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

1996

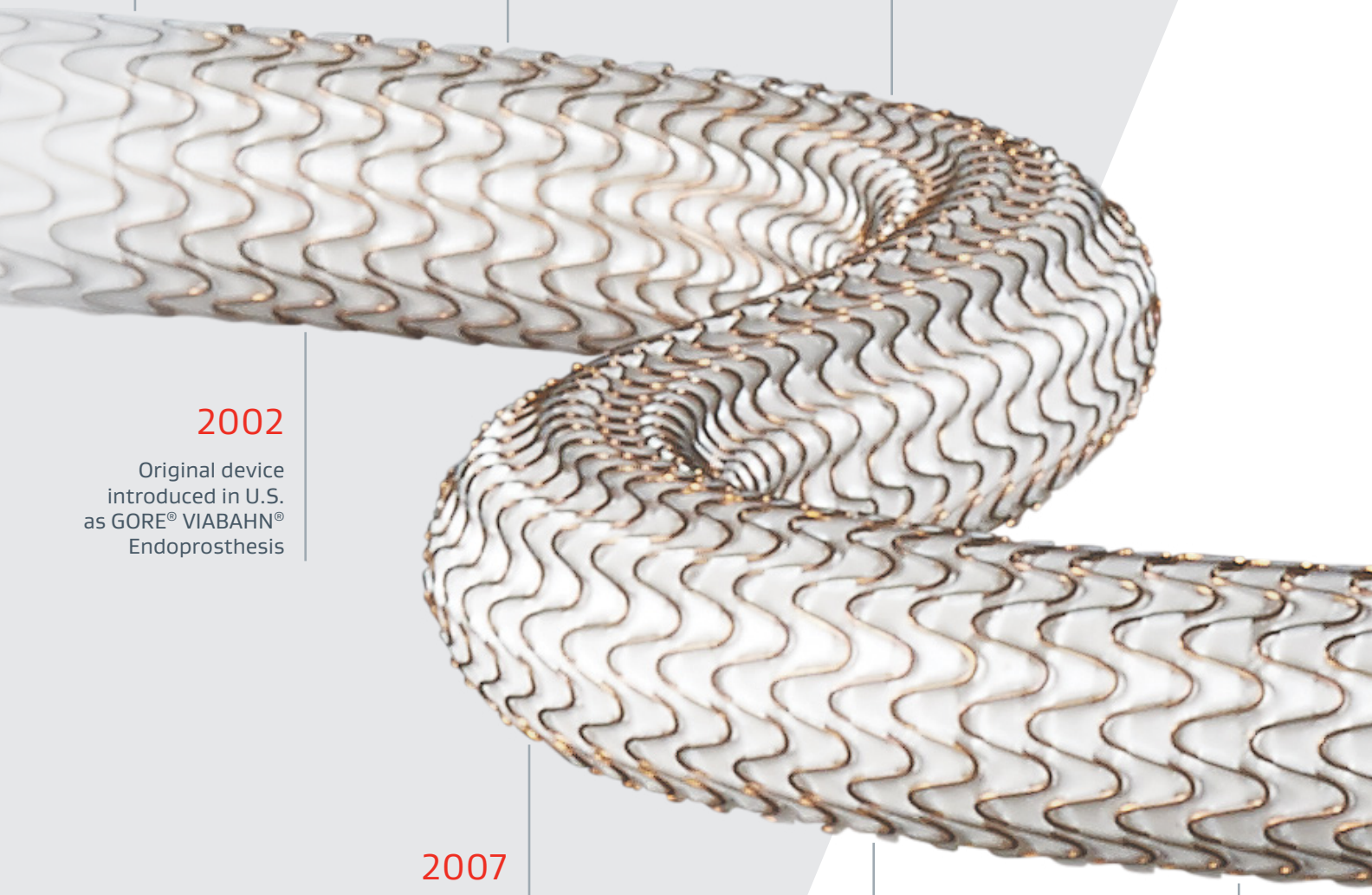
Original GORE® HEMOBAHN® Endoprosthesis introduced in Europe

2003

TIP to HUB deployment introduced on 6–8 mm devices

2005

6–8 mm devices in U.S. receive Food and Drug Administration (FDA) approval for superficial femoral artery (SFA) indication



2002

Original device introduced in U.S. as GORE® VIABAHN® Endoprosthesis

2007

GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface introduced in U.S.

