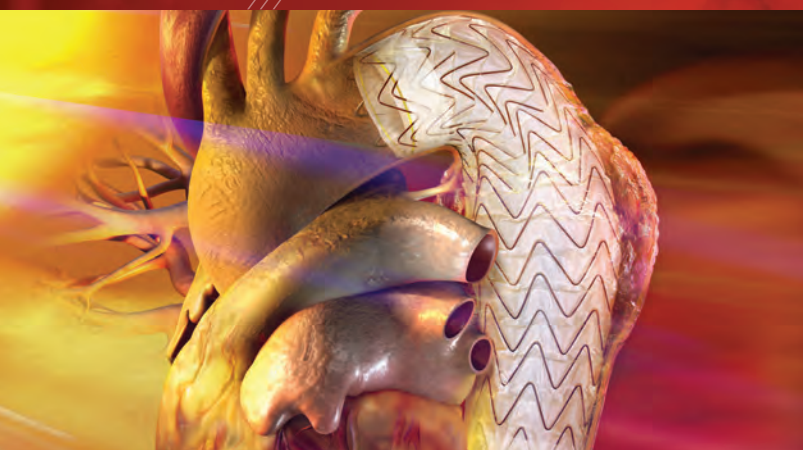


# GORE PERIPHERAL VISION

PERFORMANCE through collaboration

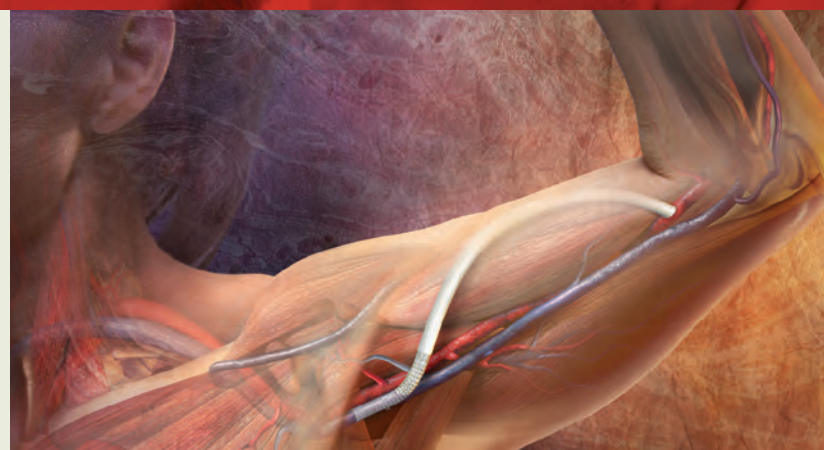


## GORE RECEIVES FDA APPROVAL FOR CONFORMABLE GORE® TAG® THORACIC ENDOPROSTHESIS

*Durable ePTFE Endoprosthesis Designed for Endovascular Repair of the Descending Thoracic Aorta Provides Conformability without Compromise*

W. L. Gore & Associates, Inc. (Gore) has received approval from the US Food and Drug Administration (FDA) to market the Conformable GORE® TAG® Thoracic Endoprosthesis as a minimally invasive treatment for patients suffering from thoracic aortic aneurysms (TAAs). The device is the only

*Continued on page 2*



## GORE® HYBRID VASCULAR GRAFT COMMERCIALLY AVAILABLE IN THE UNITED STATES

*Optimal Outflow with Expanded Treatment Options for Dialysis Access Patients, More Than 450 Successful Implants*

W. L. Gore & Associates (Gore) now offers commercial availability in the US of the GORE® Hybrid Vascular Graft. The Gore device expands treatment options and improves blood flow for dialysis access patients with end-stage renal disease (ESRD). More than 450 dialysis access patients have been successfully treated with the GORE® Hybrid Vascular Graft.

*Continued on page 3*

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**SPECIAL EDITION**

*Continued from front page*

## **GORE RECEIVES FDA APPROVAL...**

FDA approved ePTFE thoracic endoprosthesis designed for endovascular repair of the descending thoracic aorta that offers conformability and ease of use, while accommodating tapered anatomy and resisting compression. The broad oversizing window for the device ranges from 6–33%, allowing physicians to choose the appropriate oversizing for the patient anatomy.

William Jordan, MD, Chief of Vascular Surgery at the University of Alabama, Birmingham, served as national principal investigator for the Conformable GORE® TAG® Device in the Thoracic Aortic Aneurysm Trial (Gore TAG 08-03) over the past two years. According to Dr. Jordan, “This new device represents a substantial product improvement brought to us by a company that was already leading the market in aneurysm devices. Gore evaluated the real world results of the first generation endograft and engineered improvements so that the device can be used across a wider range of aortic diameters with stronger radial force to resist compression. These modifications are intended to improve the lives of our patients and provide better outcomes for challenging clinical problems.”

The following physicians completed successful procedures using the Conformable GORE® TAG® Thoracic Endoprosthesis during the first week of release.

- William McMillan, MD—Vascular Surgeon at Minneapolis Vascular Physicians
- Robert Mitchell, MD—Thoracic Surgeon at Central Baptist Hospital, Lexington, Kentucky.
- Brian Peterson, MD—Vascular Surgeon in the Department of Surgery at Saint Louis University
- Robert Rhee, MD—Associate Professor of Surgery at the University of Pittsburgh Medical Center
- Joshua Rovin, MD—Cardiovascular Surgeon at Bayfront Medical Center, St. Petersburg, Florida.
- Daniel Watson, MD—Director of Endovascular Surgery at Riverside Methodist Hospital, Columbus, Ohio

The device is available in diameters of 21–45 mm, allowing for the treatment of patients with aortic diameters of 16–42 mm. Tapered device configurations are also available.

TAAAs are a serious health risk because they can burst or rupture with little or no symptoms after developing over years. A ruptured aneurysm can cause severe internal bleeding, which can rapidly lead to shock or death. Thoracic aneurysms affect approximately 15,000 people in the US each year. Some patients may have more than one TAA or may also have an aneurysm of the abdominal aorta. Due to the high mortality risk associated with undetected and untreated TAAs, it is critical to get screened for aneurysm risk and seek early treatment if detected.

