Open More Possibilities

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface*

GORE

* PROPATEN Bioactive Surface is synonymous with the CBAS Heparin Surface.

Continued innovation for **durable outcomes and unmatched versatility.**

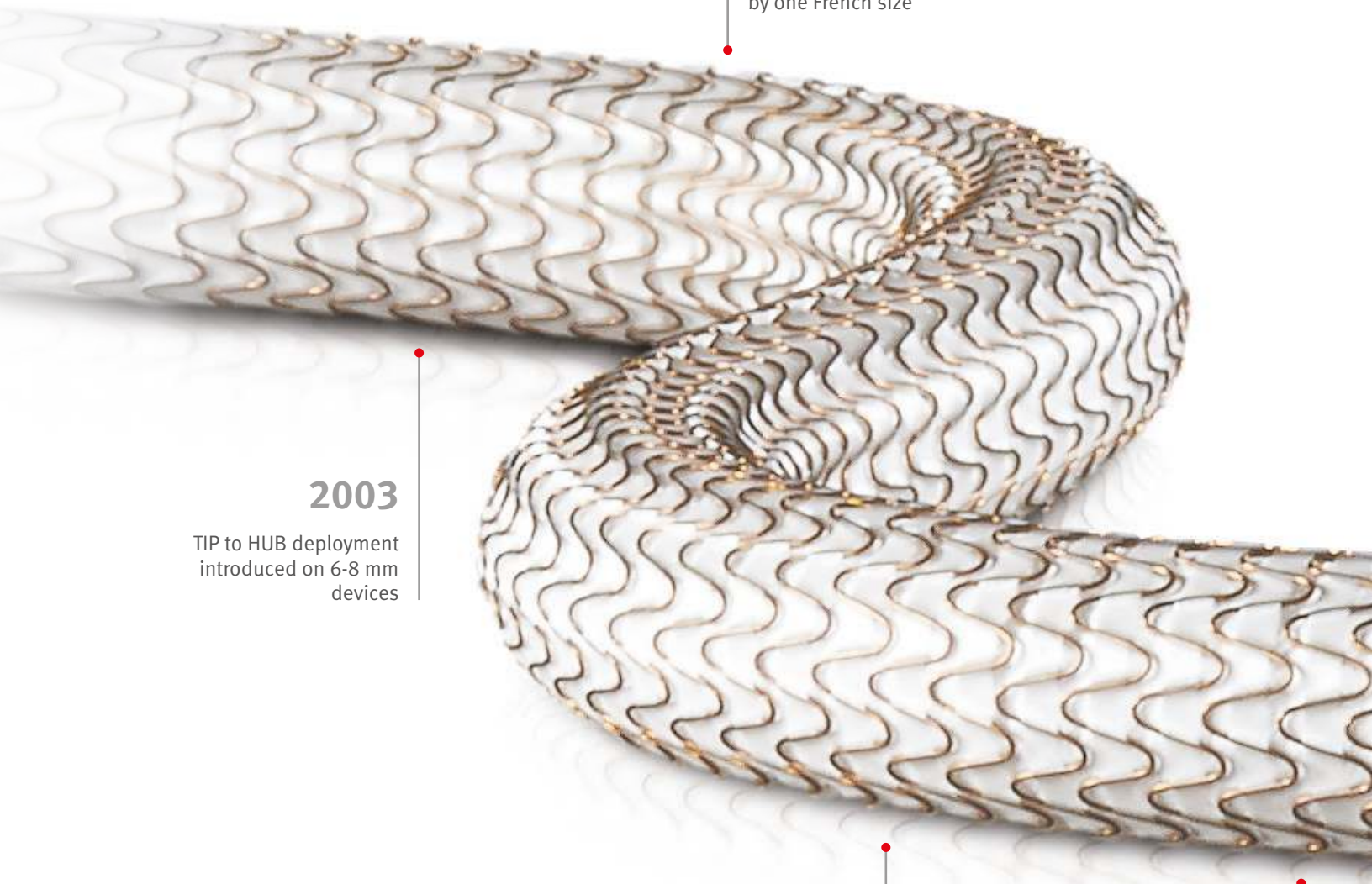
1996

Original GORE® HEMOBAHN® Endoprosthesis introduced in Europe

2008

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface introduced in Europe

5–8 mm devices decreased in profile by one French size



2003

TIP to HUB deployment introduced on 6-8 mm devices

2009

Laser technology enables the new contoured edge at proximal end

9–13 mm devices introduced with 0.035” guidewire compatibility

2010

25 cm Length: Longest stent-graft introduced in EUROPE

The GORE® VIABAHN® Endoprosthesis is a leader among stent grafts.* Decades of partnership with clinicians around the globe has resulted in unparalleled performance across multiple indications:†

