



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.

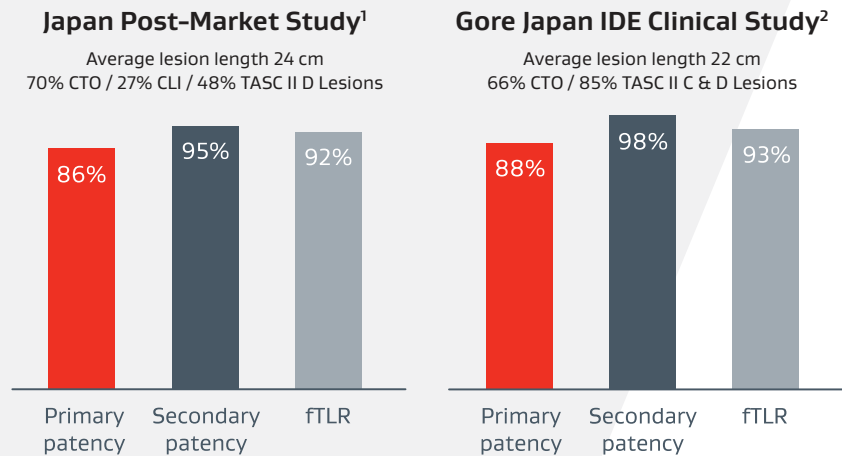
† Also referred to as the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface in some regions.

‡ 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

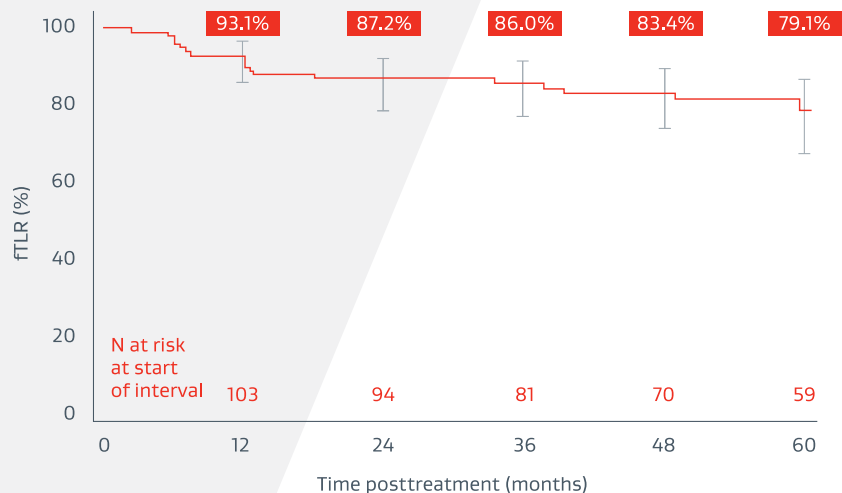
The VIABAHN® Device demonstrates consistent outcomes at one year, including 86% primary patency in a complex patient population with 27% critical limb ischemia (CLI) and 48% TASC II D lesions.¹



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 studies¹⁻⁷

1,089

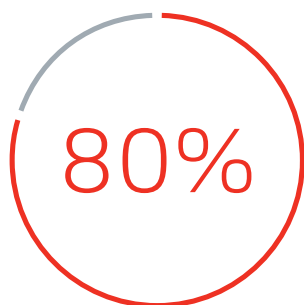
Lesions studied

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

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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. R_{X} Only

Products listed may not be available in all markets.

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