“The GORE® TAG® Device has been a leading endovascular treatment option for safely and effectively treating patients with aneurysms of the descending thoracic aorta. The device is backed by a proven safety record with more than 50,000 devices distributed worldwide and a decade of worldwide clinical data,” said David Abeyta, Gore Aortic Business Leader. “Now featuring design enhancements such as a modified stent frame, optimized graft film layers, enhanced conformability, and expanded oversizing ranges, the Conformable GORE® TAG® Device provides an optimal fit and maximum conformability for each patient’s anatomy without compromising conformability.”



*Conformable GORE® TAG® Thoracic Endoprosthesis*

*Continued from front page*

#### **GORE® HYBRID VASCULAR GRAFT...**

Three month follow-up data for newly created access implants demonstrates a trend toward a reduction in revision procedures, thrombosis events and seroma, as compared to historical graft data. In the United States, more than 300,000 people suffer from ESRD and are in need of dialysis.

The GORE® Hybrid Vascular Graft is indicated for use as a vascular prosthesis for dialysis access or bypass for other peripheral vascular diseases. The device is designed to address the most common causes of graft failure; intimal hyperplasia, thrombosis, and ultrafiltration. The device simplifies access to vessels with a new over-the-wire deployment method through a smaller than usual incision in the skin that reduces vessel injury and dissection. The GORE® Hybrid Vascular Graft has been used to create new access sites in anatomical locations that would have been abandoned otherwise, preserving the amount of access sites available throughout the patient's long-term therapy.

Since receiving FDA clearance in 2010, more than 450 patients have been treated with the GORE® Hybrid Device at multiple centers across the US. John R. Ross, MD, General Surgeon at the Orangeburg Regional Medical Center (Orangeburg, South Carolina) performed the first clinical implants.

“Outflow stenosis has been a long-standing challenge for vascular grafts. The GORE® Hybrid Vascular Graft is a promising new option because it targets intimal hyperplasia by creating a sutureless anastomosis that can be created percutaneously,” said Dr. Ross. “This new device directs the outflow so it is in-line with the vessel and shields the area most prone to intimal hyperplasia and failure.”

The GORE® Hybrid Vascular Graft combines several trusted Gore technologies. The expanded polytetrafluoroethylene (ePTFE) vascular prosthesis has a section reinforced with

nitinol. The nitinol reinforced section is partially constrained to allow for easy insertion and deployment into vessels that are difficult to reach or in challenging anatomical locations. It is the only combination graft that incorporates CARMEDA® BioActive Surface (CBAS® Surface) end-point immobilization of heparin to the luminal surface, resulting in a proven thromboresistant surface.

“We are very excited to introduce the GORE® Hybrid Vascular Graft that has the potential to significantly improve outcomes,” said Chuck Biggerstaff, Gore Venous Access Business leader. “This device is the latest addition to Gore’s long history of introducing innovative devices and technologies to positively impact the lives of patients worldwide.”



*GORE® Hybrid Vascular Graft*



# CASE STUDY

## COMPUTATIONAL FLUID DYNAMICS EVALUATION

Stephen H. Little, MD, Matthew S. Jackson, ME, Stephen R. Igo, BSc, Christof Karmonik, PhD,  
Dipan Shah, MD, and Eric K. Peden, MD

Weill Medical College of Cornell University, Cardiovascular Hemodynamics Imaging Laboratory  
The Methodist DeBakey Heart & Vascular Center

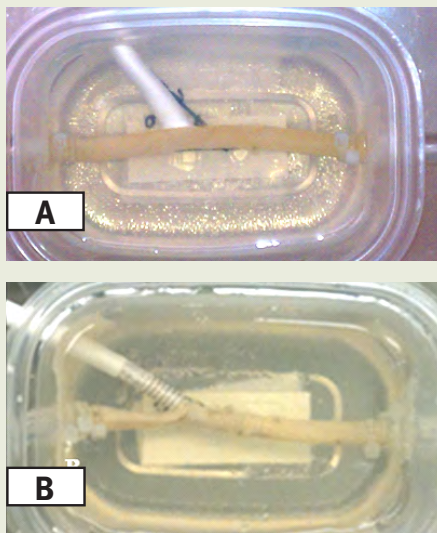
The GORE® Hybrid Vascular Graft is an expanded polytetrafluoroethylene (ePTFE) vascular prosthesis that has a section reinforced with nitinol. The nitinol reinforced section is partially constrained to allow for easy insertion and deployment into a vessel. The GORE® Hybrid Vascular Graft has a continuous lumen and includes the CARMEDA® BioActive Surface (CBAS® Surface) consisting of a stable covalently bonded, reduced molecular weight heparin of porcine origin.

### Introduction

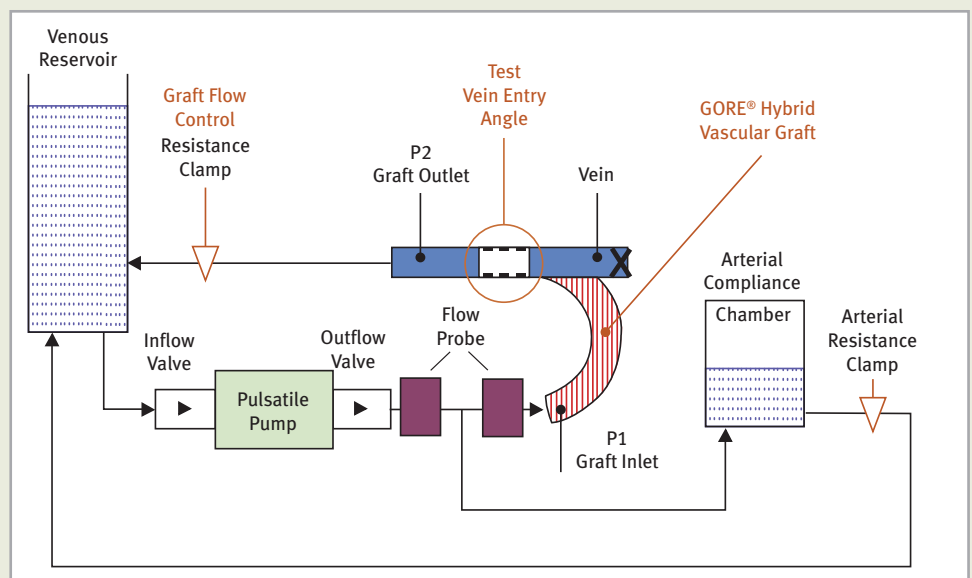
The purpose of this study was to evaluate and compare the fluid dynamics at the anastomosis created by the GORE® Hybrid Vascular Graft to the conventional end-to-side anastomosis created by a conventional arteriovenous graft (CAG). The in vitro study was performed using an MRI-compatible mock circulation developed by the Cardiovascular Imaging Section, Methodist DeBakey Heart and Vascular Center (MDHVC). Phase-contrast MRI (pc-MRI) in conjunction with Computational Fluid Dynamics (CFD) were then performed.

