FREQUENTLY ASKED QUESTIONS
Table of Contents

GORE® VIABAHN® Endoprosthesis FAQs

What is the GORE® VIABAHN® Endoprosthesis? ................................................................. 2
Can the GORE® VIABAHN® Endoprosthesis be revised if it occludes? ............................... 2
How is the device sterilized and can I resterilize it? .............................................................. 2
What is the indication for the GORE® VIABAHN® Endoprosthesis? ................................. 2
What is ePTFE? .................................................................................................................. 3
What clinical data exists for the GORE® VIABAHN® Endoprosthesis in the SFA? .............. 3
Are there any clinical considerations when using the GORE® VIABAHN® Endoprosthesis? 3
What about in-stent restenosis? .......................................................................................... 4
Is there any Level 1 clinical data for the GORE® VIABAHN® Endoprosthesis? ................ 4
What about SFA stent fractures with the GORE® VIABAHN® Endoprosthesis? .............. 4
What are the potential failure modes of the GORE® VIABAHN® Endoprosthesis? .......... 5
What is the effect of the contoured proximal edge? .......................................................... 5
What is the rate of thrombosis for the GORE® VIABAHN® Endoprosthesis? .................. 6

References ........................................................................................................................ 6  Back Page
What is the GORE® VIABAHN® Endoprosthesis?

The GORE® VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal endoprosthesis consisting of an expanded polytetrafluoroethylene (ePTFE) lining with an external nitinol support extending along its entire length.

- Ultra thin wall ePTFE lining
- Unique, durable bonding film
- Polished nitinol stent
- Contoured proximal edge
- Lengths: 2.5, 5, 10, 15 cm
- Diameters: 5 – 13 mm

Can the GORE® VIABAHN® Endoprosthesis be revised if it occludes?

The GORE® VIABAHN® Endoprosthesis can be revised.

How is the device sterilized and can I resterilize it?

The device is sterilized using Ethylene Oxide. The GORE® VIABAHN® Endoprosthesis should not be resterilized.

What is the indication for the GORE® VIABAHN® Endoprosthesis?

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.
What is ePTFE?

ePTFE is an acronym for expanded polytetrafluoroethylene. PTFE is an extremely inert, biocompatible biomaterial composed solely of carbon and fluorine. When PTFE is expanded at a high temperature and rate, ePTFE is formed with a node-fibril microstructure. This discovery was made by Bob Gore in 1969. Since the mid-1970s, ePTFE vascular grafts have been the synthetic material of choice by vascular surgeons performing peripheral bypass operations or creating dialysis access grafts.

What clinical data exists for the GORE® VIABAHN® Endoprosthesis in the SFA?

The GORE® VIABAHN® Endoprosthesis has an impressive amount of published clinical data. There have been 17 independent studies reporting primary patency for the endoprosthesis with greater than 30 patients. For the published 1103 limbs, with an average lesion length of 16 cm, the weighted average one year primary patency is 77%.

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Journal Publication / Presentation</th>
<th>No. of Limbs</th>
<th>Lesion Length (cm)</th>
<th>% Occlusions</th>
<th>Primary Patency (years / %)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lammer</td>
<td>2000</td>
<td>Radiology, 217:95-104</td>
<td>80</td>
<td>13.8</td>
<td>NR</td>
<td>79</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jahnke</td>
<td>2003</td>
<td>J Vasc Interv Radiol, 14:41-51</td>
<td>52</td>
<td>8.5</td>
<td>83</td>
<td>78</td>
<td>74</td>
<td>62</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleyn</td>
<td>2004</td>
<td>Edizioni Minerva Medica, 14:87-91</td>
<td>67</td>
<td>14.3</td>
<td>100</td>
<td>82</td>
<td>73</td>
<td>68</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Panetta</td>
<td>2005</td>
<td>Endovasc Today, August</td>
<td>41</td>
<td>30.4</td>
<td>90</td>
<td>86</td>
<td>77</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chopra</td>
<td>2006</td>
<td>AIM Symposium, November 13 – 16</td>
<td>70</td>
<td>20</td>
<td>71</td>
<td>93</td>
<td>87</td>
<td>72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coats</td>
<td>2006</td>
<td>Endovasc Today, September</td>
<td>83</td>
<td>NR</td>
<td>47</td>
<td>89</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fischer</td>
<td>2006</td>
<td>J Endovasc Ther, 13:281-290</td>
<td>59</td>
<td>10.7</td>
<td>87</td>
<td>67</td>
<td>58</td>
<td>57</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>Zander</td>
<td>2006</td>
<td>SIR Meeting, April 3</td>
<td>31</td>
<td>16.6</td>
<td>NR</td>
<td>86</td>
<td>78</td>
<td>78</td>
<td>78</td>
<td></td>
</tr>
<tr>
<td>Saxon</td>
<td>2007</td>
<td>J Vasc Interv Radiol, 18:1341-1350</td>
<td>87</td>
<td>14.2</td>
<td>42</td>
<td>76</td>
<td>65</td>
<td>60</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>Alimi</td>
<td>2008</td>
<td>Eur J Vasc Endovasc Surg, 35:346-352</td>
<td>102</td>
<td>11.7</td>
<td>NR</td>
<td>74</td>
<td>71</td>
<td>71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Djelmami-Hani</td>
<td>2008</td>
<td>SCAI Meeting, March 29 – April 1</td>
<td>132</td>
<td>21</td>
<td>39</td>
<td>80</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saxton</td>
<td>2008</td>
<td>J Vasc Interv Radiol, 18:823-832</td>
<td>97</td>
<td>7</td>
<td>21</td>
<td>65</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VIBRANT</td>
<td>2009</td>
<td>VIVA, September 19 – 22</td>
<td>72</td>
<td>19</td>
<td>60</td>
<td>60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kougias</td>
<td>2009</td>
<td>Am J Surgery, 198:645-649</td>
<td>31</td>
<td>23</td>
<td>100</td>
<td>75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Farraj</td>
<td>2009</td>
<td>J Invasive Cardiol, 21:278-281</td>
<td>32</td>
<td>15.4</td>
<td>100</td>
<td>80</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rebellino</td>
<td>2009</td>
<td>Cath Cardiovasc Interv, 73:701-705</td>
<td>32</td>
<td>NR</td>
<td>NR</td>
<td>82</td>
<td>75</td>
<td>75</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>McQuade</td>
<td>2010</td>
<td>J Vasc Surg, 52:584-591</td>
<td>50</td>
<td>25.6</td>
<td>NR</td>
<td>72</td>
<td>63</td>
<td>63</td>
<td>59</td>
<td></td>
</tr>
<tr>
<td>Average / Total</td>
<td></td>
<td></td>
<td>1103</td>
<td>16.1</td>
<td>62</td>
<td>77</td>
<td>72</td>
<td>67</td>
<td>59</td>
<td></td>
</tr>
</tbody>
</table>

NR = Not Reported

Are there any clinical considerations when using the GORE® VIABAHN® Endoprosthesis?

Some key clinical learnings that have emerged include:
- Avoid non-compliant lesions
- Ensure adequate inflow and outflow (i.e., at least one vessel run-off)
- Correct sizing is key
- Land device at least 1 cm into healthy vessel proximally and distally to the lesion
- Every region pre-treated with PTA needs to be covered by the device
- During post-dilatation, only balloon inside the region covered by the device
- Consider an antiplatelet regimen post-procedure

Please refer to Instructions for Use for full indications / contraindications
What about in-stent restenosis?

The ePTFE lining of the GORE® VIABAHN® Endoprosthesis limits in-stent restenosis, and because of this, patency is independent of lesion length. For the studies presented in the table above, a plot of the one year primary patency versus lesion length (17 studies, 1103 limbs) shows that patency is indeed independent of lesion length.

Is there any Level 1 clinical data for the GORE® VIABAHN® Endoprosthesis?

There are two published studies that present Level 1 clinical data for the GORE® VIABAHN® Endoprosthesis.

