# *Summary of Safety and Effectiveness Data (SSED)*

# Summary of Safety and Effectiveness

## 1.0 General Information

| | |
|---|---|
| Device Generic Name: | Endovascular Prosthesis |
| Device Trade Name: | GORE VIABAHN® Endoprosthesis<br>GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface |
| Applicant's Name and Address: | W.L. Gore & Associates, Inc.<br>3450 West Kiltie Lane, P.O. Box 500<br>Flagstaff, AZ 86002 |
| Date(s) of Panel Recommendation: | None |
| PMA Application Number: | P040037/S007 |
| Date of Notice of Approval to Applicant: | August 14, 2008 |

## 2.0 Indications for Use

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

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

## 3.0 Contraindications

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

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.

## 4.0 Warnings and Precautions

See Warnings and Precautions in the labeling (Instructions for Use).

## 5.0 Device Description

The VIABAHN device is comprised of an implantable endoprosthesis and a delivery system. The delivery system consists of a deployment line, a constraining mechanism, and a catheter shaft with a hub assembly (Figure 1 and Figure 2). The GORE VIABAHN® Endoprosthesis is designed for improving blood flow in patients with peripheral arterial disease. The endoprosthesis is delivered to the vessels via access of the femoral artery through hemostatic introducer sheaths. Once delivered, the endoprosthesis serves as a blood flow conduit.

The VIABAHN endoprosthesis is a flexible, self-expanding endoluminal graft consisting of an expanded polytetrafluoroethylene (ePTFE) lining with an external nitinol (NiTi = Nickel: Titanium) support extending along its entire length. The 5 – 8 mm device sizes are also available with the Heparin Bioactive Surface, where the surface of the endoprosthesis is modified with covalently bound, bioactive heparin. The endoprosthesis is compressed and attached to a dual lumen delivery catheter. The larger central catheter lumen is used for flushing and guidewire introduction. The smaller lumen acts as a pathway for elements of the deployment mechanism. The delivery catheter is attached to a hub assembly that includes a port to the central lumen for guidewire introduction and system flushing and a port for the deployment system termination (9 – 13 mm devices have separate flushing and guidewire ports). To facilitate accurate graft placement, two radiopaque metallic bands are attached to the distal tip and transition of the catheter, marking the ends of the compressed graft.

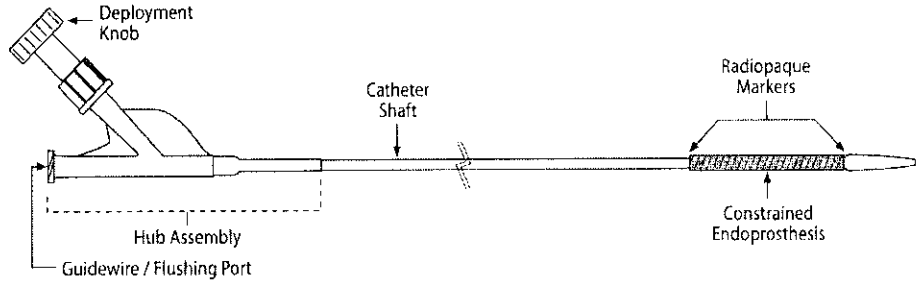



**Figure 1: GORE VIABAHN Endoprosthesis (Small Diameter) Device**

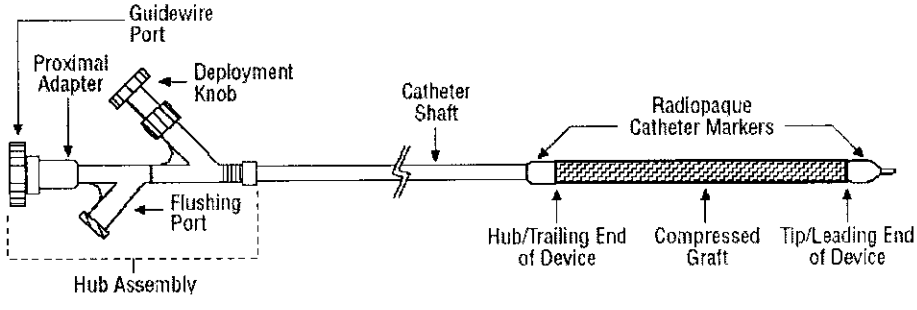



**Figure 2: GORE VIABAHN Endoprosthesis (Large Diameter) Device**

GORE initiated clinical studies under an IDE for the VIABAHN device in 1996. In the period between the study and submission of the PMA, GORE made several modifications to the device and its manufacturing processes. These modifications included the addition of a 5mm diameter device, an increase in the size of the guidewire (from 0.025" to 0.035") for the smaller devices (5mm-8mm diameter), and a

shift from a jelly-roll wrap method of placing the device onto its delivery catheter to a radially constrained method. The radial constrained method of placing the device onto its delivery catheter eliminated the need for the secondary helix fiber for the smaller devices and allowed the adoption of a modified delivery catheter. The direction of deployment for the smaller, radially constrained devices was altered from hub-to-tip to tip-to-hub.

These modifications were not implemented across all diameters of VIABAHN devices. The larger devices (9mm – 13mm diameter) remain on the original platform.

## *Principle of Operation*

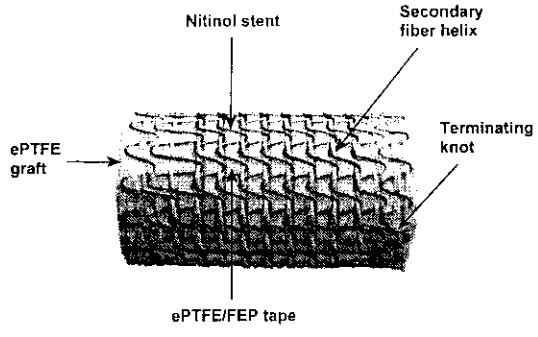
The GORE VIABAHN® Endoprosthesis functions by creating a stent-supported ePTFE-lined blood conduit. The steps of implanting the GORE VIABAHN® Endoprosthesis are described briefly below.

- The physician gains guidewire access to the target location.
- The physician pre-dilates the target lesion by inflating a PTA balloon catheter, and makes angiographic measurements to select the appropriate size endoprosthesis.
- The catheter-mounted endoprosthesis is delivered to the target location over the guidewire and positioned at the target lesion.
- The endoprosthesis is deployed from the delivery catheter.
- The delivery catheter is withdrawn from the patient.
- Physician smoothes and seats the device against the vessel wall by inflating an angioplasty balloon within it.
- When fully deployed and seated, the nitinol frame of the endoprosthesis creates a conduit and supports the target vessel, allowing blood to flow.

