

GORE[®] VIABAHN[®] Endoprosthesis with PROPATEN Bioactive Surface^{*}

PROVEN PATENCY.[†] DEMONSTRATED DURABILITY.[†]

Gore Japan Post-Market Clinical Study

 * As used by Gore, PROPATEN Bioactive Surface refers to Gore's proprietary CBAS $^{\circ}$ Heparin Surface.

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

Together, improving life

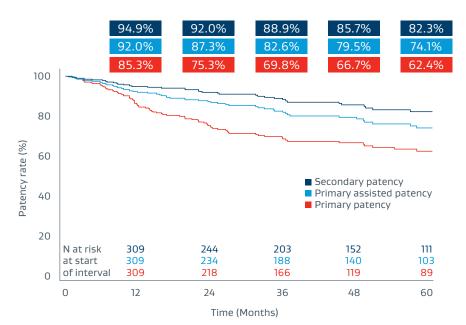
Gore Japan Post-Market Clinical Study results: Durable clinical outcomes through 5 years

Complex, real-world patient population with challenging superficial femoral artery (SFA) disease¹:

- 24 cm average lesion length
- 70% chronic total occlusions (CTO)

Proven patency

85% primary patency at 1 year, 62% at 5 years²



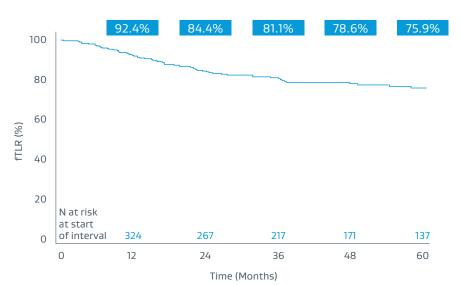
Multivariate analyses did not reveal differences in primary patency for risk factors including lesion length, TASC II class, calcification or CLTI.²

27% critical limb-threatening ischemia (CLTI)

48% TASC II D lesions

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 studies²⁻⁸

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

- lida 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. lida 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.
- 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.
- 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.
- 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. lida 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.



Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the market where this product is available. $R_{X,ONV}$

Products listed may not be available in all markets.

CBAS is a trademark of Carmeda AB, a wholly owned subsidiary of W. L. Gore & Associates, Inc. GORE, *Together, improving life*, PROPATEN, VIABAHN and designs are trademarks of W. L. Gore & Associates. © 2022, 2023 W. L. Gore & Associates, Inc. 231279058-EN DECEMBER 2023

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

