Product Name: GORE® VIABAHN® Endoprosthesis
(Peripheral Vascular Therapeutics - In Development, Cardiovascular Therapeutics, Lower Limb Advanced Arterial Therapeutics, Pathway Clinical Trial MarketTracks, Medtronic PV Lower Limb Advanced Arterial Therapeutics)

Description:
A flexible, self-expanding endoluminal nitinol stent with an expanded ePTFE (polytetrafluoroethylene) lining; The device is compressed and attached to a dual lumen polyethylene delivery catheter; Two radiopaque metallic bands are attached to the catheter marking the ends of the compressed endoprosthesis.

Company/Sponsor:
• W.L. Gore & Associates, Inc.

Vessels:
• Femoral Arteries (SFA/Superficial)
• Lower Limb Arteries
• Femoral-Popliteal Arteries (FemPop)

General Modality:
• Medical Devices

Specific Modality:
• Stents

General Product Type:
• Coated Stent

Specific Product Type:
• PTFE-coated Stents

Clinical Trials:
A Retrospective Review of Randomized Comparison of Prosthetic Femoropopliteal Bypass Versus Viabahn Endoprosthesis for Treatment of Symptomatic Femoral Artery Occlusion With Four Years Followup
Early Results with the Use of Heparin-bonded Stent Graft to Rescue Failed Angioplasty of Chronic Femoropopliteal Occlusive Lesions: TASC D Lesions Have a Poor Outcome Efficacy of Viabahn in the Treatment of Severe Superficial Femoral Artery Lesions: Which Factors Influence Long-term Patency? Evaluation of the 25 cm GORE® VIABAHN® Endoprosthesis With PROPATEN Bioactive Surface to Treat de Novo and/or Restenotic Lesions of the Superficial Femoral Artery (SFA)

Commercial Approval:
• On August 23, 2018 WL Gore received PMA approval for GORE VIABAHN Endoprosthesis to update raw material specifications and the non-compendial test methods.
• On July 27, 2018 WL Gore received PMA approval for GORE VIABAHN Endoprosthesis & GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface for transferring manufacturing of raw materials, intermediate materials and manufacturing aids to an external supplier.
• On July 5, 2018 WL Gore received PMA approval for GORE VIABAHN Endoprosthesis & GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface for new polymer processing equipment and an alternate cleaning process.
• On June 14, 2018 WL Gore received PMA approval for GORE VIABAHN Endoprosthesis & GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface for the implementation of new equipment at the existing pouch supplier.
• On February 20, 2018 WL Gore received PMA approval for GORE VIABAHN Endoprosthesis & GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface for Addition of automated packaging dispensing equipment.
• Awarded a CE Mark in 1996
• Received FDA approval on February 8, 2007 to modify the device to reduce the overall delivery profile of the device by one French size.
• Awarded a CE Mark on January 12, 2009 for the GORE VIABAHN Endoprosthesis with PROPATEN Bioactive Surface for the treatment of arterial vascular disease and is indicated for the endovascular grafting of peripheral arteries.
• Received FDA approval on August 14, 2008 for improving blood flow in patients with symptomatic peripheral arterial disease (PAD) in iliac artery lesions with reference vessel diameters ranging from 4.0 - 12.0 mm.
• Received FDA approval on April 24, 2007 for the addition of a 5 mm diameter endoprosthesis.
• Received FDA approval on June 14, 2005 for improving blood flow in patients with symptomatic peripheral arterial disease (PAD) in superficial femoral artery (SFA) lesions with reference vessel diameters ranging from 4.8 - 7.5 mm.
• Received FDA approval on June 30, 2009 for the GORE VIABAHN Endoprosthesis modification which is a result of the precision laser trimming technology which enables the removal of excess material at the device margin, resulting in a contoured edge and is indicated for the treatment of patients suffering from Peripheral Arterial Disease (PAD) in superficial femoral artery (SFA) lesions and iliac artery lesions.
• Received FDA approval on September 5, 2007 for the addition of a heparin coating, referred...
**Please Note:** All links will open in the current window - to open a link in a new window please right click the link and select "Open in New Window" or "Open in New Tab"

