Post-market study: Evaluation of the GORE® VIABAHN® Endoprosthesis for the treatment of Popliteal Artery Aneurysm

Protocol number: FPR 14-03

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W. L. Gore & Associates, Inc.
Medical Products Division

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Amendment 1: 14 July 2015

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PROTOCOL SUMMARY

Study Title	Post-market study: Evaluation of the GORE® VIABAHN® Endoprosthesis for the treatment of Popliteal Artery Aneurysm
Protocol Number	FPR 14-03
Sponsor	W. L. Gore & Associates, Inc. Medical Products Division 1801 W. Route 66, Suite 117 P.O. Box 2400 Flagstaff, AZ 86003-2400 United States Telephone: +1 800-528-1866
Study Medical Device	GORE® VIABAHN® Endoprosthesis; CE marked medical device
Study Design	This is a French multicenter, non-randomized, single arm, retrospective Post-market study with a prospective follow-up of GORE® VIABAHN® Endoprosthesis for the treatment of Popliteal Artery Aneurysm (PAA).
Study Objective	The primary objective is to document the long term safety and performance of the GORE® VIABAHN® Endoprosthesis for the treatment of patients with Popliteal Artery Aneurysms.
Study Endpoints	The primary performance endpoint for this trial is: • Primary patency at 12 months The primary safety endpoint of this trial is: • 12 month serious adverse events and adverse events related to the study procedure or the study device. The secondary endpoints of this trial are: • Serious adverse events and adverse events related to the study procedure or the study device at 24 & 36 months; • Freedom from limb loss on the study limb through 12, 24 & 36 months; • Freedom from repeat intervention at 12, 24 & 36 months; • Length of hospital stay after procedure in days; • Length of procedure in minutes; • Primary patency at 24 & 36 months; • Primary assisted patency at 12, 24 & 36 months; • Secondary patency at 12, 24 & 36 months. • Technical Success Listings:

	Listings of the following events will be provided: endoleak, migration, device fracture, and study limb amputation.
Subject Population	The study population includes patients with a symptomatic aneurysm or asymptomatic aneurysm (≥ 2 cm diameter) of the popliteal artery, or presence of mural thrombus (< 2 cm) in the popliteal artery. All patients treated per IFU with the GORE® VIABAHN® Endoprosthesis since September 15, 2012 (date of reimbursement in France) will be screened consecutively, starting with the first patient treated.
Number of Patients	Patients meeting Inclusion / Exclusion that provided Informed Consent will be enrolled in consecutive order. 50 patients with adequate follow-up to determine primary endpoints through 12 months will be enrolled. For patients that cannot be enrolled, but had a PAA treated with VIABAHN in the respective time, the date of the intervention and the reasons for non-inclusion will be collected in a screen-failure CRF.
Number of Sites	Up to 10 Sites in France.
Expected Time to Complete Enrollment	Patient identification / enrollment is expected to take up to 9 months. Patients follow-up will continue to collect 36 months data.
Schedule of Events	All patients will be followed up as per hospital standard of care for the duration of the study. As available, data will be collected on adverse events, ankle brachial index, palpable pedal pulses, medications, imaging, all re-interventions, and bypass surgeries.
[redacted]	[redacted]
Study Management	WL GORE & Associés S.A.R.L. 8, Place des Vins de France 75012 Paris France Phone: +33 1 56 95 65 65 Email: shanoka@wlgore.com Email: streutne@wlgore.com
[redacted]	[redacted]

LIST OF ABBREVIATIONS

AAA	Abdominal Aortic Aneurysm
ABI	Ankle-Brachial Index
AE	Adverse Event
CCTIRS	French Advisory Committee on Information Processing in Material Research in the Field of Health
CNIL	French Data Protection Agency
CDMS	Clinical Data Management System
CE	Conformité Européenne
CRF	Case Report Form
ePTFE	Expanded Polytetrafluoroethylene
Fr	French (sizing)
GCP	Good Clinical Practice
ICH	International Conference on Harmonization
IFU	Instruction for Use
MedDRA	Medical Dictionary for Regulatory Activities
PAA	Popliteal Artery Aneurysm
PI	Principal Investigator
SAE	Serious Adverse Event
UADE	Unanticipated Adverse Device Effect

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1. Introduction

1.1. Disease

Popliteal Artery Aneurysms (PAAs) are the most prevalent type of peripheral arterial aneurysm, accounting for 70 to 85% of all peripheral aneurysms with an overall prevalence of about 0.1% in hospitalized patients. At most, this corresponds to four or five patients per year at any major vascular center in the United States (U.S.).[1-9] The popliteal artery is considered aneurysmal once the diameter reaches either 1.5 cm or 1.5 times the size of the normal proximal artery. PAAs occur much more frequently in men than in women; reports range from approximately one woman to every fifteen men to one woman to every thirty men.[4, 8, 10-14] PAA incidence increases with age and approximately one-half of PAAs are bilateral.[5, 13, 15] Studies have reported that an abdominal aortic aneurysm (AAA) is found in 9 to 64% of PAA patients [5, 7, 12, 13, 15, 16] and about the same proportion have hypertension.[12, 13, 15]

The primary risk of PAA is generating thromboemboli that can occlude downstream vasculature and compromise lower limb tissue (leading to acute limb ischemia).[17, 18] Acute limb ischemia is often the first presenting symptom in patients with PAA. When a PAA is detected and treated with medical management, complication rates are high (15-25% at one year, 60-75% at five years).[19] Studies have suggested that the risk of complication is greatest in aneurysms larger than 2 cm, but that even smaller aneurysms with mural thrombus can lead to distal embolization.[1, 5, 20]

Depending on the aneurysm, symptoms may include local pain, swelling or severe pulsation but the most frequent and severe symptoms of PAA are thromboembolism and thrombosis, which can lead to claudication, acute limb ischemia and major amputation. Symptomatic PAAs (i.e., claudicant or ischemic limb) account for approximately 40% of diagnosed PAAs and carry a risk of major amputation as high as 30-40%.[13, 16, 20, 21] The risk of thromboembolic complications in untreated, asymptomatic PAA ranges from 24% at one year to 74% at five years.[5, 22] Although PAAs expand at a growth rate of around 10% per year [23], rupture is rare with an annual occurrence rate of 1.4%.[15]

Duplex ultrasound is the most useful test to confirm the diagnosis of PAAs and can also accurately measure the size of the aneurysm, document thrombosis, including intraluminal thrombus, and assess for compression of adjacent veins. Duplex ultrasound can be supplemented with computed tomography or conventional arteriography if surgery is planned.

The goal of PAA repair is to exclude the popliteal aneurysm and maintain or re-establish arterial downstream inflow.[24] There is general consensus that all symptomatic PAAs should be repaired regardless of size and asymptomatic PAAs are recommended to be treated if the aneurysm diameter is greater than 2 cm, mural thrombus is present or the patient has poor run-off.[1, 25]

1.2. Historical Treatments

The current gold standard of PAA repair is saphenous vein bypass grafting with either ligation (most common) or endoaneurysmorrhaphy (resection of the aneurysm).[16, 26] When ligation is used, up to a third of bypassed aneurysms may continue to enlarge due to the presence of geniculate arteries that feed the aneurysm.[27, 28] Vein bypass is generally used in the majority of patients.[2, 16]

When no suitable vein conduit is available, expanded polytetrafluoroethylene (ePTFE) grafts are typically used, with reported primary patencies up to 30% lower than vein bypass at five

and ten years.[2, 16] In general, clinical outcomes are also negatively influenced by the presence of pre-operative ischemic symptoms and poor run-off regardless of the type of re-vascularization procedure performed.[2, 14, 29, 30] Although reported outcomes vary widely due to inconsistent patient populations as well as treatment and patency definitions, most studies report bypass graft patency of 69–80% at five years and limb salvage rates between 75–100%.[3, 14, 15, 25, 31, 32] In these published studies, patency and limb salvage rates tend to be better in asymptomatic patients.

