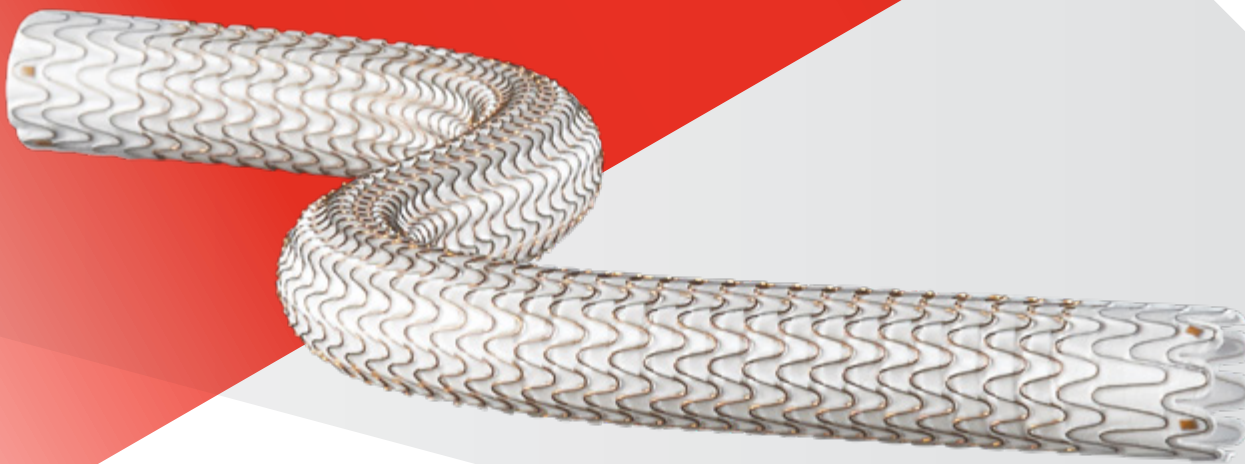




GORE® VIABAHN®

Endoprosthesis
with PROPATEN Bioactive Surface*

OPEN MORE POSSIBILITIES



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

Together, improving life

1996

Original GORE® HEMOBAHN®
Endoprosthesis introduced
in Europe

2008

GORE® VIABAHN® Endoprosthesis
with PROPATEN Bioactive Surface
approved 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

Continued innovation for durable outcomes and unmatched versatility

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

2011

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

2016

Radiopaque markers introduced on 5–8 mm devices

2022

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface 7.5 cm length introduced for the 5–9 mm devices



2014

Receives CE mark for the treatment of symptomatic venous obstruction

2021

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface: up to 3 French size profile reduction and addition of radiopaque markers on 9–13 mm devices

* GORE® VIABAHN® Endoprosthesis. W. L. Gore & Associates website. Accessed August 5, 2022. <https://www.goremedical.com/eu/VIABAHN/references>.

Backed by a growing body of clinical data in various clinical indications

The GORE® VIABAHN® Device has become a go-to device for physicians' most challenging cases



OVER
2,300
scientific
publications†



OVER
5,650
hospitals using
GORE® VIABAHN®
Device†



OVER
1,000,000
implanted in patients worldwide*†

Cephalic arch and
central vein stenosis

Isolated visceral
artery aneurysms

Dialysis access
circuit stenosis

Iliac artery stenosis

(In-stent) restenosis of
the superficial femoral and
proximal popliteal artery

Popliteal artery aneurysms

* GORE® VIABAHN® Endoprosthesis. W. L. Gore & Associates website. Accessed August 5, 2022. <https://www.goremedical.com/eu/VIABAHN/references>.

† Data shown is representative of all generations of the GORE® VIABAHN® Device.

Iliac artery stenosis

The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface can be used for treating lesions in the iliac arteries.

