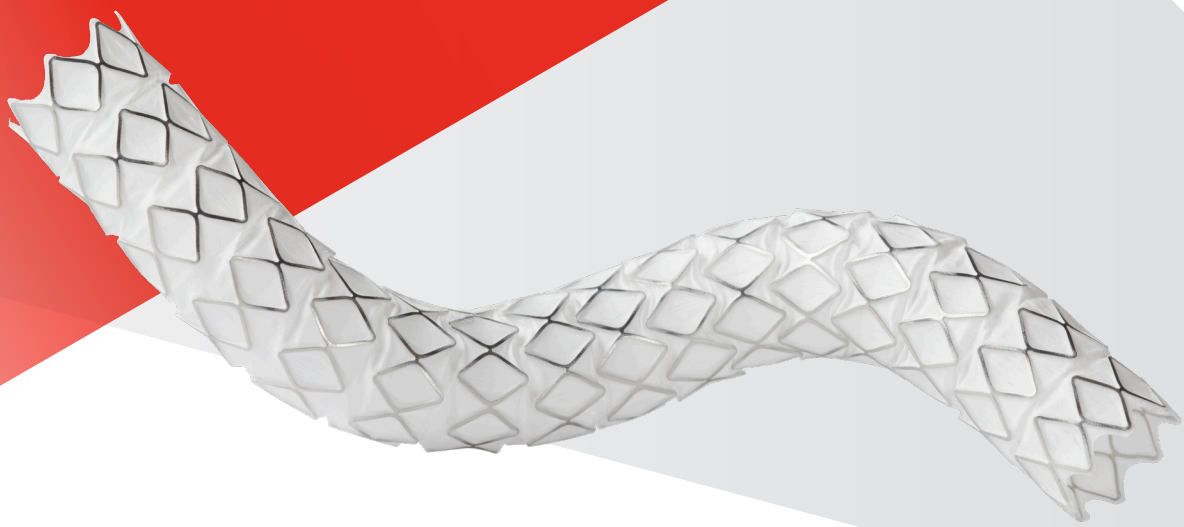
GORE® VIABAHN® VBX
Balloon Expandable Endoprosthesis

FLEXIBLE STRENGTH.
PROVEN SUCCESS.



Together, improving life

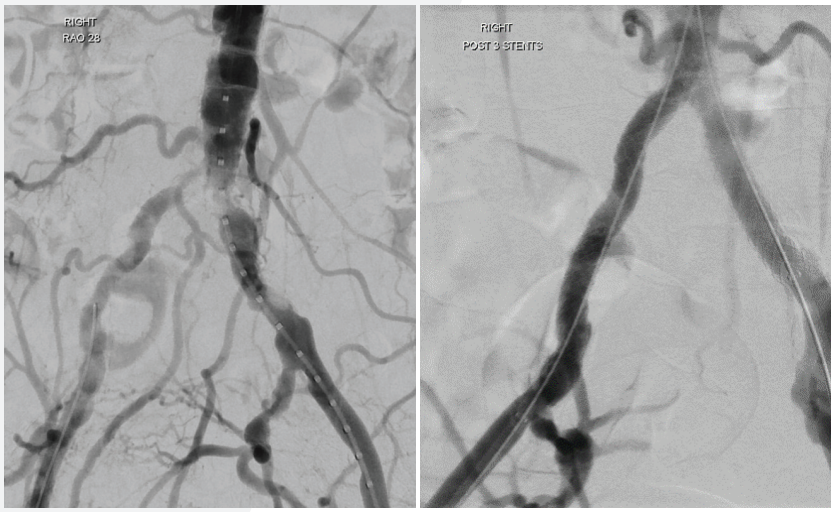
Proven procedural and clinical success

The Gore VBX FLEX Clinical Study is a prospective, multicenter, single-arm study of 134 patients with complex aortoiliac occlusive disease (32.1% TASC II C and D, 42.5% kissing stent).

In the study, 234 devices were delivered; 50% bilateral treatment, 18% contralateral deliveries and predilitation was not required.