5–8 mm devices decreased in profile by 1 Fr size

2008

All device sizes receive FDA approval for iliac artery indication

2009

Laser technology enables the new contoured edge at proximal end

9–13 mm devices introduced with .035" guidewire compatibility

* Across indications and configurations of covered stents.

† © 2022. Used with permission. Decision Resources Group (DRG).

‡ See full indications at eifu.goremedical.com

Continued innovation for durable outcomes and unmatched versatility.*

The VIABAHN® Device is a leader among stent grafts.† Decades of partnership with clinicians around the globe has resulted in reliable performance across multiple indications‡:

- Arteriovenous access
- Superficial femoral artery
- In-stent restenosis
- Iliac artery

2011

GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 5–8 mm devices decreased in profile by 1 Fr size

2013

FDA approval for revision of arteriovenous access grafts

25 cm length: Longest stent graft introduced in U.S.

2014

5-7 mm devices receive FDA approval for treatment of in-stent restenosis in the SFA

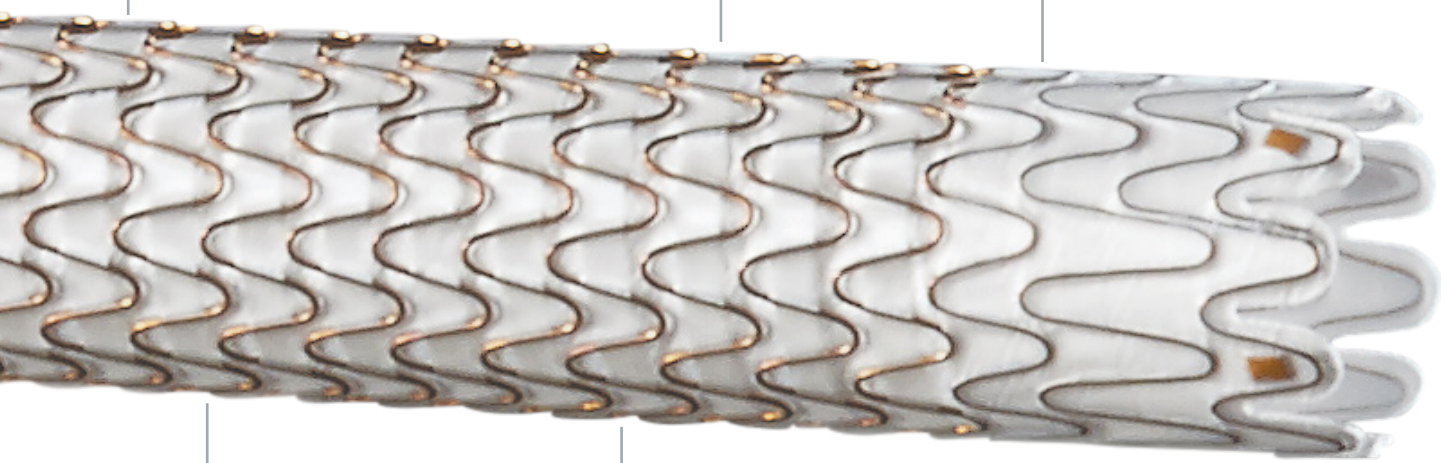
Radiopaque markers on endoprosthesis introduced on 5–8 mm devices

2016

7.5 cm length introduced in U.S. for 5–9 mm devices

2020

Up to 3 Fr size reduction in profile and addition of radiopaque markers on 9–13 mm devices



Arteriovenous (AV) Access

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

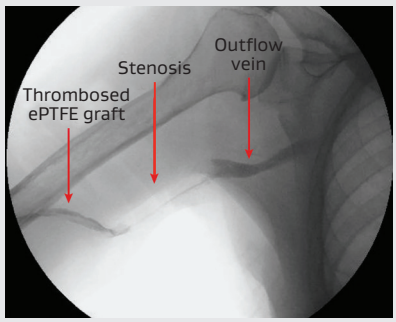
- Early percutaneous transluminal angioplasty (PTA) failures
- Lesions at points of flexion
- Thrombosed grafts

High primary patency even in the most challenging disease:

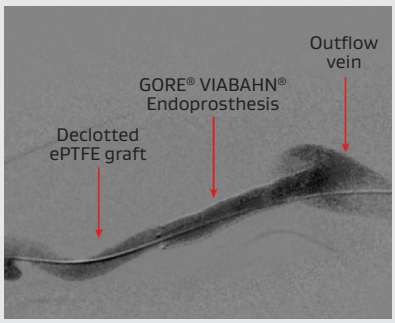
Increased trend in primary patency in thrombosed grafts of both the target lesion and the circuit by ~50% when compared to PTA at 6 months.[1]

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 anastomosis of an AV graft.