### Materials and Methods

One GORE® Hybrid Vascular Graft (6 mm diameter vascular graft section and 6 mm diameter nitinol reinforced section) and one CAG (ePTFE, 6 mm diameter) were utilized in the experiment (*Figure 1*). Both constructs were connected to a PROCOL® Vascular Bioprosthesis (approximately 6 mm in diameter). The constrained nitinol reinforced section of the GORE® Hybrid Vascular Graft was advanced into the vascular bioprosthesis by approximately 2.5 cm and deployed to create a sutureless end-to-end anastomosis. The CAG was sutured, end-to-side, to the vascular bioprosthesis



*Figure 1. Graft-vein constructs connected to the mock circulation. (A) The conventional end-to-side anastomosis. (B) Endoluminal anastomosis created with the GORE® Hybrid Vascular Graft.*



*Figure 2. Schematic of the test flow loop and MRI-compatible system.*

in a standard manner. The graft-vein constructs were then suspended in 3% gelatin and attached to the flow loop (Figure 2). Appropriate flow parameters were configured through adjustments of arterial compliance and resistance and venous resistance. The test flow loop was then positioned inside a 1.5 T MRI scanner and imaged utilizing pc-MRI. A mesh was formed from the MRI data points and CFD analysis was performed based on this mesh. The CFD analysis was computed under the assumption of an inlet flow velocity of 1 m / sec which was an approximate value based on peak systolic flow measurements. A color map of wall shear stress and flow streamlines in each graft construct under the assumed flow conditions (Figure 3).

## Conclusions

The GORE® Hybrid Vascular Graft eliminated the low wall shear stress region at the toe and the heel of the graft anastomosis site, which corresponds to the development of intimal hyperplasia in the conventional end-to-side anastomosis.<sup>1</sup> Also, due to the GORE® Hybrid Vascular Grafts occlusion of the venous inflow, flow remained laminar, where the CAG construct exhibited irregular flow patterns downstream from the entry site. Irregular, oscillating flow patterns have also been identified as a pre-cursor to intimal hyperplasia development and graft occlusion.<sup>2</sup> These observations suggest that the GORE® Hybrid Vascular Graft provides optimized flow

characteristics as compared to a conventional end-to-side anastomosis thus potentially reducing the incidence of arteriovenous access graft stenosis due to intimal hyperplasia.

## Physician Comments

“Grafts will continue to play an important role in dialysis access surgery, particularly as obesity and elderly patient numbers expand. The most common failure mode of grafts continues to be intimal hyperplasia at the venous anastomosis. Disturbed flow at the venous anastomosis is thought to be an important stimulus to the development of intimal hyperplasia.

The new GORE® Hybrid Vascular Graft attempts to influence this problem with a stent-grafted venous outflow creating a functional end-to-end anastomosis. This flow study confirms improved laminar flow compared with a conventional sutured anastomosis. Clinical experience with the GORE® Hybrid Vascular Graft remains limited and further experience should demonstrate whether improved flow characteristics translate into improved graft patencies.” — Eric K. Peden, MD

## References

- <sup>1</sup> Jackson ZS, Ishibashi H, Gotlieb AI, Langille BL. Effects of anastomotic angle on vascular tissue responses at end-to-side arterial grafts. *Journal of Vascular Surgery* 2001;34(2):300-307.
- <sup>2</sup> Ojha M. Wall shear stress temporal gradient and anastomotic intimal hyperplasia. *Circulation Research* 1994;74(6): 1227-1231.

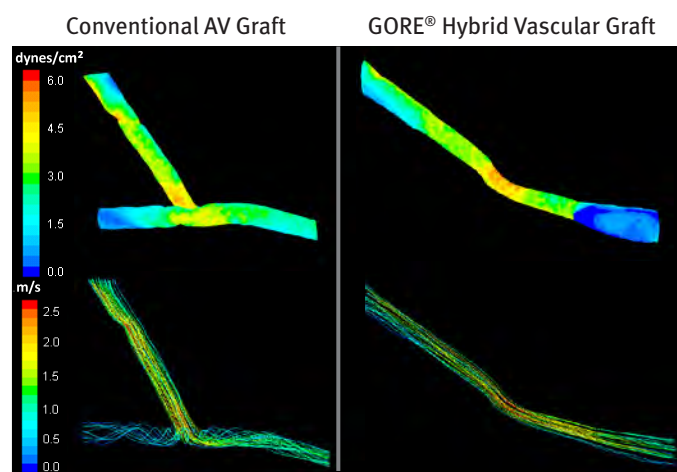


Figure 3. Wall shear stress (dynes / cm<sup>2</sup>) and flow streamlines (m / s) in the conventional end-to-side anastomosis (left side) and in the endoluminal anastomosis created with the GORE® Hybrid Vascular Graft (right side).

## USE OF 6 FR COMPATIBLE *GORE® VIABAHN®* ENDOPROSTHESIS FOR SUPERFICIAL FEMORAL ARTERY OCCLUSION

*Kamran I. Muhammad, MD and Mehdi H. Shishehbor, DO, MPH*

### Clinical Presentation

The patient is a 75-year-old male with history of hypertension, hyperlipidemia, type II diabetes mellitus, chronic kidney disease, coronary artery disease status-post prior myocardial infarction and coronary artery bypass grafting, ischemic cardiomyopathy with left ventricular ejection fraction of 30%, former tobacco use who was referred to the Cleveland Clinic Vascular Medicine outpatient clinic for evaluation of bilateral calf claudication, Rutherford stage 3. His left calf pain on ambulation had been worsening for several months to the point that he is unable to exercise, play golf or attend cardiac rehabilitation. He was on an optimal regimen of medical therapy for his cardiovascular disease including aspirin, clopidogrel, angiotensin converting enzyme inhibitor and HMG-CoA-reductase inhibitor therapy.