Several recent reports have advocated endovascular treatment of PAAs over surgical repair.[17, 33-36] Endovascular treatment provides shorter operative times; shorter hospital stays with less perioperative morbidity and faster recovery.[3, 22, 33, 37-39]

The first report of endovascular PAA repair was published in 1994, in which a vascular graft was sewn to two balloon-expandable stents and then deployed.[40] Since then, many different approaches to endovascular PAA repair have been reported, including both stented grafts (ePTFE, vein or Dacron grafts attached to balloon-expandable stents) and commercial Dacron stent-grafts. Early outcomes with these devices were mixed, primarily due to high rates of thrombosis and mechanical failure.[21, 36, 41-44] More recent studies report the use of the GORE® VIABAHN® Endoprosthesis manufactured by W. L. Gore & Associates, Inc. (Gore) to treat PAAs with long-term clinical outcomes comparable to traditional surgical bypass.[4, 6, 18, 33, 39, 45-47] With its lower morbidity and mortality, endovascular repair provides an option for patients who are not surgical candidates due to existing comorbidities.[24] Importantly, physicians may choose to intervene on asymptomatic patients earlier (prior to thromboembolic events) without precluding surgical bypass at a later date.[24, 48] As described above, the main goal of treatment is to prevent distal embolization and acute limb ischemia.

[redacted]

1.3. Study Device Description

The GORE® VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal endoprosthesis consisting of an ePTFE lining with an external nitinol (NiTi=Nickel: Titanium) support extending along its entire length (Figure 1). Having a CE mark since 1996, the GORE® VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal prosthesis for endovascular grafting of peripheral arteries. The intent of the device in this Post-market study is to exclude the PAA from the blood flow.

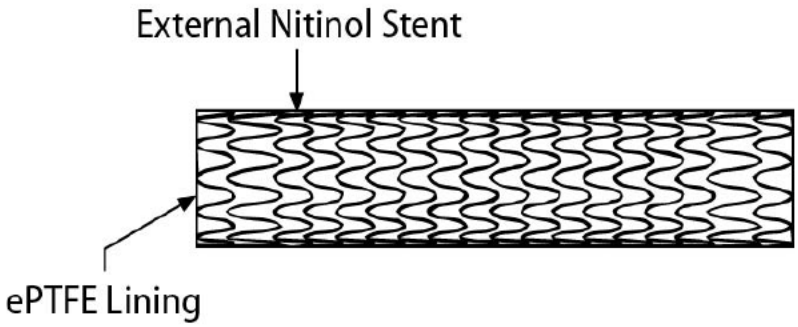

Figure 1. GORE® VIABAHN® Endoprosthesis

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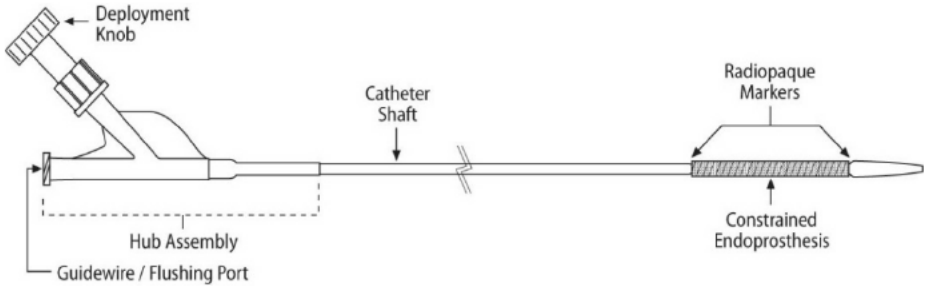


Figure 2. Dual Lumen Delivery Catheter

Available sizes of the GORE® VIABAHN® Endoprosthesis can be found in Table 1.

[redacted]

1.4. Clinical Data

[redacted]

Publications in recognized peer reviewed journals regarding the use of GORE® VIABAHN® Endoprosthesis in PAAs are available since 2006 and as of today clinical data relating to more than 400 study limbs with follow-up of more than 10 years can be found in the literature.

1.4.1. Overall Data Review

A summary of published data from 16 studies in which the GORE® VIABAHN® Endoprosthesis was used to treat over 400 limbs (34 limbs were treated with alternate stent-grafts) is presented in Table 2.

Table 2. Summary of Clinical Data from Endovascular Repair of PAAs

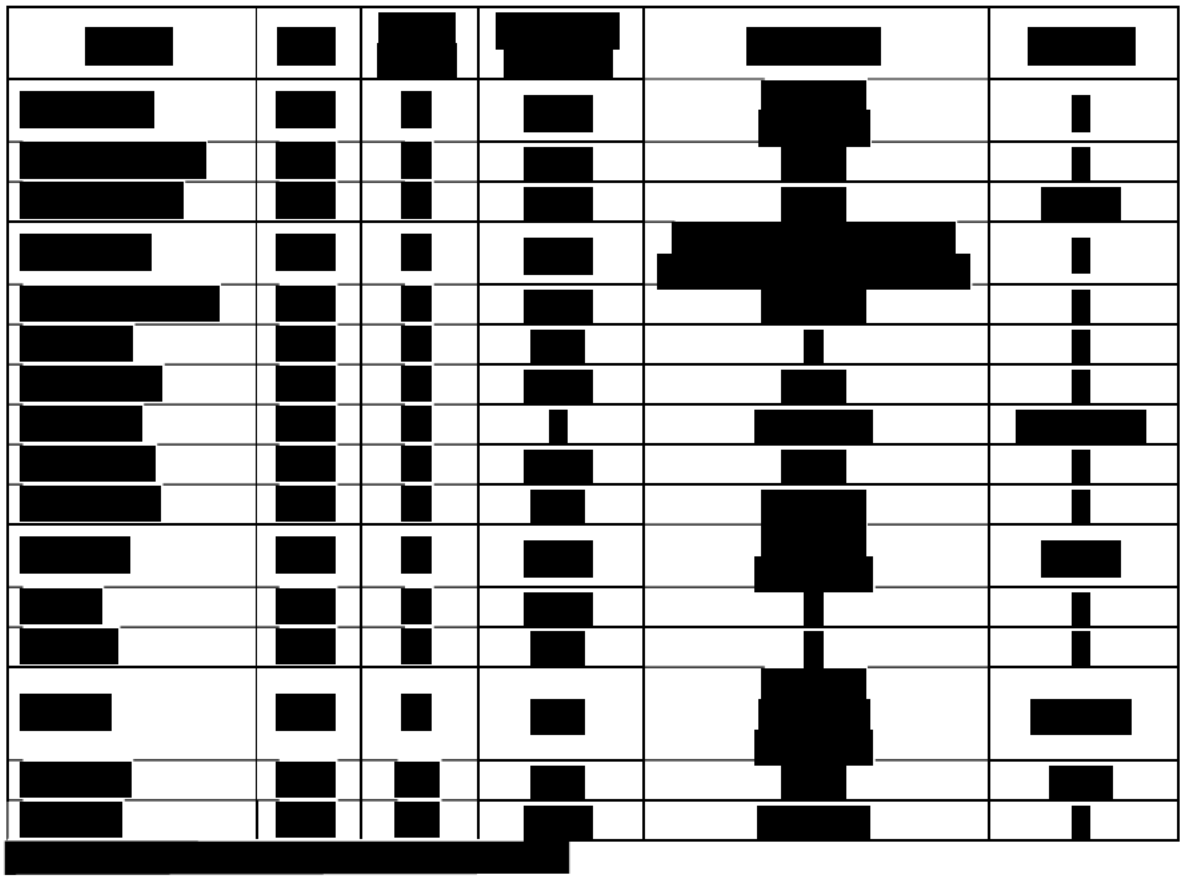
Author	Year	Limbs	[redacted]	Latest Follow-up (year)	[redacted]	Study Type	[redacted]
Mohan [18]	2006	30[a]	[redacted]	3	[redacted]	Retrospective, Multicenter	[redacted]
Rajasinghe [37]	2007	23	[redacted]	1	[redacted]	Retrospective, Single Center	[redacted]
Antonello [33]	2007	21	[redacted]	6	[redacted]	Prospective, Randomized, Comparative, Single Center	[redacted]

