GORE® VIABAHN®
Endoprosthesis with PROPATEN
Bioactive Surface*

Together, improving life

THEIR NEXT FIVE YEARS **IS IN YOUR HANDS**

in SFA†

Your choice today can shape your patients' future. Choose the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface with 100% freedom from acute limb ischemia (ALI)[1] at 5 years and with 79.1% freedom from target lesion revascularization (fTLR)[2] at 5 years, for long-lasting intervention-free outcomes.

*As used by Gore, PROPATEN Bioactive Surface refers to Gore's proprietary CBAS® Heparin Surface.
†SFA, superficial femoral artery.

GORE

When treating complex superficial femoral artery (SFA) disease, how does long-term durability impact your choice of treatment?

SFA disease is a leading cause of symptomatic peripheral artery disease (PAD), including intermittent claudication and chronic limb-threatening ischemia (CLTI).[3,4]

Endovascular intervention is an established procedure for the management of SFA disease. However, conventional techniques like balloon angioplasty and bare metal stenting can have **restenosis rates as high as 40% at 12 months,** creating a potential burden for patients and health care systems.[5–10]

A study of target lesion revascularization (TLR) procedures conducted across 13 hospitals in Europe (N = 482)[11] found that:

The mean cost for all TLR procedures, including open, endovascular and hybrid procedures, was

€21,917 ± €2,110

43% of patients

were admitted to an intensive care unit (ICU) following a TLR procedure, with a mean cost of €1,193 per overnight ICU stay.[11]

Lesion complexity has been shown to drive the cost of SFA endovascular interventions. Despite the wide range of treatment options available, chronic total occlusions and calcification may continue to contribute to the burden on health care systems.[12–14]

This highlights the need for endovascular devices engineered to withstand the anatomical demands of the SFA and slow disease progression, ultimately helping to maximize the potential for long-term intervention-free outcomes.[12–14]

With proven long-term procedural success in complex SFA lesions, the VIABAHN® Device delivers durable performance for up to 5 years, to enhance the endovascular treatment journey and support patient care.[1,9]

The long-term performance of the VIABAHN® Device was assessed in a real-world Japanese practice setting[1]

AIM

Assess the 5-year safety and effectiveness outcomes of the VIABAHN® Device as a treatment for patients with symptomatic PAD in complex femoropopliteal (FP) lesions.

METHODS

Outcome measures evaluated at 5 years included:

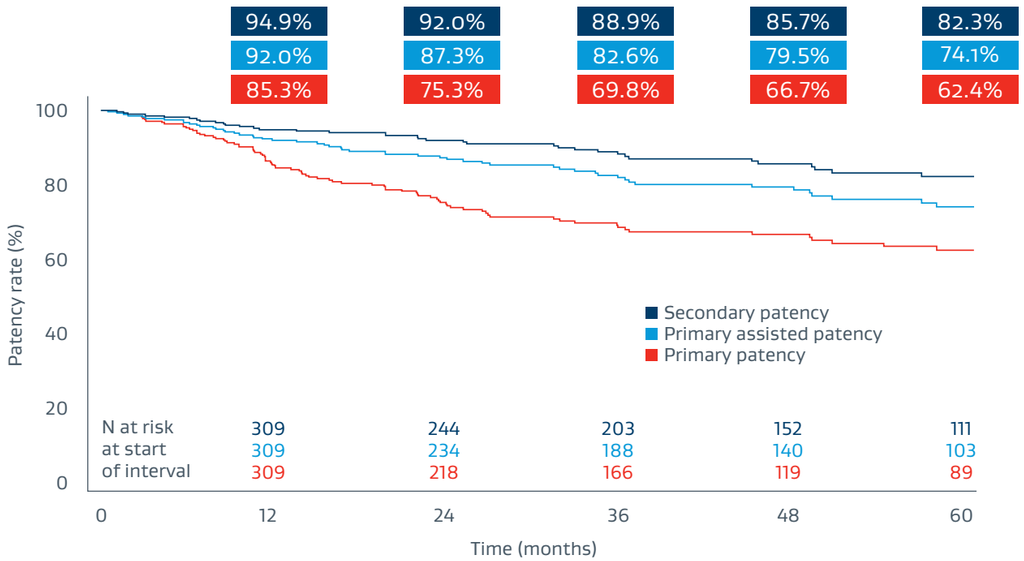
- Primary patency
- Primary-assisted patency
- Secondary patency
- fTLR
- Occurrence of device or procedure-related serious adverse events
- Occurrence of stent fractures

POPULATION

321 patients from 64 sites in Japan were included in the study. Patients with symptomatic PAD in FP lesions ≥ 10 cm and reference vessel diameters ranging from 4.0–7.5 mm were eligible for enrollment.