On physical examination the blood pressure was 132/62 mmHg, heart rate 72 bpm, body-mass index 29 kg/m<sup>2</sup>. General medical and cardiac examination was within normal limits. No carotid bruits were appreciated. Examination of the lower extremities

demonstrated 3+ femoral and popliteal pulses on the right, and 1-2+ dorsalis pedis and posterior tibial pulses on the right. The left femoral pulse was 3+, however the popliteal, dorsalis pedis and posterior tibial pulses were not palpable with a weak monophasic signal noted on Doppler signal at the left dorsalis pedis. No skin breakdown or ulcers were noted on the legs or feet. There was hair loss of both lower extremities, left greater than right. There was no lower extremity edema noted.

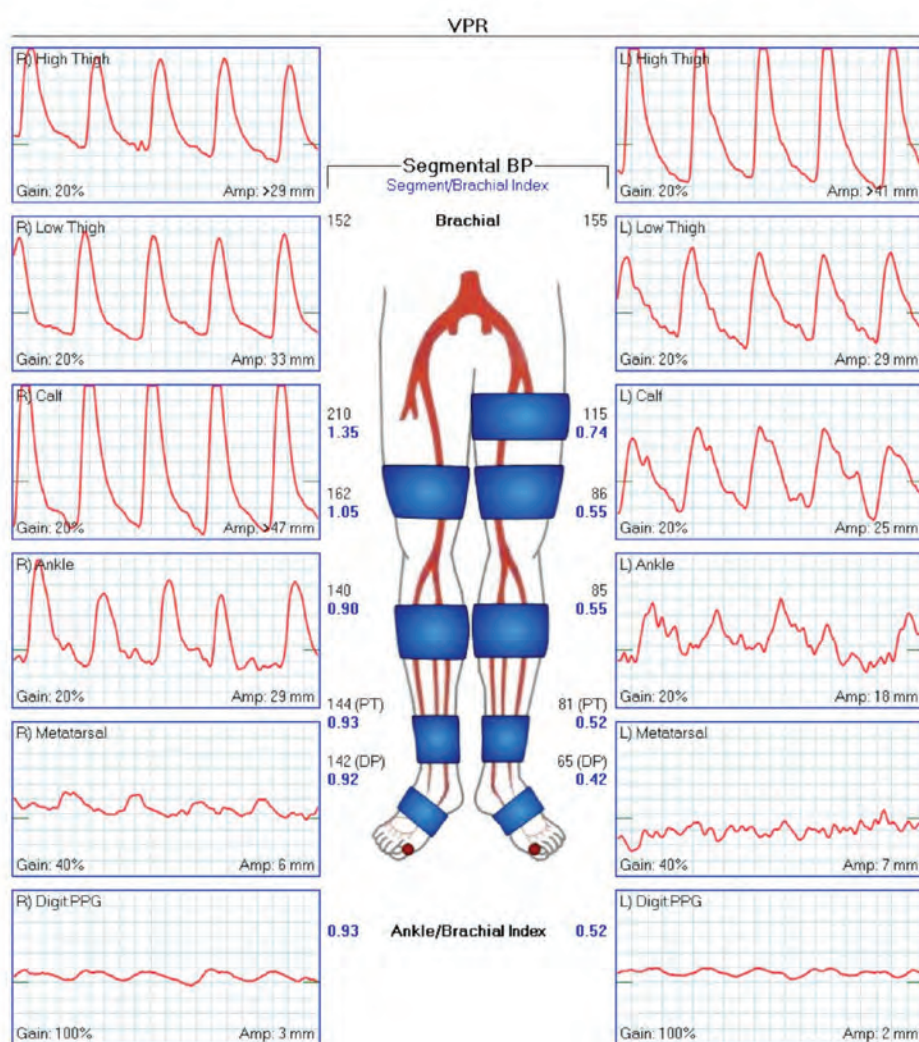
Bilateral ankle-brachial index (ABI) was performed in the office with an ABI of 0.52 on the left and 0.93 on the right (*Figure 1*).

Given the patient's severe lifestyle limiting claudication coupled with his desire to return to a more active lifestyle, he made an informed decision to proceed with lower extremity angiography with possible percutaneous intervention. He received prophylaxis against contrast-induced nephropathy and was brought to the Cleveland Clinic Cardiac Catheterization Laboratory.

## Procedure Details

Access was obtained in the right common femoral artery using modified Seldinger technique where a 5 Fr sheath was inserted. A straight 5 Fr pigtail was advanced to the infra-renal aorta where abdominal aortic angiography was performed (*Figure 2*). This demonstrated a small infra-renal aortic aneurysm, mild-moderate diffuse disease of the bilateral iliofemoral systems as well as an aneurysm of the right common femoral artery. The right internal iliac artery was noted to be occluded and filling in retrograde fashion from

a profunda femoris branch collateral. Following this, a 5 Fr GLIDECATH® Catheter (Terumo) was advanced to the left superficial femoral artery (SFA) over a VERSACORE® Wire (Abbott Vascular) where selective angiography was performed. This demonstrated total occlusion of the mid superficial femoral artery with reconstitution distally via profunda femoris collaterals (*Figure 3*). The length of the left SFA total occlusion was 8 cm, with the total length of the diseased SFA segment equal to 13 cm — a type B lesion according to the TransAtlantic InterSociety Consensus (TASC) II classification. The diameter of the proximal disease-



*Figure 1.*  
Initial ankle-brachial index suggesting aortic or bilateral iliofemoral disease as well as left superficial femoral disease.



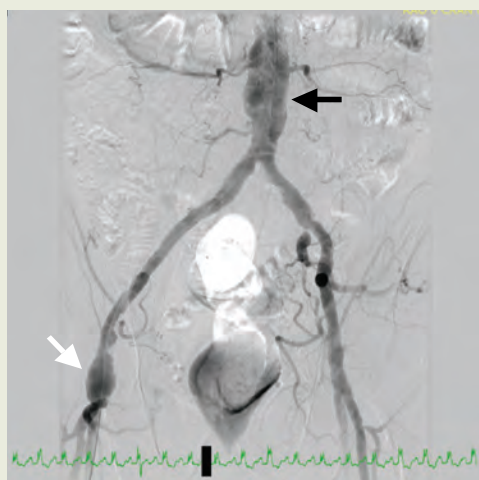
# CASE STUDY (continued)

free reference segment of the left SFA was 5 mm. There was two-vessel distal runoff via the posterior tibial and peroneal arteries; the anterior tibial artery was noted to be occluded proximally.

