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.

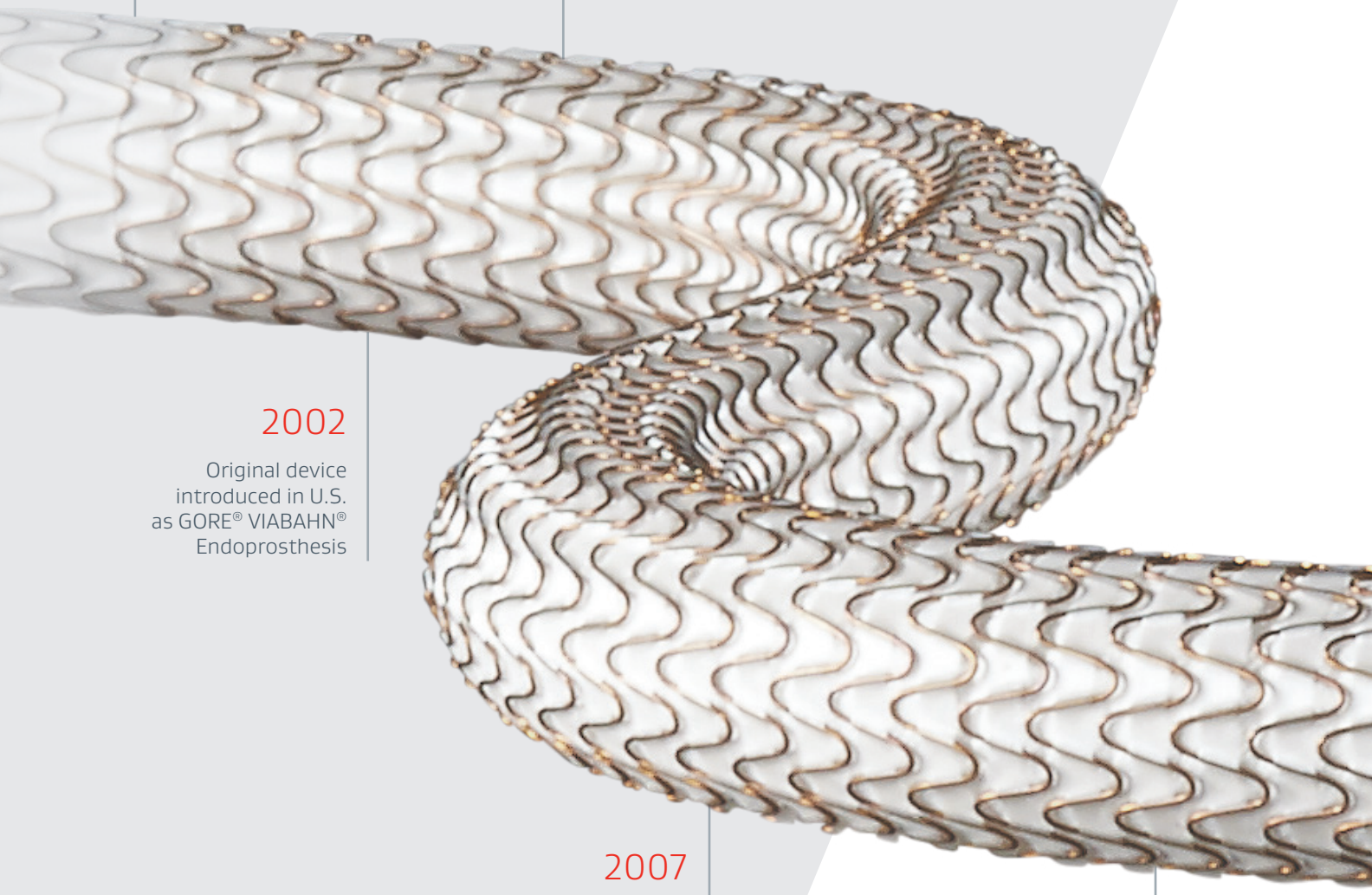
Together, improving life

1996

Original GORE® HEMOBAHN® Endoprosthesis introduced in Europe

2003

TIP to HUB deployment introduced on 6–8 mm devices



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 one French size

2008

All device sizes receive FDA approval for Iliac artery indication

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

† See full indications at goremedical.com.