- **Arteriovenous Access**
- **Superficial Femoral Artery**
- **In-stent Restenosis**
- **Iliac Artery**
- **Popliteal Artery Aneurysm**

2011

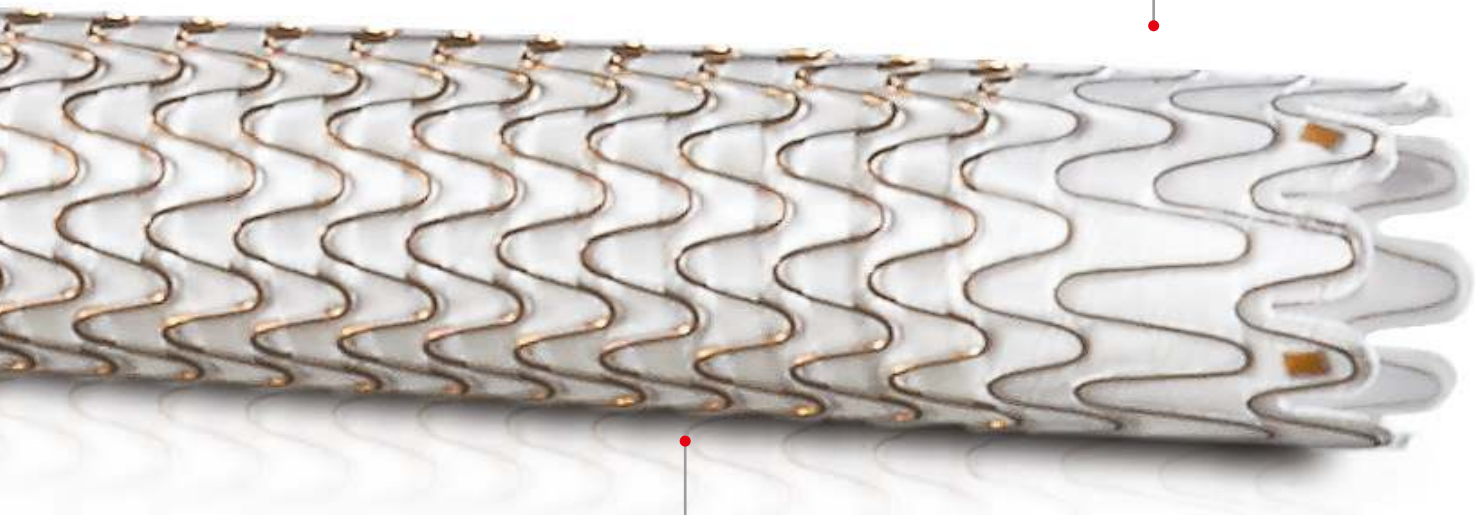
GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface 5-8 mm devices decreased in profile by one French size

2014

Receives CE mark for the treatment of symptomatic venous obstruction

2016

Radiopaque markers introduced on 5–8 mm devices in Europe



* Based on Millennium Research Group, Inc. data, reflecting unit and revenue share, June 2018.

† See full indications at goremedical.com.

Arteriovenous (AV) Access

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

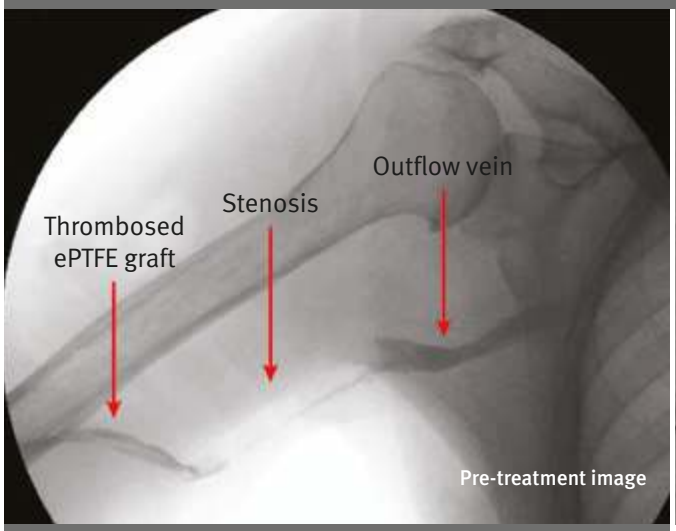
- Early percutaneous transluminal angioplasty (PTA) failures
- Lesions at points of flexion
- Thrombosed grafts

