GORE® VIABAHN®
Endoprosthesis
with Heparin Bioactive Surface*

OPEN MORE POSSIBILITIES

*As used by Gore, Heparin Bioactive Surface refers to Gore's proprietary CBAS Heparin Surface.

Together, improving life

Arteriovenous (AV) Access

Proven success in AV Access, even the most challenging cases, including:

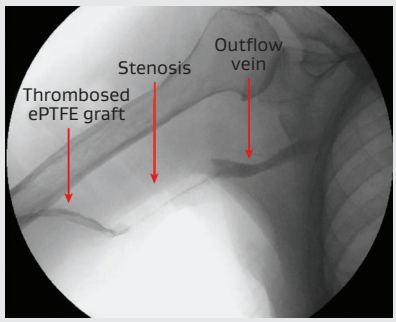
- Early percutaneous transluminal angioplasty (PTA) failures
- Lesions at points of flexion
- Thrombosed grafts

High primary patency even in the most challenging disease:

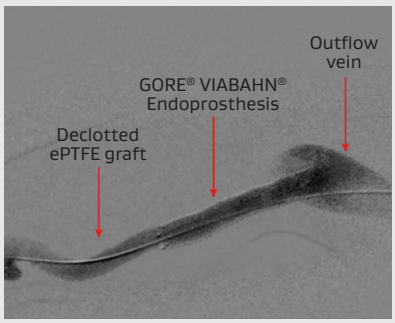
Increased trend in primary patency in thrombosed grafts of both the target lesion and the circuit by ~50% when compared to PTA at six months.[1]

Provided consistent patency independent of the number of times a lesion has previously been treated.[1]

Durable treatment of thrombosed AV grafts



Before: Graft thrombosis secondary to outflow stenosis at the venous anastamosis of an AV graft.



After: At 60 months post-placement, the GORE® VIABAHN® Endoprosthesis has maintained secondary patency without any further episodes of thrombosis.

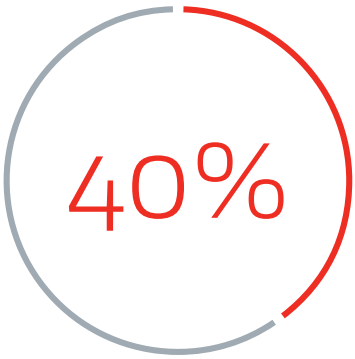
Images courtesy of Daniel V. Patel, M.D. Used with permission.

* Caution should be used when interpreting post-hoc analysis.

† The difference between the diameter of the vein and the device is ≥ 1 mm.

‡ The difference between the diameter of the vein and the device is < 1 mm.

Durable clinical study outcomes in complex cases: 83% access secondary patency and zero device fractures at two years when placed across the elbow.[2]



Proven to reduce reinterventions:

Lowered mean number of interventions over two years in thrombosed grafts[3]

Recommendations for optimal outcomes in AV Access

- Outflow wall apposition to the outflow vein is not necessary for quality outcomes
- Follow the IFU recommendation for 5-20% oversizing using the graft inner diameter as the target vessel
- Do not use PTA outside of the device

A post-hoc analysis of the Gore REVISE Clinical Study demonstrated that undersizing the stent graft to the outflow vein trended toward increased patency[*,4]

	Device apposition relative to the outflow vein	
6-month outcomes	**Undersized[†]**	**Apposed[‡]**
Target lesion primary patency	60%	47%
Circuit primary patency	47%	40%

Note: The GORE® VIABAHN® Endoprosthesis should always be sized 5% to 20% greater than the AV graft diameter per the *Instructions for Use*.

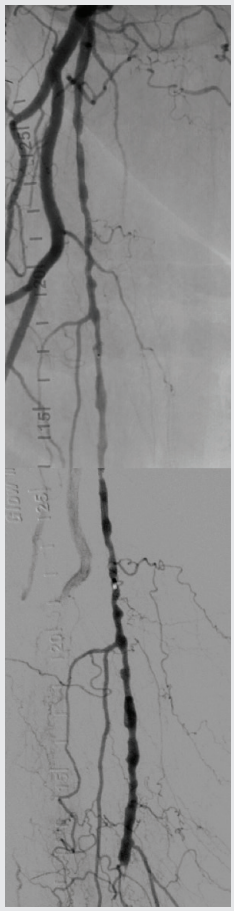
Superficial femoral artery (SFA)

Strong clinical performance in the most challenging cases including long SFA lesions and chronic total occlusions (CTOs).