## *Description of the VIABAHN Endoprosthesis*

The GORE VIABAHN® Endoprosthesis consists of an ultra-thin expanded polytetrafluoroethylene (ePTFE) film-reinforced graft, with an external electropolished nickel-titanium alloy (Nitinol) wire supporting stent structure (stent). The stent wire diameter varies, depending on the diameter of the GORE VIABAHN Endoprosthesis. The stent is attached to the graft with a tape comprised of ePTFE and fluorinated ethylene propylene (FEP). The larger diameters (9 – 13 mm diameters) incorporate an ePTFE filament (secondary fiber helix) that is sewn through the adjacent apices of the stent structure and that is part of the device delivery system (Figure 3). The smaller diameter devices (5 – 8 mm diameters) are mounted on the delivery catheter in such a way that there is no need to have the secondary fiber helix (Figure 4).

**Figure 3: Large Diameter GORE VIABAHN Endoprosthesis**



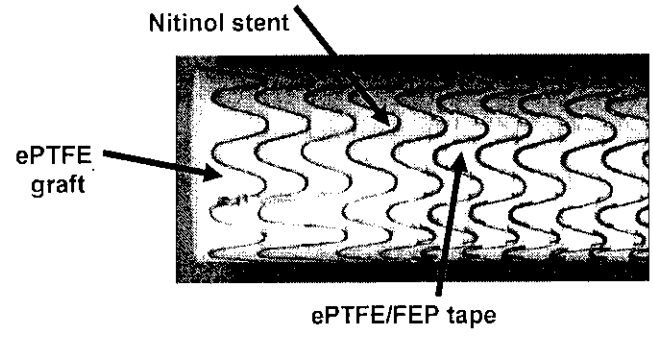



**Figure 4: Small Diameter GORE VIABAHN Endoprosthesis**

## *Description of the VIABAHN Delivery System*

### GORE VIABAHN Delivery System for Large Diameter Devices

The larger GORE VIABAHN Endoprosthesis is folded flat, rolled along the longitudinal axis of the endoprosthesis, and constrained in the rolled state on the distal end of the delivery catheter. The endoprosthesis is constrained onto the catheter by knotting a continuous ePTFE filament through the endoprosthesis' secondary fiber helix. The filament extends beyond the endoprosthesis to create the deployment line. The endoprosthesis is deployed by pulling on the deployment line, which releases the knots and allows the endoprosthesis to expand by unrolling. The endoprosthesis deploys in a direction toward the distal tip of the delivery catheter (hub-to-tip).

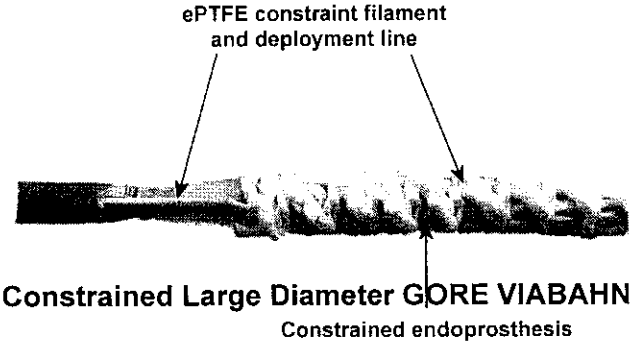
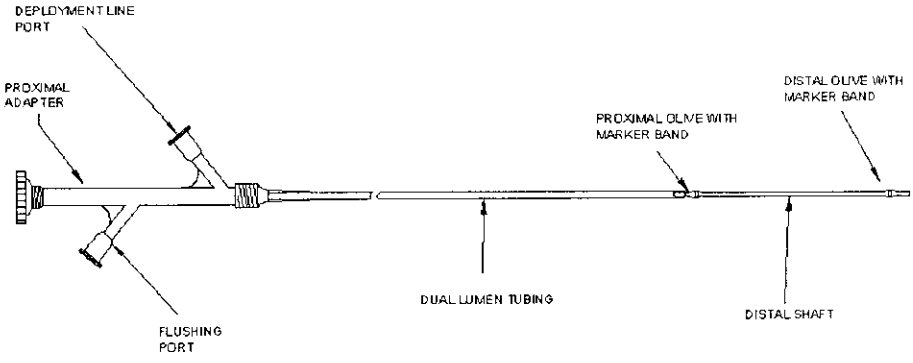



**Figure 5: Constrained Large Diameter GORE VIABAHN Endoprosthesis**

The large diameter endoprosthesis delivery catheter is compatible with guidewires of 0.025 inches or less in diameter and is comprised of three functional sections: the distal shaft, the dual lumen tubing, and the hub assembly (Figure 6). The distal shaft forms the distal-most portion of the delivery catheter. It is comprised of a single lumen tubing, distal and proximal olives and radiopaque markers. The endoprosthesis is constrained to this portion of the delivery catheter between the proximal and distal olives. The radiopaque markers aid in the placement/delivery of the endoprosthesis.

**Figure 6: Small Diameter GORE VIABAHN Endoprosthesis Delivery Catheter**




The dual lumen tubing forms the majority of the working length of the delivery catheter. The tubing is comprised of two circular lumens as shown in Figure 7. The flushing or guidewire lumen is continuous with the lumen of the distal shaft. The deployment line lumen contains the deployment line. The proximal end of the dual lumen tubing is attached to the hub assembly.

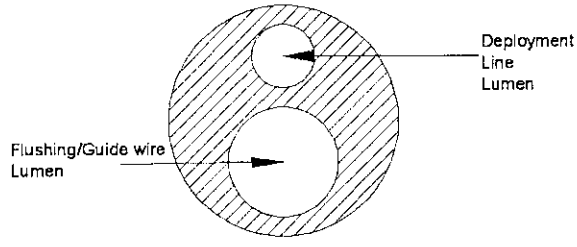



**Figure 7: Cross-section of the Large Diameter GORE VIABAHN Dual Lumen Tubing**

The three port hub assembly consists of a central port with an "O"-ring style compression seal for guidewire introduction, a flushing port for system irrigation, and a port for the deployment line/deployment knob (Figure 6). The deployment line is routed from the proximal end of the constrained endoprosthesis through the proximal olive, through the deployment line lumen of the dual lumen tubing, to the deployment line port of the hub assembly where it is attached to the deployment knob. The deployment knob/deployment line assembly allows the physician to actuate deployment of the endoprosthesis.

**GORE VIABAHN Delivery System – Small Diameter Devices**

The small diameter delivery system is composed of a hub assembly, catheter shaft, transition, distal shaft, tip, constraint mechanism, and a deployment line (Figure 8). Catheters are available in working lengths of 75 or 120 cm.

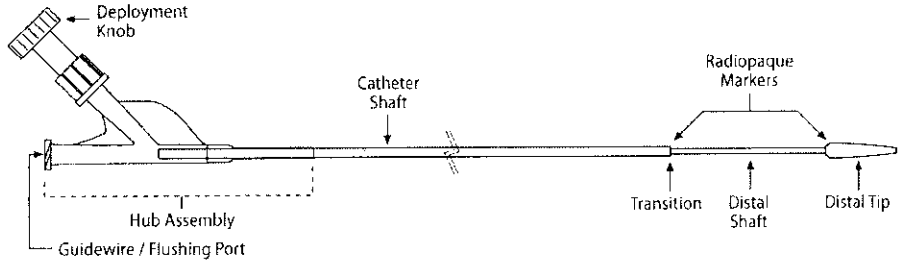



**Figure 8: Small Diameter VIABAHN Delivery System**

The delivery catheters are compatible with 0.035" guidewires and are comprised of the following components: the distal tip, the distal shaft, the transition, the catheter shaft, and the hub assembly. One radiopaque marker is embedded into the transition at the proximal end of the distal shaft while the other is embedded into the distal tip (Figure 8). The endoprosthesis is constrained to the portion of the delivery catheter between the transition and the distal tip. The radiopaque markers aid in the placement/delivery of the endoprosthesis.