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

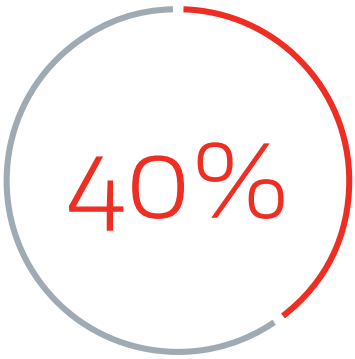
Images courtesy of Daniel V. Patel, M.D. Used with permission.

* 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 2 years when placed across the elbow.[2]



Proven to reduce reinterventions:

Lowered mean number of interventions over 2 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 *Instructions for Use* (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[*,2]

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

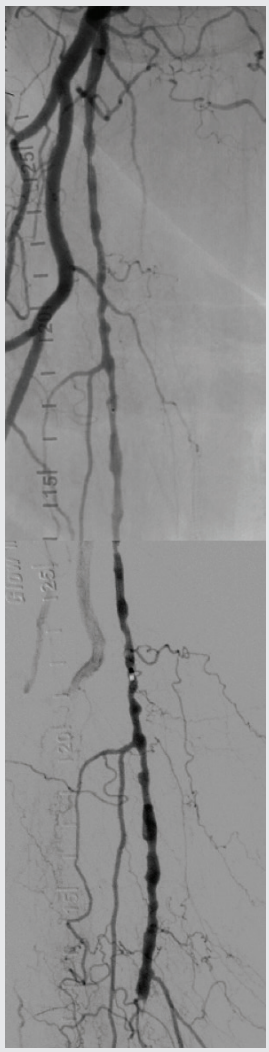
Note: The VIABAHN® Device should always be sized 5% to 20% greater than the AV graft diameter per the IFU.[12]

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.

Long lesion of the right SFA



Before: Proximal SFA disease and mid-SFA occlusion.

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

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

Proven patency for complex SFA lesions across 7 multicenter, prospective, randomized or single-arm studies.[4–10]

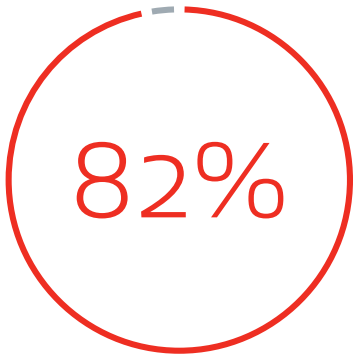
1,089 lesions studied	**71%** CTOs
23 cm average lesion length*	**80%** average primary patency†

* Weighted average lesion length.

† 1-year weighted average primary patency.

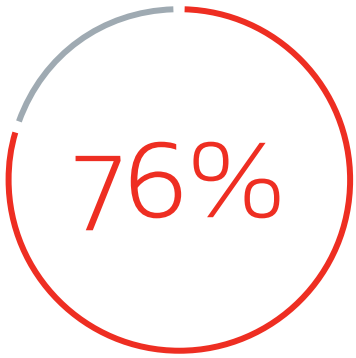
Durable clinical study outcomes in complex cases:

Comparable clinical results to surgical above-the-knee bypass (both prosthetic[11] and native vein[7]).