Author	Year	Limbs	[redacted]	Latest Follow-up (year)	[redacted]	Study Type	[redacted]
Ghotbi [45]	2007	27	[redacted]	4	[redacted]	Prospective, Single Center	[redacted]
Thomazinho [47]	2008	11	[redacted]	1.7	[redacted]	Prospective, Single Center	[redacted]
Maru [50]	2008	50	[redacted]	2	[redacted]	Retrospective, Multicenter	[redacted]
Idelchik [51]	2009	33[b]	[redacted]	4.5	[redacted]	Prospective, Single Center	[redacted]
Tielliu [35]	2010	78	[redacted]	10	[redacted]	Retrospective, Single Center	[redacted]
Ascher [52]	2010	15	[redacted]	2.5	[redacted]	Prospective, Single Center	[redacted]
Etezadi [53]	2010	18	[redacted]	0.5	[redacted]	Retrospective, Single Center	[redacted]
Jung [46]	2010	15	[redacted]	6	[redacted]	Retrospective, Single Center	[redacted]
Le [54]	2010	21	[redacted]	0.6	[redacted]	Retrospective, Single Center	[redacted]
Kim [39]	2010	24	[redacted]	1	[redacted]	Retrospective, Single Center	[redacted]
Midy [4]	2010	57[c]	[redacted]	3	[redacted]	Retrospective, Multicenter	[redacted]
Garg [63]	2012	26	[redacted]	2	[redacted]	Retrospective, Single Center	[redacted]
Pulli [62]	2013	134	[redacted]	4	[redacted]	Retrospective, Multicenter	[redacted]

[redacted]

In the majority of the studies, the physician chose to repair aneurysms that were either symptomatic or had aneurysm diameter either greater than 2 cm in diameter or greater than 1.5 times the healthy native vessel.

[redacted]



2. Study Objectives

2.1. Primary Objectives

The primary objectives of the GORE® VIABAHN® Endoprosthesis Popliteal Artery Aneurysm study are to document the safety and performance of the GORE® VIABAHN® Endoprosthesis for the treatment of PAAs at 12 months.

2.2. Secondary Objectives

The secondary objectives of the GORE® VIABAHN® Endoprosthesis Popliteal Artery Aneurysm study are to document long-term (through 36 months) safety and performance by evaluating freedom from limb loss, length of hospital stay after study procedure, length of study procedure, serious adverse events (SAEs), device or procedure related adverse events (AEs), technical success, primary patency, primary assisted patency, secondary patency and freedom repeat intervention. In addition, listings of device migration, endoleak, device fracture, and study limb amputation will be reported separately.

3. Study Design

3.1. Study Design Schema

The study design is depicted in Figure 3 below.

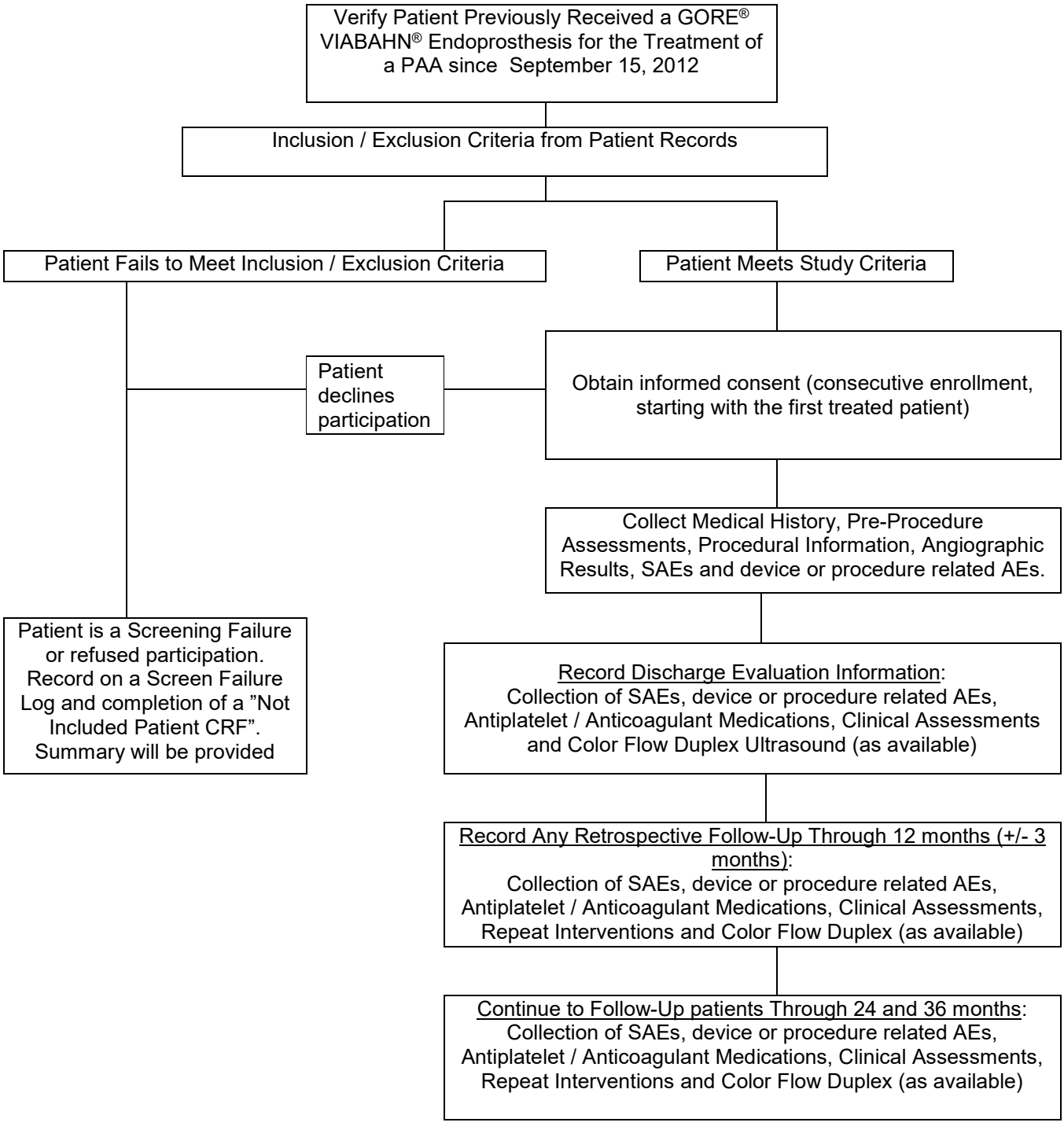


Figure 3. Study Design Schema

3.2. Description of Study Design

This is a retrospective, multicenter, non-randomized single-arm clinical study with a prospective follow-up to evaluate the safety and performance of the GORE® VIABAHN® Endoprosthesis for the treatment of patients with PAAs. All patients will have received the GORE® VIABAHN® Endoprosthesis for treatment of a PAA since September 15, 2012 (date at which reimbursement for the GORE®VIABAHN® device was received in France). Inclusion for all patients will be retrospective, follow-up visit(s) can be prospective.