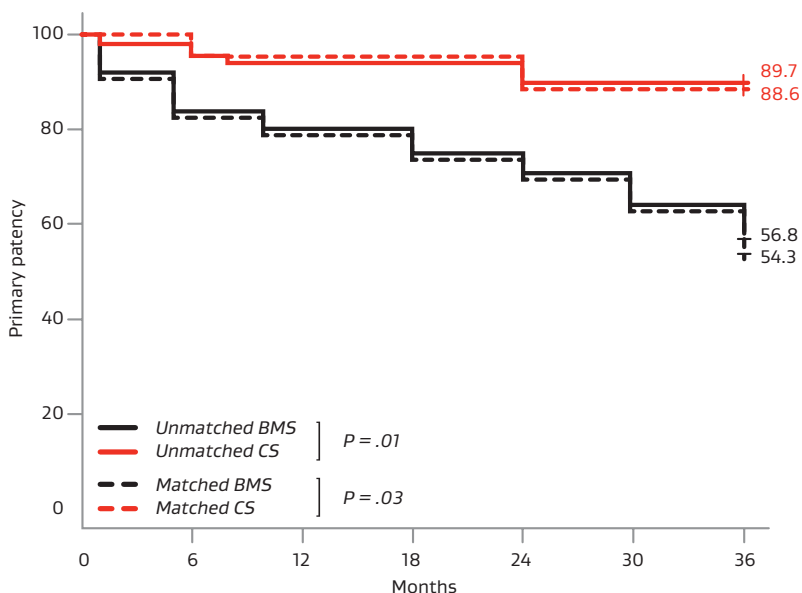
High primary patency even in the most challenging disease: Demonstrated 87% primary patency at three years.¹

Durable clinical study outcomes in complex cases:

Stent grafts have demonstrated superiority over bare metal stents (BMS) for treating complex iliac lesions.^{1,2}

Self-expanding stent grafts, at three years, have demonstrated improved patency over BMS when treating TASC D iliac lesions.¹

Higher patency out to three years for TASC II D lesions:¹



Three-year self-expanding covered stents versus bare metal stents in iliac artery occlusions; primary patency rates at three years



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® Device and 7 mm x 59 mm balloon expandable covered stent.

Arteriovenous (AV) Access

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

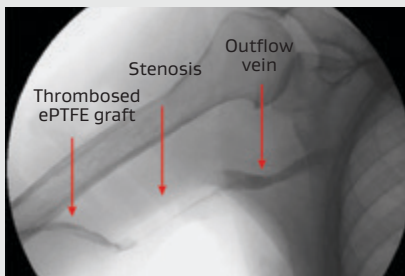
- Early percutaneous transluminal angioplasty (PTA) failures
- Lesions at points of flexion
- Thrombosed grafts

High primary patency even in the most challenging disease:

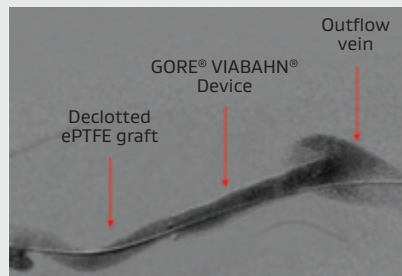
Increased trend in primary patency in thrombosed grafts of both the target lesion and the circuit by ~50% when compared to PTA at six months.³

Provided consistent patency independent of the number of times a lesion has previously been treated.³

Durable treatment of thrombosed AV grafts

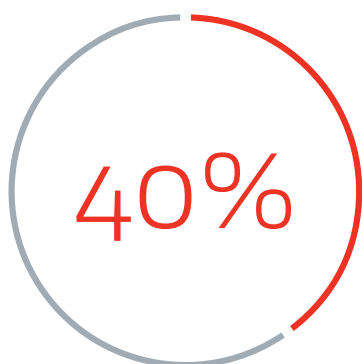


Before: Graft thrombosis secondary to outflow stenosis at the venous anastomosis of an AV graft.



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

Durable clinical study outcomes in complex cases:
83% access secondary patency and zero device
fractures at two years when placed across the elbow.⁴



Proven to reduce reinterventions:
Lowered mean number of
interventions over two years
in thrombosed grafts when
compared to PTA⁵

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^{*,6}

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

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

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.