100%

restoration of lumen diameter[1]



Before After

≤ 30% residual stenosis due to high radial strength, even in highly calcified and non-compliant lesions

100%

delivery to target lesion with no device dislodgement[1]

100%

stent retention[1]

100%

deployment at the target site[1]

Proven patency at one year[2]

94.5%

primary patency at one year[2]

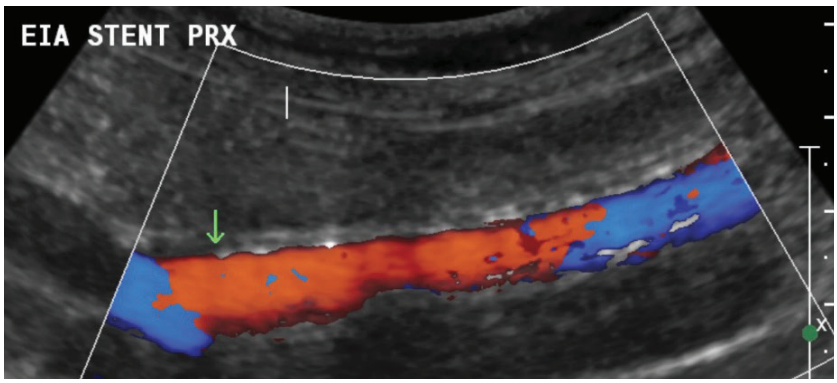


Image reflects results at nine months

96.1% primary patency in TASC C and D lesions at one year[2]

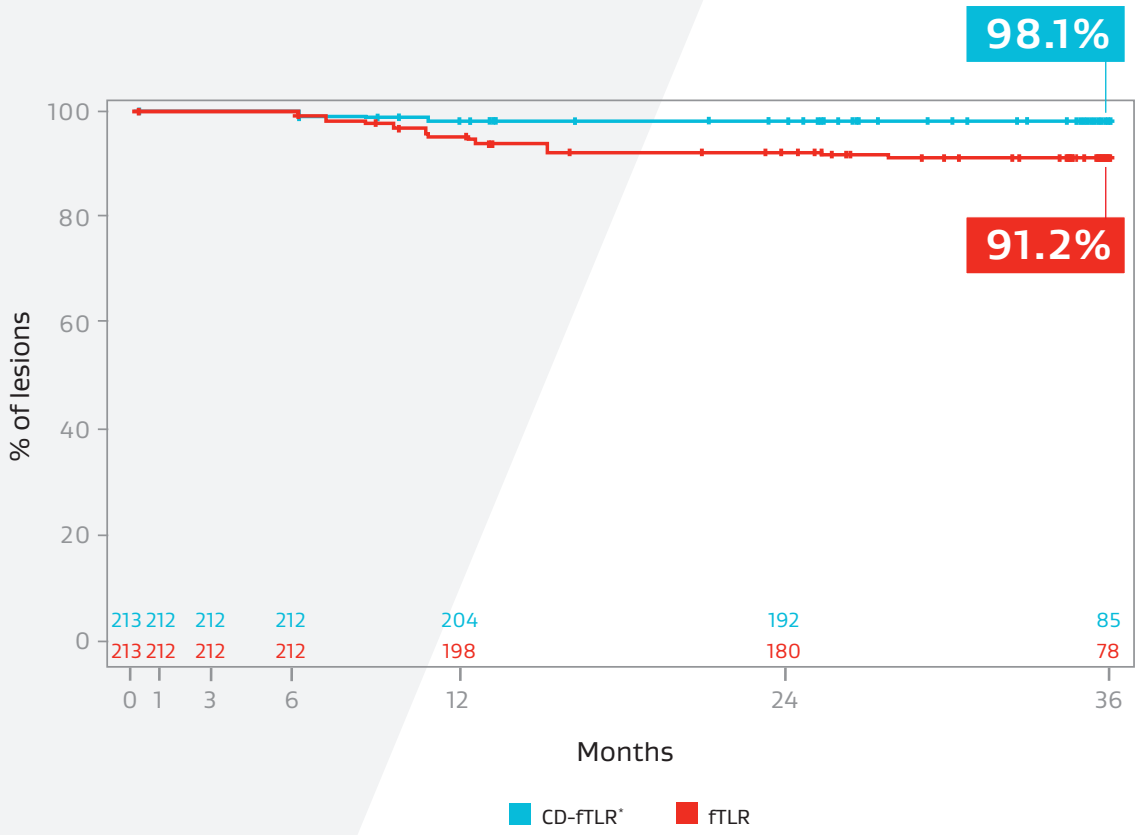
96.4% primary patency in the kissing stent cohort at one year

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

Sustained clinical effectiveness through three years[2]

98.1% clinically driven freedom from target lesion revascularization (fCD-TLR)

91.2% freedom from target lesion revascularization (fTLR)



Kaplan-Meier graph of fCD-TLR and fTLR per lesion with number of lesions at risk

Durable patient benefit through three years[2]