A maximum of 10 Clinical Investigative Sites (referred to as “Sites” in the remainder of this document) in France will participate in this study. 50 patients with an adequate follow-up to assess primary endpoints will be enrolled. All patients will have received the GORE® VIABAHN® Endoprosthesis for treatment of a PAA since 15 September 2012 and meet all of the inclusion and none of the exclusion criteria as specified in Sections 4.2 and 4.3 of this protocol.

Data entry will be monitored and enrollment will be stopped when 50 subjects have data for the 12 months follow-up visit entered.

Patients with bilateral PAAs treated with GORE® VIABAHN® Endoprosthesis at different dates can be enrolled in the study. The first limb enrolled will be considered the study limb. Patients with both limbs treated within the same procedure will not be enrolled in the study.

Follow-up examinations through 12 months (+/- 3 months) post-implant will be collected for the primary endpoint analysis. This will include clinical assessment, imaging-based evaluations, SAEs, device, and procedure related AEs. Patients will be further followed through 24 and 36 months post-procedure.

3.3. Study Endpoints

3.3.1. Definitions

Acute Limb Ischemia[55]**:** Defined by the operating or treating physician. Typically defined as emergently threatened, whether marginally or immediately, implying reversible ischemia in a limb that is salvageable without a major amputation if arterial obstruction is relieved quickly or irreversible ischemic change requiring major amputation.

Adverse Event (AE): Any untoward medical occurrences, unintended disease or injury or any untoward clinical signs (including abnormal laboratory findings) in patients, users or other persons related to the investigational medical device or procedure.[56] For this study, only device or procedure related AEs need to be reported.

Device Fracture: A stent fracture was defined as any discontinuity of the normal structure of the stent as diagnosed on x-ray.

Endoleak (Modified from White et al.)[57]**:**

Type I – Present when a persistent perigraft channel of blood flow develops due to inadequate or ineffective seal at the graft ends.

Type II – Occurs when there is persistent collateral blood flow into the aneurysm sac flowing retrogradely from collateral branches.

Type III – Arises at the mid-graft region due to leakage through a defect in the graft fabric or between the segments of multiple grafts.

Type IV –Blood diffusion across the pores of the graft fabric or through tiny holes in the graft fabric caused by sutures or stent struts.

Type V - Leakage from an unknown origin.

Hinge Point: Located at the adductor tubercle, which corresponds to the upper border of the patella, in a plane perpendicular to the femoral axis.

Length of Hospital Stay: The number of days the subject remains in the hospital due to endovascular repair of a PAA with VIABAHN ("index procedure").

Length of Procedure: The number of minutes the subject remains in the operating room or catheterization laboratory due to endovascular repair of a PAA. If no specific information is available the first and last angiographic timestamp can be used to capture the length of the procedure.

Limb Loss: An amputation on the study limb above the metatarsals.

Migration: Any post-operative device migration requiring treatment.

Patency:

Primary Patency: Blood flow without occlusion maintained through the device after implant without an intervention.

Primary Assisted Patency: Blood flow maintained through the device after implant regardless of re-interventions performed (without occlusion).

Secondary Patency: Blood flow through the device regardless of re-interventions performed (with or without occlusion) and freedom from surgical bypass.

Re-intervention: Endovascular or surgical procedure performed to treat a stenosis or occlusion within the study device(s) or within 5 mm of the proximal or distal edge of the device(s), treatment of endoleaks or other reasons.

Serious Adverse Event (SAE)[56]: An AE that led to death or lead to serious deterioration in the health of the subject that resulted in a life threatening illness or injury, or a permanent impairment of a body structure of body function, or in-patient or prolonged hospitalization, or a medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or a body function.

Technical Success: Successful aneurysmal exclusion using the GORE® VIABAHN® Endoprosthesis at time of the procedure without Type I or III endoleaks that require post-procedure intervention within 30 days.

3.3.2. Primary Endpoints

The primary performance endpoint for this trial is:

- Primary patency at 12 months.

The primary safety endpoint for this trial is:

- Serious adverse events and adverse events related to the study procedure or the study device at 12 months.

3.3.3. Secondary Endpoints

The secondary endpoints for this trial are:

- Technical success;
- Freedom from limb loss on the study limb at 12, 24 & 36 months;

- Freedom from repeat intervention at 12, 24 & 36 months;
- Length of procedural hospital stay in days;
- Length of procedure in minutes;
- Serious adverse events and adverse events related to the study procedure or study device at 24 & 36 months;
- Primary patency at 24 & 36 months;
- Primary assisted patency at 12, 24 & 36 months;
- Secondary patency at 12, 24 & 36 months.

3.3.4. Listings

Listings of the following reported events will be provided:

All Endoleaks

Device Migration

Device Fracture

Major amputation on the study limb

Minor amputation on the study limb

4. Study Population

4.1. Description of Population

The study population includes patients with a symptomatic aneurysm or asymptomatic aneurysm (≥ 2 cm diameter) of the popliteal artery, or presence of mural thrombus (< 2 cm) in the popliteal artery. All patients treated per IFU with the GORE® VIABAHN® Endoprosthesis since September 15, 2012 (date of reimbursement in France) will be screened consecutively, starting with first treated patient.

4.2. Inclusion Criteria

Inclusion to the study requires the patient:

1. Received a GORE® VIABAHN® Endoprosthesis to treat a popliteal artery aneurysm
2. Had a symptomatic aneurysm or asymptomatic aneurysm (≥ 2 cm diameter) of the popliteal artery, or the presence of mural thrombus (< 2 cm) in the popliteal artery;
3. Was 18 years of age or older at the time of the treatment;
4. Had an elective popliteal artery aneurysm procedure;
5. Has provided Informed Consent, personally or through lawful representation as determined by applicable local regulations and state law (Section 5.2).

4.3. Exclusion Criteria

Prior to or at the time of implant the patient is / has:

1. Bilateral popliteal artery aneurysms with initial treatment on the same day;
2. Thrombotic occlusion of the popliteal artery or PAA
3. Marfan syndrome or Ehlers-Danlos syndrome;
4. Unable to tolerate antiplatelet therapy;
5. Thrombophilia requiring long term anticoagulation
6. Known allergies to the GORE® VIABAHN® Endoprosthesis components;

7. Enrolled in another investigational drug or medical device trial where participation may have affected the outcome or treatment of the subject in the popliteal artery aneurysm study with the GORE® VIABAHN® Endoprosthesis or had previous surgery for the popliteal artery aneurysm in the study limb.