High primary patency even in the most challenging disease:

- 88% 12-month primary patency in SFA lesions averaging 22 cm in length[5]

Long SFA lesion of the right SFA



Before: Proximal SFA disease and mid-SFA occlusion.

After: Post-placement of three 5 mm GORE® VIABAHN® Devices.

Images courtesy of James Persky, M.D. Used with permission.

* Data on file 2020; W. L. Gore & Associates, Inc; Flagstaff, AZ.

† Weighted average lesion length.

‡ One-year weighted average primary patency.

Proven patency for complex SFA lesions across six multicenter, prospective, randomized or single arm studies[5–10]

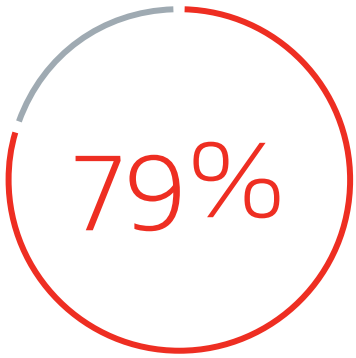
746 Limbs studied	71% CTOs*
22 cm Average lesion length†	80% Average primary patency‡

Durable clinical study outcomes in complex cases:

Comparable clinical results to above the knee surgical bypass (both prosthetic[11] and native vein[8]).

3-year secondary patency in complex disease

(27 cm average lesion length, 93% CTOs)[12]



5-year freedom from target lesion revascularization (fTLR)[13]

Recommendations for optimal outcomes in the SFA

Device sizing considerations

- Treat all of the disease (stent "normal to normal")[12]
- Overlap devices by at least 1 cm[12]
- Avoid excessive oversizing (> 20%)[12]

Implantation considerations

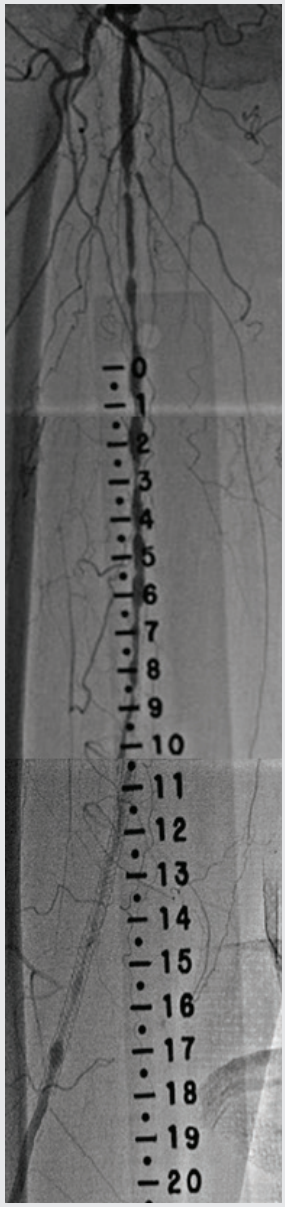
- Ensure adequate inflow and outflow[12]
- Post dilate[12]
- Do not use PTA outside of the device[12]
- Place device at the SFA origin if proximal SFA disease is present[12]