Continued innovation for durable outcomes and versatility.

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†:

- Superficial femoral artery*
- Iliac artery

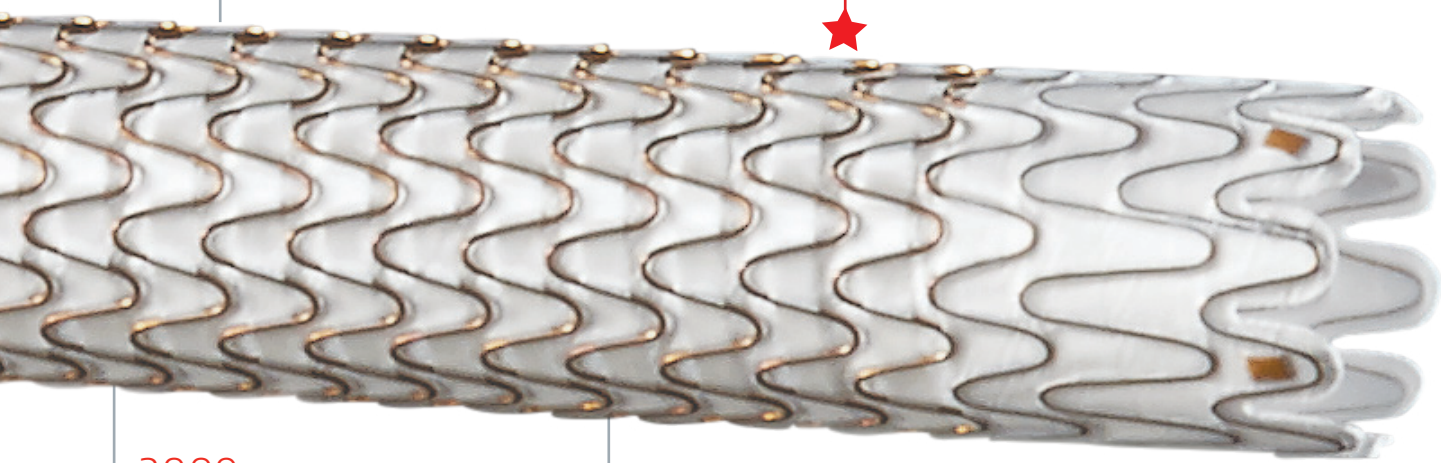
*Not applicable for certain configurations

2023

GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 9–13 mm devices with radiopaque markers and up to 3 Fr size reduction in profile introduced in China.

2019

GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 5–8 mm devices with radiopaque markers and .014" or .018" guidewire compatibility introduced in China.



2009

Laser technology enables the new contoured edge at proximal end

9–13 mm devices introduced with 0.035" guidewire compatibility

2011

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

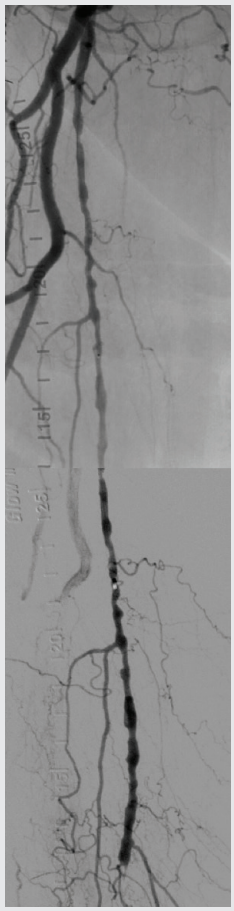
Superficial femoral artery (SFA)

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[1]

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.