The endoprosthesis is radially constrained on the distal end of the delivery catheter with a multi-filament knitted ePTFE constraint sleeve (Figure 9). The constraint sleeve extends beyond the endoprosthesis to create the deployment line. The endoprosthesis is deployed by pulling on the deployment line, which unravels the constraint sleeve allowing the endoprosthesis to expand radially. The endoprosthesis deploys in a direction from the distal tip of the catheter back in the direction toward the hub assembly (Tip to Hub).

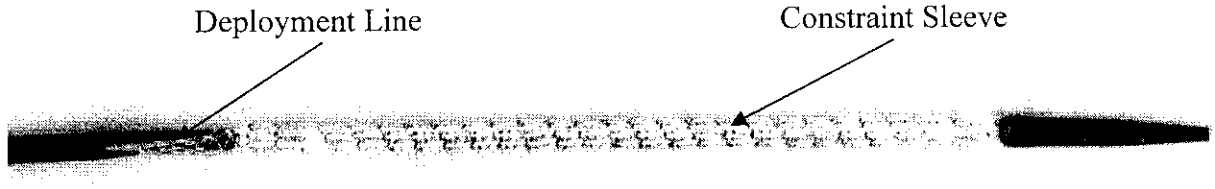



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**Figure9: Constrained Small Diameter VIABAHN Endoprostheses**

The dual lumen tubing forms the majority of the working length of the delivery catheter. The tubing is comprised of two round lumens for the catheter (Figure 10). The flushing or guidewire lumen is continuous with the lumen of the distal shaft. The deployment line lumen contains the deployment line. The proximal end of the dual lumen tubing is attached to the hub assembly.

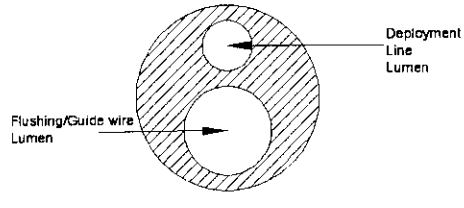


**Figure 10: Cross-section of the Small Diameter VIABAHN Dual Lumen Tubing**

The dual port hub assembly consists of a guidewire introduction port and a port for the deployment line/deployment knob. The deployment line is routed from the proximal end of the constrained endoprosthesis through the deployment line lumen of the transition and dual lumen tubing to the deployment line port of the hub assembly where it is attached to the deployment knob. The deployment knob/deployment line assembly allows the physician to actuate deployment of the endoprosthesis.

### *Heparin Bioactive Surface*

The small diameter VIABAHN endoprosthesis may be purchased with or without the addition of a Heparin Bioactive Surface (also known as Carmeda Bioactive Surface or CBAS). The Heparin Bioactive Surface uses "end-point attachment" of heparin to biomaterials thereby permitting heparin molecules to be covalently bound to a surface without impeding the heparin's biological properties. The USP porcine heparin used to make the Heparin Bioactive Surface is derivatized by a proprietary process established by Carmeda AB, Upplands Väsby, Sweden. Heparin bioactivity (ability to bind antithrombin III) is retained in the binding process due to the single-point attachment that does not interfere with the heparin active site.

**Control of Contamination of the Heparin API**

The following provisions ensure that Gore manufactured and distributed devices containing heparin are not contaminated with over sulfated chondroitin sulfate.

1. The source of heparin sodium API used in the production of Gore CBAS-2 heparin-containing medical devices is North American origin only. The Gore devices utilize a surface treatment of covalently bound CBAS-2 heparin. Scientific Protein Laboratories (SPL) LLC, Waunakee, WI, is the sole source of heparin sodium API.
2. This North American heparin sodium API is certified to meet the pertinent monograph sections of the United States Pharmacopeia and the European Pharmacopeia. Further, results of tests performed by the API supplier, SPL, using Capillary Electrophoresis (CE) and Nuclear Magnetic Resonance (H-NMR) analysis per US FDA methodologies on the heparin API lot, demonstrates the heparin sodium API raw material used by Carmeda is not contaminated with over sulfated chondroitin sulfate.
3. In order to ensure future heparin lots are contaminant free, Carmeda and Gore have made appropriate changes to their respective quality system raw material specifications to require acceptable results of CE and H-NMR testing.
4. Gore continues to monitor reported adverse events involving all products, but more specifically products that utilize the CBAS-2 heparin. This real time adverse event review is intended to provide ongoing compliance with FDA's reporting guidelines and confirmation that Gore medical devices continue to perform, as expected, in a safe and efficacious manner.

## 6.0 Alternative Practices or Procedures

Alternative procedures include use of other commercially available stents, percutaneous transluminal angioplasty (PTA), medical management, atherectomy and bypass graft surgery.

## 7.0 Marketing History

The GORE VIABAHN® Endoprosthesis is currently available and marketed for vascular use in the following countries: Argentina; Australia; Austria; Barbados; Belgium; Bermuda; Boliva; Brazil; Chile; Columbia; Costa Rica; Dominican Republic; Denmark; El Salvador; Finland; France; Germany; Greece; Guatemala; Hong Kong; Iceland; India; Indonesia; Ireland; Italy; Luxembourg; Maylaysia; Mexico; Netherlands; New Zealand; Norway; Panama; Paraguay; Peru; Philippines; Portugal; Singapore; Spain; Sweden; Switzerland; Thailand; Trinidad / Tobago; Uruguay; Venezuela; Vietnam; United Kingdom.

The GORE VIABAHN® Endoprosthesis received pre-market approval (P040037) from the FDA in June 2005 for treatment of occlusive superficial femoral artery (SFA) disease for treatment of vessels ranging from 4.8-7.5 mm in diameter. Changes to the endoprosthesis and delivery catheter were approved in February 2007 (P040037/S002). In April 2007, PMA Supplement P040037/S003 was approved for the addition of the 5mm diameter devices for the SFA indication in the United States (vessel diameter 4.0-4.7 mm). Also, a supplement (P040037/S005) to retrofit existing manufacturing equipment with computer-controlled hardware was approved in May 2007. Finally, PMA Supplement P040037/S004 was approved in July 2007 for the addition of the Heparin Bioactive Surface to the endoprosthesis in the United States (SFA vessel diameter 4.0-7.5 mm).

The GORE VIABAHN® Endoprosthesis has not been withdrawn from marketing for any reason relating to the safety or effectiveness of the device.