Follow-up considerations

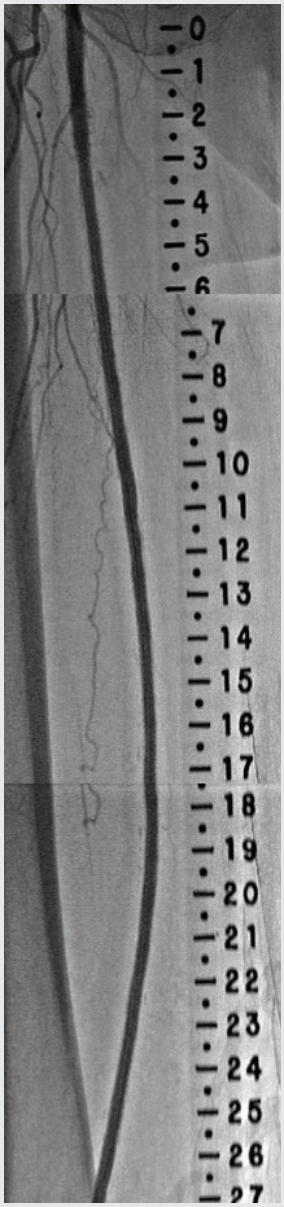
- Regular duplex ultrasonography follow-up[14]
- Prescribe appropriate antiplatelet therapy[12]
- Treat progressing disease[14]

In-stent restenosis (ISR) of the SFA

Durable treatment for complex in-stent restenotic lesions.



Before: Diffuse SFA ISR in long-stented segment in the SFA.



After: Completion angiogram after placement of GORE® VIABAHN® Devices for ISR in the SFA.

High primary patency even in the most challenging disease:

75% one-year primary with an average lesion length of over 17 cm.[15]

Fewer than one third the number of patients required an intervention at one year compared to PTA.[12]

Durable clinical study outcomes in complex cases:

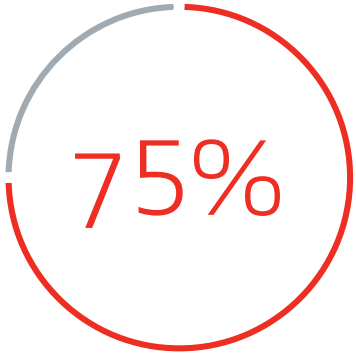
Four times greater primary patency compared to PTA at two years.[16]

More than three times greater fTLR compared to PTA at two years.[12]

Proven to reduce reinterventions:

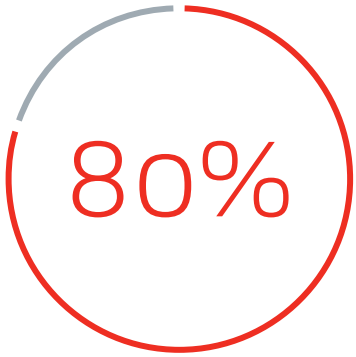
Fewer patients had reintervention procedures compared to PTA at two years.[12]

Images courtesy of Robert Minor, M.D. Used with permission.



primary patency at one year[15]

17.3 cm mean lesion length[15]



fTLR at one year[15]

Recommendations for optimal outcomes in ISR

- Extend the device at least 1 cm proximally and distally from the previously placed stent[12]
- Cover any adjacent disease at least 1 cm beyond the proximal and distal margins of the lesion[12]
- Follow the IFU recommendation for 5–20% oversizing using the healthy vessel diameter immediately proximal and distal to the lesion[12]
- Ensure guidewire has traversed the lesion intraluminally before completing PTA[12]

Iliac artery

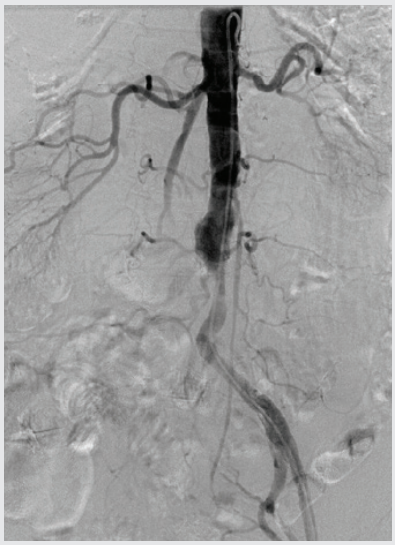
The GORE® VIABAHN® Endoprosthesis is the only self-expanding stent graft indicated to treat iliac lesions.