From 1998 – 1999, the GORE® VIABAHN® Endoprosthesis was evaluated in a randomized, multicenter trial, and published in the Journal of Vascular and Interventional Radiology in 2008¹. The purpose of the study was to compare the safety and effectiveness of the GORE® VIABAHN® Endoprosthesis to percutaneous transluminal angioplasty (PTA) in patients with chronic lower limb ischemia or chronic lifestyle altering claudication due to superficial femoral artery (SFA) atherosclerotic disease. A total of 241 patients or 244 cases (limbs) were treated in the study. Each site was permitted up to two training cases. A total of 47 training cases were performed; 197 cases were randomized with 100 assigned to PTA and 97 to the GORE® VIABAHN® Device. The GORE® VIABAHN® Endoprosthesis showed 25% better 12-month redefined primary patency than PTA: 65% vs. 40%. Patency in this study was defined as target vessel, not target lesion, patency (PSVR < 2.0 via DUS at 12 months).

A second study was published in the Journal of Vascular Surgery by McQuade et al.² in 2010. In this randomized, single center study, the GORE® VIABAHN® Endoprosthesis was compared to prosthetic fem-pop surgical bypass in treating superficial femoral artery occlusive disease. Fifty limbs were enrolled into each study arm with ankle-brachial indices and color duplex flow sonography imaging performed at 3, 6, 9, 12, 18, 24, 36, and 48 months. The primary patency rate for the stent graft group at 12, 24, 36, and 48 months was 72%, 63%, 63%, and 59%, respectively, while the primary patency for the surgical bypass group was 76%, 63%, 63%, and 58%, respectively. The average treatment length was 25.6 cm for the GORE® VIABAHN® Endoprosthesis.

What about SFA stent fractures with the GORE® VIABAHN® Endoprosthesis?

The device has excellent flexibility and is well-suited for the SFA. There is a very low incidence (< 0.01%) of reported stent fractures in the SFA.
What are the potential failure modes of the GORE® VIABAHN® Endoprosthesis?

Although primary patency at one year is excellent (77%), the literature does report some failure modes and how they can be mitigated. Examples include:

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Mitigators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edge Restenosis</td>
<td>Don’t balloon outside the device; properly oversize the device (5 – 20%)</td>
</tr>
<tr>
<td>Progression of Disease</td>
<td>Cover all of the diseased vessel; distal and proximal landing zones should be in healthy vessel</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>Complete post-dilatation; appropriate antiplatelet therapy; regular patient follow-up</td>
</tr>
</tbody>
</table>

What is the effect of the contoured proximal edge?

The contoured proximal edge is a manufacturing change that was implemented to improve repeatability in processing, and leads to improved apposition of the device to the vessel wall. The conformable fit of the stent-graft may improve flow dynamics at the proximal edge of the stent.
What is the rate of thrombosis for the GORE® VIABAHN® Endoprosthesis?

There are two thrombosis events to consider: acute and late.

**Acute Thrombosis (< 30 days of procedure).** As reported in the literature, the GORE® VIABAHN® Endoprosthesis has an acute thrombosis rate of 2 – 5%.\(^3\),\(^4\),\(^5\),\(^6\). This is similar to the 3 – 4% acute thrombosis rates of bare nitinol stents\(^7\),\(^8\). Thus, this acute thrombosis rate is likely procedure related rather than related to any inherent thrombogenicity of the device.

**Late Thrombosis (> 30 days of procedure).** If a GORE® VIABAHN® Endoprosthesis fails, it may present itself as a thrombosed endoprosthesis. Often this is secondary to another failure mode (edge stenosis or disease progression) and a result of low blood flow through the endoprosthesis. The occluded endoprosthesis can be revised, and the adjacent disease treated using an additional endoprosthesis. The long-term patency of the GORE® VIABAHN® Endoprosthesis at five years in a selected patient population was recently reported to be 62% (primary patency) and 90% (secondary patency) by Fischer, *et al*\(^9\). This secondary patency demonstrates the durability and patency of the endoprosthesis after revision.

![Images courtesy of Richard Saxon, MD](https://example.com)
References


[Consult Instructions for Use]