Proven 5-year patency in complex SFA lesions[1]

5-year patency outcomes with the VIABAHN® Device[1]



The multivariate analyses did not reveal any differences in primary patency for the following risk factors: Trans-Atlantic Inter-Society consensus (TASC) II length, lesion length, diabetes mellitus, gender, proximal vessel diameter, calcification, hemodialysis or CLTI.[1]

85.3%

1-year primary patency[1]

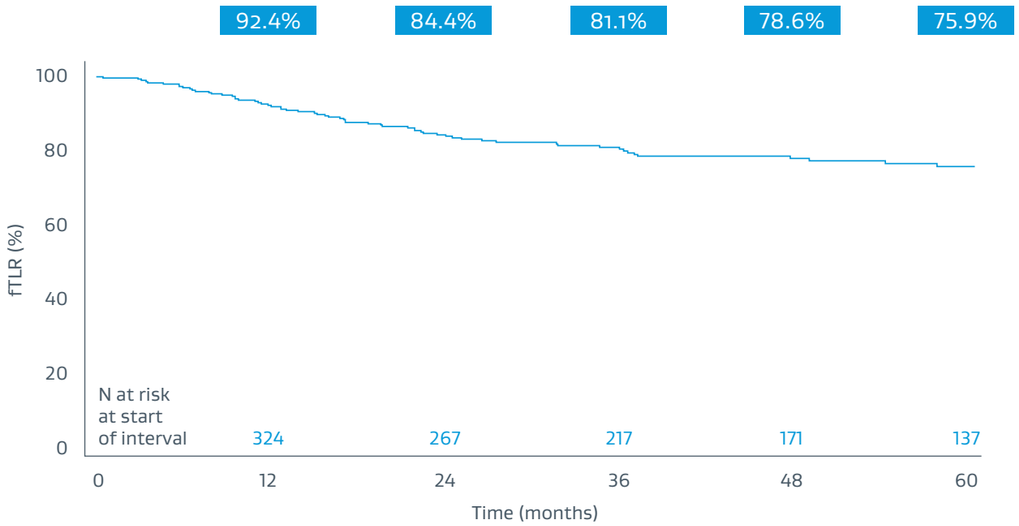
62.4%

5-year primary patency[1]

Enhance durability and establish long-term patency in your SFA procedures with the VIABAHN® Device.[1,9]

Sustained durability through 5 years in SFA treatment[1]

5-year fTLR outcomes with the VIABAHN® Device[1]



75.9%

fTLR at 5 years[1]

100.0%

freedom from ALI and stent fractures through 5 years[1]

Change in Rutherford classification at 5 years[1,2,15,16]

77.6%

(n = 90/116) patients classified at Rutherford category 0

2.3 ± 1.4

Mean improvement from baseline

The VIABAHN® Device has been shown to improve patient quality of life compared to baseline.[1,2,15,16]

Could the VIABAHN® Device provide true value for you and your patients in complex SFA procedures?

Designed by the experts to deliver reliable long-term performance in SFA treatment[1]

The combination of an **ultra-thin ePTFE** tube and a single external **nitinol wire stent** creates a smooth barrier that provides flexible, lasting support.[17]

Contoured edge
Minimizes in-folding for enhanced apposition.[24]

Fitted with **4 radiopaque markers** on each end for accurate placement and enhanced device visibility.[17]

The largest device offering available, for suitability across **a wide range of lesion types,** including the most challenging SFA cases[17–23]:

- Diameters ranging from 5–13 mm
- Maximum length of 25 cm

Nitinol stent pattern along its entire length[17]:

- No longitudinal connections
- Flexibility maintains flow at points of flexion and enables use across a range of anatomical options

Featuring **Gore's CBAS® Heparin Surface**
An end-point covalent heparin bonding technology designed to resist thrombus formation.[25]

At Gore Medical, we're committed to empowering physicians to succeed. It's been that way since our founding over half a century ago. Today, we build transformative technologies designed to elevate the clinical experience and help address patients' needs.

We're driven by something different. Because what's at stake is everything.

ALI, acute limb ischemia; CLTI, chronic limb-threatening ischemia; FP, femoropopliteal; fTLR, freedom from target lesion revascularization; ICU, intensive care unit; PAD, peripheral artery disease; SFA, superficial femoral artery; TASC, TransAtlantic Inter-Society consensus; TLR, target lesion revascularization.

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