- **GORE VIABAHN** Endoprosthesis Versus Bare Nitinol Stent in the Treatment of Long Lesion (>8cm) Superficial Femoral Artery Occlusive Disease
- HEMOBANH / VIABAHN Covered Stentgraft Trial In-Stent Restenosis Post-Approval Study
- RELINE - The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface versus Plain Old Balloon Angioplasty (POBA) for the Treatment of Superficial Femoral Artery In-Stent Restenosis
- RELINE MAX Clinical Study Results With Viabahn-Assisted Subintimal Recanalization for TASC C and TASC D Superficial Femoral Artery Occlusive Disease
- SALVAGE - Study to Evaluate the Safety and Performance of Spectranetics Laser Angioplasty (POBA) for the Treatment of Superficial Femoral Artery (SFA) In-Stent Restenosis
- Viabahn™ for FemoroPopliteal Artery In-Stent Restenosis
- VIASTAR - GORE® VIABAHN® Endoprosthesis Versus Bare Nitinol Stent in the Treatment of TASC B+, C and D lesions in Superficial Femoral Artery Occlusive Disease
- VIBRANT - Viabahn veRsus bAre Nitinol stenT
- VIPER Study - GORE VIABAHN Endoprosthesis
- With Heparin Bioactive Surface in the Treatment of SFA Obstructive Disease

**Development Status - Commercial Events:**
- The Viabahn endoprosthesis was formerly known as Hemobahn.
- On February 19, 2011 Gore announced the European availability of the GORE® VIABAHN® Endoprosthesis for femoropopliteal artery disease. This approval allows for the use of the endoprosthesis in the treatment of symptomatic peripheral arterial disease lesions in the superficial femoral artery (SFA).
- On November 6, 2014, Gore received FDA approval for the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface on a lower profile delivery system which enables a reduction in delivery profile to 6 French (Fr) for 5 and 6 mm devices and 7 Fr for 7 and 8 mm devices and is delivered over a 0.018” or 0.014” guidewire.

**Development Status - Clinical Trials:**
- W.L. Gore announced the enrollment of the first two patients on February 25, 2008 in the SALAVGE trial, which evaluates the GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface and the Spectranetics Turbo-Booster and Turbo elite laser catheter with the CVX-300 Excimer Laser System for the treatment of peripheral vascular disease (PVD) in the superficial femoral artery (SFA); specifically, the study will evaluate the effectiveness of this combination therapy as a treatment for patients with chronic lower-limb ischemia associated with femoro-popliteal in-stent restenosis.
- On October 17, 2005 W. L. Gore & Associates, Inc. announced the treatment of the first patient in the VIBRANT (Viabahn veRsus bAre Nitinol stenT) study of comparative treatments for the superficial femoral artery.
- On January 3, 2008 Gore announced patient enrollment had completed on the VIBRANT trial.
- On April 7, 2008 W. L. Gore announced FDA approval to proceed with the Gore REVISE (VasculaR AccEss ReVision with Viabahn EndoproStheses vs PercutanEous Transluminal Angioplasty) Study which is a randomized, multi-center clinical trial intended to establish efficacy and safety of the GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface to revise arterio-venous grafts at the venous anastomosis in hemodialysis patients.
- In March 2008 trial results were published for a retrospective trial between 2000 to 2005 in which the Hemobahn/Viabahn endoprosthesis was used in 95 patients (102 limbs) to evaluate primary stent treatment by covered stents; the trial authors concluded that "Severity of lesions, rather than preoperative symptoms or runoff, is mainly to be considered before using Hemobahn/Viabahn endoprosthesis in severe SFA occlusive lesions."
- Results at 18-months for the SALAVGE trial, including the Spectranetics CVX-300 Excimer Laser, Turbo-Booster and Turbo elite laser catheter with 39 patients (40 limbs) were presented at TCT 2008 by Gary M Ansel, Charles F Botti, Mitchell J Silver, and Melinda J Taylor; the authors found Average Lesion Length to be 25cm (5-44cm), Primary Patency of 52% (17/33), Primary assisted Patency of 67% (23/33) and Secondary Patency of 82% (27/33).