5-year secondary patency in complex disease

(24 cm average lesion length, 70% CTOs)[12]



5-year freedom from target lesion revascularization (fTLR)[12]

Recommendations for optimal outcomes in the SFA:

Device sizing considerations

- Treat all of the disease (stent "normal to normal").[13]
- Overlap devices by at least 1 cm.[13]
- Avoid excessive oversizing (> 20%).[13]

Implantation considerations

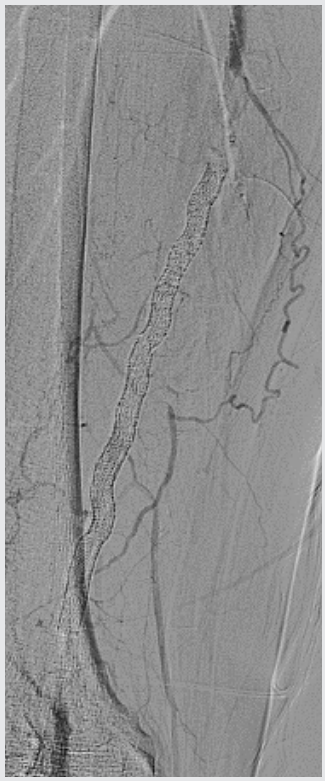
- Ensure adequate inflow and outflow.[13]
- Post dilate.[13]
- Do not use PTA outside of the device.[13]
- Place device at the SFA origin if proximal SFA disease is present.[13]

Follow-up considerations

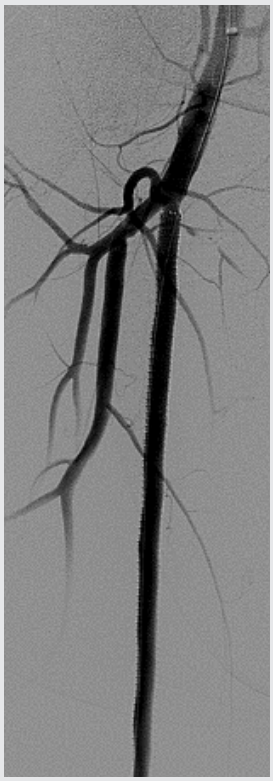
- Regular duplex ultrasonography follow-up.[14]
- Prescribe appropriate antiplatelet therapy.[13]
- Treat progressing disease.[14]

In-stent restenosis (ISR) of the SFA

Safe and effective treatment for in-stent restenotic lesions.[15–17]



Before: SFA ISR lesion with occluded bare metal stent.



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

Proven patency in real-world lesions across 2 multicenter, prospective studies. 125 total lesions studied, averaging:[15–17]

11%
chronic limb-threatening ischemia (CLTI)*

27%
CTOs*

14 cm
lesion length*

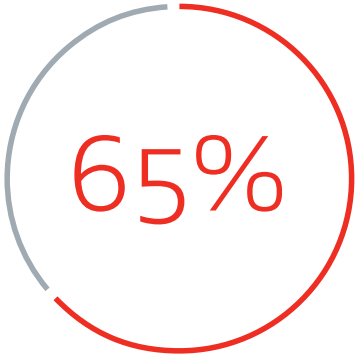
75%
primary patency at 1 year*

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

* Weighted average.

† In a cohort including Rutherford category 4+ patients at baseline.

Durable clinical study outcomes through 3 years:[14]



3-year fTLR with no statistically significant difference relative to degree of calcification, number of runoff vessels, gender or diabetes status.[15]

> 80% of patients maintained a ≥ 1 Rutherford category improvement.[15]

freedom from major amputations† and VIABAHN® Device stent fractures through 3 years.[15]

Recommendations for optimal outcomes in ISR:

- Extend the device at least 1 cm proximally and distally from the previously placed stent.[13]
- Cover any adjacent disease at least 1 cm beyond the proximal and distal margins of the lesion.[13]
- Measure the healthy vessel diameter in the proximal and distal landing zones and follow the IFU recommendation for 5–20% oversizing.[13]
- Ensure guidewire has traversed the lesion intraluminally before completing PTA.[13]

Iliac artery

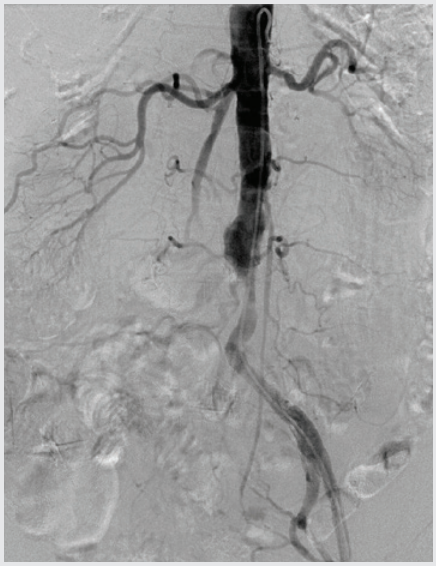
The VIABAHN® Device is the only self-expanding stent graft indicated to treat stenotic iliac lesions.