Given the concordance of the angiographic findings with the patient's symptoms and non-invasive testing as well as the angiographic classification of the left SFA lesion as above, we proceeded to endovascular intervention. The 5 Fr right common femoral artery sheath was exchanged for a 6 Fr 45 cm DESTINATION® Sheath (Terumo) which was advanced to the left common femoral artery. Intravenous heparin was administered for an activated clotting time of greater than 250 seconds. The left SFA total occlusion was crossed successfully using a 0.035" stiff shaft GLIDEWIRE® Guidewire (Terumo) with the 5 Fr Glidecath. We confirmed position in the distal true lumen with an injection in the GLIDECATH® Catheter. The GLIDEWIRE® Guidewire was exchanged for a 0.018" V-18 CONTROL WIRE® (Boston Scientific) guidewire. We then

dilated the left SFA total occlusion with a 5 x 100 mm FOX PLUS® balloon catheter (Abbot Vascular) with 40% residual stenosis. We then stented the left SFA lesion with a 6 x 150 mm GORE® VIABAHN® Endoprosthesis. This particular device was chosen given the growing body of literature demonstrating encouraging patency rates for this device in the superficial femoral artery<sup>1-6</sup>. The GORE® VIABAHN® Device was delivered easily and without difficulty to the target lesion. There was no perceptible migration or movement of the device during deployment. Final angiography demonstrated an excellent result with no residual left superficial femoral artery stenosis and excellent flow (*Figure 4*).

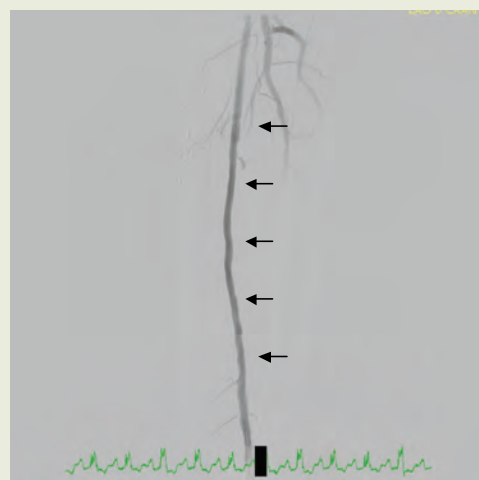
The patient was discharged six hours following the procedure with instructions to continue aspirin indefinitely and clopidogrel for at least one year.



*Figure 2. Aortogram demonstrating small infra-renal aortic aneurysm (black arrow), mild-moderate bilateral iliofemoral disease and right common femoral artery aneurysm (white arrow).*



*Figure 3. Angiogram of the left superficial femoral artery demonstrating total occlusion in the mid-portion with reconstitution distally via profunda femoris collaterals. TASC II type B lesion.*



*Figure 4. Angiogram of the left superficial femoral artery following placement of GORE® VIABAHN® Endoprosthesis (arrows) demonstrating no residual stenosis with excellent flow.*



## Follow-Up

The patient was seen in clinic for follow-up one month following his procedure. He reported significant improvement in his left calf claudication with tremendous improvement in his mobility. Examination demonstrated 2+ left femoral, popliteal, dorsalis pedis and posterior tibial pulses. Repeat ABI was performed and found to be

normalized at 0.97 on the treated left side (Figure 5). Vascular ultrasound evaluation was also performed at the time of follow-up demonstrating a patent stent in the left SFA. He has ongoing right calf claudication with an abnormal ABI which will be evaluated further with angiography and possible intervention.

## References

- 1 Jahnke T, Andresen R, Müller-Hülsbeck S, *et al.* Hemobahn stent-grafts for treatment of femoropopliteal arterial obstructions: midterm results of a prospective trial. *Journal of Vascular & Interventional Radiology* 2003; 14(1): 41-51.
- 2 Railo M, Roth WD, Edgren J, *et al.* Preliminary results with endoluminal femoropopliteal thrombass. *Annales Chirurgiae et Gynaecologiae* 2001; 90(1): 15-18.
- 3 Fischer M, Schwabe C, Schulte K-L. Value of the Hemobahn / Viabahn Endoprosthesis in the treatment of long chronic lesions of the superficial femoral artery: 6 years of experience. *Journal of Endovascular Therapy* 2006; 13(6): 281-290.
- 4 Hartung O, Otero A, Dubuc M, *et al.* Efficacy of Hemobahn® in the treatment of superficial femoral artery lesions in patients with acute or critical ischemia: a comparative study with claudicants. *European Journal of Vascular & Endovascular Surgery* 2005; 30(3): 300-306.
- 5 Lammer J, Dake MD, Bleyn J, *et al.* Peripheral arterial obstruction: prospective study of treatment with a transluminally placed self-expanding stent graft. *Radiology* 2000; 217(1): 95-104.
- 6 Kedora J, Hohmann S, Garrett W, Munschaur C, Theune B, Gable D. Randomized comparison of percutaneous Viabahn stent-grafts versus prosthetic femoral-popliteal bypass in the treatment of superficial femoral arterial occlusive disease. *Journal of Vascular Surgery* 2007; 45(1): 10-16.

