.4 ± 12.4	0.168 [1]
Weight (kg)	83.7 ± 29.3	81.2 ± 26.2	82.5 ± 27.7	0.511 [1]
BMI	29.7 ± 9.1	29.5 ± 8.6	29.6 ± 8.8	0.891 [1]
Medical History				
N (Data Available)	145	148	293	
History of Diabetes	94 (64.8%)	98 (66.2%)	192 (65.5%)	0.807 [2]
History of Hypertension	143 (98.6%)	144 (97.3%)	287 (98.0%)	0.684 [2]
Duration of Time Since Starting Hemodialysis (Yrs.)	3.64 ± 3.93	4.06 ± 4.16	3.85 ± 4.05	0.342 [1]
Age of Vascular Access Graft (Yrs.)	1.93 ± 1.92	2.28 ± 2.64	2.11 ± 2.31	0.624 [1]
Mean Number of Prior Interventions at the Target Lesion	1.85 ± 2.20	1.81 ± 2.34	1.83 ± 2.27	0.562 [1]
Mean Number of Prior Interventions to the Current Prosthetic Graft or Circuit	2.28 ± 2.75	2.26 ± 2.90	2.27 ± 2.82	0.676 [1]

Percentages cited are the percentage of subjects out of the data available.
Means include ± Standard Deviation
Subjects may select multiple races.
[1] p-value assesses treatment differences using a two-tailed Wilcoxon rank-sum test.
[2] p-value assesses treatment differences using a two-tailed Fisher's exact test.

Procedural assessments: The anatomical, clinical, and procedural success for the GORE® VIABAHN® Device group compared to the PTA group are presented in Table 23.

TABLE 23: SUMMARY OF ANATOMICAL, CLINICAL, AND PROCEDURAL SUCCESS

	GORE® VIABAHN® Device Treatment Group	PTA Treatment Group	Overall	
	(n = 131)	(n = 138)	(n = 269)	p-value
Anatomic Success	131 (100.0%)	116 (84.1%)	247 (91.8%)	<0.001 [1]
Clinical Success	128 (97.7%)	135 (97.8%)	263 (97.8%)	1.000 [1]
Procedural Success	128 (97.7%)	113 (81.9%)	241 (89.6%)	<0.001 [1]

Percentages cited are the percentage of subjects out of the data available.
[1] p-value assesses treatment differences using a two-tailed Fisher's exact test.

Primary Effectiveness Endpoint: The primary effectiveness endpoint of the AVR 06-01 study was met with the GORE® VIABAHN® Device group demonstrating statistical superiority of target lesion primary patency over the PTA group as described in Table 24. The GORE® VIABAHN® Device group also demonstrated statistical superiority of circuit primary patency over the PTA group. The GORE® VIABAHN® Device group was also consistently better in terms of patency for all other efficacy endpoints, albeit, not statistically significant.

TABLE 24: SUMMARY OF THE EFFECTIVENESS ENDPOINT AND ASSESSMENTS

	GORE® VIABAHN® Device Treatment Group (n = 131)				PTA Group (n = 138)			
	3 mo	6 mo	12 mo	24 mo	3 mo	6 mo	12 mo	24 mo
Primary Endpoint*								
Target Lesion Primary Patency	66.8%	52.9%	30.2%	15.7%	53.1%	35.5%	18.2%	9.9%
Additional Assessments								
Circuit Primary Patency	61.4%	43.4%	21.4%	9.6%	49.4%	29.4%	15.2%	6.8%
Assisted Primary Patency	66.8%	56.2%	43.5%	29.2%	62.6%	51.1%	35.3%	29.0%
Access Secondary Patency	94.5%	91.2%	82.7%	68.9%	88.1%	86.5%	78.6%	66.6%
Treatment Site Secondary Patency	93.8%	90.4%	82.1%	68.4%	88.1%	86.5%	78.6%	66.6%

* Logrank p-value testing the superiority of the GORE® VIABAHN® Device group over the PTA group: p = 0.008.
Percentages cited in the Months columns are Kaplan-Meier estimates

Primary Safety Endpoint: The primary safety endpoint of the AVR 06-01 study was met. The GORE® VIABAHN® Device group demonstrated statistical non-inferiority as compared to the PTA group for major device, procedure, and treatment-site related adverse events through 30 days post-procedure as described in Table 25 ($p < 0.001$).

TABLE 25: SUMMARY OF SAFETY ENDPOINT

	GORE® VIABAHN® Device Treatment Group	PTA Treatment Group	p-value
Intent-to-Treat Population	145	148	
Subjects Experiencing Major Device, Procedure, and Treatment Site Related Adverse Events Through 30 Days Post-Procedure	0 (0.0%)	2 (1.4%)	<0.001[1]

Percentages cited are the percentage of subjects from the intent-to-treat population.