## 8.0 Potential Adverse Effects of the Device on Health

Adverse events (in alphabetical order) that may be associated with the use of a vascular stent/stent graft in the iliac artery include:

- Amputation
- Aneurysm
- Arteriovenous (AV) fistula formation
- Atheroembolization
- Death
- Dissection/intimal injury
- Drug reactions to antiplatelet agents/contrast medium
- Fever
- Hematoma/hemorrhage
- Hypotension/hypertension
- Infection and/or pain at the access site
- Myocardial infarction
- Occlusion / restenosis of the treated vessel
- Pseudoaneurysm
- Pulmonary embolism

- Puncture site complications
- Renal failure
- Restenosis of stented segment
- Stent embolization
- Stent malapposition
- Stent migration
- Stroke
- Vessel perforation or rupture
- Vessel spasm

## 9.0 Summary of Preclinical Studies

The preclinical testing below was previously performed in support of PMA application numbers P040037, P040037/S002, P040037/S003, and P040037/S004 for the SFA indication. The data presented below was previously reported in the SSEDs for those submissions; however, additional testing has been added to this SSED for the 9-13mm diameter devices. Testing on both the 9-13mm diameter devices and the 5-8mm diameter devices was performed and reported in PMA application P040037, but only the 5-8mm results were included in that SSED.

Although preclinical test results were used to support an SFA indication in the US, the preclinical tests were designed for applicability to a broad peripheral vascular use. Thus, in combination with appropriate clinical data, the in vitro testing would provide reasonable assurance of device suitability for a variety of vascular beds. Specific to the iliac and superficial femoral arteries, many of the design requirements are identical for biocompatibility, delivery catheter attributes (eg. bond strength, visibility), and endoprosthesis attibutes (eg. MRI compatibility, corrosion). In areas where there is deviation in the required attributes, use of the device in the SFA environment provides a more demanding vascular bed for such attibutes as catheter trackability, endoprosthesis kink radius, and radial compression strength. The testing previously performed on the devices was sufficiently rigorous to support applicability in the SFA and iliac arteries. The risks and benefits of endovascular treatment of the iliac and superficial femoral arteries are similar, with the SFA being a more demanding vessel for successful endovascular treatment.

### 9.1 Biocompatibility Testing

Biocompatibility Testing was conducted in accordance with Federal Good Laboratory Practices per 21 CFR §58. The GORE VIABAHN® Endoprosthesis is classified per ISO 10993 as an implant device with permanent blood contact; its delivery catheter was classified as an externally communicating device with limited exposure to circulating blood (less than 24 hours).

The GORE VIABAHN® Endoprosthesis is made of expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP), and nickel-titanium alloy (nitinol). The delivery catheter (5-8mm devices) is made of Pebax®, polycarbonate, acrylic, polyolefin, stainless steel, and polyimide, radiopaque markers (Pt/Ir alloy), and ePTFE. For the 9-13mm devices, the delivery catheter is high density polyethylene, polycarbonate, acrylic, polyolefin, silicone-rubber, stainless steel, ethylene vinyl acetate, radiopaque marters (Pt/Ir alloy), and ePTFE. The Heparin Bioactive Surface consists of USP heparin, polyethyleneimine, and dextran sulfate.

Table 1 summarizes the biocompatibility test results for the GORE VIABAHN® Endoprosthesis implant.

**Table 1. Summary of GORE VIABAHN® Endoprosthesis Implant Biocompatibility Testing**

| Category of Testing | Test | Results |
|---|---|---|
| **Cytotoxicity** | MEM Elution | Non-Cytotoxic |
| **Sensitization** | Kligman Maximization | Non-Sensitizing |
| **Irritation/ Intracutaneous Toxicity** | Intracutaneous Injection | Negligible Irritant |
| **Acute Systemic Toxicity** | Systemic Injection | No significantly greater biologic reaction than the controls. |
| **Pyrogenicity** | Rabbit Pyrogen | Non-Pyrogenic |
| **Subchronic Toxicity** | Canine Implant Study | No systemic effects observed. |
| **Genotoxicity** | S. typhimurium Reverse Mutation Assay | Non-Mutagenic |
| | CHO/HPGRT Forward Mutation Assay | Non-Mutagenic |
| | Chromosomal Aberration in Chinese Hamster Ovary Cells (CHO) | Non-Clastogenic |
| **Implantation** | Short Term Intramuscular Implantation (14 days) | Non-Toxic |
| | Short Term Intramuscular Implantation (28 days) | Slightly Toxic* |
| **Hemocompatibility** | Hemolysis | Non-Hemolytic |
| **Chronic Toxicity** | Canine Implant Study | No systemic effects observed. |
| **Carcinogenicity** | ISO 10993-1 states, "Carcinogenicity tests should be conducted only if there are suggestive data from other sources." There is no data known to Gore suggestive of carcinogenic risk. Therefore, carcinogenicity testing was not performed. | N/A |

** Slight toxicity at 28 days is based on a toxicity rating of 1.03 due to increased tissue response at some of the implant sites. Implantation test used 1x1x10mm strip cut from a device for intramuscular implant. Cut wire ends were exposed during sample preparation that may have artifactually increased local tissue irritation. There were no clinical signs of toxicity in any of the animals tested. In another study the device was implanted intact in a more anatomically relevant location. The tissue response to the device was acceptable in this study.*

Table 2 summarizes the biocompatibility test results for the delivery catheter.

**Table 2. Summary of VIABAHN Endoprosthesis Delivery Catheter Biocompatibility Testing**

| Category of Testing | Test | Results |
|---|---|---|
| **Cytotoxicity** | MEM Elution | Non-Cytotoxic |
| **Sensitization** | Kligman Maximization | Non-Sensitizing |
| **Irritation/ Intracutaneous Toxicity** | Intracutaneous Injection | Negligible Irritant |
| **Acute Systemic Toxicity** | Systemic Injection | No significantly greater biologic reaction than the controls. |
| **Hemocompatibility** | Direct Contact | Non-Hemolytic |
| **Pyrogenicity** | Rabbit Pyrogen | Non-Pyrogenic |
| **Endotoxin** | LAL Test (5-8mm only) | Non-pyrogenic |
| **Heavy Metals** | Heavy Metals Method I (5-8mm only) | Pass |

The heparin-bonded surface (Heparin Bioactive Surface) is identical to that for the FDA cleared GORE PROPATEN Vascular Graft (K062161). Table 3 summarizes the biocompatibility tests results for the GORE PROPATEN Vascular Graft.

**Table 3: Summary of Biocompatibility Tests Performed on the PROPATEN Vascular Graft**

| Test | Result |
|---|---|
| **Cytotoxicity** | Non-toxic |
| **Sensitization** | No reaction (0)% sensitization |
| **Intracutaneous Toxicity** | Negligible Irritant |
| **Systemic Toxicity** | Negative |
| **Genotoxicity** | Non-mutagenic |
| **Gene Mutation** | Non-mutagenic |
| **Implantation** | No adverse effects on tissue organs or animal |
| **Hemocompatibility** | Passed |
| **Hemolysis** | Non-hemolytic |
| **Complement Activation** | Does not induce complement activation |
| **Unactivated Partial Thomboplastin Time** | UPTT not significantly decreased |
| **Prothrombin Time** | Prothrombin coagulation time not adversely affected. |
| **Thrombogenicity** | Improved Thromboresistance |
| **Pyrogenicity** | Non-pyrogenic |

Additionally, testing of the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface for cytotoxicity, pyrogenicity, heavy metals, and nickel leaching showed that the product met the acceptance criteria.