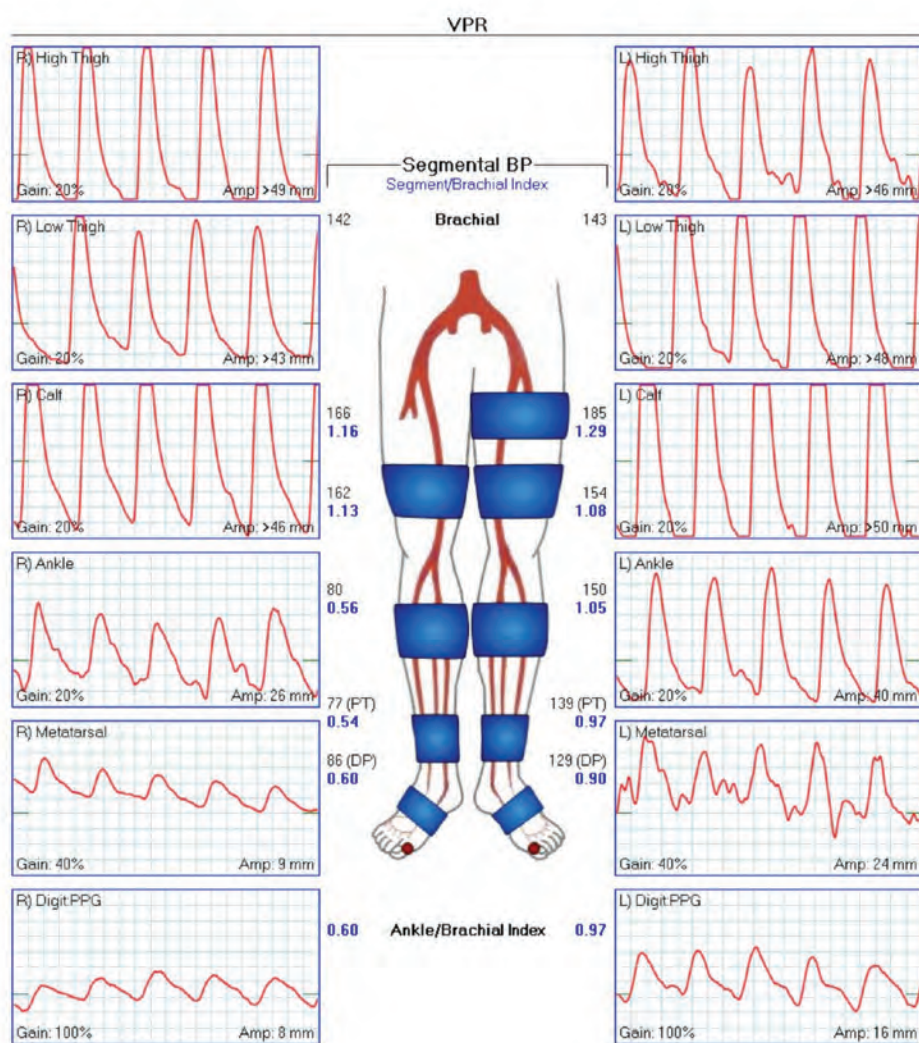


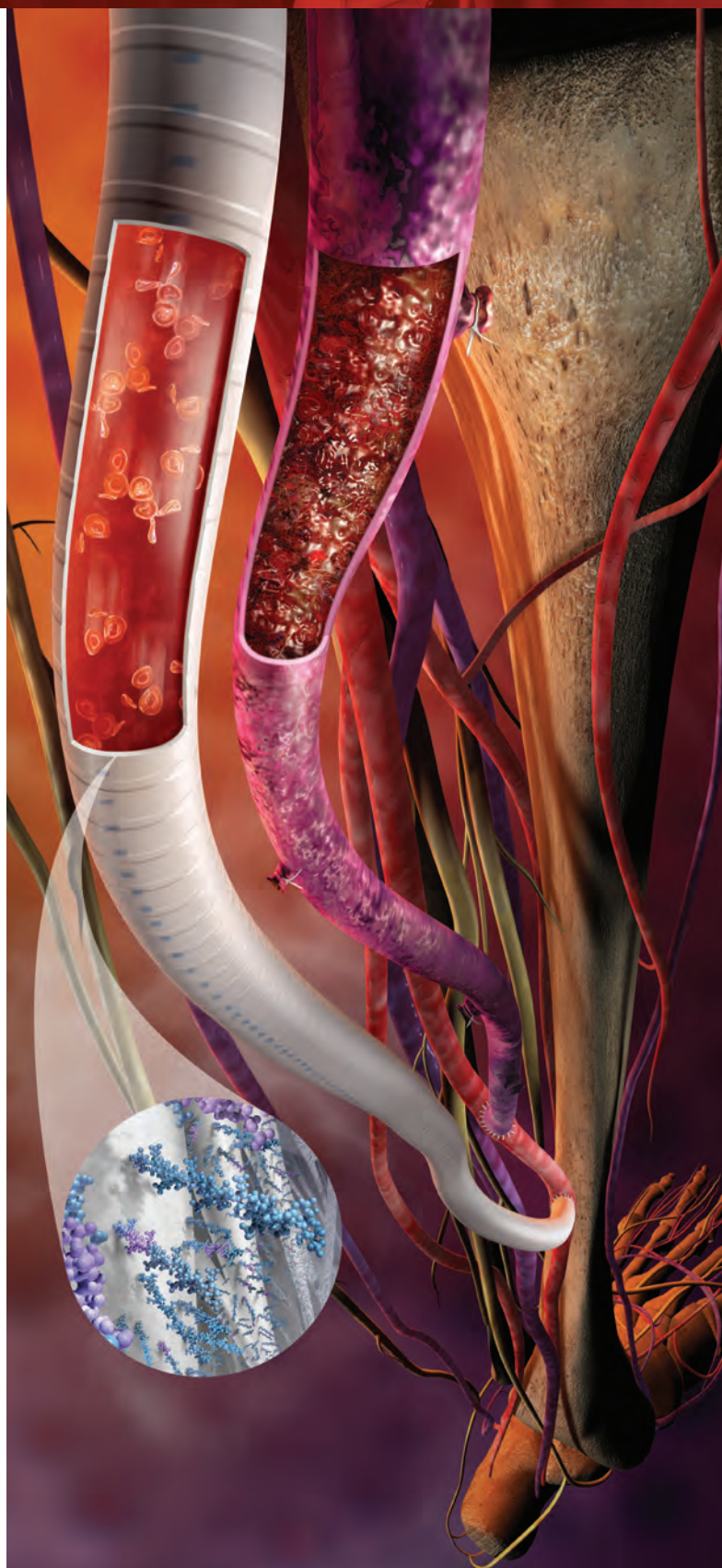
Figure 5.  
Follow-up ABI one month after intervention  
demonstrating normalization of the left-sided ABI.

## UNSURPASSED CLINICAL PERFORMANCE OF THE GORE® PROPATEN® VASCULAR GRAFT IN LOWER EXTREMITY BYPASS

When autologous saphenous vein is unsuitable or unavailable, the GORE® PROPATEN® Vascular Graft is the prosthetic bypass conduit of choice for many surgeons around the world. The unique CARMEDA® BioActive Surface (CBAS® Surface) bound to the luminal surface of the graft employs a proprietary heparin end-point covalent bonding mechanism to provide thromboresistance at the blood-graft interface. The bound CBAS® Surface does not elute.