[1] p-value assesses the non-inferiority of VIABAHN compared to PTA using a one-sided test of non-inferior proportions with delta=0.15

There were no major device, procedure, or treatment site-related adverse events reported during any time interval over the 24-month study period in the GORE® VIABAHN® Device group. The proportion of subjects experiencing any major adverse event not related to the device, procedure, and treatment-site between the GORE® VIABAHN® Device group and the PTA group are presented in Table 26. Notably, no fractures or device-related migrations were reported (See Table 26).

TABLE 26: SUMMARY OF ALL ADVERSE EVENTS (MAJOR AND MINOR)

	GORE® VIABAHN® Device Treatment Group (n = 145)				PTA Treatment Group (n = 148)			
	3 mo	6 mo	12 mo	24 mo	3 mo	6 mo	12 mo	24 mo
Adverse Events	33.2%	48.4%	65.3%	78.2%	42.0%	54.0%	61.3%	80.1%
Other: Non-Access-Related [1]	29.5%	44.2%	60.5%	73.7%	34.0%	45.9%	54.6%	73.5%
Other: Access-Related [2]	7.2%	9.7%	18.3%	24.0%	9.4%	11.8%	16.6%	28.5%
Infection: Systemic	1.4%	4.9%	7.7%	12.5%	1.4%	3.9%	6.7%	8.9%
Myocardial Infarction	0.0%	1.7%	4.7%	7.1%	0.8%	0.8%	0.8%	0.8%
Pseudoaneurysm	0.7%	1.6%	2.7%	6.7%	0.7%	3.2%	3.2%	4.6%
Infection: Access-Related [3]	0.0%	0.9%	0.9%	3.7%	2.2%	4.8%	6.9%	9.5%
Perforation or Rupture	0.8%	0.8%	1.7%	1.7%	0.0%	0.0%	0.0%	0.0%
Bleeding: Minor	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%
Device Migration	0.7%	0.7%	0.7%	0.7%	0.0%	0.0%	0.0%	0.0%
Bleeding: Major	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Device Deployment Failure	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Device Fracture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Device Malposition	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dissection	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Drug Reaction	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.1%
Embolism, Arterial	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.0%	1.0%
Embolism, Pulmonary: Symptomatic	0.0%	0.0%	0.0%	0.0%	0.0%	0.8%	0.8%	0.8%
Heparin Induced Thrombocytopenia	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Intraprocedural Access Thrombosis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Spasm: Intraprocedural	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Time intervals for estimates: 3 Months (91 Days), 6 Months (183 Days), 12 Months (365 days), 18 Months (548 days), 24 Months (730 days).
Percentages cited in the Months columns are Kaplan-Meier estimates for the percentage of subjects having experienced an AE.
[1] Other Non-Access Related: These are events unrelated to the access, procedure, or the device (including but not limited to: volume overload, chest pain, hemodialysis related symptoms, urinary tract infection, or pneumonia).
[2] Other - Access Related: events related to the access but not to the procedure, or device that occurred after the index procedure (including but not limited to: bleeding, hematoma, thrombosis, infections not related to the prosthetic graft or the VIABAHN device).
[3] Based on the protocol, Infection: Access-Related was defined as microbial infection directly related to the prosthetic graft or the VIABAHN device with or without systemic infection.

CONCLUSIONS DRAWN FROM AVR 06-01

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. Multicenter, randomized clinical study results demonstrated that the GORE® VIABAHN® Device when compared to PTA resulted in higher rates of primary target lesion patency over a two-year treatment period for AV access revision. Furthermore, the GORE® VIABAHN® Device group demonstrated non-inferior safety as the PTA group.

DIRECTIONS FOR USE

MATERIALS REQUIRED FOR IMPLANTATION

- GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface
- Marker guidewire or catheter (for calibrated measurement reference)
- Syringe filled with heparinized saline
- Introducer sheath of appropriate size (Table 1)
- Stiff guidewire: diameter must be = 0.035" (0.889 mm)
- Guidewire length should be at least twice the length of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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 or prosthetic graft.

B. Imaging and Measurement

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

C. Percutaneous Transluminal Angioplasty (PTA) (if treating stenotic or occlusive lesions)

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

D. Sizing and Selection of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface

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 or prosthetic graft 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. For arteriovenous access revision of a prosthetic graft venous anastomosis, sizing need only be done relative to the lumen of the prosthetic graft (Table 1).
   b. The endoprosthesis lengths of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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. For lesions that start 30 mm or less from a prosthetic graft venous anastomosis in an arteriovenous access, the endoprosthesis should overlap the prosthetic graft by at least 1 cm and should not extend more than 1 cm past the lesion.
   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 with Heparin Bioactive Surface