High primary patency even in the most challenging disease:

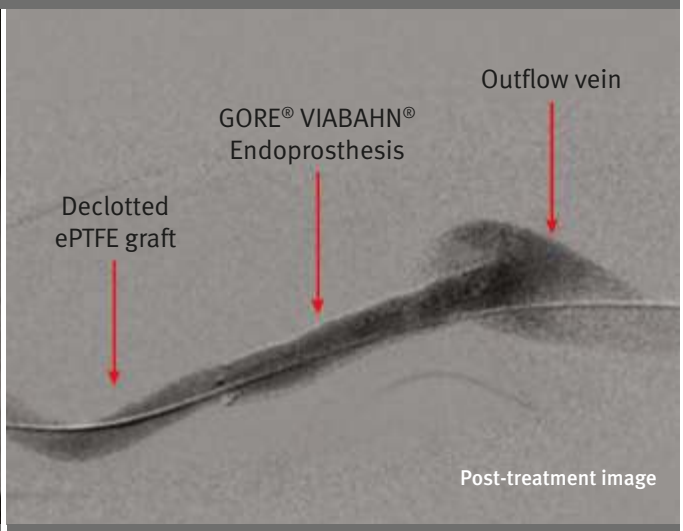
Increased primary patency in thrombosed grafts of both the target lesion and the circuit by **~50%** when compared to PTA at six months.[1]

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.

Durable clinical study outcomes in complex cases:

Zero device fractures and 83% access secondary patency at 2 years when placed across the elbow.[2]

Proven to reduce reinterventions:

Lowered the mean number of interventions over 2 years by

40%

in thrombosed grafts[3]

Recommendations for optimal outcomes in AV Access

1. Outflow wall apposition to the outflow vein is not necessary for quality outcomes.
2. Follow the *Instructions for Use* (IFU) recommendation for 5–20% oversizing using the graft inner diameter as the target vessel.
3. 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	62%	47%
Circuit primary patency	48%	41%

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

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

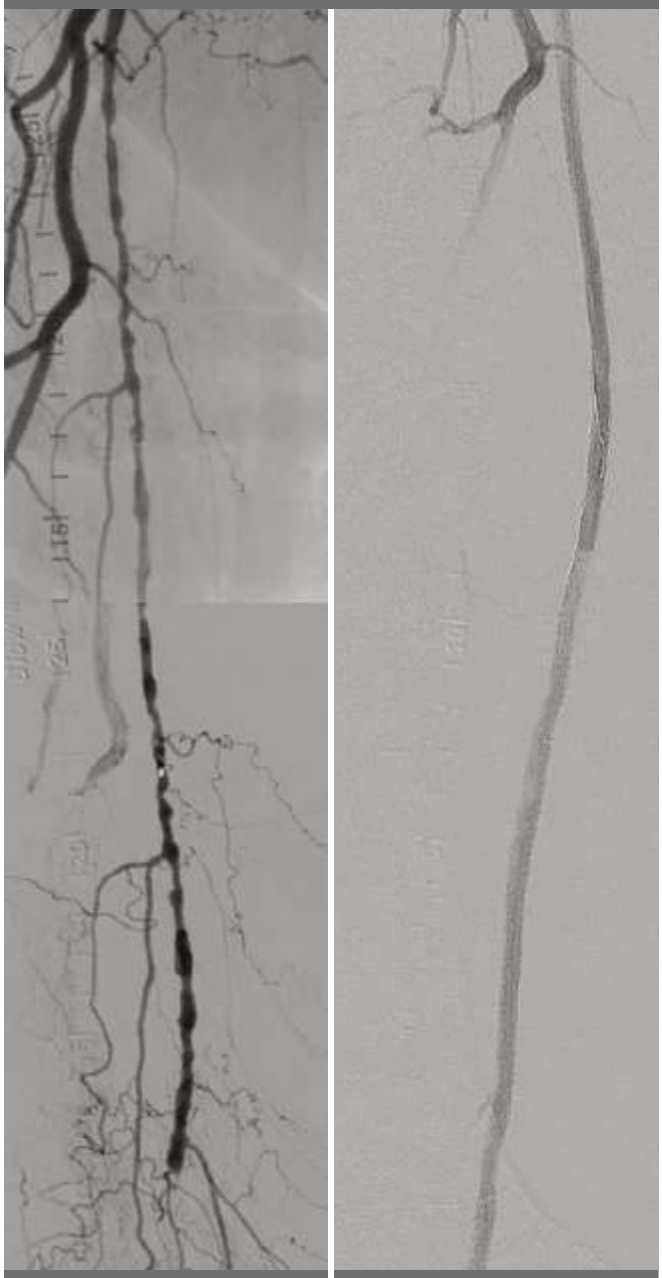
† The difference between the diameter of the vein and the device is ≥ 1 mm.