Since its market introduction in 2002, numerous clinical studies investigating lower extremity arterial bypass using the GORE® PROPATEN® Vascular Graft have demonstrated excellent results (*Table 1*). Of particular note is a large, randomized trial of 546 patients (PI: Dr. Jes Lindholt, Viborg Hospital, Viborg, Denmark) that showed a statistically significant improvement in patency for GORE® PROPATEN® Vascular Graft bypasses compared to standard ePTFE bypasses. Dr. Lindholt is presenting the two-year update of this trial on Friday morning during Session 26 at VEITHsymposium™.

A second highlight is the first published US clinical experience with the GORE® PROPATEN® Vascular Graft (PIs: Dr. Edward Woo and Dr. Melissa Krikwood, University of Pennsylvania Health System, Philadelphia, Pennsylvania), which showed excellent results in all bypass locations. Dr. Woo is also presenting a two-year update during Session 26.





The data presented here support the use of the GORE® PROPATEN® Vascular Graft as the first-choice alternative when autologous conduit is unsuitable or unavailable.

**Table 1**

| Study Characteristics                                             | Study Reference                         |                                     |                                  |                                                      |                                         |                                   |                                      |                                      |
|-------------------------------------------------------------------|-----------------------------------------|-------------------------------------|----------------------------------|------------------------------------------------------|-----------------------------------------|-----------------------------------|--------------------------------------|--------------------------------------|
|                                                                   | Walluscheck, <i>et al.</i> <sup>1</sup> | Peeters, <i>et al.</i> <sup>2</sup> | Hugl, <i>et al.</i> <sup>3</sup> | Daenens, <i>et al.</i> <sup>4</sup>                  | Lösel-Sadée, <i>et al.</i> <sup>5</sup> | Pulli, <i>et al.</i> <sup>6</sup> | Lindholt, <i>et al.</i> <sup>7</sup> | Kirkwood, <i>et al.</i> <sup>8</sup> |
| Number of patients / bypasses with GORE® PROPATEN® Vascular Graft | 40 / 43                                 | 138 / 153                           | 142 / 139                        | 240                                                  | 75                                      | 425                               | 546                                  | 68                                   |
| Mean or median patient age (years)                                | 71                                      | 73                                  | 69.8                             | 70.4                                                 | 73                                      | 73.5                              | 65.5                                 | 69                                   |
| Patient sex (M / F)                                               | 24 / 16                                 | 97 / 41                             | 96 / 46                          | 161 / 79                                             | 39 / 36                                 | 338 / 87                          | 288 / 258                            | 38 / 30                              |
| Number of above-knee FP bypasses                                  | 12                                      | 75                                  | 87                               | 86                                                   | 0                                       | 101                               | 238*                                 | 9                                    |
| Number of below-knee bypasses (FP / FC)                           | 31<br>(17 / 14)                         | 78<br>(41 / 37)                     | 52<br>(37 / 15)                  | 154<br>(57 / 97)                                     | 75<br>(30 / 45)                         | 324<br>(238 / 86)                 | NR                                   | 29 (14 / 15)                         |
| Mean follow-up duration (months)                                  | 17                                      | 36                                  | 12                               | 25 (Above-knee, Below-knee-FP)<br>19 (Below-knee-FC) | 23                                      | 26                                | 10.3                                 | 10.4                                 |
| Overall one-year primary patency (%)                              | NR                                      | 80                                  | 80                               | NR                                                   | NR                                      | 75                                | 86.4†                                | 86‡§                                 |
| Overall two-year primary patency (%)                              | NR                                      | 74                                  | NI                               | NR                                                   | NR                                      | 66                                | NI                                   | NI                                   |
| Overall three-year primary patency (%)                            | NI                                      | 72                                  | NI                               | NR                                                   | NR                                      | 61                                | NI                                   | NI                                   |
| Above-knee bypasses: one-year primary patency (%)                 | 91                                      | 81                                  | 83                               | 92                                                   | NI                                      | 80                                | 81*                                  | 86‡                                  |
| Below-knee bypasses: one-year primary patency (%)                 | 92                                      | 86 (FP)<br>71 (FC)                  | 74 (FP)<br>79 (FC)               | 92 (FP)<br>79 (FC)                                   | 77 (FP)<br>64 (FC)                      | 75 (FP)<br>66 (FC)                | NI                                   | 92 (FP)<br>61 (FC)‡                  |
| Above-knee bypasses: two-year primary patency (%)                 | 68                                      | 78                                  | NI                               | 83                                                   | NI                                      | 72                                | NI                                   | NI                                   |
| Below-knee bypasses: two-year primary patency (%)                 | 81                                      | 79 (FP)<br>60 (FC)                  | NI                               | 83 (FP)<br>69 (FC)                                   | 71 (FP)<br>57 (FC)                      | 67 (FP)<br>57 (FC)                | NI                                   | NI                                   |
| Above-knee bypasses: three-year primary patency (%)               | NI                                      | 75                                  | NI                               | NI                                                   | NI                                      | 72                                | NI                                   | NI                                   |
| Below-knee bypasses: three-year primary patency (%)               | NI                                      | 75 (FP)<br>60 (FC)                  | NI                               | NI                                                   | 71 (FP)<br>50 (FC)                      | 61 (FP)<br>52 (FC)                | NI                                   | NI                                   |

FP, femoro-popliteal; FC, femoro-crural; NI, not investigated; NR, not reported.

\*Includes an unreported number of below knee FP bypasses.

†Includes femoro-femoral bypasses.

‡18-month patency rate.

§Includes extra-anatomic bypasses.