4.4. Patient selection

For this Post-market study it has been decided that the screening of the patient records will start with patients treated September 15, 2012 and continuously go forward.

At each Site the Principal Investigator and his team will confirm in- and exclusion criteria for each patient and will contact the patient to obtain his agreement to collect medical data:

a. If the patient meets the criteria and gives his agreement to participate he will be considered as enrolled.
b. If the patient does not agree to participate or fails to meet the Inclusion / Exclusion criteria he will be considered as a screening failure and the reason will be documented in the Not Included Patient CRF.
c. If the patient does not respond after three call attempts he will be considered as lost to follow-up and this will be documented in the Not Included Patient CRF.
d. If the PI and his team are informed by the family during one of this calls that the patient previously died in another hospital they will inquire the reason and the date of the death. This will be registered in the Not Included Patient CRF. If the family refuses to give details only the death will be registered in the Not Included Patient CRF but no more details.

In case the PI and his team have clinical information available that patient died in their hospital cause and date of death will be registered and the Not Included Patient CRF will be completed.

5. Study Procedures / Evaluations

5.1. Schedule of Events

The schedule of events for this study can be found in Table 4 and described in further detail below (see Sections 5.2 to 5.9).

Table 4. Schedule of Events

Event	Screening, enrollment and 12 month (+/- 90 days) FU visit	24 month (+/- 90 days) FU visit	36 month (+/- 90 days) FU visit
GORE® VIABAHN® Endoprosthesis since 15 September, 2012	X		
Inclusion / Exclusion Criteria	X		
Informed Consent Procedure	X		
Medical History	X		
Procedural Information	X		
SAEs and device / procedure related AEs	X	X	X
Clinical Assessment	X	X	X
Re-intervention (if applicable)	X	X	X
Antiplatelet / Anticoagulant Medications	X	X	X
Color Flow Duplex Ultrasound Results (if available)	X	X	X
Angiography Results (if available)	X	X	X

5.2. Informed Consent Process

Each patient that meets the criteria for this evaluation should be informed of any requirements, risks and / or rights for participating in observational data collection. Patients will sign and date a consent form to meet regulatory and / or institutional requirements before data can be entered into the Post-market study. The original signed informed consent form will be retained in the Subject records. A copy of the informed consent document will be given to the patients for their records.

5.3. Pre-Screening / Screening

Patients who received a GORE® VIABAHN® Endoprosthesis for the treatment of PAAs since 15 September, 2012 will be considered for screening for this study. Any screened patient that meets all of the inclusion criteria (Section 4.2) and none of the exclusion criteria (Section 4.3) and has completed a patient information and consent form should be enrolled in this study.

5.4. Enrollment

Patients are considered enrolled if they have met all of the inclusion criteria (Section 4.2) and none of the exclusion criteria (Section 4.3) and have signed the patient information and consent form. Any patient not meeting all of the inclusion criteria and none of the exclusion criteria should be recorded on a screening failure log along with the reason for failure, in addition a screen-failure CRF will be completed. A summary of screen failures including the following information: subject number, date of procedure, and reason for failure will be reported.

Enrollment will be performed in consecutive order beginning with the first patient treated since September 15, 2012. Patients with bilateral PAAs treated with GORE® VIABAHN® Endoprosthesis at different dates can be enrolled in the study. The first limb enrolled will be considered the study limb. Bilateral patients with initial treatment on the same day will not be enrolled. The number of included patients will be monitored via entries in the electronic CRF and Sites will be informed when the inclusion goal (50 patients with data for the 12 month follow-up visit) is met.

5.5. Procedure

As part of the retrospective study the subject previously received the study device. Procedural information related to placement of the device(s) such as overlap, oversizing, number of devices, landing zone, post-deployment dilatation, SAEs, and AEs related to the initial study procedure or the study device will be recorded on the Case Report Forms (CRFs), as available.

5.6. Repeat Interventions

Repeat interventions may take place prior to or after hospital discharge. Procedures taking place during the study procedure should not be captured as repeat intervention. Any available procedural data and angiographic or ultrasound data related to these repeated interventions should be recorded in the CRFs.

5.7. Follow-Up

Follow-up visits need to be done in a window of +/- 90 days in order to be documented as study visits. This means that 12 month follow-up visit needs to take place between 275 and 455 days post-procedure, the 24 months follow-up visit between 640 and 820 days post-procedure, and the 36 month follow-up visit between 1005 and 1185 days post-procedure. All visits occurring from the time of procedure through 1185 days post-procedure should be recorded for each subject. If a subject had an office visit between 1005-1185 (three years $\pm$ 90) days post-procedure, then no further information will be collected on the subject after 1185 days. Device or procedure related AEs, antiplatelet / anticoagulant medications, clinical assessment, ultrasound, and angiographic information should be collected, during each follow-up visit as applicable and available.

5.7.1. SAEs and device or procedure related AEs

SAES and device or procedure related AEs found in the subject chart should be recorded at each follow-up visit. Additional details regarding AE recording can be found in Section 9.

5.7.2. Medications

Medications being recorded for this study include post-procedural antiplatelet and anticoagulation medications. Start date, end date, dose, and frequency should be recorded for each subject. Medications used during the procedure such as intravenous Heparin do not need to be recorded.

5.7.3. Clinical Assessment

Clinical Assessments include the presence of palpable pedal pulses and an Ankle Brachial Index (ABI). The ABI of each subject should be recorded. A Toe Brachial Index may not be used in place of an ABI.

5.7.4. Color Flow Duplex Ultrasound

When possible Color Flow Duplex Ultrasound information should be recorded for each subject at each study visit; verification of the presence or absence of blood flow should be recorded. Additionally, aneurysmal dimensions will be evaluated.

5.8. Subject Withdrawal from the Clinical Study

All patients have the right to withdraw themselves from participation at any point during the study. In addition, Principal Investigators also have the authorization to terminate a subject's participation in the study.

A description of the reason for the subject's termination will be documented. Reasons for termination include: completion of study, subject's voluntary withdrawal, physician-directed subject withdrawal, and death.

Upon study exit the subject will be followed per standard of care by Investigator and / or another physician.

5.9. Subject Study Completion

A subject has completed the study when 36 months (1185 days or 3x365 + 90 days) of follow-up data has been recorded on the CRFs. Any subject that does not complete these requirements due to voluntary withdrawal, death, lost secondary patency (e.g. had a study limb bypass) or any other reason will be considered a withdrawal and the reason for discontinuation will be marked on the CRF.

If a subject is lost to follow-up, the appropriate CRF must be completed as soon as possible after subject status has been determined. If a subject fails to comply with follow-up evaluations, the Site must make at least three attempts to contact the patient and his family and potentially his General Practitioner. Each attempt to contact the subject and the method used (e.g., telephone contact, registered letter) must be documented in the subject's records.

5.10. Device Deficiencies

Device deficiencies are defined as inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. The process for reporting device deficiencies should be done through normal product surveillance mechanisms.

5.11. Explant Procedures

The GORE® VIABAHN® Endoprosthesis may be explanted during a surgical procedure or as part of an autopsy. If the explanted study device is available, Sites are requested to return the explanted device to the Sponsor for gross and histological evaluation. Contact the Gore Associate managing the study to facilitate shipment of a specimen shipping kit. The specimen

kit provides specific packaging and handling instructions for the specimen and contains a shipping container.