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

Superficial Femoral Artery (SFA)

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

Long SFA Lesion of the Right SFA



Before: Proximal SFA disease and mid-SFA occlusion

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

Images courtesy of James Persky, MD. Used with permission.

* Weighted average lesion length.

† 12-month weighted average primary patency.

High primary patency even in the most challenging disease:

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

Proven patency for complex SFA lesions[5-9]

Across five multicenter, prospective, randomized or single arm studies

422 *Limbs studied*

302 *CTOs*

22 cm *Average lesion length**

75% *Average primary patency†*

Durable clinical study outcomes in complex cases:

Comparable clinical results to above knee surgical bypass (both prosthetic[10] and native vein[8]).

97%

3-year secondary patency in complex disease

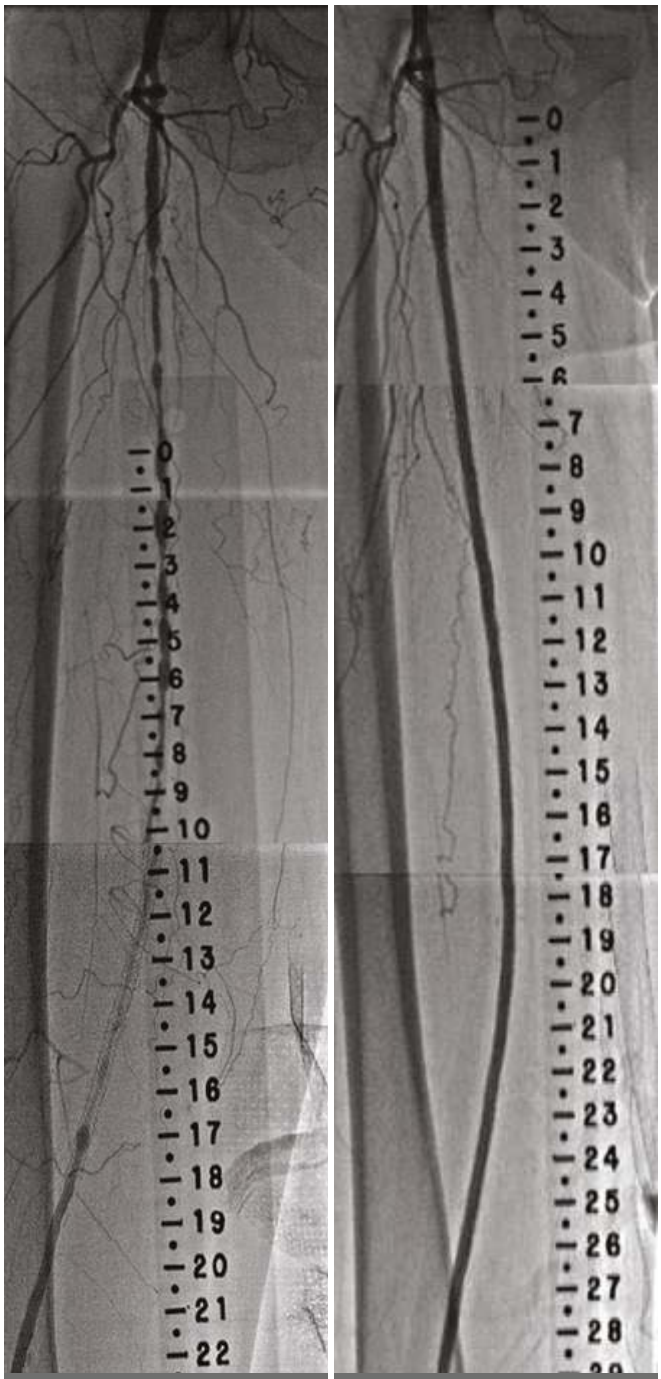
(27 cm average lesion length, 93% CTOs)[11]

