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

PROVEN PATENCY.‡
DEMONSTRATED DURABILITY.‡

Gore Japan Post-Market Clinical Study
Gore Japan IDE Clinical Study

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

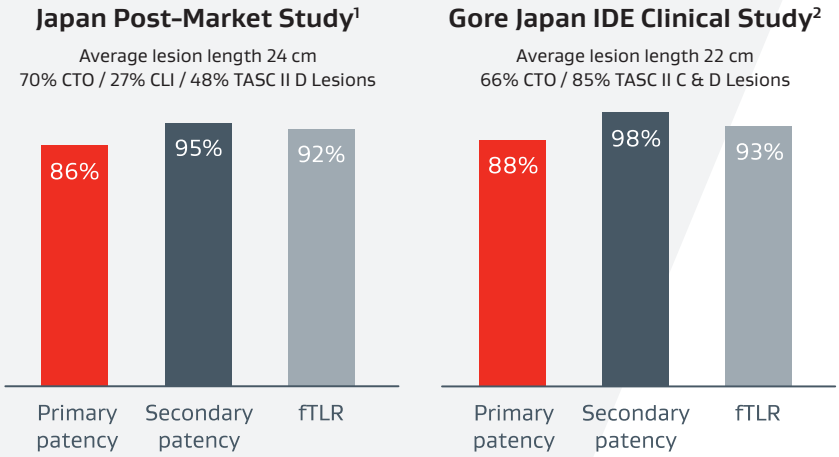
† Also referred to as the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface in some regions.

‡ GORE® VIABAHN® Endoprosthesis. W. L. Gore & Associates website. Accessed January 28, 2021. https://www.goremedical.com/VIABAHN/references.

Together, improving life

Gore Japan Post-Market Clinical Study results: Proven patency in challenging disease at one year

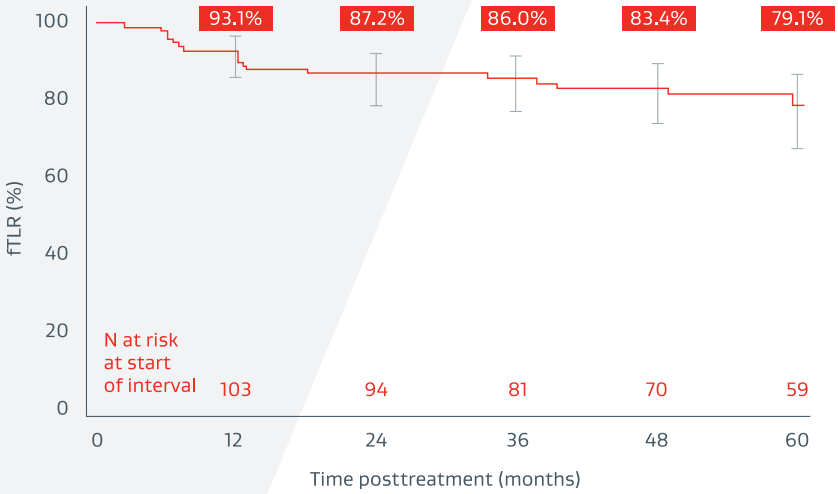
The VIABAHN® Device demonstrates consistent outcomes at one year, including 86% primary patency in a complex patient population with 27% critical limb ischemia (CLI) and 48% TASC II D lesions.[1]



Japan IDE Study results: Durable clinical outcomes through five years

79.1% freedom from target lesion revascularization (fTLR) at five years.[2]

At five years, patients experienced 100% limb salvage, no acute limb ischemia and no stent fractures.*,[2]



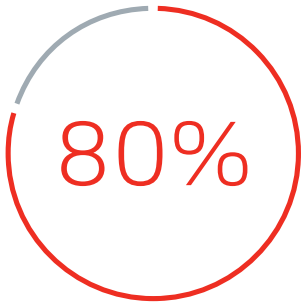
* At five years, patient population, n = 61.
† Weighted average lesion length.
‡ One-year weighted average primary patency.
§ CTO percentage defined as percentage of TASC II D.

Proven patency in complex superficial femoral artery (SFA) lesions across seven multicenter, prospective, randomized or single-arm studies[1–7]

1,089
Lesions studied

71%
Chronic total occlusions (CTO)

23 cm
Average lesion length†



Average primary patency‡

Over 1,000 complex lesions studied

Trial name	Number of lesions	Mean lesion length (cm)	CTOs (%)	One-year primary patency (%)	One-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
Japan IDE Study[2]	103	22	66	88	98
Japan Post-Market Study[1]	324	24	70	86	95
VANQUISH Study[7]	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. 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
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. 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 Endovas*c*ular 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. $\mathrm{R}_{\mathrm{X\ Only}}$

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