1. Open the Sterile Package. Carefully inspect the packaging for damage to the sterile barrier. Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface after the "use by" (expiration) date. Peel back the outer pouch and remove the sterile inner pouch and coil containing the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface. Beginning at one corner, peel back the edge of the inner pouch and gently remove the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface.
2. Inspection Prior to Use.
   - Prior to using the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface, 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 with Heparin Bioactive Surface if the sterile package is compromised or the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is damaged.
3. Preparation of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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 with Heparin Bioactive Surface

1. Select the compatible size introducer sheath from Table 1.
2. Ensure the stiff guidewire is = 0.035" (0.889 mm).
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 with Heparin Bioactive Surface is introduced through the hemostasis valve, remove and inspect the delivery system for damage. Do not reuse the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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 with Heparin Bioactive Surface 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 with Heparin Bioactive Surface from the vessel prior to deployment, do not withdraw the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface back into the introducer sheath after the endoprosthesis is fully introduced. To remove the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface prior to deployment, the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface can be withdrawn to a position close to but not into the introducer sheath. Both the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface and introducer sheath can then be removed in tandem. After removal, neither the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface nor the introducer sheath should be reused.

G. Deployment of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface

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

REF Catalogue Number

LOT Batch Code

MR Conditional

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

STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

Do Not Use if Package is Damaged

Keep Dry

Store in a Cool Place

Catheter Length

Device Deploys from Tip to Hub

Diameter

Guidewire Compatibility

Manufacturer

Vessel Diameter

20019560

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

Creative Technologies Worldwide

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

DECEMBER 2013
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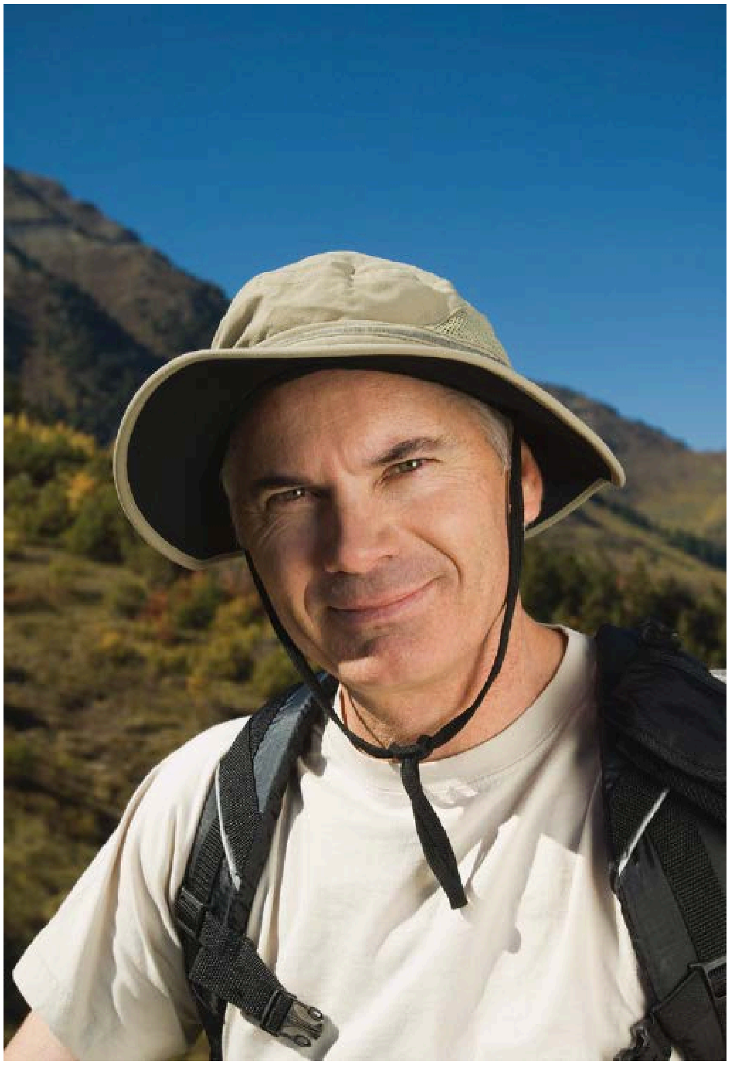


Patient Information for Hemodialysis Treatment

GORE VIABAHN® ENDOPROSTHESIS

This brochure has been provided as a courtesy from Gore & Associates. It is designed to provide helpful information about risk factors and common symptoms associated with treatment of dysfunctional hemodialysis access. Additionally, it provides information about a new, minimally-invasive procedure. We hope this information will be helpful to you and your family.

