

GORE® VIABAHN®

Endoprosthesis  
with Heparin Bioactive Surface\*



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

The Gore RELINE MAX Clinical Study<sup>1</sup>, 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 (TLR).

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

**> 80%**

of patients maintained a  $\geq 1$  Rutherford category improvement.

**.24**

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

\* 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.<sup>2-8</sup>

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

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



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

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 Consult Instructions for Use  
[eifu.goremedical.com](http://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](http://eifu.goremedical.com) for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available.  $\text{Rx}$  Only

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W. L. Gore & Associates, Inc.  
[goremedical.com](http://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

