GORE® VIABAHN®
Endoprosthesis
with Heparin Bioactive Surface*

DEMONSTRATED DURABILITY IN SUPERFICIAL FEMORAL ARTERY (SFA) IN-STENT RESTENOSIS (ISR)

The Gore RELINE MAX Clinical Study[1], a prospective, single-arm, multicenter study, demonstrates the safety and efficacy of the VIABAHN® Device through **three years** in the treatment of real-world SFA ISR lesions.

Safe

100% freedom from major amputations in a cohort including Rutherford category 4+ patients at baseline.

100% freedom from VIABAHN® Device stent fractures.

Three-year follow-up of 86 patients

ISR lesion presentation:

- **52% long diffuse lesions**
- **29% total occlusions**
- **33% moderate-severe calcification**

Effective

65% freedom from target lesion revascularization (fTLR).

fTLR outcomes were independent of degree of calcification, gender or diabetes status.

> 80% of patients maintained a ≥ 1 Rutherford category improvement.

.24 improvement in mean resting ankle-brachial index (ABI) ($P < .001$, .92 mean ABI).†

* As used by Gore, Heparin Bioactive Surface refers to Gore's proprietary CBAS® Heparin Surface.
† ($P < .001$) Statistically significant change from pre-procedure.

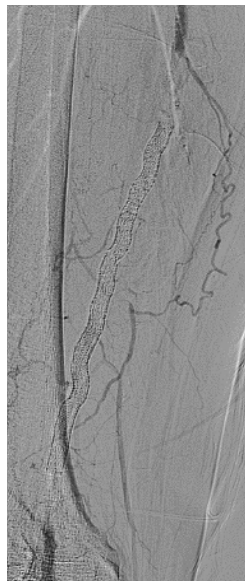
Together, improving life

Manage SFA disease complexity with confidence

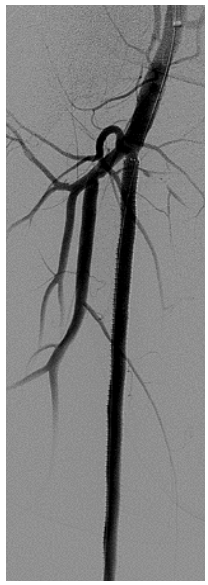
Case complexities such as calcification, total occlusion and long lesions have been associated with an increased rate of restenosis, occlusion and provisional stenting in SFA disease.[2–8]

Endoluminal bypass with stent grafts offers advantages for complex SFA lesions, including ISR:

- Excluding plaque[9]
- Preventing in-stent neointimal hyperplasia[10]
- Decreasing the risk of complications stemming from distal embolization, perforation, rupture or dissection[9]



SFA ISR lesion with occluded bare metal stent



Post-reline with two 7 x 25 cm VIABAHN® Devices

Images courtesy of Peter Soukas, M.D. Used with permission.

References

1. Soukas P. Three-year results of the GORE® VIABAHN® stent-graft in the superficial femoral artery for in-stent restenosis. Presented at VEINS (Venous Endovascular INterventional Strategies) and VIVA (Vascular InterVentional Advances) Annual Conference; October 31, 2022- November 2, 2022; Las Vegas, NV. **2.** Kum S. Evolution and challenges of ISR. How to approach. Presented at Leipzig Interventional Course (LINC 2020); January 28-31, 2020; Leipzig, Germany. **3.** Tepe G, Laird J, Schneider P, *et al*; IN.PACT SFA Trial Investigators. Drug-coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and popliteal peripheral artery disease: 12-month results from the IN.PACT SFA Randomized Trial. *Circulation* 2015;131(5):495-502. **4.** Iida O, Takahara M, Soga Y, *et al*; ZEPHYR Investigators. 1-year results of the ZEPHYR Registry (Zilver PTX for the Femoral Artery and Proximal Popliteal Artery): predictors of restenosis. *JACC:Cardiovascular Interventions* 2015;8(8):1105-1112. **5.** Kistner CM, Lammer J, Willfort-Ehringer A, *et al*. Paclitaxel-eluting balloon versus standard balloon angioplasty in in-stent restenosis of the superficial femoral and proximal popliteal artery: 1-year results of the PACUBA Trial. *JACC: Cardiovascular Interventions* 2016;9(13):1386-1392. **6.** Stavroulakis K, Argyriou A, Watts M, *et al*. How to deal with calcium in the superficial femoral artery. *The Journal of Cardiovascular Surgery.* 2019;60(5). **7.** Varghese V, Virk HUH, Lakhter V, *et al*. Femoral artery chronic total occlusion revascularization (FACTOR) score and algorithm: feasibility and validation in a single-center study of femoropopliteal occlusions. *Journal of Invasive Cardiology* 020;32(12):E338-E348. **8.** Scheinert D, Micari A, Brodmann M, *et al*; IN.PACT Global Study Investigators. Drug-coated balloon treatment for femoropopliteal artery disease. *Circulation: Cardiovascular Interventions* 2018;11(10):e005654. **9.** Ohki T, Kichikawa K, Yokoi H, *et al*. Outcomes of the Japanese multicenter Viabahn trial of endovascular stent grafting for superficial femoral artery lesions. *Journal of Vascular Surgery* 2017;66(1):130-142.e1 **10.** Geraghty PJ, Mewissen MW, Jaff MR, Ansel GM; VIBRANT Investigators. Three-year results of the VIBRANT trial of VIABAHN endoprosthesis versus bare nitinol stent implantation for complex superficial femoral artery occlusive disease. *Journal of Vascular Surgery* 2013;58(2):386-395.e4.

Consult Instructions for Use
eifu.goremedical.com

INTENDED USE/INDICATIONS: 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.

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