Table of Contents

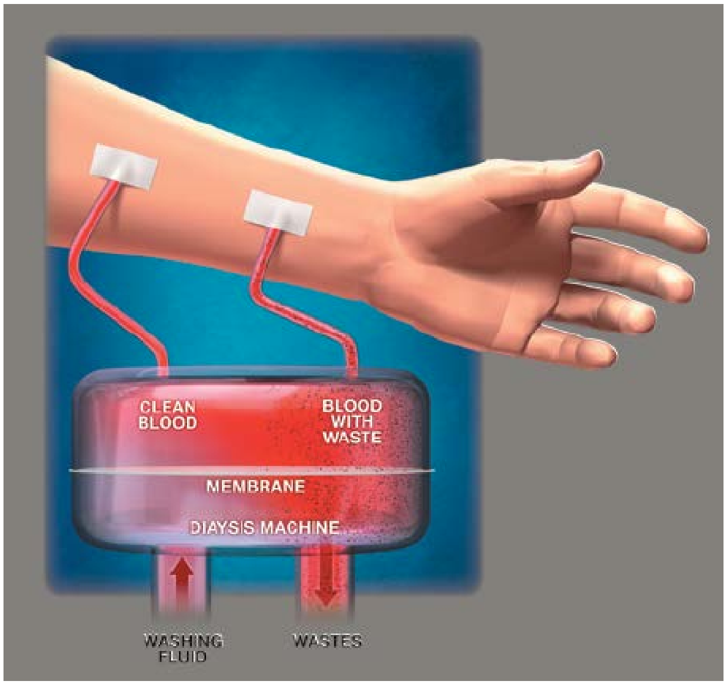
As you read this document, we encourage you to write questions you would like addressed by your healthcare provider on the back pages.

Introduction

The failure of any organ in the body has both physical and emotional consequences. **Kidney failure** is no exception. However, there are effective ways to cope with the loss of function of your kidneys.

Knowledge concerning the care you receive from your kidney specialist and the dialysis staff can help you to take control of your situation. Controlling your medical condition, however, means that you will have to adopt some new behaviors and lifestyles. Your kidneys did an important job, but now you must consciously make choices to compensate for the role they played in maintaining your health.

The two basic functions of the kidneys are to cleanse the body of waste products and to regulate the amount of water and certain chemicals in the blood. Dialysis helps do both, but watching what you eat and drink and following your doctor's advice about taking medications are very important. This booklet will focus on the dialysis part of your treatment.



In hemodialysis, blood is removed through a needle and cleansed by running it through a dialysis machine. The blood is returned to the body through a second needle. You and your doctor should discuss the treatment options and together decide the best course is for you.

What is hemodialysis?

Hemodialysis treatment replaces the function of a failing or failed kidney. The treatment filters wastes, salts, and fluids directly from your blood like a functioning kidney would do.

Most likely, you are receiving dialysis treatment through a **hemodialysis access** called an **arteriovenous graft** or **arteriovenous fistula**.

The purpose of both methods is to provide an access point of rapid blood flow for your dialysis caregivers to connect your **cardiovascular system** to the **dialysis machine**.

Adequate dialysis is only achieved when sufficient blood flow exists in your arteriovenous graft or fistula.

For an arteriovenous fistula, the surgeon connected your vein directly to your artery.

For an arteriovenous graft, the surgeon connected your vein to your artery with a synthetic graft that allows blood to flow rapidly from the artery through the graft to the vein.

Why did my hemodialysis access need treatment?

Your hemodialysis access needs treatment because it currently has inadequate blood flow to administer effective dialysis. Likely, your blood flow has become inadequate due to a constriction in the vein of your hemodialysis access called a **venous stenosis**, as illustrated below.

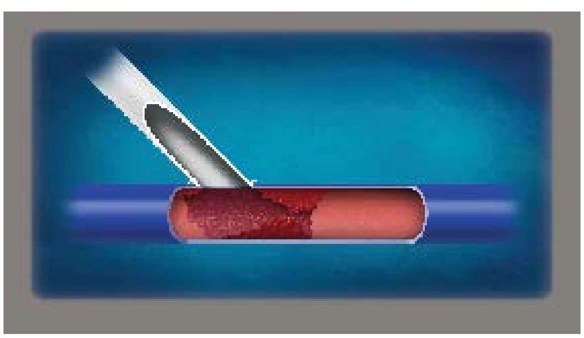
When your dialysis caregiver detects inadequate blood flow, they may refer you to a specialist that can restore adequate blood flow to your hemodialysis access by opening the venous stenosis via various medical procedures.

Physical symptoms can be used to detect the presence of a stenosis in your hemodialysis access. Those physical symptoms include:

- Arm swelling
- Continued bleeding at the sites of needle puncture well after dialysis is completed
- A lack of vibration, also called a thrill, in your access from rapid blood flow
- Pulsatile or non-continuous blood flow felt in your access

Early detection of a stenosis can help prevent clot formation called thrombosis, which reduces the life expectancy of your current hemodialysis access.