5.12. Duration of Investigation

Each subject will be followed for approximately 36 months and then exit the investigation. It is anticipated that all patients will be enrolled within a period of nine months. The subject enrolment period is expected to occur from March 2015 to December 2015. The last subject primary endpoint follow-up is expected to occur by the end of 2017.

6. Study Administration

6.1. Training

Each physician deploying the GORE® VIABAHN® Endoprosthesis has extensive experience with this commercially available device and study Sites will be selected accordingly. No additional training for this product will be required.

6.2. Monitoring

[redacted]

The monitors are qualified by training and experience to oversee the progress of the study at the Site and will ensure that the Investigators and their staff understand and adhere to both the applicable regulatory requirements and the study protocol. In addition, they may assist in resolution of any problems that may arise during the study. A monitoring plan will be developed prior to the initiation of the Post-market study which outlines the extent and nature of monitoring appropriate for the study, including the frequency of visits, the strategy for source data verification, based on considerations such as the objective, design, complexity, size, critical data points, and endpoints of the study.

6.2.1. Site Initiation

Site initiation will be performed to assure that each Investigator and his / her staff understands the protocol, applicable regulations, human subject protection requirements and the Investigator's obligations. This visit will ensure that required documentation with the appropriate approval is in place prior to subject enrollment.

6.2.2. Periodic Site Monitoring

Periodic Site monitoring will occur as necessary to ensure continuing adequacy of facilities and adherence to the clinical study protocol, Good Clinical Practice (GCP), ISO 14155 and applicable regulations, and laws that pertain to the conduct of the clinical study.

All data will be verified to source during the monitoring process, other than instrument data directly downloaded into the investigational database. [redacted] will be responsible for monitoring this Post-market study.

The monitoring plan will specify Site audits and inspections as indicated by the Sponsor. Regulatory authorities will have the ability to inspect and audit the investigational Site during the clinical study.

6.3. Device Accountability and Storage

The GORE® VIABAHN® Endoprosthesis is a commercially available product and has already been used, so accountability or storage for this study is not required. The lot and serial number for each commercial device used in the study will be recorded in the subject records and transcribed to the CRF.

6.4. Protocol Deviations

A protocol deviation is defined as any change, divergence or departure from the study design or procedures of a research protocol that is under the Investigator's control. The Investigator is responsible for promptly reporting protocol deviations to the Sponsor. The Sponsor will determine the effect of the protocol deviation on the scientific soundness of the clinical study and subject safety, and determine if additional reports or actions are required. Additional action may include Site retraining and / or Site termination.

6.5. Protocol Amendments

The Sponsor will obtain CCTIRS and CNIL approval before starting collecting the data; on all amendments will also be submitted in a timely manner to the CCTIRS and to CNIL. The Sponsor will ensure proper training of Investigator and Site staff on all protocol amendments.

6.6. Access to Source Data / Documents

Source data are defined as all information necessary for the reconstruction and evaluation of the clinical investigation. The Investigator will keep all study records and source data available for inspection by the Sponsor, MedPass monitors, CCTIRS, CNIL, and other regulatory authorities.

6.7. Study Records Retention

All data shall be produced and maintained in a way that assures control and traceability. Source documents are required for each subject enrolled. The Investigator will maintain complete, accurate and current study records as required by applicable regulatory requirements. Records will be maintained during the clinical study and for a minimum of 15 years after the latter of the date on which the study is terminated or completed, or the date the records are no longer required to support regulatory approval of the device. In any event, clinical study records will not be disposed of, nor custody of the records transferred, without prior written Sponsor approval. Where copies of the original source document as well as printouts of original electronic source documents are retained, these shall be signed and dated by a member of the investigational Site team with a statement that it is a true reproduction of the original source document.

Investigator records will include, but not be limited to:

- All correspondence with another Investigator, CCTIRS, CNIL, the Sponsor, a monitor, including required reports.
- Records of each subject's case history and exposure to the device. Case histories include the CRFs and supporting data, medical records, including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include:
  - All relevant observations, including records concerning AEs, the information, date and condition of each subject upon entering the trial, information about relevant previous medical history, and the results of all diagnostic tests.

- A record of the exposure of each subject to the device, including the date and time of implant, and any other therapy.
- The protocol, any amendments and documentation of any deviations from the protocol, including the dates, and the reasons for such deviations.
- Any other records that are required to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

The Investigator will prepare and submit the following reports:

- **Protocol Deviations:** Protocol Deviations shall be reported as described in Section 6.4
- **Other:** Any other reports as reasonably requested by the Sponsor.

6.8. Publication Plan

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a trials-registration policy as a condition for publication. This policy requires that all clinical trials be registered in a public trials registry. The Sponsor will register the study and post-results as required by this policy.

It is the intent of the Sponsor that the multicenter results of this study will be submitted for publication (in a peer reviewed journal). A publications committee will be established to review the multicenter results and develop publications at the completion of the study. Individual Sites should coordinate requests for publication through the publications committee or the Sponsor.

7. Data Collection and Submission

The Clinical Data Management System (CDMS) for this study will be provided by:

[redacted]

7.1. Data Collection Methods

This study will report clinical data using a web-based application. The CDMS will be the database of record for the protocol and subject to regulatory inspections. All users will be trained to use the CDMS and will comply with study specific guidelines / instructions as well as applicable regulatory requirements.

Subject data will be collected using protocol-specific CRFs. Site staff will enter data directly into the CRFs for transmission to the Sponsor. The Sites will be notified of any significant amendments to the CRFs.

7.2. Data Clarification and Correction

Once entered, data will be evaluated to ensure that it is complete, consistent with related source documents and logically sound. If changes to the data in the CDMS are required, all changes, reasons for changes, and persons making the changes will be captured in the CDMS's audit trail.

The CRO is the coordinating center for data management for this Post-market study. The monitors will verify that all data entered into the CRFs are accurate against the source. Visual and computer error checks will be carried out as appropriate, and the investigative Site will be queried on errors concerning completeness and consistency of the data on the CRFs.

Confidentiality of data shall be observed by all parties involved at all times throughout the Post-market study. All data shall be secured against unauthorized access.

7.3. CRF Completion Schedule

All CRFs including the AE CRFs should be completed on a regular basis and as soon as reasonably possible upon enrollment of the subject in the trial.

8. Risk Assessment

[redacted]

Risks associated with these devices including the GORE® VIABAHN® Endoprosthesis or the interventional procedure include, but are not limited to:

- Hematoma
- Stenosis
- Thrombosis
- Occlusion
- Distal embolism
- Side branch occlusion
- Vessel wall trauma
- Rupture
- False aneurysm
- Infection inflammation
- Fever
- Pain
- Deployment failure
- Migration
- Device failure
- Endoleak
- Open surgical conversion
- Death

Risks associated with the interventional procedure include, but are not limited to:

- Access site infection
- Entry site bleeding
- Hematoma
- Vessel thrombosis
- Occlusion
- Pseudoaneurysm

- 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
- Open surgical conversion
- Death

8.2. Minimization of Risks

Potential risks associated with the use of the GORE® VIABAHN® Endoprosthesis may be minimized by the following activities:

- The Sponsor has performed qualification testing on the device and device components, and appropriate quality control measures have been implemented in production;
- Investigators will be selected who are knowledgeable and experienced in interventional radiology procedures, and vascular anatomy;
- The Site Investigator, Sub-Investigators, Clinical Study Coordinator(s) or designee at each Site will be trained to the protocol;
- Protocol inclusion / exclusion criteria are designed to select appropriate patients and identify potential complications;
- Data completed by the Sites will be monitored to evaluate protocol compliance, data accuracy and subject safety; and
- Safety and performance data obtained during the clinical study will be shared with the Site Investigators to aid understanding of the device and potential complications associated with its use.