The results from these evaluations and testing provide evidence that the material composition of the GORE VIABAHN® Endoprosthesis device meets the biological safety criteria for an external communicating device having limited exposure to the blood (catheter delivery system) and an implant device having permanent exposure to tissues and blood (endoprosthesis).

## 9.2 *In Vitro* Preclinical Testing

In vitro testing has been performed on the GORE VIABAHN® Endoprosthesis and its delivery system and met the requirements of ISO 25539-1, Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses. Many of the key attributes described in the ISO standard are relevant to the GORE VIABAHN® Endoprosthesis and its intended clinical application.

The in vitro testing was conducted to verify that the performance attributes of the GORE VIABAHN® Endoprosthesis are sufficient to minimize the risk of adverse events under anticipated clinical use conditions. Results obtained from the in vitro test regimen provide evidence demonstrating the safety and effectiveness of the device.

A summary of results is presented below for each of the in vitro tests. Table 4 summarizes test results associated with the functional requirements of the delivery system, and Table 5 summarizes test results related to functional requirements of the endoprosthesis or implant.

The results of the in vitro testing demonstrate that the GORE VIABAHN® Endoprosthesis meets established functional requirements for endovascular prostheses. Furthermore, these data demonstrate the safety and effectiveness of the device which is expected to perform as intended when used in accordance with its labeled indications.

**Table 4. Summary of *In Vitro* Test Results Related to Functionality of the Delivery System for the GORE VIABAHN® Endoprosthesis**

| Test | Relevant Functional Attribute | Summary of Test Results |
|---|---|---|
| Delivery Catheter Bond Strength | Ability to access the intended location<br><br>Ability to deploy the implant<br><br>Ability to retract delivery system | A total of 207 catheter bonds were tested over three junctions. The minimum tensile force observed for each of the three critical catheter junctions exceeded the requirements for the respective bonds. Additionally, the minimum expected tensile strength of any individual catheter bond is compliant with the relevant standard, and is sufficient to tolerate anticipated worst-case tensile loading of the GORE VIABAHN® Endoprosthesis delivery catheter. |
| Delivery Catheter Leak | Haemostasis | This test evaluated the leak resistance of the delivery catheter. No leakage occurred in any test when pressurized up to a pre-determined pressure far in excess of the pressure likely to encountered clinically. |
| Delivery Catheter Length | Ability to access the intended location | Measurements using a calibrated ruler were made on a total of 92 finished delivery catheters. All individual samples passed the acceptance criteria. Conformance to specifications is ensured through inspection requirements prior to being released for sale. |
| Delivery System Deployment Force | Ability to deploy the implant | A total of 161 finished GORE VIABAHN® Endoprosthesis sytems were subjected to deployment force testing in a clinically relevant model. No individual or mean deployment force values were above the acceptance limit. |
| Delivery System Visibility | Ability to access the intended location<br><br>Ability to deploy the implant<br><br>Ability to retract delivery system<br><br>Fluoroscopic visualization | Various tissue densities were simulated by using various thicknesses of aluminum plates. The in-vitro radiopacity evaluation of the GORE VIABAHN® Endoprosthesis demonstrates that the overall radiopacity is comparable to that of approved devices already in clinical use (e.g., EXCLUDER Bifurcated Endoprosthesis) under a range of simulated tissue densifications. Test results indicate that the delivery system and endoprosthesis can be visualized at various simulated tissue densities and have sufficient radiopacity for clinical use. |
| Delivery System Profile | Ability to access the intended location<br><br>Ability to retract delivery system<br><br>Haemostasis | 234 out of 237 samples passed with three samples rejected. Conformance to profile specifications is ensured through inspection. |

| Test | Relevant Functional Attribute | Summary of Test Results |
|---|---|---|
| Delivery System Simulated Use (Deployment Reliability) | Ability to access the intended location<br><br>Ability to deploy the implant<br><br>Ability to retract delivery system | All testing was performed in a clinically relevant model. Evaluations included the following: successful deployment; accuracy; retraction force; and visual inspection. Appropriately sized hemostatic introducer sheaths, guidewires, and balloon catheters, were used according to the Instructions for Use in evaluating the overall deployment reliability of the GORE VIABAHN® Endoprosthesis System. A total of 270 finished GORE VIABAHN® Endoprosthesis devices were tested, with 100% of the samples deploying successfully. The data demonstrate a very high likelihood that the GORE VIABAHN® Endoprosthesis will deploy correctly. |
| Delivery System Torquability | Ability to access the intended location<br><br>Ability to deploy the implant<br><br>Ability to retract delivery system | Torquing the delivery system is not required in order to deliver the device. Nevertheless, characterizations were conducted on approximately 92 samples were deployed with approximately 360° of torque applied to the catheter shaft in a clinically relevant deployment model. All devices deployed successfully, demonstrating that torque does not impact deployment of the GORE VIABAHN® devices. |
| Delivery System Trackability | Ability to access the Intended location | 101 samples were tested, utilizing devices across all diameters. Devices were tracked over 0.035" or 0.025" guidewire, as appropriate. Testing was conducted in a clinically relevant model using a contralateral approach to deliver the endoprosthesis to the target location. All tested GORE VIABAHN® Endoprosthesis delivery systems tracked well through a tortuous model over the recommended size guidewire. |
| Delivery Tubing Tensile Strength | Ability to access the intended location<br><br>Ability to deploy the implant<br><br>Ability to retract delivery system | Eight samples of tubing (distal shaft and dual lumen) were tested to characterize tensile strength. The lowest mean tensile strength result well exceeded the lower minimum bond strength requirement. Therefore, the delivery system tubing is expected to perform as intended in the clinical environment. |
| Deployment Knob/Line Assembly Tensile Strength | Ability to deploy the implant | Fifty deployment knob to line assemblies and 81 deployment line samples were tensile tested for a total of 131 samples. All values exceeded the acceptance level. |