Recommendations for optimal outcomes in the SFA[12]

1. Avoid excessive oversizing (> 20%).[11]
2. Ensure adequate inflow and outflow.[11]
3. Treat all of the disease (stent “normal to normal”).[11]
4. Regular duplex ultrasonography follow-up.[12]
5. Prescribe appropriate antiplatelet therapy.[11]
6. Post dilate.[11]
7. Do not use PTA outside of the device.[11]
8. Treat progressing disease.[12]
9. Place device at the SFA origin if proximal SFA disease is present.[11]
10. Overlap devices by at least 1 cm.[11]

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® Endoprosthesis for ISR in the SFA

Images courtesy of Robert Minor, MD. Used with permission.

High primary patency even in the most challenging disease:

75% 12-month primary with an average lesion length of **over 17 cm.**[13]

Fewer than one third the number of patients required an intervention at 12 months compared to PTA.[11]

Durable clinical study outcomes in complex cases:

Four times greater primary patency compared to PTA at two years.[14]

More than three times greater freedom from target lesion revascularization (fTLR) compared to PTA at two years.[11]

Proven to reduce reinterventions:

Fewer patients had reintervention procedures compared to PTA at two years.[11]

75%

Primary patency at 12 months[13]

17.3 cm

Mean lesion length[13]

80%

fTLR at 12 months[13]

Recommendations for Optimal Outcomes in ISR

1. Extend the device at least 1 cm proximally and distally from the previously placed stent.[11]
2. Cover any adjacent disease at least 1 cm beyond the proximal and distal margins of the lesion.[11]
3. Follow the IFU recommendation for 5-20% oversizing using the healthy vessel diameter immediately proximal and distal to the lesion.[11]
4. Ensure guidewire has traversed the lesion intraluminally before completing PTA.[11]

Iliac Artery

The GORE® VIABAHN® Endoprosthesis is indicated to treat iliac lesions.

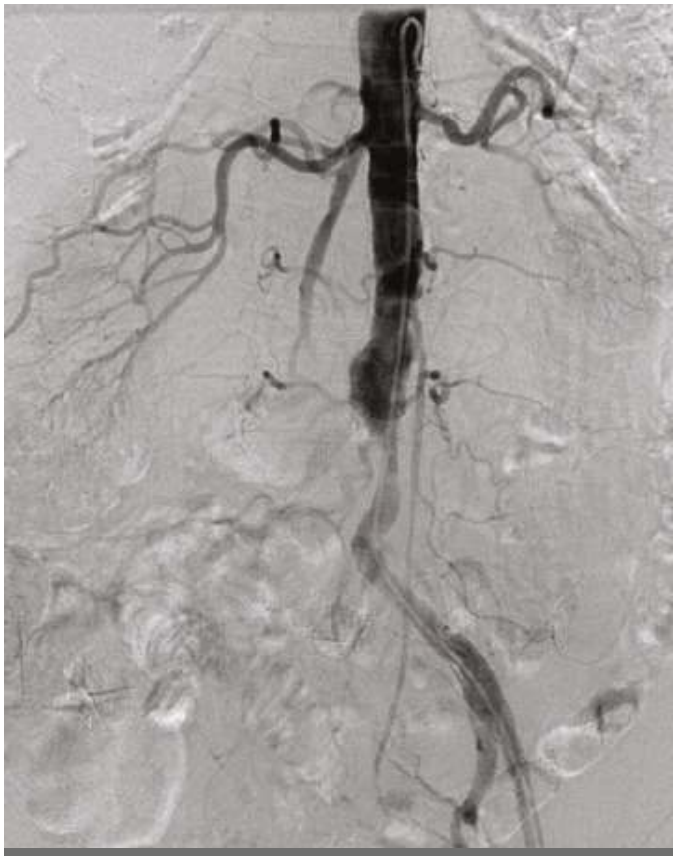
High primary patency even in the most challenging disease:

Demonstrated **91% 12-month primary patency.**[15]