§ Refer to *Instructions for Use* at eifu.goremedical.com

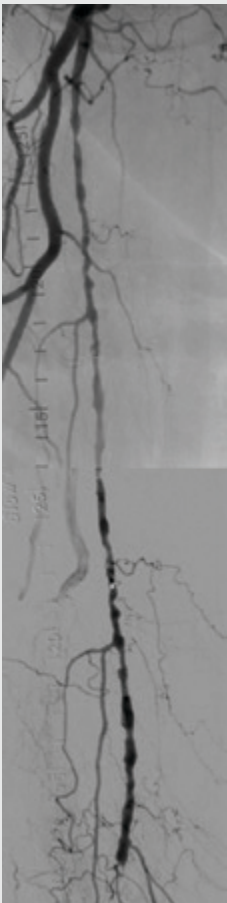
Superficial femoral artery (SFA)

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

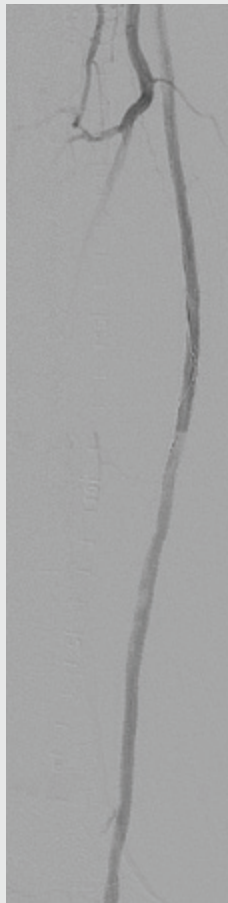
High primary patency even in the most challenging disease:

- 88% 12-month primary patency in SFA lesions averaging 22 cm in length⁷

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.

Proven patency for complex SFA lesions across seven multicenter, prospective, randomized or single arm studies⁷⁻¹³

1,089

Limbs studied

71%

CTOs*

23 cm

Average lesion length†

80%

Average primary patency‡

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

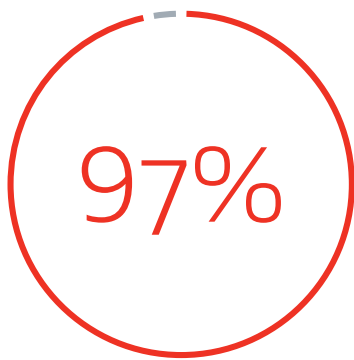
* Data on file 2020; W. L. Gore & Associates, Inc; Flagstaff, AZ.

† Weighted average lesion length.

‡ One-year weighted average primary patency.

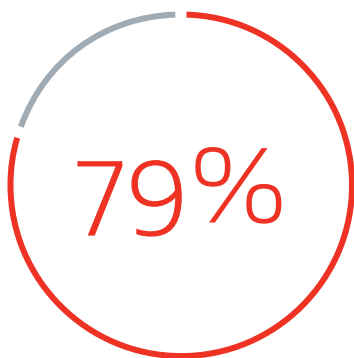
Durable clinical study outcomes in complex cases:

Comparable clinical results to above the knee surgical bypass (both prosthetic¹⁴ and native vein¹⁰).



Three-year secondary patency
in complex disease

(27 cm average lesion length, 93% CTOs)¹⁵



Five-year freedom from target
lesion revascularization (fTLR)¹⁶

Recommendations for optimal outcomes in the SFA

Device sizing considerations

- Treat all of the disease (stent “normal to normal”)¹⁵
- Overlap devices by at least 1 cm⁸
- Avoid excessive oversizing (> 20%)¹⁵