**Table 5. Summary of *In Vitro* Test Results Related to Functionality of the Endoprosthesis for the GORE VIABAHN® Endoprosthesis**

| Test | Relevant Functional Attribute | Summary of Test Results |
|---|---|---|
| Deployed Endoprosthesis Kink Radius | Patency of the implant | All device diameters were evaluated with a total of 40 devices. The results show that the endoprosthesis is able to bend around relatively small diameters. Clinical experience demonstrates that the bend radius of the endoprosthesis is sufficient to allow the device to navigate through tortuous anatomy and conform to the host vessel anatomy. |
| Endoprosthesis Burst Strength | Durability and integrity of the implant | The burst strengths of 65 GORE VIABAHN® Endoprostheses were determined. The results were used to determine that the likelihood that any individual burst strength will be above 120 psi is very high. |
| Endoprosthesis Diameter | Appropriate sizing of the implant | A total of 75 finished devices were measured for device inner diameter. All individual samples met the acceptance criteria. In addition, the data show with a very high degree of confidence that any individual sample will be within the acceptance criteria. |
| Endoprosthesis Length | Appropriate sizing of the implant | Devices were deployed and then measured. A total of 84 finished devices were measured post-deployment, representing all lengths. All devices met the stated design specifications. |
| Endoprosthesis Longitudinal Tensile | Durability and integrity of the implant | The longitudinal tensile strengths of 40 finished GORE VIABAHN® Endoprostheses were determined. All individual tensile strength values were above the acceptance criteria. The likelihood that any individual tensile strength will be above the acceptance criteria is very high. |
| Endoprosthesis Magnetic Resonance Imaging Safety | MRI Compatibility | The results indicated that there were no magnetic field interactions (e.g., translational attraction or torque) at 3.0 Tesla. There was no substantial MRI-related heating, and image artifacts were characterized and shown to be relatively minor. Thus, GORE VIABAHN®® Endoprosthesis is not anticipated to present a hazard or additional risk to an implant recipient or individual undergoing an MR procedure using an MR system operating with a shielded, static magnetic field of 3.0 Tesla or less. As such, the GORE VIABAHN® Endoprosthesis should be considered "MR Conditional" according to the specific conditions used for testing. |

| Test | Relevant Functional Attribute | Summary of Test Results |
|---|---|---|
| Endoprosthesis Simulated Use (Deployment Reliability) | Ability to accurately deploy the implant<br><br>Durability and integrity of the implant | All testing was performed in a clinically relevant model. Acceptance criteria included successful deployment, accuracy and visual inspection. Appropriately sized hemostatic introducer sheaths, guidewires, and balloon catheters were used according to the Instructions for Use in evaluating the overall deployment reliability of the GORE VIABAHN® Endoprosthesis System. A total of 270 finished GORE VIABAHN® Endoprosthesis devices were tested, with 100% of the samples deploying successfully. The data demonstrate a very high likelihood that the GORE VIABAHN® Endoprosthesis will deploy correctly. |
| Endoprosthesis Visibility | Ability to accurately deploy the implant<br><br>Fluoroscopic visualization | Various tissue densities were simulated by using various thicknesses of aluminum plates. The in-vitro radiopacity evaluation of the GORE VIABAHN® Endoprosthesis demonstrates that the overall radiopacity is comparable to that of the clinically approved devices (e.g., EXCLUDER Bifurcated Endoprosthesis) under a range of simulated tissue densifications. Test results indicate that the delivery system and endoprosthesis can be visualized at various simulated tissue densities and have sufficient radiopacity for clinical use. |
| Endoprosthesis Microscopic Determination of Porosity | Permeability considerations<br><br>Patency of the implant | GORE VIABAHN® Endoprosthesis base tubes of ePTFE are identical regardless of diameter or length. Ten fibril length measurements were collected from each of two samples from each of seven lots of material (140 data points overall). Results: All individual readings and the means of all readings met the acceptance criteria. The probability that any individual sample will meet the individual acceptance criteria is very high. |
| Endoprosthesis Radial Compression Strength | Fixation effectiveness of the implant<br><br>Durability and integrity of the implant<br><br>Appropriate sizing of the implant<br><br>Patency of the implant | A total of 82 devices were tested across all diameter ranges. All devices tested met the radial compression force specification. In addition, the confidence that any individual radial compression strength will be above the acceptance criteria is very high for all sizes and configurations of the endoprosthesis. |

| Test | Relevant Functional Attribute | Summary of Test Results |
|---|---|---|
| Endoprosthesis Stent Free Surface Area Calculation | Patency of the implant | Based on the length of wire used to wind the various sections of the stent, wire diameter, and device diameter at various percent compressions, the percentage of stent free surface area was calculated. The maximum change in stent-free surface area between the recommended vessel diameters for the various labeled diameters is 4% of the total surface area of the stent graft. Stent-free surface area calculations range between 72 and 77% at the minimum recommended vessel diameters and between 75 and 80% at the maximum recommended vessel diameters. |
| Endoprosthesis Finite Element Analysis | Durability and integrity of the implant | The maximum principal strain was determined for both the radial crush and fold-roll methods of attaching the GORE VIABAHN® Endoprosthesis to the delivery catheter. The maximum, mean and alternating strains were determined for all diameters of the GORE VIABAHN® Endoprosthesis as a function of worst case in-vivo oversizing and pulsatile loading conditions. The predicted strains are below the break strength of the Nitinol wire. |
| Nitinol Mechanical Properties & Material Analysis | Durability and integrity of the implant | 1) Chemical Composition; 2) Surface Characteristics; 3) Thermomechanical Properties. of the GORE VIABAHN® Endoprosthesis were compared to those of the EXCLUDER Bifurcated Endoprosthesis (approved in PMA020004). Chemical Composition: The nitinol wire possesses the same material composition as the wire used to manufacture EXCLUDER Bifurcated Endoprostheses. Surface Characteristics: The surface condition of the nitinol wire is processed similarly, resulting in a surface condition and chemistry virtually identical to the EXCLUDER Bifurcated Endoprosthesis device. Thermomechanical Properties: Material is sampled, tested, and certified to ensure that the GORE VIABAHN® Endoprosthesis devices are superelastic at body temperature. Additionally, tensile testing has been conducted on representative wire samples to characterize the mechanical properties of the material. The results demonstrate that the tensile properties of the wire meet or exceed the established design specifications. |

| Test | Relevant Functional Attribute | Summary of Test Results |
|---|---|---|
| Endoprosthesis Pulsatile Fatigue | Fixation effectiveness of the implant<br><br>Durability and integrity of the implant | Thirty-six finished endoprostheses (6.8 mm devices) were subjected to 10 years (380 million cycles). Cyclic loading of the 6.8-mm device was performed to a calculated deflection between diastolic and systolic pressures to simulate physiological conditions. The test deflection was calculated to represent the highest strain experienced by the worst-case device diameter at the stated pressure differential. Devices were inspected for signs of stent wear and fracture. The inspection of the device at the end of the test cycle revealed that the device is expected to exhibit adequate mechanical integrity for at least 10 years. |
| GORE VIABAHN® Endoprosthesis Corrosion | Durability and integrity of the implant | The Nitinol wire components of the GORE VIABAHN® Endoprosthesis and the approved EXCLUDER™ Bifurcated Endoprosthesis (PMA P020004) consist of the same specification material, follow identical electropolishing processes, and follow very similar thermal processing. The finished devices utilize virtually identical construction methods and are exposed to the same in vivo environment. For these reasons it is expected that both devices will exhibit similar corrosion performance. The approved EXCLUDER Bifurcated Endoprosthesis has demonstrated adequate corrosion resistance in previous testing and in clinical use; the GORE VIABAHN® Endoprosthesis can be reasonably expected to exhibit similar corrosion resistance that is clinically sufficient for the intended indication. |
| GORE VIABAHN® Endoprosthesis Stent to Graft Attachment | Durability and integrity of the implant | Nine GORE VIABAHN® Endoprostheses were selected (5mm, 8mm, and 13mm devices). Three samples of each diameter were tested for characterization. All test samples demonstrated the stent was attached to the graft. |
| **Tests Specific to the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface** | | |
| Endoprosthesis Chemical Residuals | Durability and integrity of the implant | This test shows that the device does not have an unacceptable level of chemical residues remaining on the device after application of the heparin coating. The residuals in all devices (n=6) were below the allowable limits. |
| Heparin Activity | Bioactive, heparin bonded surface | Heparin activity was evaluated as part of Device Accelerated Aging. This report demonstrates evidence of a bioactive surface. |