Failure of your current hemodialysis access may result in an **open surgery** to create a new hemodialysis access in another location of your body. You are limited to the number of available locations for a hemodialysis access, so care must be taken to preserve the functionality of your current hemodialysis access.



Venous stenosis reduces the internal diameter of the vein leading to a reduction in blood flow. Often, venous stenosis is associated with tissue growth within the vein wall in response to the rapid blood flow required for adequate hemodialysis.

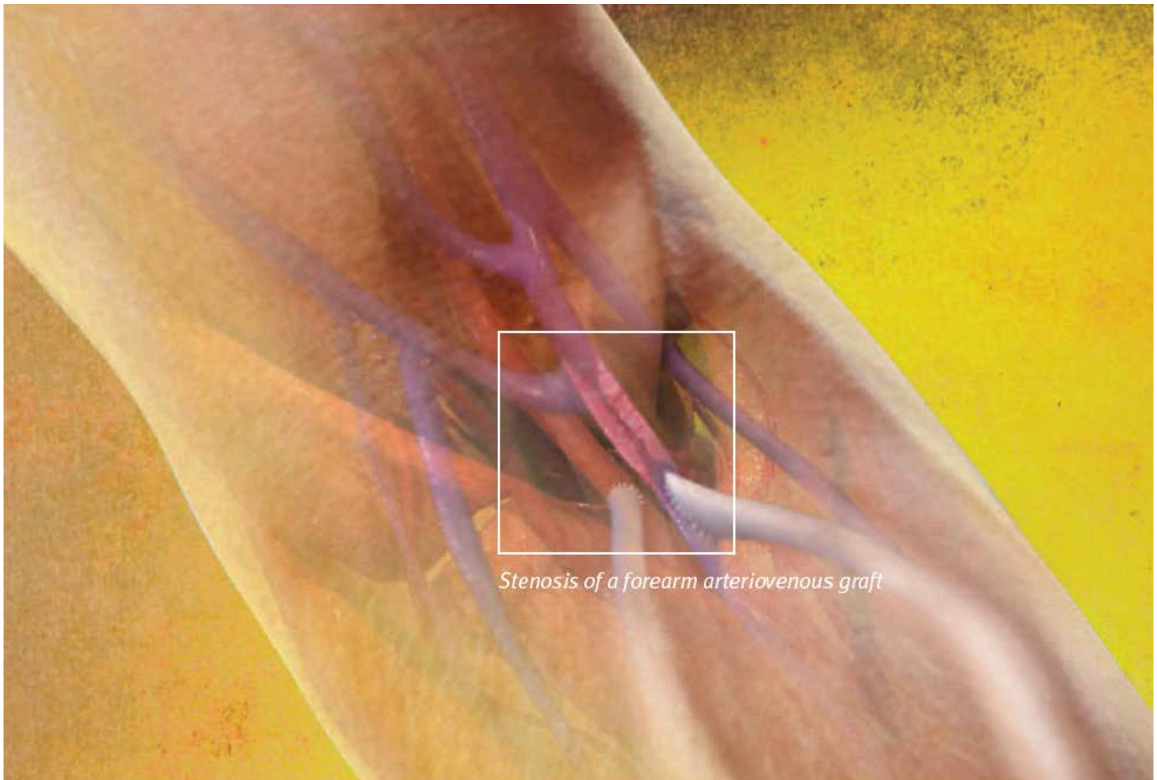
What are my treatment options?

Your healthcare provider will likely choose between open surgical and **percutaneous treatment** options to restore adequate blood flow to your hemodialysis access:

Open surgical treatment options: If your healthcare provider has surgical training, they can elect to bypass or remove the stenosis. The surgical procedure requires the healthcare provider to expose the stenosis with an incision. In a **bypass surgery**, a graft or native vessel is implanted to re-route blood around the stenosis. If the stenosis is removed, the tissue will be replaced by a **patch** composed of synthetic material.

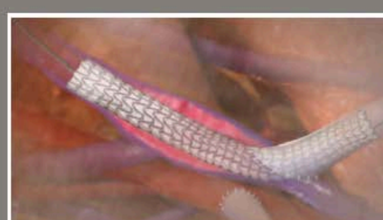
Percutaneous treatment options: Alternatively, many of the potential complications that could occur with traditional open surgery may be avoided with minimally invasive percutaneous treatment options. These options require only small punctures for insertion of medical devices into your hemodialysis access guided by X-ray images projected on a monitor during the procedure. These treatments include:

- **Balloon Angioplasty:** A small balloon is inflated within your vein to open the stenosis as illustrated in the image on the next page. The balloon is then deflated and removed from the body, restoring blood to flow for adequate hemodialysis. Although balloon angioplasty is the current standard of care, the stenosis typically returns soon after the procedure due to continued tissue growth and / or **elastic recoil** of the vein.
- Endoluminal Bypass: A device composed of a metal scaffold and graft material called an **endovascluar stent-graft** is implanted to bypass the stenosis from within the treated vein. The metal scaffolding opens the stenosis and prevents elastic recoil while the graft material prevents continued tissue growth.