92% of patients with improvement in Rutherford category

+.17 improvement in mean resting ankle-brachial index (ABI) ($P < .001$, .93 mean ABI)†

2-3x improvement in median walking impairment questionnaire (WIQ) measures‡

	Pre-procedure	9-months	2-years	3-years
Walking distance	8 (N = 134)	22 (N = 114)	22 (N = 104)	22 (N = 90)
Walking speed	3 (N = 134)	11 (N = 114)	10 (N = 104)	10 (N = 90)
Stair climbing	4 (N = 127)	9 (N = 114)	9 (N = 102)	9 (N = 87)

* CD-TLR referred to treated segment revascularization when there was evidence of new ischemic signs, namely, target lesion diameter stenosis >50% or worsening of the Rutherford category stemming from the lesion.

† ($P < .001$) statistically significant change from pre-procedure.

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

Procedural economic value

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft) delivers an estimated savings of $1,124/case[3]

Fewer devices
Long (79 mm) available lengths may reduce the total number of devices needed

Fewer balloons
Not required to pre-dilate with the VBX Stent Graft

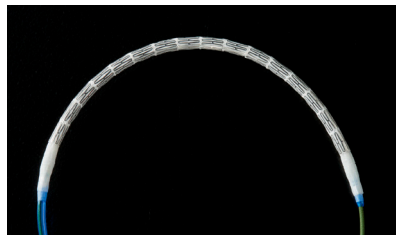
Fewer dislodgements
Reliable delivery with no device dislodgements

Fewer errors
Accurate placement helps avoid need for additional stent grafts

Advanced technology and unique design

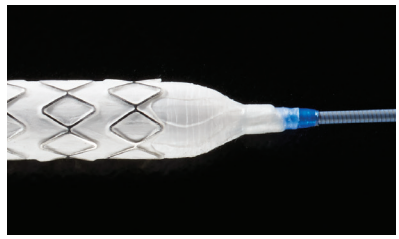
The only BX stent graft with stainless steel independent rings[4,5]

- Enhances flexibility and conformability
- Minimizes foreshortening
- Provides high radial strength



The only BX stent graft with a semi-compliant covered balloon[4,5]

- Enables diameter customization
- Improves device retention on the catheter while tracking in tortuous anatomy and tight angles

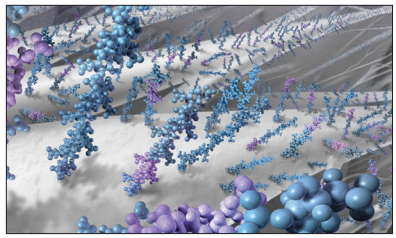


Broadest offering of diameters and lengths[4,5]

- The longest BX stent graft
- The biggest max post-dilated stent diameter BX stent graft*

Proven leader in stent graft technology

- Twenty years of peripheral stent graft clinical experience
- Leverages the stent graft technology of the GORE® VIABAHN® Endoprosthesis
- Featuring Gore's CBAS Heparin Surface, the proven heparin bonding technology for lasting thromboresistance.[6]



* Expansion beyond 13 mm is outside of the indication – see *Instructions For Use*.

References

1. Bismuth J, Gray BH, Holden A, Metzger C, Panneton J; VBX FLEX Study Investigators. Pivotal study of a next-generation balloon-expandable stent-graft for treatment of iliac occlusive disease. *Journal of Endovascular Therapy* 2017;24(5):629-637. http://journals.sagepub.com/doi/full/10.1177/1526602817720463
2. Panneton JM, Bismuth J, Gray BH, Holden A. Three-year follow-up of patients with iliac occlusive disease treated with the Viabahn Balloon-Expandable Endoprosthesis. *Journal of Endovascular Therapy* 2020;27(5):728-736. https://journals.sagepub.com/doi/10.1177/1526602820920569
3. W. L. Gore & Associates, Inc. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. (VBX Stent Graft) Cost Savings Calculator. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2017. [Cost Savings Calculator]. AV1693-EN1.
4. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2019. MD172914.
5. LifeStream™ Balloon Expandable Vascular Covered Stent [Instructions for Use]. Tempe, AZ: Bard Peripheral Vascular, Inc; 2016. PK1345700 Rev. 4 07/16.
6. CBAS Heparin Surface. W. L. Gore & Associates website. Accessed February 4, 2021. https://www.goremedical.com/cbas/references

Consult Instructions for Use
eifu.goremedical.com

INTENDED USE/INDICATIONS: The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm–13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation. **CONTRAINDICATIONS:** Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis 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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