| Test | Relevant Functional Attribute | Summary of Test Results |
|---|---|---|
| Endoprosthesis Corrosion | Durability and integrity of the implant | Cyclic potentiodynamic polarization corrosion testing was conducted to evaluate the corrosion resistance of the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface. The rest potential, breakdown potential, and protection potential for the nitinol wire within the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface were determined and compared to data from a device with proven corrosion performance, the GORE EXCLUDER® Bifurcated Endoprosthesis. Sixteen GORE VIABAHN® Endoprostheses with Heparin Bioactive Surface were tested. Corrosion resistance of GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface was statistically equivalent or superior to the GORE EXCLUDER® Bifurcated Endoprosthesis. |
| Heparin Elution | Bioactive, heparin bonded surface | The purpose of this study was to assess the elution of heparin from the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface under continuous-flow exposure to protein-containing aqueous eluent. The measured heparin eluted was insignificant relative to that routinely administered clinically. |

## 9.3 Sterilization, Packaging, and Shelf-Life

The GORE VIABAHN® Endoprosthesis is sterilized using a validated ethylene oxide cycle in accordance with ANSI/AAMI/ISO 11135:1994 Medical Devices Validation and Routine Control of Ethylene Oxide Sterilization. The sterilization process has been shown to be acceptable for sterilization of the device to an SAL of $10^{-6}$.

The packaging for the GORE VIABAHN® Endoprosthesis consists of four components: coil, primary pouch, secondary pouch, and box. The packaging is designed to protect the device from damage or alteration during customary conditions of processing, storage, handling, and distribution. The package is designed to maintain sterility of the device.

The GORE VIABAHN® Endoprosthesis has a three year shelf-life.

## 9.4 *In Vivo* Preclinical Animal Studies

Four preclinical *in vivo* studies were conducted to evaluate the performance of the GORE VIABAHN® Endoprosthesis. The purpose of the preclinical animal studies was to evaluate the safety and performance of the GORE VIABAHN® Endoprosthesis in an *in vivo* environment that modeled the clinical application. The studies were intended to demonstrate the safety of the device prior to clinical use.

The canine model was used for assessment of the delivery system to:

- successfully access the target site

- accurately deploy the endoprosthesis and be able to easily remove the catheter from the vasculature

The canine model was also used to assess the following aspects of the implantable endoprosthesis:

- test the ability of the endoprosthesis to resist migration
- evaluate device functionality
- determine the biological response to the implanted endoprosthesis

In selecting the appropriate animal models, an effort was made to evaluate device performance in models that would demonstrate performance attributes in a clinically meaningful fashion. In conducting the preclinical animal studies for the GORE VIABAHN® Endoprosthesis, the same introduction and deployment methods that would be used in the clinical setting were modeled as much as possible. Devices used in these in vivo studies are representative of the finished product. Standard imaging techniques such as angiography and intravascular ultrasound (IVUS), which provide visualization and localization of the device, were used, as appropriate, in these studies. Gross inspection and histological assessment were used to evaluate the explanted device. Successful device implantation included the ability to visualize and accurately deploy the device with techniques similar to those required in animals, and firm fixation of the device at the site of original deployment. Additional measures of evaluation included the absence of device migration, sustained luminal patency, and acceptable host tissue response and device incorporation.

A total of 64 devices were implanted into 35 different canines in 4 different studies. With the exception of the acute animal study 1853SC, the animals were alive from 10 – 365 days. Overall conclusions from these studies demonstrated the following:

- The delivery system was acceptable to the implanting surgeon and that the device can be deployed properly and accurately with minimal difficulty or complications.
- No twisting or kinking of the device was observed after implantation.
- The majority of the devices remained patent during the in-life period
- Stenosis of the device over time was minimal
- There was minimal inflammation response caused by a device or device implant
- No adverse biological reactions to the device were observed.
- The occurrence of thrombosis in the device was low.
- Healing response to the device was good
- In vivo testing showed the endoprosthesis to be safe and to function as an endovascular device.

## 10.0 Summary of VIABAHN Case Review for the Iliac Arteries

The Viabahn Endoprosthesis was approved for use in the superficial femoral artery (SFA) on June 14, 2005. To support this approval the sponsor conducted a study to compare the safety and effectiveness of the Viabahn Endoprosthesis to percutaneous transluminal angioplasty (PTA) in patients with chronic lower limb ischemia or chronic lifestyle altering claudication due to SFA atherosclerotic disease. This study is described in detail in the SSED for P040037. The applicant provided confirmatory clinical data collected outside of the United States to establish a reasonable assurance of safety and effectiveness for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions with the Viabahn Endoprosthesis.

These confirmatory data were the basis for this PMA approval decision. A summary of the confirmatory data is presented below.

### 10.1 Study Design

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 U.S. (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.

The primary assessment was primary patency of the treated lesion at 12-months. Technical success, procedural success, clinical improvement, and device-related adverse events were also measured as part of this study.

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.

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 and clinical assessments were completed post-operatively and at 1, 3, 6, and 12-months post-procedure.

### 10.2 Patient Enrollment and Availability for Follow-up

CRF records were reviewed for 42 subjects with 45 limbs enrolled in the study. Follow-up compliance at the 12-month visit was 90.5% (38 / 42).

### 10.3 Demographic and Baseline Medical History Data

Demographic data for the subjects available for analysis is presented in Table 6. A majority of subjects were male (71.4%), the mean age was 59.6 yrs, and the mean Body Mass Index (BMI) was 29.8. Race for 11 subjects was reported as Other (8 "European", 2 "German", 1 "North African").

**Table 6: Summary of Demographics**

| Variable | GORE VIABAHN® Device |
|---|---|
| Age (years), Mean ± SD | 59.6 ± 10.5 |
| Male | 30 (71.4%) |
| Race | |
| Caucasian | 29 (69.0%) |
| Black | 1 (2.4%) |
| Asian | 1 (2.4%) |

| | |
|---|---|
| Hispanic | 0 (0.0%) |
| Native American | 0 (0.0%) |
| Other | 11 (26.2%) |
| Body Mass Index, Mean ± SD | 29.8 ± 28.2 |

Available baseline medical history data for the treated patients is presented in Table 7. The majority of subjects had a history of nicotine use (90.2%) and hyperlipidemia (56.1%). Hypertension was also common (41.5%).