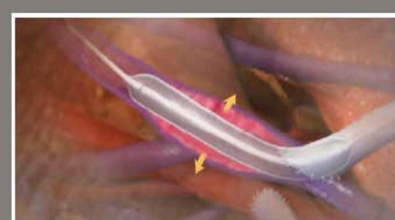


Stenosis of a forearm arteriovenous graft

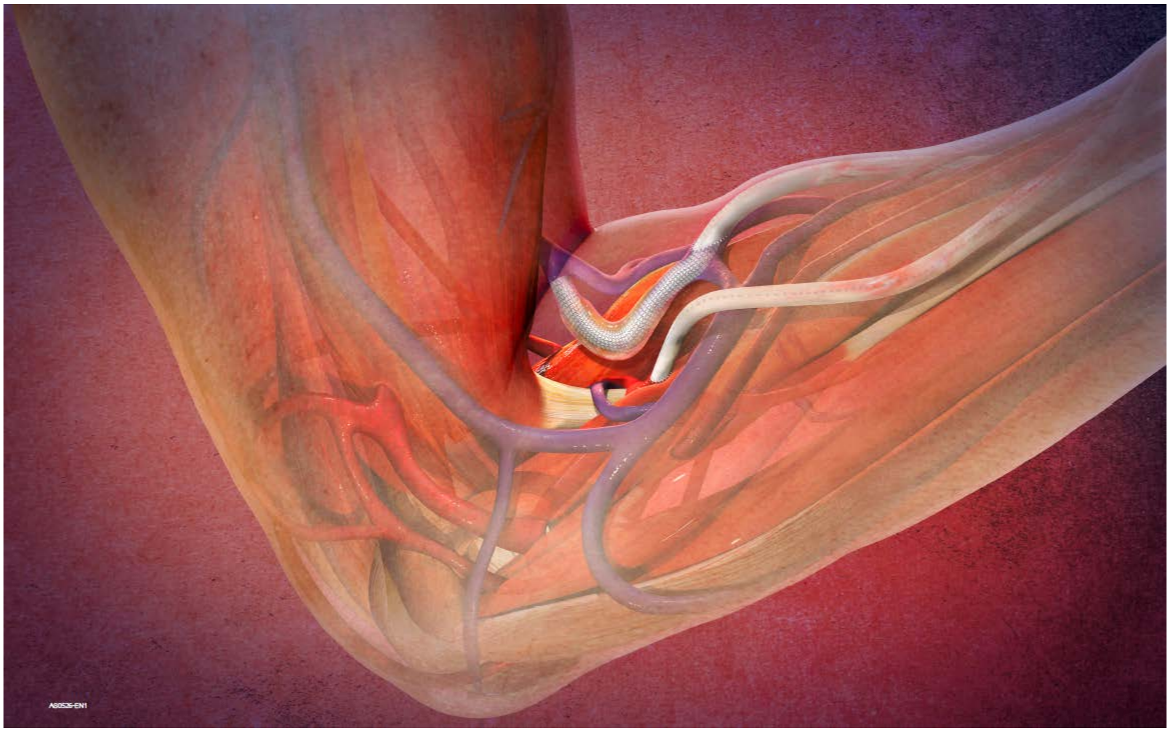
Percutaneous Treatment Options



Endoluminal bypass



Balloon angioplasty



What is the GORE® VIABAHN® Endoprosthesis?

The GORE® VIABAHN® Endoprosthesis is an endovascular stent-graft. The stent is made of a flexible, high-strength metal called **Nitinol**. The graft is a tube made from a thin layer of synthetic material that has been used safely and effectively in the body for more than 30 years.

The endovascular stent-graft is loaded on the end of a long, thin, tube-like device called a **delivery catheter**. This allows the device to be inserted into your bloodstream through a small hole and guided to the stenotic area of the blood vessel without open surgery. The stenosis is then opened by releasing the endoprosthesis from the delivery catheter inside the vein, allowing blood to flow through the device for adequate hemodialysis.

How is the GORE® VIABAHN® Endoprosthesis implanted?

To treat your venous stenosis, the GORE® VIABAHN® Endoprosthesis is placed inside the blood vessel to create a new, disease-free channel for blood flow. The endovascular stent-graft is implanted using X-ray viewed on a monitor in these simple steps:

1. The stenosis is pre-dilated (opened) with a small balloon to create a path for the delivery catheter.
2. A delivery catheter is inserted into the hemodialysis access and carefully guided to the site of the stenosis.
3. Once the delivery catheter reaches the stenosis, the endovascular stent-graft is released.
4. The device self-expands to the diameter of the blood vessel being treated. The endovascular stent-graft is designed to open the stenosis; at the same time it provides a new surface lining to facilitate rapid blood flow.
5. The delivery catheter is withdrawn from the body.