High primary patency even in the most challenging disease: Demonstrated 91% one-year primary patency.[17]

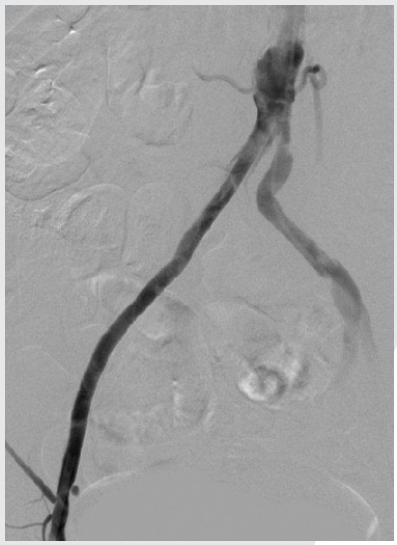
Durable clinical study outcomes in complex cases:

Stent grafts have demonstrated superiority over bare metal stents (BMS) for treating complex iliac lesions.[18,19]

Self-expanding stent grafts, at three years, have demonstrated improved patency over BMS when treating TASC D iliac lesions.[19]



Before: Flush ostial CTO of the right common iliac artery with reconstitution of the proximal common femoral artery.



After: Post-placement of 7 mm x 150 mm GORE® VIABAHN® Endoprosthesis and 7 mm x 59 mm balloon expandable covered stent.

Images courtesy of Barry Weinstock, M.D. Used with permission.

Recommendations for optimal outcomes in the iliac artery

Device sizing considerations

- Treat all of the disease (stent "normal to normal")[12]
- Overlap devices by at least 1 cm[12]
- Avoid excessive oversizing (> 20%)[12]

Implantation considerations

- Ensure adequate inflow and outflow[12]
- Post dilate[12]
- Do not use PTA outside of the device[12]

Follow-up considerations

- Prescribe appropriate antiplatelet therapy[12]
- Treat progressing disease[14]

Features and benefits

The unique design of the GORE® VIABAHN® Endoprosthesis enables treatment of even the most challenging peripheral cases.

Performs as an endoluminal bypass:

Covers and excludes diseased and irregular tissue.

Provides a barrier from tissue ingrowth, minimizing ISR.

Conformable yet durable design:

Like with all Gore single nitinol wire stents, the design and frame construction reduces strain to provide mechanical durability.

Proven flexibility maintains flow at points of flexion and increases anatomical options.

Ease of use:

Robust configurations cover a broad range of patient needs.

Radiopaque markers enhance endoprosthesis visibility.

Low profile delivery system makes it potentially easier to reach and treat challenging lesions.

Lasting thromboresistance:

CBAS Heparin Surface, also featured in the GORE® PROPATEN® Vascular Graft, is the proven lasting heparin bonding technology designed to resist thrombus formation.[20]

GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface

The bioactive luminal surface of a 5 mm diameter GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface appears free of thrombus after two hours in an in vitro blood loop model.

Control endoprosthesis

The non-bioactive luminal surface of a control endoprosthesis (5 mm diameter) appears covered with thrombus after 90 minutes in the same blood loop model (Data on file; W. L. Gore & Associates, Inc; Flagstaff, AZ).

The GORE® VIABAHN® Endoprosthesis has a reported fracture rate of < .015% across all uses.

(Data on file 2020; W. L. Gore & Associates, Inc.; Flagstaff, AZ.)

Sizing table

GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface

.035" guidewire compatibility

Device sizing		Introducer sheath (Fr)					
Endoprosthesis labeled diameter* (mm)	**Recommended vessel diameter† (mm)**	**2.5 cm device length***	**5 cm device length***	**10 cm device length***	**15 cm device length***	**25 cm device length***	**Recommended balloon diameter for device touch-up (mm)**
5	4.0–4.7	7	7	7	7	7	5
6	4.8–5.5	7	7	7	7	7	6
7	5.6–6.5	8	8	8	8	8	7
8	6.6–7.5	8	8	8	8	8	8
9	7.6–8.5	–	8	8	8	–	9
10	8.6–9.5	–	8	8	8	–	10
11	9.6–10.5	–	10	10	–	–	12
13	10.6–12.0	–	10‡	10‡	–	–	14

* Labeled device diameters and lengths are nominal.

† Recommended endoprosthesis compression within the vessel is approximately 5-20%.

‡ The 13 mm diameter device is not compatible with the 10 Fr COOK® FLEXOR® CHECK-FLO® Sheath.

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W. L. Gore & Associates, Inc.
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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