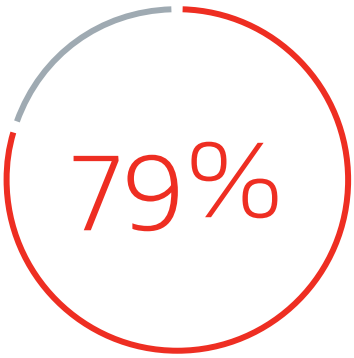
Proven patency for complex SFA lesions across six multicenter, prospective, randomized or single arm studies[1–6]

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

Durable clinical study outcomes in complex cases:

3-year secondary patency in complex disease

(27 cm average lesion length, 93% CTOs)[7]



5-year freedom from target lesion revascularization (fTLR)[8]

Device sizing considerations

- Treat all of the disease (stent "normal to normal")[7]
- Overlap devices by at least 1 cm[7]
- Avoid excessive oversizing (> 20%)[7]

Implantation considerations

- Ensure adequate inflow and outflow[7]
- Post dilate[7]
- Do not use PTA outside of the device[7]
- Place device at the SFA origin if proximal SFA disease is present[7]

Follow-up considerations

- Regular duplex ultrasonography follow-up[9]
- Prescribe appropriate antiplatelet therapy[7]
- Treat progressing disease[9]

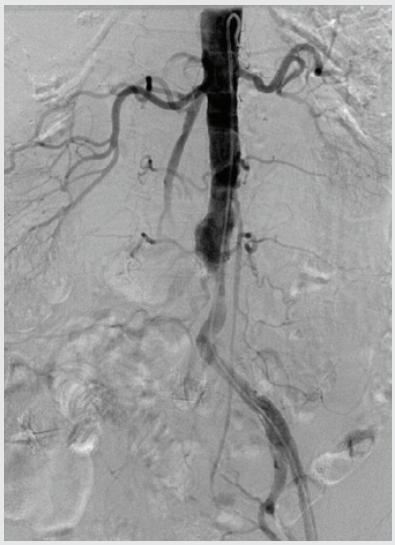
Iliac artery

The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is a self-expanding stent graft indicated to treat iliac lesions.

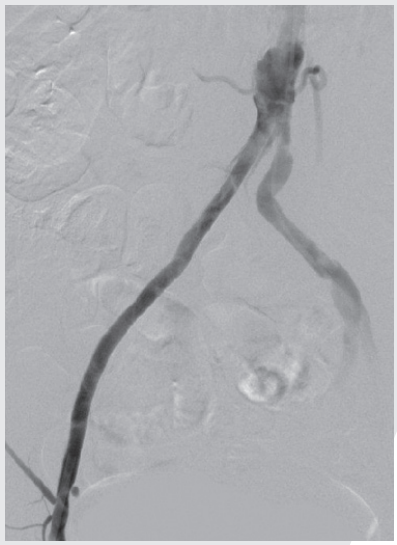
High primary patency even in the most challenging disease: Demonstrated 91% one-year primary patency.[10]

Durable clinical study outcomes in complex cases:

Self-expanding stent grafts, at three years, have demonstrated 88 percent patency in TASC D iliac lesions.[11]



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")[7]
- Overlap devices by at least 1 cm[7]
- Avoid excessive oversizing (> 20%)[7]

Implantation considerations

- Ensure adequate inflow and outflow[7]
- Post dilate[7]
- Do not use PTA outside of the device[7]

Follow-up considerations

- Prescribe appropriate antiplatelet therapy[7]
- Treat progressing disease[9]

Features and benefits

The special design of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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 in-stent restenosis (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.[12]

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 tables

GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface

.035" Guidewire compatibility (with radiopaque markers)

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***	**Recommended balloon diameter for device touch-up‡ (mm)**
5	4.0–4.7	7	7	7	7	5
6	4.8–5.5	7	7	7	7	6
7	5.6–6.5	8	8	8	8	7
8	6.6–7.5	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

.014" or .018" Guidewire compatibility (with radiopaque markers)

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***	**Recommended balloon diameter for device touch-up (mm)**
5	4.0–4.7	6	6	6	6	5
6	4.8–5.5	6	6	6	6	6
7	5.6–6.5	7	7	7	7	7
8	6.6–7.5	7	7	7	7	8

* 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 13 mm diameter device is not compatible with the 10 Fr COOK FLEXOR CHECK-FLO Introducer.

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12. CBAS Heparin Surface. W. L. Gore & Associates website. Accessed October 28, 2020. https://www.goremedical.com/cbas/references

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. $\text{R}_{\text{X Only}}$

Products listed may not be available in all markets.

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