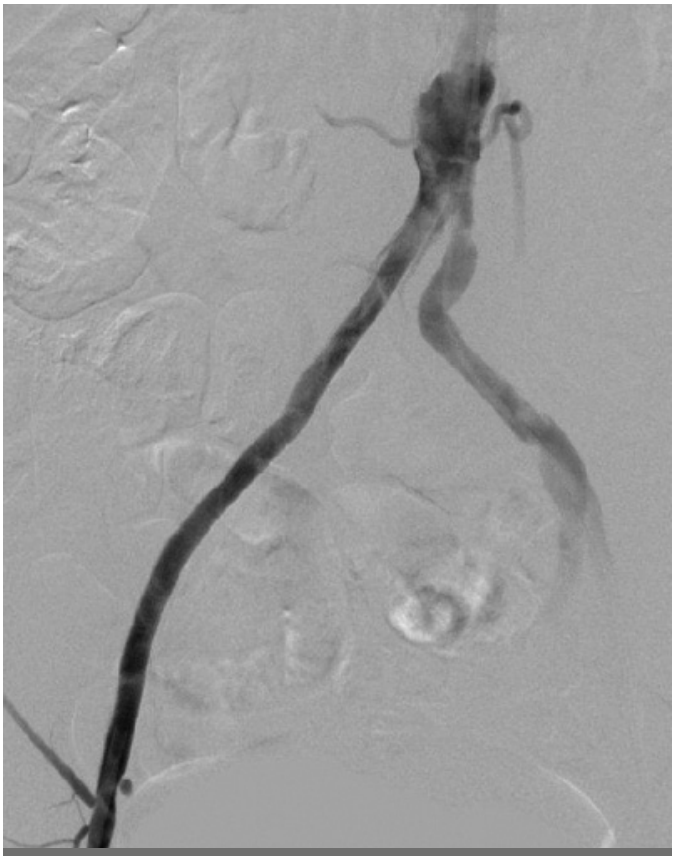
Durable clinical study outcomes in complex cases:

Stent grafts have demonstrated **superiority over bare-metal stents (BMS)** for treating complex iliac lesions.[16,17]

Self-expanding stent grafts, at three years, have demonstrated **improved patency over BMS** when treating TASC D iliac lesions.[17]



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, MD. Used with permission.

Recommendations for optimal outcomes in the Iliac Artery[12]

1. Avoid excessive oversizing (> 20%).[11]
2. Ensure adequate inflow and outflow.[11]
3. Treat all of the disease (stent “normal to normal”).[11]
4. Prescribe appropriate antiplatelet therapy.[11]
5. Post dilate.[11]
6. Do not use PTA outside of the device.[11]
7. Treat progressing disease.[12]
8. Overlap devices by at least 1 cm.[11]

Popliteal Artery Aneurysm (PAA)

Strong clinical performance in challenging PAA cases

Endovascular repair of popliteal aneurysms is associated with acceptable long-term patency and a very low risk of limb loss[18]

- Patency rates at two to six years in PAA (70 – 86%) are comparable to those reported for surgical bypass at five years (69 – 88%)[19–24]
- GORE® VIABAHN® Endoprosthesis 10-year primary, primary assisted and secondary patency rates in PAA of 51%, 57% and 60% respectively[18]