- Walluscheck KP, Bierkandt S, Brandt M, Cremer J. Infrainguinal ePTFE vascular graft with bioactive surface heparin bonding – first clinical results. *Journal of Cardiovascular Surgery* 2005; 46(4): 425-430.
- Peeters P, Verbist J, Deloosse K, Bosiers M. Will heparin-bonded PTFE replace autologous venous conduits in infrapopliteal bypass? *Italian Journal of Vascular & Endovascular Surgery* 2008; 15(3): 143-148.
- Hugl B, Nevelsteen A, Daenens K, *et al*; PEPE II Study Group. PEPE II - a multicenter study with an end-point heparin-bonded expanded polytetrafluoroethylene vascular graft for above and below knee bypass surgery: determinants of patency. *Journal of Cardiovascular Surgery* 2009; 50(2): 195-203.
- Daenens K, Schepers S, Fourneau I, Houthoofd S, Nevelsteen A. Heparin-bonded ePTFE grafts compared with vein grafts in femoropopliteal and femorocrural bypasses: 1-and 2-year results. *Journal of Vascular Surgery* 2009; 49(5): 1210-1216.
- Lösel-Sadée H, Alefelder C. Heparin-bonded expanded polytetrafluoroethylene graft for infragenicular bypass: five-year results. *Journal of Cardiovascular Surgery* 2009; 50(3): 339-343.
- Pulli R, Dorigo W, Castelli P, *et al*; Propaten Italian Registry Group. Midterm results from a multicenter registry on the treatment of infrainguinal critical limb ischemia using a heparin-bonded ePTFE graft. *Journal of Vascular Surgery* 2010; 51(5): 1167-1177.
- Lindholt JS, Gottschalksen B, Johannesen N, *et al*. The Scandinavian Propaten® Trial – 1-year patency of PTFE vascular prostheses with heparin-bonded luminal surfaces compared to ordinary pure PTFE vascular prostheses – a randomised clinical controlled multi-centre trial. *European Journal of Vascular & Endovascular Surgery* 2011; 41(5): 668-673.
- Kirkwood ML, Wang GJ, Jackson BM, Golden MA, Fairman RM, Woo EY. Lower limb revascularization for PAD using a heparin-coated PTFE conduit. *Vascular & Endovascular Surgery* 2011; 45(4): 329-334.

# VEITH symposium™ 2011 EVENTS

## Join Us in the Gore Pavilion for these Educational Opportunities

### Wednesday, November 16

#### LUNCH SYMPOSIUM

- **The role of stent-grafts in a clinical algorithm to treat SFA disease**  
*Michael Silva, MD*
- **Clinical experience with the GORE® VIABAHN® Endoprosthesis**  
*Richard Saxon, MD*
- **Optimizing outflow: one year results with GORE® Hybrid Vascular Graft in a challenging AV access patient population**  
*John Ross, MD*

#### EVENING EVENT, 5:30 pm, **Pioneers in Performance**

In 2011, the past recipients of the award nominated candidates who have demonstrated a strong and ongoing commitment to improving clinical and patient performance through collaboration. Now it is your turn to decide who will be honored as a 2012 Pioneer in Performance—United States. Please take a moment to meet this year's nominees and cast your vote.

### Thursday, November 17

#### LUNCH SYMPOSIUM

- **Should asymptomatic patients be treated with carotid artery stenting?**  
*Sumaira Macdonald, MBChB (Comm.), FRCP, FRCR, PhD*  
*William A. Gray, MD*

#### EVENING EVENT, 6:00 pm

**The versatility of an endoluminal anastomosis: expanding treatment options with the GORE® Hybrid Vascular Graft**  
*Jean Bismuth, MD*

### Friday, November 18

#### LUNCH SYMPOSIUM

- **New options in thoracic aneurysm treatment: the impact of true conformability**  
*Mark Fillinger, MD*
- **New devices in acute thoracic treatment**  
*Mark Farber, MD*
- **Repositioning as an insurance policy for EVAR: benefits for both straightforward and challenging anatomies**  
*Darren Schneider, MD*

#### EVENING EVENT, 5:30 pm

#### **Innovation Showcase**

### Saturday, November 19

#### LUNCH SYMPOSIUM, LATIN AMERICA DAY

- **Registro Aortico G.R.E.A.T. BRASIL**  
**G.R.E.A.T. Aortic Brazil Registry**  
*Pierre Galvagni, MD*
- **Protesis GORE® PROPATEN® Vascular Graft en isquemia Crítica de Miembros Inferiores Resultados a Largo Plazo**  
**GORE® PROPATEN® Vascular Graft in acute lower limb ischemia: long-term follow-up**  
*Mariano Ferreira, MD*
- **Angioplastia Carotídea utilizando GORE® Flow Reversal System**  
**GORE® Flow Reversal System in carotid angioplasty**  
*Samuel Moreira, MD*
- **Função da GORE® VIABAHN® Endoprosthesis em Aneurisma da Artéria Poplítea**  
**Role of GORE® VIABAHN® Endoprosthesis in Popliteal Artery Aneurysm**  
*Ricardo Aun, MD*

## Gore Simulation Pavilion, 9:00 am–5:00 pm, Wednesday–Friday • 9:00 am–2:00 pm, Saturday

Join us in the Gore Simulation Pavilion to experience first-hand the GORE® Hybrid Vascular Graft, and a life-like virtual environment with the Conformable GORE® TAG® Device, and the GORE® EXCLUDER® Device featuring C3 Delivery System.

### Thursday, November 17, 2:00 pm, **Experience Conformability through Simulation, Erika Kashef, MD**

To comply with current AdvaMed Code of Ethics, state laws and Gore policies, Gore reminds you that only program attendees may attend the reception and meal portions of the program. Spouses, family members or other guests cannot attend Gore programs or meals. Please advise if you are licensed to practice medicine in the State of Massachusetts or the State of Vermont, even if you practice in another state. Under the new laws in Massachusetts and Vermont, (effective 01 July 2009), Gore must report all payments and expenses relating to your attendance at this course. In addition, Gore may only provide meals in venues approved under the law (hospitals, clinics or academic medical centers)—in other venues Gore may not furnish your meals.



Consult Instructions for Use

**INDICATIONS FOR USE:** The GORE® TAG® Thoracic Endoprosthesis is intended for endovascular repair of aneurysms of the descending thoracic aorta in patients who have appropriate anatomy, including: Adequate iliac / femoral access; Aortic inner diameter in the range of 16–42 mm;  $\geq 20$  mm non-aneurysmal aorta proximal and distal to the aneurysm. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; Patients with a systemic infection who may be at increased risk of endovascular graft infection. Refer to *Instructions for Use* at [goremedical.com](http://goremedical.com) for a complete description of all warnings, precautions and adverse events.  $\text{Rx Only}$

**INTENDED USE / INDICATIONS** The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery lesions with reference vessel diameters ranging from 4.0 – 7.5 mm. The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions with reference vessel diameters ranging from 4.0 – 12 mm. **CONTRAINDICATIONS** The GORE® VIABAHN® Endoprosthesis is contraindicated for non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at [goremedical.com](http://goremedical.com) for a complete description of all warnings, precautions and adverse events.  $\text{Rx Only}$

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**Have a story idea or case study to share?**

Send your suggestions to [peripheralvision@wlgore.com](mailto:peripheralvision@wlgore.com)



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