However, there is no risk to the patient by participating in this retrospective study because the procedure has already been performed and no additional procedures are requested except hospital standard of care.

[redacted]

8.4. Risk-to-Benefit Rationale

This study does not lead to any change in patient management and patients will receive the same treatment as they would have received if they had decided not to participate. Therefore, there is neither an additional risk nor a direct benefit related to the participation in the study.

9. Adverse Events and Safety Monitoring

AEs are defined as any untoward medical occurrences, unintended disease or injury or any untoward clinical signs (including abnormal laboratory findings) in patients, users or other persons whether or not related to the investigational medical device.[56] According to the primary and secondary endpoints of this study, the documentation of adverse events will concern all serious adverse events and adverse events related to the initial study procedure or the study device, regardless of the severity throughout 36 months.

9.1. Anticipated Adverse Events

Anticipated AEs are complications that are known to be associated with patients undergoing endovascular PAA repair. See Section 8 Risk Assessment. Additional AEs may include: clinical sequelae associated with amputation, aneurysm enlargement, edema, dehiscence, vascular spasm, vascular trauma, coagulopathy, claudication, clinical sequelae associated with device fracture; stroke; non-improving wound; allergic reaction to the device or other components or perforation of the vessel.

9.1.1. Adverse Event Relationship

Each reported AE will be assessed by the Investigator for its primary suspected relationship to the device or procedure.

Only one primary relationship will be assigned to each reported AE. The relationships include: Study Device Related, Study Procedure Related, Not Related or an Unknown Relationship. Relationship descriptions are provided below:

- **Study Device Related:** The functioning or characteristics of the study device caused or contributed to the AE.
- **Study Procedure Related:** The initial study procedure (and not the device) caused or significantly contributed to the AE.
- **Not Related:** An AE which cannot be attributed to the study device or initial study procedure.
- **Unknown Relationship:** The relationship of the AE to the device or procedure cannot be determined.

9.1.2. Adverse Event Classification

Each AE will be assessed by the Investigator to determine if it is serious or non-serious.

Serious Adverse Event (ISO 14155 Definition)[56]

A SAE is an AE that:

- led to death
- led to serious deterioration in the health of the subject that either resulted in:
  - a life threatening illness or injury, or
  - a permanent impairment of a body structure or body function, or
  - inpatient or prolonged hospitalization, or

  - medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function
- led to fetal distress, fetal death or a congenital abnormality or birth defect.

SAEs include device deficiencies that might have led to a SAE if suitable action had not been taken or if an intervention had not been made or if circumstances had been less fortunate. Any planned hospitalization for pre-existing conditions, without serious deterioration in health, is not considered a SAE.

9.1.3. Adverse Event Reporting and Coding

AEs will be reported on the appropriate CRF for that visit and documented in the subject's permanent medical record. The Investigator at each Site is ultimately responsible for reporting AEs to the Sponsor. The Investigator shall supply the Sponsor with any additional requested information.

Timely and complete reporting of safety information assists the Sponsor in identifying any untoward medical occurrence, thereby allowing: (1) protection of safety of study patients; (2) a greater understanding of the overall safety profile of the GORE® VIABAHN® Endoprosthesis; (3) appropriate modification of study protocols; and (4) adherence to worldwide regulatory requirements.

The following information should be collected for each reported AE:

- AE Name
- AE Onset Date
- Relationship
- Classification (serious / non-serious)
- Treatment
- Outcome
- Resolution Date

All reported AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA).

In reporting AEs the following submission guidelines should be followed:

- AE reporting begins once the subject has received a GORE® VIABAHN® Endoprosthesis and continues until study completion / discontinuation.
  - NOTE: Any AE that occurs while the subject is in the operating room / catheterization laboratory should not be recorded as an AE, unless it is unresolved when the subject leaves the operating room / catheterization laboratory.
  - NOTE: Any AE occurring after the final study visit will not be recorded in this study.
- AEs with an outcome status of "Ongoing" should be assessed at each follow-up evaluation to determine if the event has resolved. AEs ongoing at study completion / discontinuation should be left as "Ongoing" on the AE CRF.

- Clinical sequelae present at baseline should be recorded on the Medical History CRF. If the clinical sequela increases in severity or frequency from baseline then it should be reported as an AE.
- If known, the diagnosis of the underlying illness or disorder should be recorded, rather than its individual symptoms. If unable to provide a diagnosis, report the symptoms as separate events. AEs should be reported using the full name without abbreviations or narratives.
- If an event increases in severity (goes from a non-serious to a serious adverse event) then a stop date for the non-serious event should be provided and a new event with increased severity should be recorded.
- Subject death is not considered an AE. (See Section 9.1.4)
- A device fracture is not an AE but the clinical sequelae associated with the fracture should be recorded as an AE.
- PAA enlargement is an AE if it grows by more than 10 mm from the baseline measurement.
- Endoleaks
  - For type I, II and III endoleaks the possible relationship to the procedure or device will be based on the Investigators assessment as described in Section 9.1.1.
  - Type IV endoleaks should be considered related to the study device regardless of when the endoleak occurs.
  - Type V endoleaks should be classified as an unknown relationship.

All endoleaks should be reported as Adverse Events and the respective CRF pages need to be completed.

9.1.4. Subject Death

Death is not an AE but instead an outcome of an AE. In rare cases the known cause of death or one specific AE responsible for death may not be able to be declared as the major contributor to death. When possible, death should be an outcome and the underlying cause of the death recorded as an AE (e.g. cardiac arrest).

Any ongoing AE at the time of death will be indicated as ongoing on the CRF unless it is the single event that resulted in death of the subject.

9.2. Unanticipated Adverse Device Effects (UADE)

An UADE is defined in 21 CFR 812.3(s) as “any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously identified in nature, severity or degree of incidence in the investigational plan or protocol.”[59]

The Sponsor is required to notify FDA and French Health Authorities (Agence Nationale de Sécurité du Médicament et des Produits de Santé (**ANSM**)) of any UADE. Therefore, if a complication occurs that the Investigator believes may be a potential UADE, the Site should immediately contact the Sponsor to determine reporting requirements. In addition, when there is a reason to believe a device may have malfunctioned, causing potential harm to a subject, the Site should immediately notify the Sponsor.

The Investigator shall submit to the reviewing EC a report of any UADE occurring during an investigation as soon as possible, but in no event later than 10 working days after the Investigator first learns of the effect. All UADEs must be documented by the Investigator including the date of onset, a complete description of the event, possible reason(s) for the event, severity, duration, actions taken and outcome. Copies of all supporting documents should be submitted concurrently with the appropriate CRF.

A report from the Sponsor will be submitted to the FDA and participating Investigators within 10 working days after the Sponsor first receives notice of the effect.

10. Statistical Analysis

10.1. Study Objectives

The primary objective of the GORE® VIABAHN® Endoprosthesis Popliteal Artery Aneurysm study is to evaluate the safety and performance of the GORE® VIABAHN® Endoprosthesis for the treatment of patients with PAAs. The safety will be measured through evaluation of serious adverse events and adverse events related to the study procedure or the study device at 12 months. The performance will be measured through primary patency at 12 months.