**Evaluated in a PTFE bypass vs. thrupass clinical trial published on May 1, 2009 titled "PTFE bypass or thrupass for superficial femoral artery occlusion? A randomised controlled trial" in the Eur J Vasc Endovasc Surg by Leptalto M, Laurila K, Roth WD, Rossi P, Lavonen J, Mkinen K, Manninen H, Romsø P, Perj J, Bergqvist D and the Scandinavian Thrupass Study Group; Patient recruitment stopped early at 44 patients due to data demonstrating primary patency rates excluding technical failures for the PTFE Thruspass (with the Viabahn endoprosthesis) of 48% at 1 year, compared to 95% (p=0.02) for PTFE bypass; additionally these results stayed consistent with 1 year follow-up for the Viabahn thruspass and PTFE bypass with primary patencies excluding technical failures of 46% and 84% (p=0.18), secondary patencies including technical failure of 63% and 100% (p=0.05) and secondary patancy excluding technical failure of 51% and 100% (p=0.02), respectively; the authors concluded that "Treatment of SFA occlusions (TASC IIb and C or Imelda IA and II) should be done by PTFE bypass rather than by PTFE thruspass, as thruspass is connected with worse early outcome. These results represent only a small category of femoral disease".

**Evaluated in an article titled "One-year outcomes for recanalization of long superficial femoral artery chronic total occlusions with the Viabahn stent graft" by Farraj N, Srivastava A and Pershad A published in J Invasive Cardiol. 2009 Jun;21(6):27:81. The authors sought to determine the safety and efficacy of the Viabahn in patients with SFA CTOs undergoing endovascular treatment. In 30 patients (32 limbs) the authors concluded that "Percutaneous e-PTFE stent-grafting with the Viabahn stent graft is a viable treatment option for TASC D occlusions in the SFA in claudicants and patients with critical limb ischemia. Primary and primary assisted patency rates at 1 year are comparable to historical surgical outcomes using
PTFE grafts as bypass conduits. Long-term data (> 5 years) in a larger patient cohort are necessary before definite conclusions can be drawn.

In a U.S. pivotal study, 244 cases (241 patients) were treated at 25 U.S. investigational sites. The study compared the effectiveness of the VIABAHN endoprosthesis with PTA in patients with chronic lower limb ischemia or chronic lifestyle altering claudication due to SFA atherosclerosis disease. 197 cases were randomized with 97 assigned to the VIABAHN device and 100 to PTA.

This study demonstrated that the VIABAHN device resulted in higher rates of treatment and technical success, and in 12-month patency compared to PTA. (May 2004)

At the 14th Annual Interventional Cardiology Fellows Course in San Jose, CA put on by the Cardiovascular Research Foundation (CRF) John R. Laird Jr, MD presented Endovascular Intervention Part 1: Iliac and SFA Intervention: Clinical Syndromes, Devices and Long-Term Results which contained an overview of 14 Viabahn clinical trials between 2000 and 2007 with the following total & averages:
- Total Number of Limbs: 708
- Avg. Lesion Length (cm): 15
- Avg. % Occlusions: 66%
- Avg. Primary Patency at 1 year: 84%
- Avg. Primary Patency at 2 years: 79%
- Avg. Primary Patency at 3 years: 71%
- Avg. Primary Patency at 4 years: 66%
- Avg. Primary Patency at 5 years: 55%

In pre-clinicals (May 1998)

Comments:
- The device has been used in femoropopliteal, SFA, and iliac applications

Sources:


