Gore VIPER Clinical Study
One-Year Results


Product with radiopaque markers planned for European availability in 2016.

## Gore VIPER Clinical Study Centers and Principal Investigators

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| Holy Cross Hospital, Fort Lauderdale, Florida    | Michael Rush, MD                                |
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# Gore VIPER Clinical Study Overview

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface for treatment of long SFA disease

| Objective                                                                 | Evaluate the performance of GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface (W. L. Gore & Associates, Inc.) in treating long-segment SFA disease (> 5 cm in length) |
|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------
| Design                                                                    | Single-arm, prospective, 12 sites, 120 limbs                                                                                                    |
| Primary Endpoints                                                         | Primary patency at 12 months  
  • No evidence of restenosis or occlusion within the originally treated lesion based on CDUS; PSVR < 2.5;  
  • No angiographic evidence of stenosis > 50% if CDUS is uninterpretable or unavailable  
  Proportion of subjects experiencing major procedure related adverse events within 30 days of procedure |
| Secondary Endpoints                                                       | Primary assisted patency  
  Secondary patency  
  Device-related major adverse events at 12 months |

Endoprosthesis Description

- Ultra-thin wall ePTFE tube
- Unique, durable bonding film
- Polished nitinol support
- Contoured proximal edge
- CBAS® Heparin Surface
- Lengths: 2.5, 5, 10, 15, 25 cm
- Diameters: 5 – 13 mm

Product with radiopaque markers planned for European availability in 2016.
Contoured Proximal Edge

Manufacturing change during study

IVUS demonstrates device apposition to artery in canine model

Post-mortem dissection demonstrates device apposition to artery
CBAS® Heparin Surface

- **End-point covalent bonding**
  - CBAS® Heparin Surface technology allows for retention of bioactivity.

- **Sustained bioactivity**
  - Active site catalytically facilitates antithrombin-thrombin complex formation and then becomes available to repeat the reaction.

- **Intended to provide a thromboresistant surface**
  - Clinical history: Long-term activity and safety.  


# Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>Gore VIPER Clinical Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limbs Enrolled</td>
<td>119</td>
</tr>
<tr>
<td>Treated Occlusions</td>
<td>56%</td>
</tr>
<tr>
<td>Lesion Length</td>
<td>19 cm</td>
</tr>
<tr>
<td>Lesion Calcification</td>
<td></td>
</tr>
<tr>
<td>none-mild</td>
<td>39%</td>
</tr>
<tr>
<td>moderate-severe</td>
<td>61%</td>
</tr>
<tr>
<td>Tibial Runoff</td>
<td></td>
</tr>
<tr>
<td>One vessel</td>
<td>21%</td>
</tr>
<tr>
<td>Two vessel</td>
<td>33%</td>
</tr>
<tr>
<td>Three vessel</td>
<td>46%</td>
</tr>
<tr>
<td>TASC II Lesion Classification</td>
<td></td>
</tr>
<tr>
<td>Type A</td>
<td>14%</td>
</tr>
<tr>
<td>Type B</td>
<td>25%</td>
</tr>
<tr>
<td>Type C</td>
<td>29%</td>
</tr>
<tr>
<td>Type D</td>
<td>31%</td>
</tr>
</tbody>
</table>

Safety – Major Adverse Events

- **Primary Endpoint**: 30-day procedure-related MAE
  - One event, (0.8%): surgical bypass after target lesion occlusion

- **Secondary Endpoint**: One-year device-related MAE
  - Zero events

- **Major Adverse Events (MAE)**: require significant therapy, including unplanned increase in the level of care, permanent sequelae, hospitalization, or death. Repeat interventions, stenosis, and occlusions are not adverse events.
One-Year Patency

12-Month Patency:
Gore VIPER Clinical Study Data

% Patients Maintaining Patency

Primary Patency
Secondary Patency

Months Post-Treatment

103 / 119 limbs available for follow-up at 12 months
# One-Year Primary Patency by Subgroup

<table>
<thead>
<tr>
<th></th>
<th>Primary Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
<td>73%</td>
</tr>
<tr>
<td><strong>Device Diameter</strong></td>
<td></td>
</tr>
<tr>
<td>5 mm (n= 23)</td>
<td>79%</td>
</tr>
<tr>
<td>6 mm (n= 85)</td>
<td>69%</td>
</tr>
<tr>
<td>7 mm (n= 8)</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Lesion Length</strong></td>
<td></td>
</tr>
<tr>
<td>( \leq 20 \text{ cm} ) (n= 68)</td>
<td>75%</td>
</tr>
<tr>
<td>&gt; 20 cm (n= 51)</td>
<td>70%</td>
</tr>
</tbody>
</table>

Effects of Device Sizing: Proximal

12-Month Primary Patency: Gore Viper Clinical Study Data Primary Patency as a Function of Proximal Oversizing

% Patients Maintaining Patency

- Oversized ≤ 20%, N = 38
- Oversized > 20%, N = 57

p < 0.05

Device oversizing assessed by independent Core Lab, data on file
Oversizing

CASE 1

6x15 GORE® VIABAHN® Endoprosthesis

90% Stenosis at Day 150
Proximal and Distal Edge

37% Oversize

CASE 2

6x15 GORE® VIABAHN® Endoprosthesis

Occlusion at Day 25
27% Oversize

4.4 mm

3.8 mm

3.4 mm

43% Oversize

4.4 mm

3.0 mm

50% Oversize

Conclusions

- **The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface Exhibits 73% Patency in Long SFA Lesions**
  - Patency is independent of lesion length
    - Long lesions (> 20 cm) equivalent to medium lesions (5–20 cm)
  - 5 mm device patency is equivalent to other sizes
    - Appears to have no dependence on device diameter in contrast to previous experience
  - Sizing is Critical
    - Primary patency is significantly better when IFU sizing is not exceeded at the proximal edge
      - 88% versus 70% at 12 months (p < .05, sizing by Core Lab)

- **European VIASTAR Trial adds more Comparative Data**
  - Randomized trial of Bare Nitinol Stents versus the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface for long SFA lesions

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Primary Patency in SFA Stenting


The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface is known in some markets as the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface.

Products listed may not be available in all markets.

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