High primary patency even in the most challenging disease: demonstrated 91% 1-year primary patency.[18]

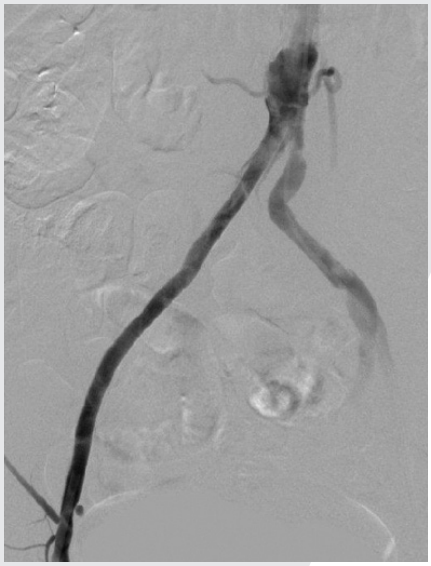
Durable clinical study outcomes in complex cases:

Stent grafts have demonstrated superiority over bare metal stents (BMS) for treating complex iliac lesions.[19,20]

Self-expanding stent grafts, at 3 years, have demonstrated improved patency over BMS when treating TASC D iliac lesions.[20]



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 VIABAHN® Device 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").[13]
- Overlap devices by at least 1 cm.[13]
- Avoid excessive oversizing (> 20%).[13]

Implantation considerations

- Ensure adequate inflow and outflow.[13]
- Post dilate.[13]
- Do not use PTA outside of the device.[13]

Follow-up considerations

- Prescribe appropriate antiplatelet therapy.[13]
- Treat progressing disease.[14]

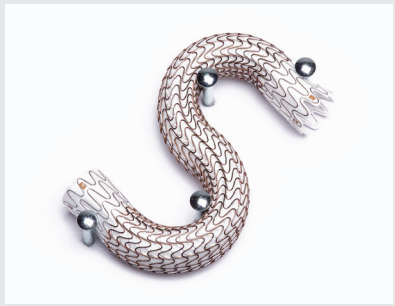
Features and benefits

The unique design of the VIABAHN® Device 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.

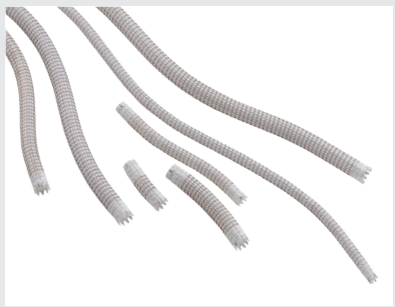


Conformable yet durable design:

Like with all Gore single nitinol wire stents, the design and frame construction reduce strain to provide mechanical durability.[1,12]

Proven flexibility maintains flow at points of flexion and increases anatomical options.[1,12]

Bench-top evaluations are intended to demonstrate relative physical characteristics and may not correlate to clinical results.



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.[21]

GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface

The bioactive luminal surface of a 5 mm diameter VIABAHN® Device appears free of thrombus after 2 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 VIABAHN® Device has a reported fracture rate of .0032% across all uses.

(Data on file 2022; W. L. Gore & Associates, Inc; Flagstaff, AZ.)

Sizing tables

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***	**7.5 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	7	5
6	4.8–5.5	7	7	7	7	7	7	6
7	5.6–6.5	8	8	8	8	8	8	7
8	6.6–7.5	8	8	8	8	8	8	8
9	7.6–8.5	–	8	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

.014" or .018" guidewire compatibility

Device sizing		Introducer sheath (Fr)						
Endoprosthesis labeled diameter* (mm)	**Recommended vessel diameter† (mm)**	**2.5 cm device length***	**5 cm device length***	**7.5 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	6	6	6	6	6	6	5
6	4.8–5.5	6	6	6	6	6	6	6
7	5.6–6.5	7	7	7	7	7	7	7
8	6.6–7.5	7	7	7	7	7	7§	8

* 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® Introducer.

§ The 8 mm x 25 cm device is not compatible with the 7 Fr COOK® FLEXOR® CHECK-FLO® Introducer.

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Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: 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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