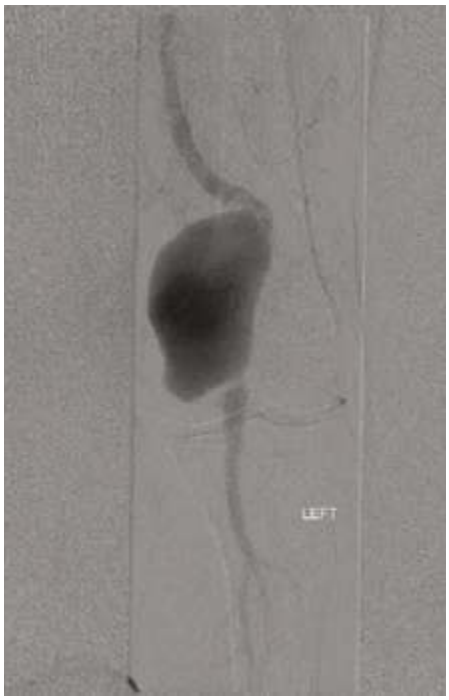


Figure 1. Large (5 mm diameter) left popliteal artery aneurysm

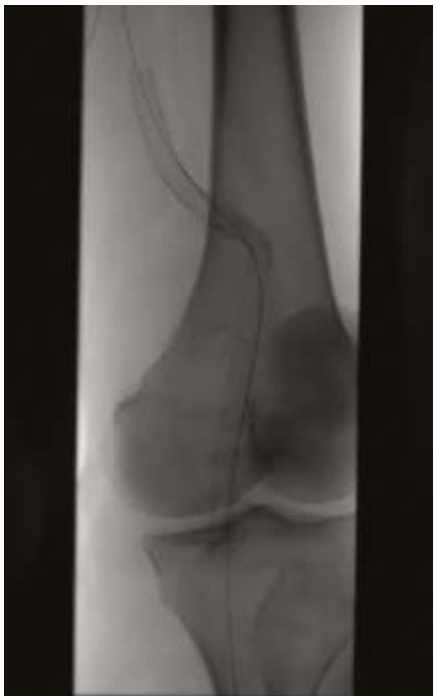


Figure 2a. GORE® VIABAHN® Endoprosthesis placement to exclude the aneurysm

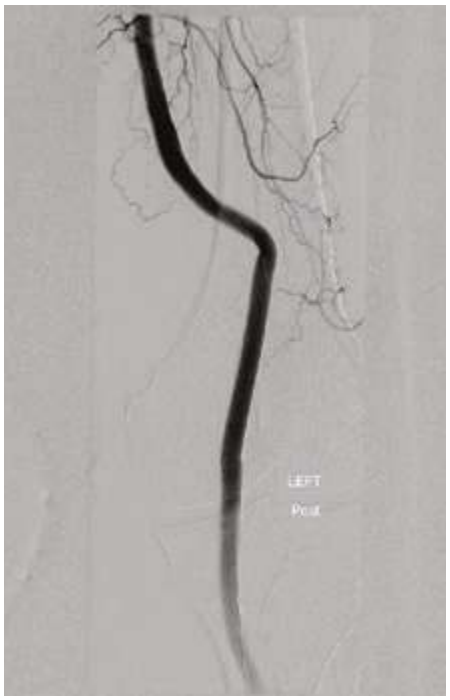


Figure 2b. Completion angiography showing good conformability to the artery tortuosity and total exclusion of the aneurysm by GORE® VIABAHN® Endoprosthesis

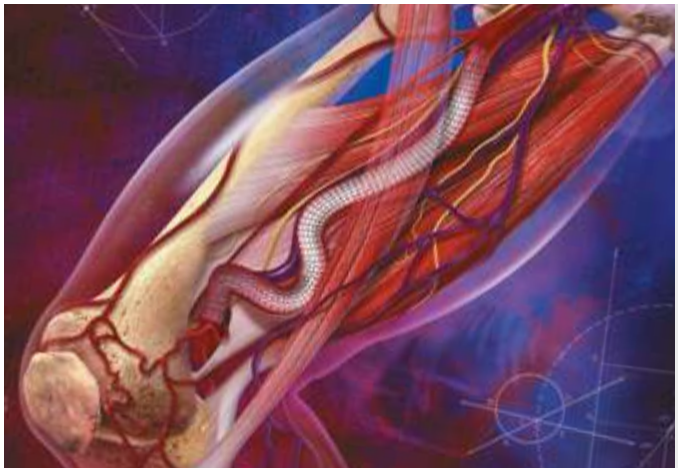
Images courtesy of Barry S. Weinstock, MD. Used with permission.

Recommendations for optimal outcomes in PAA's

1. Pre-procedure planning with adequate imaging (CT/CTA or MRI/MRA) to determine intended landing zones, vessel diameters and potential overlap locations.
2. Prescribe appropriate antiplatelet therapy.
3. Use a stiff guidewire.
4. Select appropriate device length. Experience has shown that devices can shorten by 10% as they are deployed within the aneurysm.[21]
5. Select device diameter according to IFU.
6. Overlap multiple devices by at least 2 cm. Overlapping devices should not differ by more than 1 mm in diameter, with one exception: if 13 mm and 11 mm devices are overlapped, the 11 mm device should be placed first and the 13 mm should be placed inside of the 11 mm device.
7. Avoid overlapping multiple devices in the hinge point zone of the popliteal artery.
8. Deploy the GORE® VIABAHN® Endoprosthesis relatively slowly to prevent deployment inaccuracy.
9. Select at least 2 cm of non-aneurysmal artery (proximal and distal) to serve as landing zones.
10. Avoid unnecessary coverage of potential future proximal and distal anastomotic sites for surgical bypass.
11. Perform flexion arteriography post-implantation to verify adequate device placement.

