



**GORE® VIABAHN®**

Endoprosthesis  
with Heparin Bioactive Surface<sup>\*,†</sup>

PROVEN PATENCY.<sup>‡</sup>  
DEMONSTRATED DURABILITY.<sup>‡</sup>

Gore Japan Post-Market Clinical Study



\* As used by Gore, Heparin Bioactive Surface refers to Gore's proprietary CBAS® Heparin Surface.

† Also referred to as the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface in some regions.

‡ GORE® VIABAHN® Endoprosthesis. W. L. Gore & Associates website. Accessed October 24, 2023. <https://www.goremedical.com/VIABAHN/references>.

***Together, improving life***

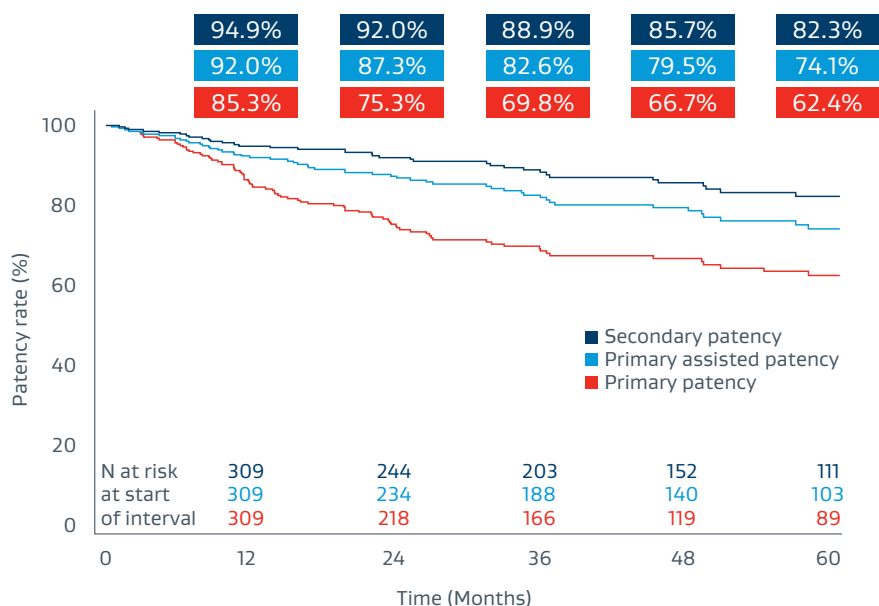
# Gore Japan Post-Market Clinical Study results: Durable clinical outcomes through 5 years

Complex, real-world patient population with challenging superficial femoral artery (SFA) disease<sup>1</sup>:

- 24 cm average lesion length
- 70% chronic total occlusions (CTO)
- 27% critical limb-threatening ischemia (CLTI)
- 48% TASC II D lesions

## Proven patency

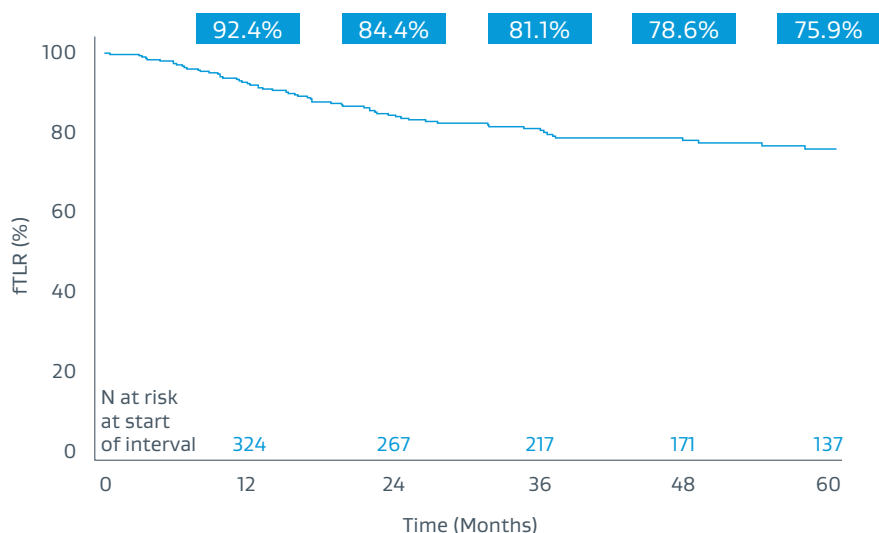
85% primary patency at 1 year, 62% at 5 years<sup>2</sup>



Multivariate analyses did not reveal differences in primary patency for risk factors including lesion length, TASC II class, calcification or CLTI.<sup>2</sup>

## Demonstrated durability

92.4% freedom from target lesion revascularization (fTLR) at 1 year, 75.9% at 5 years<sup>2</sup>



No acute limb ischemia or stent fractures through 5 years.<sup>2</sup>

\* Weighted average lesion length. † One-year weighted average primary patency. ‡ CTO percentage defined as percentage of TASC II D.

Proven patency at 1 year in complex SFA lesions across 7 multicenter, prospective, randomized or single-arm studies<sup>2-8</sup>

1,089

lesions  
studied

71%

chronic total  
occlusions (CTO)

23 cm

average  
lesion length\*

80%

average  
primary patency†

Trial name	Number of lesions	Mean lesion length (cm)	CTOs (%)	1-year primary patency (%)	1-year secondary patency (%)
SuperB Study <sup>3</sup>	63	23	75 <sup>‡</sup>	65	86
Gore VIPER Clinical Study <sup>4</sup>	119	19	56	73	92
VIASTAR Trial <sup>5</sup>	66	19	79	78	90
25 cm Trial <sup>6</sup>	71	27	93	67	97
Gore Japan IDE Clinical Study <sup>7</sup>	103	22	66	88	98
<b>Gore Japan Post-Market Clinical Study<sup>2</sup></b>	<b>324</b>	<b>24</b>	<b>70</b>	<b>85</b>	<b>95</b>
VANQUISH Study <sup>8</sup>	343	25	71	80	N/A
<b>Combined results (Weighted average, as appropriate)</b>	<b>1,089</b>	<b>23</b>	<b>71</b>	<b>80</b>	<b>94</b>

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8. Iida O, Takahara M, Soga Y, *et al.*; VANQUISH Investigators. One-year outcomes of heparin-bonded stent-graft therapy for real-world femoropopliteal lesions and the association of patency with the prothrombotic state based on the prospective, observational, multicenter Viabahn Stent-Graft Placement for Femoropopliteal Diseases Requiring Endovascular Therapy (VANQUISH) Study. *Journal of Endovascular Therapy* 2021;28(1):123-131.



**INDICATIONS FOR USE IN THE U.S.:** The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0–7.5 mm. The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0–6.5 mm. The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0–12 mm. The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts. **CONTRAINDICATIONS:** The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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 incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at [eifu.goremedical.com](http://eifu.goremedical.com) for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available.  $R_{X\text{Only}}$

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