At the end of the procedure, your doctor will check the position of the implanted device and blood flow.

Am I eligible to receive the GORE® VIABAHN® Endoprosthesis?

You may be eligible to receive the GORE® VIABAHN® Endoprosthesis unless you meet any of the following criteria:

- You have a known or suspected systemic or hemodialysis access infection
- You have a known bleeding disorder (e.g., hemophilia or von Willebrand's disease)
- You have a defined hypercoagulable disorder
- You have a known sensitivity to heparin
- You have an untreatable allergy to radiographic contrast material

Consult your healthcare provider to determine if endoluminal bypass treatment with the GORE® VIABAHN® Endoprosthesis is appropriate for you.

What are the risks of the GORE® VIABAHN® Endoprosthesis?

Implantation of a GORE® VIABAHN® Endoprosthesis may cause complications at the insertion site, or in the hemodialysis access intended to be treated. Complications that are related to the device may include but are not limited to:

- **Hematoma** (bruise)
- Bleeding/hemorrhage
- Stroke
- Congestive heart failure
- Edema (swelling) in the arm or hand
- Rise or drop in blood pressure
- Steal syndrome (lack of sufficient blood flow to the access graft area)
- Stenosis
- Thrombosis
- **Occlusion** (complete blockage of the blood flowing in the vein or device)
- Vessel trauma, aneurysm (weakening of the walls), abrupt narrowing, and/or rupture
- Infection
- Inflammation
- Fever and / or pain in the absence of infection
- Device failure (such as fracture)
- Allergic reaction to **the x-ray dye** or other procedural components (including metals in the device) or drugs
- Radiation injury
- X-Ray induced kidney failure
- **Device embolism** (movement of the device to a non-intended implantation site)
- Death

Be sure to discuss these risks and any other concerns you have with your physician.

How will the GORE® VIABAHN® Endoprosthesis aid in my dialysis treatment?

The GORE® VIABAHN® Endoprosthesis is indicated by the FDA to treat the venous junction of hemodialysis access grafts to maintain or re-establish vascular access for hemodialysis. The GORE® VIABAHN® Endoprosthesis has been proven to be safe and effective in this application and superior to balloon angioplasty alone through clinical studies.

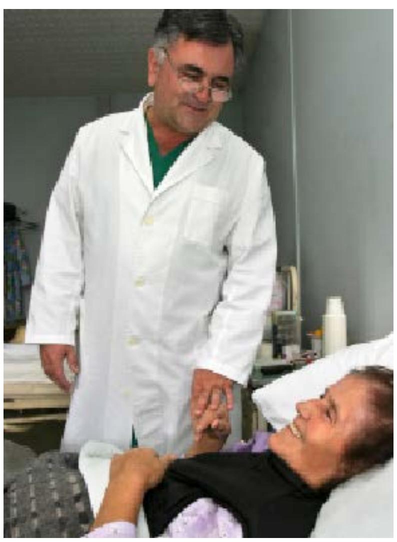
The implantation of the GORE® VIABAHN® Endoprosthesis will extend the life of your hemodialysis access by allowing a longer time period of dialysis treatment without the need for intervention as compared to balloon angioplasty.

What should the rest of my dialysis team know about the GORE® VIABAHN® Endoprosthesis before treating me?

Inform your dialysis team that you have received a GORE® VIABAHN® Endoprosthesis and direct them to its location using the anatomy charts on the following pages 17 and 18 of this booklet. If possible, the following actions should be avoided when the endovascular stent-graft has been implanted:

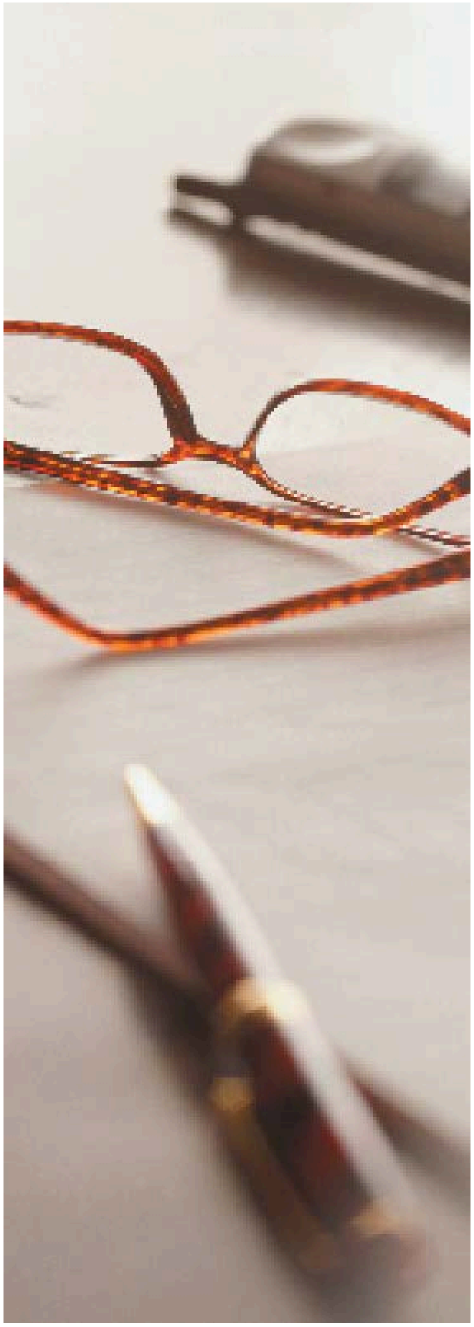
- Puncturing the endovascular stent-graft with a dialysis needle
- Holding constant, direct pressure over the endovascular stent-graft

Please consult your healthcare provider that implanted the GORE® VIABAHN® Endoprosthesis if you have any questions or concerns about the treatment by your dialysis caregivers.



At some point, your healthcare provider might want to perform an imaging test called magnetic resonance imaging or MRI. Non-clinical testing has demonstrated that the GORE® VIABAHN® Endoprosthesis is MR Conditional. It can be scanned safely under certain conditions.

Please inform your healthcare provider of your implanted GORE® VIABAHN® Endoprosthesis before the MRI is performed.



Glossary of Terms

Arteriovenous fistula

A direct connection between an artery and a vein, where the vein is punctured during hemodialysis.

Arteriovenous graft

Synthetic material connecting an artery and a vein and is punctured during hemodialysis.

Artery

Vessel carrying blood from the heart to the body

Balloon angioplasty

Opening a blockage in a vessel by inflating a small balloon in the stenotic area

Bypass surgery

Surgical implantation of a graft or native vessel to re-route blood around a stenosis

Cardiovascular system

An organ system comprised of the heart, blood, and blood vessels that transports nutrients and removes waste from the body

Catheter

A tube percutaneously inserted into a vein to facilitate the delivery of tools such as an endovascular stent-graft to the treatment site

Central veins

Veins located in the chest

Delivery catheter

A long, thin, tube-like tool that assists in the positioning and delivering of an endovascular stent-graft through the vascular system

Device embolism

Movement of a device away from its intended location of implantation within the blood vessel

Dialysis machine

Machine that pumps blood from your cardiovascular system through a filter to remove toxic materials then returns the blood to your cardiovascular system

Elastic recoil

The rapid return of vessel stenosis after it has been opened

Endoluminal bypass

Percutaneous implantation of an endovascular stent-graft to make a new path for blood to flow from within the blood vessel being treated

Endovascular stent-graft

A synthetic graft supported by a metal frame that is implanted within a diseased vessel intended to support weakened vessel walls without the use of open surgery techniques

Hemodialysis access

An access point of rapid blood flow for your dialysis caregivers to connect your cardiovascular system to the dialysis machine.

Hemodialysis treatment

Removal of toxic substances from the body (dialysis) to maintain balance of important blood components in the case of failed or failing kidney function.

Hemotoma (bruise)

Small blood vessels that tear or rupture under the skin leaving blood to leak and cause a black-and-blue color

Kidney failure

The inability of your kidney's to adequately remove toxic substances from your blood.

Magnetic Resonance Imaging (MRI)

An imaging technique that can view the organs inside your body by generating electric waves from a large moving magnet

Nitinol

An inert, high-strength metal which is a mixture of nickel and titanium

Occlusion

The blocking of a blood vessel, causing blood flow to stop

Open surgery

An invasive operation where an incision is made into the body to expose a particular organ for treatment

Patch

Synthetic material that is used to replace removed tissue of blood vessels

Percutaneous treatment

A minimally invasive procedure requiring a small puncture through the skin

Thrill

Vibration caused by the flowing of blood through an arteriovenous fistula or graft

Thrombosis

Blood that thickens into a clot and blocks blood flow

Vein

Vessel carrying blood from the body back to the heart

Venous stenosis

A constriction in the vein of your hemodialysis access

X-ray dye

A drug injected into the vascular system to show blood flow through the blood vessels on the X-ray image

Anatomy charts for indicating placement

of your GORE® VIABAHN® Endoprosthesis

Right Arm

Left Arm

Question for my doctor –

Question for my doctor –

W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)
00800.6334.4673 (Europe)
800.437.8181 (United States)
928.779.2771 (United States)

goremedical.com