Implantation considerations

- Ensure adequate inflow and outflow¹⁵
- Post dilate⁸

- Do not use PTA outside of the device¹⁵

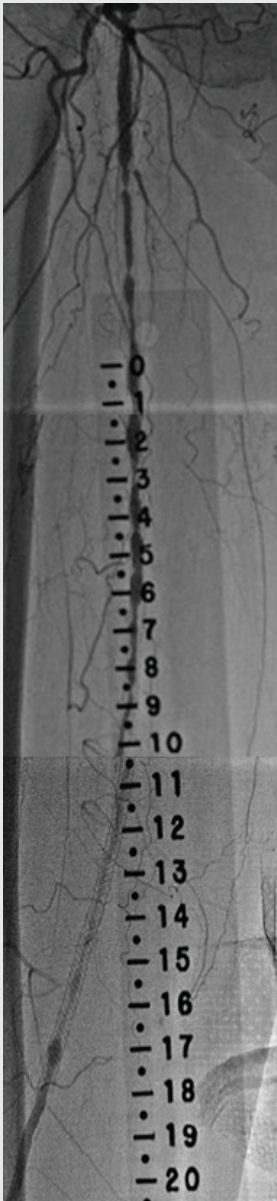
- Place device at the SFA origin if proximal SFA disease is present¹⁵

Follow-up considerations

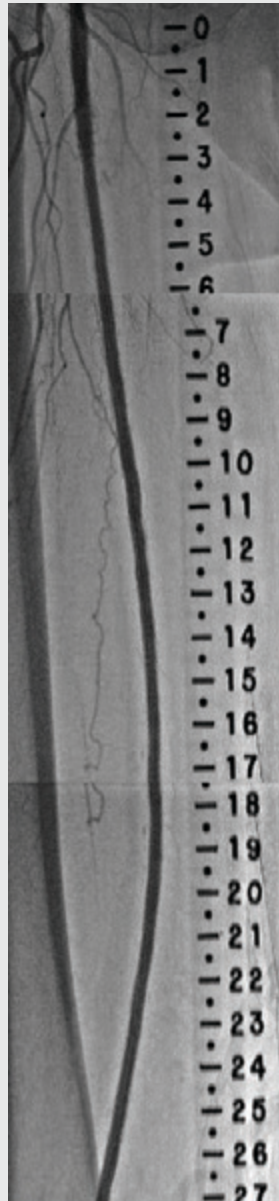
- Regular duplex ultrasonography follow-up¹⁷
- Prescribe appropriate antiplatelet therapy¹⁵
- Treat progressing disease¹⁷

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.¹⁸

Fewer than one third the number of patients required an intervention at one year compared to PTA.¹⁵

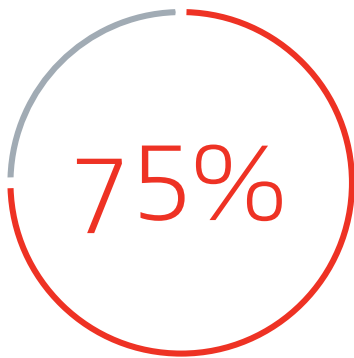
Durable clinical study outcomes in complex cases:

Four times greater primary patency compared to PTA at two years.¹⁹

More than three times greater FTLR compared to PTA at two years.¹⁵

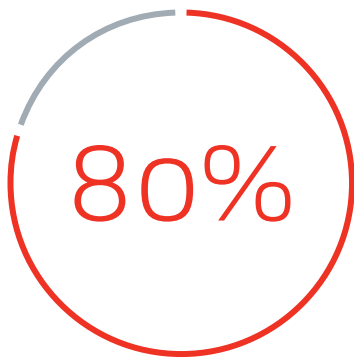
Proven to reduce reinterventions:

Fewer patients had reintervention procedures compared to PTA at two years.¹⁵



primary patency at one year¹⁸

17.3 cm mean lesion length¹⁸



fTLR at one year¹⁸

Recommendations for optimal outcomes in ISR

- Extend the device at least 1 cm proximally and distally from the previously placed stent¹⁵
- Cover any adjacent disease at least 1 cm beyond the proximal and distal margins of the lesion¹⁵
- Follow the IFU recommendation for 5–20% oversizing using the healthy vessel diameter immediately proximal and distal to the lesion¹⁵
- Ensure guidewire has traversed the lesion intraluminally before completing PTA¹⁵

Popliteal Artery Aneurysm (PAA)

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.¹⁹

Endovascular Repair vs Open Repair

Early Outcomes²⁰ (30 days)