[redacted]

10.3. Data Analysis

10.3.1. Timing of Analyses

An interim analyses of the primary endpoints and secondary endpoints (where possible) is planned for 12 month follow-up data after enrollment is completed. Complete analyses of the secondary endpoints will take place after the 36 month data for these patients are available. Patients that are lost to follow-up after their 12 month visit, will not be replaced, but any attempt will be made by the Investigator to document the reasons.

10.3.2. Analysis Populations

All enrolled Patients will be included in the analysis. Patients who have had bilateral PAAs treated with the GORE® VIABAHN® Endoprosthesis in both limbs will have only the data from the first limb collected in this study when the limbs were treated at different dates. Patients that had PAAs treated in both limbs on the same date will be excluded to avoid confounding issues with select endpoints.

10.3.3. Pooling of Data

Data from all study Sites will be pooled on a clinical basis, i.e., the study Sites will follow a common protocol, the study will be monitored to assure compliance with the protocol and applicable government regulations, and the data collection and handling procedures will be the same at all study Sites.

10.3.4. Primary Endpoints

Performance will be evaluated by primary patency at 12 months of the GORE® VIABAHN® Endoprosthesis in the treatment of Popliteal Artery Aneurysms. A point estimate will be calculated requiring primary patency at the one year visit to be declared a success. Having loss of primary patency at day 365 will be tabulated as a failure. Primary patency is defined in section 3.3.1.

Safety of the GORE® VIABAHN® Endoprosthesis will be assessed through 12 months by evaluation of serious adverse events (SAEs) and adverse events related to the study procedure or the study device. Counts will be tabulated at 12 months.

10.3.5. Secondary Endpoint(s)

Primary patency, which is defined as blood flow maintained through the device without an intervention. Blood flow should be determined at the follow-up visits, by either angiography or color-coded duplex sonography. In the event that duplex sonography is not obtained, blood flow will be assessed by clinician exam. Primary patency at 12, 24, & 36 months after implant will be estimated through time-to-event analysis.

Serious adverse events and adverse events relative to the study device and procedure will be obtained through 36 months for assessment of the device safety. Counts will be tabled at 24, & 36 months.

Length of hospital stay will be measured in calendar days. Length of hospital stay will be calculated omitting all patients with unknown endpoint status.

Length of procedure will be measured in minutes. Length of procedure will be calculated omitting all patients with unknown endpoint status.

Primary assisted patency at 12, 24, & 36 months after implant will be estimated through time-to-event analysis. Blood flow should be determined by angiography or color-coded duplex sonography. In the event that duplex sonography is not obtained, blood flow will be assessed by clinician exam.

Freedom from limb loss of the study limb at 12, 24, & 36 months after implant will be estimated through time-to-event analysis.

Freedom from repeat intervention at 12, 24, & 36 months after implant will be estimated through time-to-event analysis.

Secondary patency at 12, 24, & 36 months after implant will be estimated through time-to-event analysis. Blood flow should be determined by angiography or color-coded duplex sonography. In the event that duplex sonography is not obtained, blood flow will be assessed by clinician exam.

Technical Success

Technical success is defined as successful aneurysmal exclusion using the GORE® VIABAHN® Endoprosthesis at time of the procedure without Type I and III endoleaks that require post-procedure intervention within 30 days. All subjects without known status for this endpoint will be omitted in calculating this statistic.

Additional listings

In addition, listings of the following events will be provided: endoleak, migration, fracture, and amputation.

10.4. Control of Bias

Bias will be controlled by strict adherence to patient eligibility criteria and to the study protocol. Sites will be monitored for compliance with study protocol, including subject eligibility criteria, and will be audited for both compliance with the protocol and for data quality.

10.5. Data Analysis

Analysis will be performed after all of the data has been obtained, entered, cleaned, and locked for the interim as well as the final analyses.

11. Ethical and Regulatory Considerations

11.1. Statement of Compliance

The study will be conducted in compliance with this protocol, International Conference on ISO 14155, and applicable regulatory requirements (see **Table 5** below).

Table 5. Applicable Regulations for this Clinical Study.

ICH-GCP E6	International Conference on Harmonisation Regulations Guideline For Good Clinical Practice
ISO 14155:2011	Clinical investigation of medical devices for human patients – Good clinical practice
Medical Device Directive (93/42/EEC) Article 15 Annex X	Council Directive 93/42/EEC of 14 June 1992
Amendment to the MDD (2007/47/EC) Article 15 Annex X	Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007

11.2. Compliance Responsibilities

The Sponsor will conduct the clinical study in accordance with all applicable regulations and laws. The Sponsor will be responsible for documenting that Investigators have the necessary skills, training, and information to properly conduct the clinical study. The Sponsor will ensure proper monitoring of the clinical study and ensure appropriate approvals were obtained prior to enrollment. The Sponsor will provide information to the Investigators concerning the progress of the clinical study and any new, material information about the clinical study.

The Investigator will conduct the clinical study in accordance with all applicable regulations and laws, any relevant agreements, the study protocol, and all approval conditions of the reviewing Committees. The Investigator is responsible for protecting the rights, safety, and welfare of patients under his / her care.

11.3. Informed Consent

It is the responsibility of the Investigator to give each patient prior to inclusion in the investigation, full and adequate verbal and written information about the objectives of the study. The patients must be informed about their right to withdraw from the investigation at any time and for any reason without sanction, penalty or loss of benefits to which they are otherwise entitled and that withdrawal from the investigation will not jeopardize their future medical care. Written Patient Information should be given to each patient before enrolment.

In compliance with national regulatory requirements, the Patient Information Sheet and Informed Consent Form will be submitted to the CCTIRS and to CNIL to be compliant with their requirements. The Investigator will provide the original copy of the signed and dated informed consent to the subject and a copy will be maintained in the subject's medical record. In addition, the signed and dated informed consent will be reviewed by the clinical monitor during the monitoring visit to ensure that it is properly executed in compliance with regulation. The Investigator, or his / her designee, must document in the subject's medical record that informed consent was obtained prior to study participation.

If applicable the Informed Consent will be updated or amended whenever new information becomes available that may be relevant to the patient and the patient advised of this information and re-consented. All modifications to the Informed Consent template must be approved by Gore prior to any submission and use.

11.4. Conflict of Interest

All Investigators will follow their Site's conflict of interest policies.

11.5. Confidentiality

This research is subject to the law of January 6, 1978 relating to Data Protection, as amended and will be submitted to the French Advisory Committee on Information Processing in Material Research in the Field of Health (CCTIRS), and then the French Data Protection Agency (CNIL) before its actual commencement.

All subject records will be kept confidential to the extent provided by applicable laws and regulations. The study monitors and other authorized representatives of the Sponsor may inspect all documents and records required to be maintained by the Investigator, including but not limited to medical records.

Such records may also be reviewed by other regulatory bodies.

The Investigator will inform the patients that their records may be reviewed.

11.6. Study Discontinuation or Suspension

Gore reserves the right to terminate the investigation but intends only to exercise this right for valid scientific or administrative reasons and reasons related to protection of patients. Investigators will be notified in writing in the event of termination.

In addition, Gore will consider terminating or suspending the participation of the investigative Site if monitoring identifies serious or repeated deviations related to this investigation.

If the Sponsor prematurely discontinues the study, all enrolled patients will be informed and followed as standard of care at each institution.

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