**Table 7: Summary of Baseline Medical History**

| Variable | GORE VIABAHN® Device |
|---|---|
| History of Nicotine Use | 37 (90.2%) |
| Hypertension | 17 (41.5%) |
| Hyperlipidemia | 23 (56.1%) |
| Coronary Arterial Disease | 10 (25.0%) |
| Congestive Heart Failure | 1 (2.4%) |
| Diabetes Mellitus | 9 (21.4%) |
| Pulmonary Disease | 6 (14.3%) |
| Abnormal Renal Function | 2 (4.8%) |

### 10.4 Baseline Vascular Status and Anatomical Data

Table 8 reports the baseline vascular status for the available subjects and limbs. The majority of limbs (90.2%) had a Clinical Category of 2 or greater. The mean ABI was 0.58.

**Table 8: Summary of Baseline Vascular Status**

| Variable | GORE VIABAHN® Device |
|---|---|
| Ankle-Brachial Index, Mean ± SD | 0.58 ± 0.17 |
| Clinical Category (Rutherford Scale) | |
| N (Data Available) | 41 |
| 0 - Asymptomatic | 0 (0.0%) |
| 1 - Mild Claudication | 4 (9.8%) |
| 2 - Moderate Claudication | 16 (39.0%) |
| 3 - Severe Claudication | 17 (41.5%) |
| 4 - Ischemic Rest Pain | 1 (2.4%) |
| 5 - Minor Tissue Loss | 3 (7.3%) |

| | |
|---|---|
| 6 - Major Tissue Loss | 0 (0.0%) |

Table 9 reports the anatomical data for the treated limbs. Most limbs had either the external or common iliac artery treated (42.2% and 46.7%, respectively); 5 limbs (11.1%) were treated in both. Mean lesion length treated was 4.2cm. Most limbs had two or three vessel run-off (85.7%).

**Table 9: Summary of Anatomical Data**

| Variable | GORE VIABAHN® Device |
|---|---|
| Treated Limb | |
| Left | 17 (37.8%) |
| Right | 28 (62.2%) |
| Lesion Location | |
| Common Iliac Only | 21 (46.7%) |
| External Iliac Only | 19 (42.2%) |
| Both Common and External Iliac | 5 (11.1%) |
| Reference Vessel Diameter (mm), Mean ± SD | 7.8 ± 1.8 |
| Minimum Lumen Diameter 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 |
| Lesion Severity (Ahn Scale) | |
| Type A | 10 (23.8%) |
| Type B1 | 18 (42.9%) |
| Type B2 | 11 (26.2%) |
| Type C | 3 (7.1%) |
| Run-off Vessels | |
| 3 Vessels | 20 (47.6%) |
| 2 Vessels | 16 (38.1%) |
| 1 Vessel | 6 (14.3%) |

### 10.5 Devices Implanted

Device utilization for the 45 limbs included in the analysis is presented in Table 11. Of the 45 limbs implanted, 37 (82.2%) required only one device.

A total of 54 devices were implanted in 45 limbs. The average number of devices implanted per limb was 1.2. Diameters 7, 8, and 9mm were the most commonly used (83.3%). The most common length implanted was 5cm (85.2%) and the maximum stented length was 15cm (not accounting for overlap).

**Table 11: Device Sizes Implanted**

| Devices Implanted<br>Diameter (mm) x Length (cm) | All Limbs |
|---|---|
| N (Data Available) | 45 |
| One Device Implanted | 37 (82.2%) |
| 6x5 | 1 |
| 7x5 | 9 |
| 7x10 | 3 |
| 8x5 | 8 |
| 8x10 | 2 |
| 9x5 | 9 |
| 9x10 | 2 |
| 10x5 | 1 |
| 11x5 | 2 |
| Two Devices Implanted | 7 (15.6%) |
| 8x5, 8x5 | 4 |
| 8x5, 8x10 | 1 |
| 9x5, 9x5 | 1 |
| 10x5, 10x5 | 1 |
| Three Devices Implanted | 1 (2.2%) |
| 10x5, 10x5, 11x5 | 1 |

## 10.6 Safety Results

**Device-Related Adverse Events**

No serious device-related events were reported (Table 12). Three non-serious deployment-related events were reported: "distal olive caught by sheath," "rupture of carrier catheter", and "prosthesis caught on guidewire". In all cases the GORE VIABAHN® device was deployed successfully and there were no clinical sequelae.

**Table 12: Summary of Device-related Adverse Events**

| Adverse Events | Serious AEs | | All AEs | |
|---|---|---|---|---|
| | 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 | - | - | - | - |

| Adverse Events | Serious AEs | | All AEs | |
|---|---|---|---|---|
| | Early (≤30 days) | All (≤365 days) | Early (≤30 days) | All (≤365 days) |
| 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 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.

**All Adverse Events**

A total of 11 subjects (26.2%) experienced a serious AE throughout the course of the study; of these, 6 subjects (7 limbs) experienced early serious adverse events (Table 13). 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 adverse event through the course of the study, with 17 of these subjects experiencing an event within 30 days post-procedure (Table 13). 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 13: Summary of All Adverse Events**

| Adverse Events | Serious AEs | | All AEs | |
|---|---|---|---|---|
| | 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**

No deaths were reported during the course of the study for the 42 subjects in this case review summary.

**Observed Device Malfunctions**

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

## 10.7 Effectiveness Results

The primary patency results and technical success reported for the GORE VIABAHN® Endoprosthesis in this analysis are reported in Table 14. 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 (2 embolisms and 1 "lost guidewire"). All three of these events were resolved at the time of procedure and there were 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 15. ABI, clinical category (Rutherford), and limb ischemia score all showed improvement at 12 months compared to baseline.

**Table 14: Summary of Effectiveness Outcomes**

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

**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 15: Summary of Clinical Outcomes**

| Clinical Measures | GORE VIABAHN® Device |
|---|---|
| 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 |

## 11.0 Conclusions Drawn from the Studies

The preclinical 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.

The primary patency at 12 months is consistent with rates for previously approved iliac stents. All six device failures at one year can be attributed to factors related to the implantation. Two were oversized and demonstrated incomplete apposition to the vessel wall. One stent did not cover the entire lesion length. The remaining three all came from one clinical site and can be attributed to failure to post-dilate with a balloon catheter along the entire length of the stent. These failures are attributable to poor technique at implantation. The current IFU outlines the importance of proper sizing, both in diameter and length, and proper post-dilatation as it pertains to long term patency.

## 12.0 Panel Recommendation

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Cardiovascular Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

## 13.0 CDRH Decision

FDA issued an approval order on August 14, 2008.

The applicant's manufacturing facility was inspected and was found to be in compliance with the Quality System Regulation (21 CFR 820).

In P040037, the sponsor demonstrated safety and effectiveness for use in the Superficial Femoral Artery (SFA). In this PMA Supplement, the sponsor has provided confirmatory clinical study data to support an expanded indication for the Gore Viabahn Endprosthesis for use in the iliac artery environment. While no quantitative statistical inferences or conclusions can be reached based on the data, the qualitative clinical assessment provided for the iliac indication confirms that the device is

perform as good as or better in the iliac enviornment than when used in the more challenging SFA environment.

## 15.0 Approval Specifications

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.