Hospital stay ↓
Wound complications ↓
Primary Patency 1Y ↓

3Y Outcomes²⁰

Primary patency →↔
Secondary patency →↔
Mortality →↔
Amputation →↔

↓ Lower than open repair

→↔ No statistical difference to open repair

Endovascular Repair – Long-Term Outcomes

10Y Outcomes¹⁹

51% Primary patency
60% Secondary patency
79% Amputation free survival
0% Major amputations

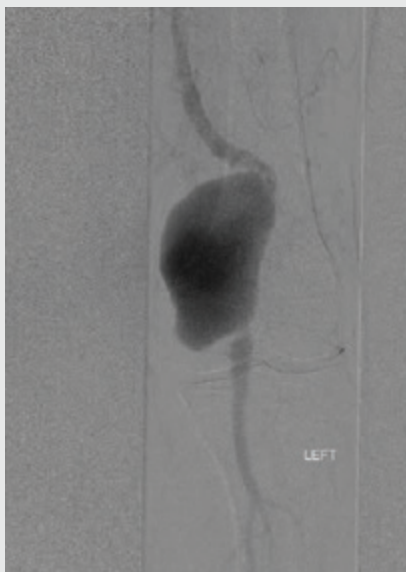


Figure 1.
Large (5 cm diameter) left popliteal artery aneurysm



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

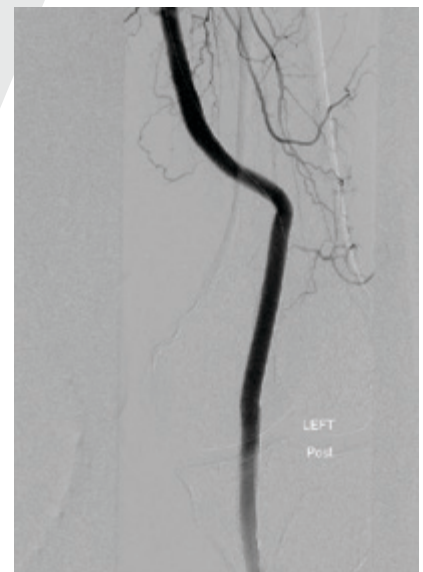
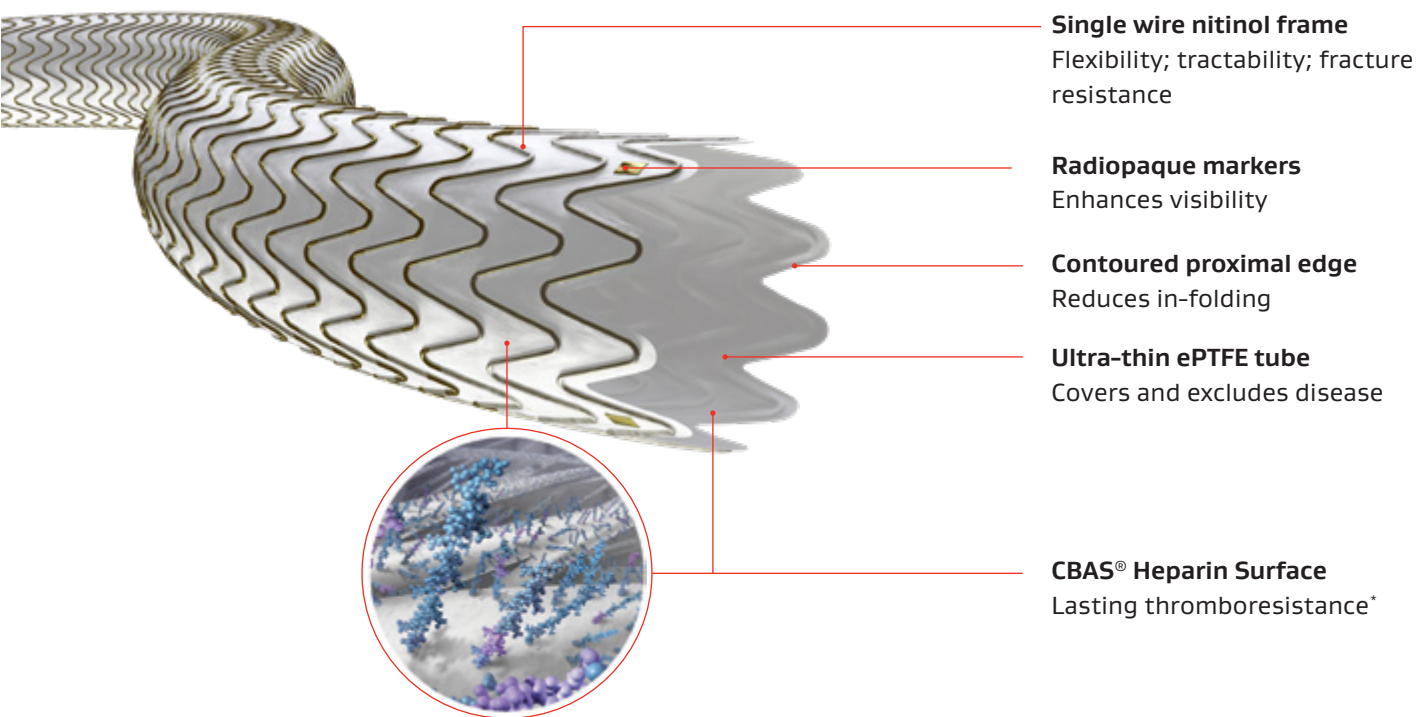