Features and Benefits

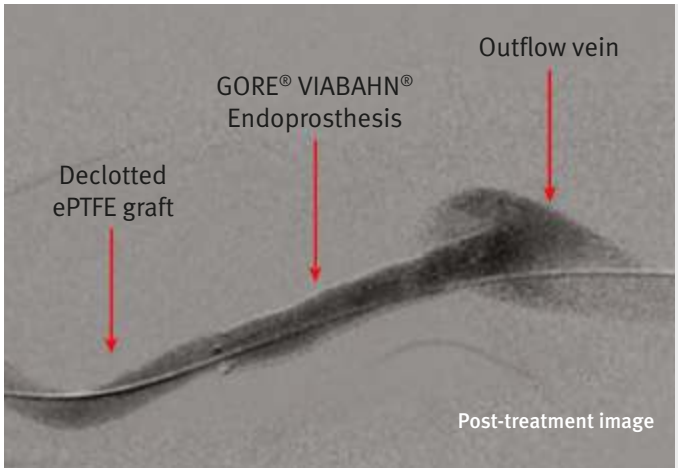
The unique design of the GORE® VIABAHN® Endoprosthesis enables treatment of even the most challenging peripheral cases.



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 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.*

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface

The bioactive luminal surface of a 5 mm diameter GORE® VIABAHN® Endoprosthesis with PROPATEN 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

<0.015%

across all uses

(Data on file 2018; W. L. Gore & Associates, Inc.; Flagstaff, AZ)

* CBAS Heparin Surface. W. L. Gore & Associates Web site. https://www.goremedical.com/cbas/references. Accessed July 30, 2018.

Sizing Table

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface

Device Deployment – 0.014" or 0.018" Guidewire Compatibility

Device Sizing		Introducer Sheath (Fr)			
Endoprosthesis Labeled Diameter* (mm)	Recommended Vessel Diameter† (mm)	Device Profile (Fr)	Endoprosthesis Length* (cm)	Catheter Length‡ (cm)	Recommended Balloon Diameter for Device Touch-up‡ (mm)
5	4.0-4.7	6	2.5, 5, 10, 15, 25	120	5
6	4.8-5.5	6	2.5, 5, 10, 15, 25	120	6
7	5.6-6.5	7	2.5, 5, 10, 15, 25	120	7
8	6.6-7.5	7	2.5, 5, 10, 15, 25	120	8

Device Deployment – 0.035" Guidewire Compatibility

Device Sizing		Introducer Sheath (Fr)			
Endoprosthesis Labeled Diameter* (mm)	Recommended Vessel Diameter† (mm)	Device Profile (Fr)	Endoprosthesis Length* (cm)	Catheter Length‡ (cm)	Recommended Balloon Diameter for Device Touch-up‡ (mm)
5	4.0-4.7	7	2.5, 5, 10, 15, 25	120	5
6	4.8-5.5	7	2.5, 5, 10, 15, 25	75, 120	6
7	5.6-6.5	8	2.5, 5, 10, 15, 25	75, 120	7
8	6.6-7.5	8	2.5, 5, 10, 15, 25	75, 120	8
9	7.6 – 8.5	9	5, 10, 15	120	9
10	8.6 – 9.5	11§	5, 10, 15	120	10
11	9.6 – 10.5	11	5, 10	120	12
13	10.6 – 12.0	12	5, 10	120	14

* Labeled device diameters and lengths are nominal.

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

‡ For the 11 and 13 mm diameter devices, balloon inflation pressure should not exceed 8 atm.

§ The 10 mm diameter device is compatible with the following 10 Fr introducer sheaths: CORDIS AVANTI® Sheath Introducer, BOSTON SCIENTIFIC SUPER SHEATH Introducer Sheath, B. BRAUN INTRADYN Tear-Away Introducer Sheath.

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Notes

Notes

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Consult Instructions for Use
eifu.goremedical.com

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All device configurations (lengths and diameters) may not be commercially available in all markets.

Products listed may not be available in all markets.