GORE® VIABAHN®
Endoprosthesis
with Heparin Bioactive Surface*,†

PROVEN PATENCY.‡ DEMONSTRATED DURABILITY.‡

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

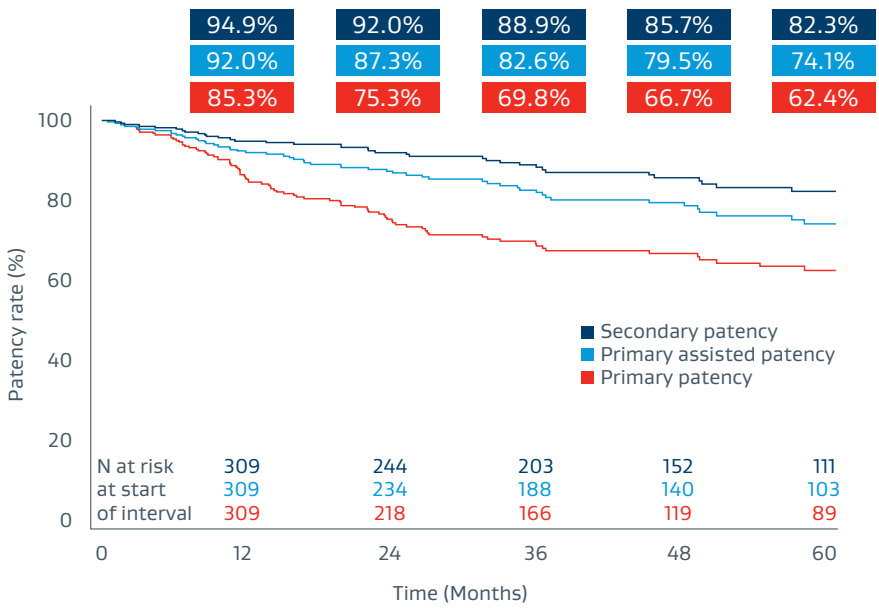
Gore Japan Post-Market Clinical Study results: Durable clinical outcomes through 5 years

Complex, real-world patient population with challenging superficial femoral artery (SFA) disease[1]:

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

Proven patency

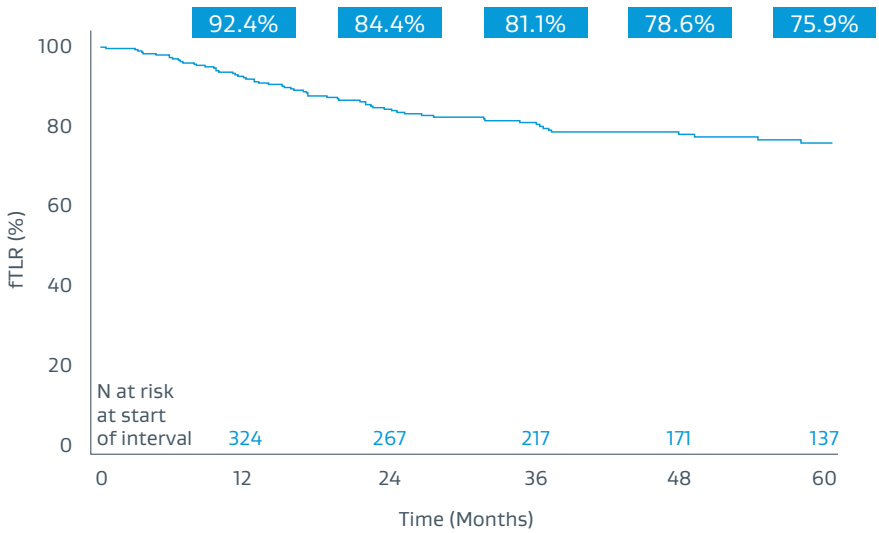
85% primary patency at 1 year, 62% at 5 years[2]



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

Demonstrated durability

92.4% freedom from target lesion revascularization (fTLR) at 1 year, 75.9% at 5 years[2]



No acute limb ischemia or stent fractures through 5 years.[2]

* 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[2–8]

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[3]	63	23	75‡	65	86
Gore VIPER Clinical Study[4]	119	19	56	73	92
VIASTAR Trial[5]	66	19	79	78	90
25 cm Trial[6]	71	27	93	67	97
Gore Japan IDE Clinical Study[7]	103	22	66	88	98
Gore Japan Post-Market Clinical Study[2]	**324**	**24**	**70**	**85**	**95**
VANQUISH Study[8]	343	25	71	80	N/A
Combined results (Weighted average, as appropriate)	**1,089**	**23**	**71**	**80**	**94**

References

1. Iida O, Ohki T, Soga Y, *et al.* Twelve-month outcomes from the Japanese post-market surveillance study of the Viabahn Endoprosthesis as treatment for symptomatic peripheral arterial disease in the superficial femoral arteries. *Journal of Endovascular Therapy* 2022;29(6):855-865. https://journals.sagepub.com/doi/full/10.1177/15266028211067739
2. Iida O. 5-year outcomes of the Gore® Viabahn® Endoprosthesis for the treatment of complex femoropopliteal lesions in a Japanese population. Presented at the 21st Annual Vascular InterVentional Advances (VIVA); October 30, 2023-November 2, 2023; Las Vegas, NV.
3. Reijnen MMPJ, van Walraven LA, Fritschy WM, *et al.* 1-year results of a multicenter randomized controlled trial comparing heparin-bonded endoluminal to femoropopliteal bypass. *JACC: Cardiovascular Interventions* 2017;10(22):2320-2331. http://www.sciencedirect.com/science/article/pii/S1936879817319775
4. Saxon RR, Chervu A, Jones PA, *et al.* Heparin-bonded, expanded polytetrafluoroethylene-lined stent graft in the treatment of femoropopliteal artery disease: 1-year results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) Trial. *Journal of Vascular & Interventional Radiology* 2013;24(2):165-173.
5. Lammer J, Zeller T, Hausegger KA, *et al.* Heparin-bonded covered stents versus bare-metal stents for complex femoropopliteal artery lesions: the randomized VIASTAR trial (Viabahn endoprosthesis with PROPATEN bioactive surface [VIA] versus bare nitinol stent in the treatment of long lesions in superficial femoral artery occlusive disease). *Journal of the American College of Cardiology* 2013;62(15):1320-1327.
6. Zeller T, Peeters P, Bosiers M, *et al.* Heparin-bonded stent-graft for the treatment of TASC II C and D femoropopliteal lesions: the Viabahn-25 cm Trial. *Journal of Endovascular Therapy* 2014;21(6):765-774.
7. Ohki T, Kichikawa K, Yokoi H, *et al.* Long-term results of the Japanese multicenter Viabahn trial of heparin bonded endovascular stent grafts for long and complex lesions in the superficial femoral artery. *Journal of Vascular Surgery* 2021;74(6):1958-1967.e2. https://www.sciencedirect.com/science/article/pii/S0741521421010119
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 *Via*bahn Ste*n*t-Graft Placement for Femoropopliteal Diseases Re*qui*ring Endova*s*cular T*h*erapy (VANQUISH) Study. *Journal of Endovascular Therapy* 2021;28(1):123-131.

Consult Instructions for Use
eifu.goremedical.com

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 for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

W. L. Gore & Associates, Inc.
goremedical.com

Asia Pacific +65 6733 2882 **Australia/New Zealand** 1800 680 424 **Europe** 00800 6334 4673
United States Flagstaff, AZ 86004 800 437 8181 928 779 2771