Figure 2b.
Completion angiography showing good conformability to the artery tortuosity and total exclusion of the aneurysm by GORE® VIABAHN® Device

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

Technology and clinical benefits

The unique design of the GORE® 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 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.

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

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

* CBAS® Heparin Surface. W. L. Gore & Associates Web site. <https://www.goremedical.com/cbas/references>. Accessed May 20, 2019.

Lasting thromboresistance. Proven technology.*

The CBAS® Heparin Surface of the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface* consists of a proprietary covalent end-point bond that preserves the active site, thus retaining heparin's anticoagulant activity.



Proven heparin availability

Performance-ready heparin active site.^{21,22}



Proven heparin bioactivity

Unmatched, persistent ability to take up antithrombin^{23,24}



Proven lasting thromboresistance

Improved surface hemocompatibility resulting from heparin availability and bioactivity.²¹⁻²⁵

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).

* CBAS® Heparin Surface. W. L. Gore & Associates Web site. <https://www.goremedical.com/eu/cbas/references>. Accessed September 25, 2019.

Sizing tables

GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface

0.035" Guidewire compatible

Device sizing		Introducer Sheath (Fr)						Recommended balloon diameter for device touch-up [§] (mm)
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 [*]	
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

0.018" Guidewire compatible

Device sizing		Introducer Sheath (Fr)						Recommended balloon diameter for device touch-up (mm)
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 [*]	
5	4.0–4.7	6	6	6	6	6	6	5
6	4.8–5.5	6	6	6	6	6	6	5
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® Sheath.

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

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

COOK, CHECK-FLO and FLEXOR are trademarks of Cook Medical, Inc.

Advancing Care Through Access

A new standard of flexibility to treat more challenging anatomies

- Deliver with ease: Hydrophilic coating and enhanced flexibility provide exceptional access to challenging anatomies and branch vessels
- Minimize blood loss: Exclusive GORE® DrySeal valve enables introduction of multiple devices with proven hemostasis control

GORE® DRYSEAL Flex Introducer Sheath — 10 Fr

Catalogue number	Sheath size (Fr)	Minimum sheath ID (mm)	Nominal sheath OD (mm)	Working length (cm)
DSFI033	10	3.3	4.0	33
DSFI045	10	3.3	4.0	45
DSFI065	10	3.3	4.0	65



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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. Rx Only

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W. L. Gore & Associates, Inc.
goremedical.com

Asia Pacific +65 6733 2882 **Australia/New Zealand** 1800 680 424 **Europe** 00800 6334 4673
United States Flagstaff, AZ 86003 800 437 8181 928 779 2771

