



GORE® VIABAHN® VBX
Balloon Expandable Endoprosthesis

NOW
6Fr
compatible

GREATER
VERSATILITY

TRUSTED PERFORMANCE.
UNMATCHED VERSATILITY.*



* Across indication inclusivity, and configuration breadth/capability of balloon expandable covered stents.

Together, improving life

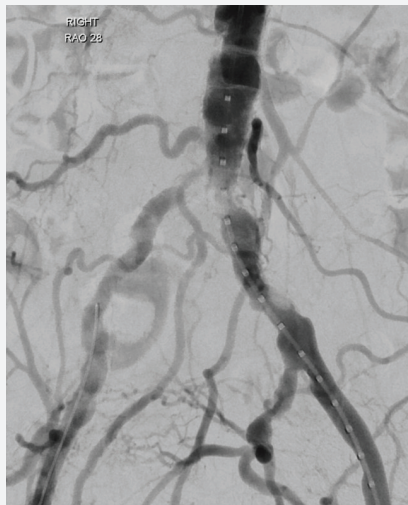
Trusted procedural and clinical performance

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 & D, 42.5% kissing stent).

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

100%

restoration of lumen diameter¹



Before



After

< 30% residual stenosis due to high radial strength, even in highly calcified and non-compliant lesions¹

100%

delivery to target lesion with no device dislodgement¹

100%

stent retention¹

100%

deployment at the target site¹

Trusted patency and patient benefit

1-year outcomes

94.5%
primary patency²

96.1% primary patency in TASC C & D lesions at 1 year*

99.5% secondary patency²

3-year outcomes

91.2% freedom from target lesion revascularization (fTLR)²

+ .17 improvement in mean resting ankle-brachial index (ABI) ($P < .001$, .93 mean ABI)²

92% of patients improved ≥ 1 Rutherford category vs. baseline²

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

Trusted clinical results

VBX Stent Graft durability through 5 years assessed in a physician-initiated study that enrolled 59 patients from 3 participating centers representative of the VBX FLEX Study cohort.

Physician-initiated **5-year** follow-up of patients from 3 centers participating in the VBX FLEX Study

5-year outcomes

89.5%

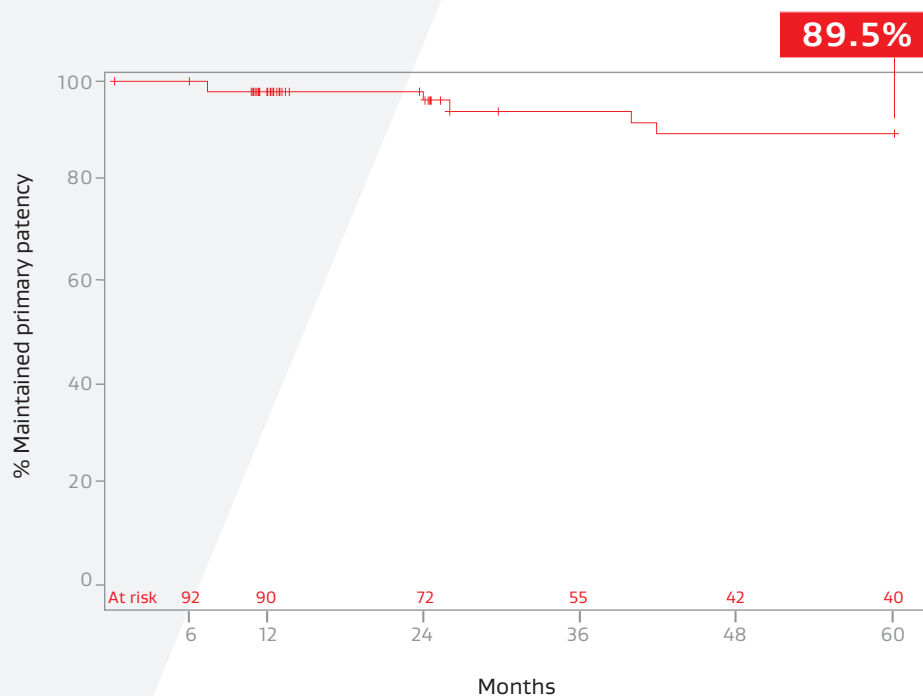
primary
patency per
lesion³

96.1%

primary
assisted patency
per lesion³

89.1%

fTLR
per subject³



Kaplan-Meier graph of primary patency with number of lesions at risk

Additional patient benefits vs. baseline

Follow-up of patients treated with the **VBX Stent Graft**

5-year outcomes

+.15 improvement in mean resting ABI
(from .76 to .95) [$P < .001$]³

3x improvement in median walking
impairment questionnaire
(WIQ) measures³

89% of patients improved ≥ 1 Rutherford
category vs. baseline³

Procedural economic value

The VBX Stent Graft delivers an estimated savings of \$3,606/case over 3 years.*,⁴

Fewer devices

Long (79 mm) available lengths may reduce the total number of devices needed⁴

Fewer reinterventions

Relative to competitive devices as demonstrated in 3-year outcomes data^{2,5,6}

Fewer dislodgements

Reliable delivery with no device dislodgements¹

Fewer errors

Accurate placement helps avoid need for additional stent grafts¹

* Cost savings reflected in 2021 USD.

† Across indication inclusivity, and configuration breadth/capability of balloon expandable covered stents.

‡ Technical limit of the device as determined by in-vitro testing for the indicated use; device expansion beyond 13 mm was not studied as part of the VBX FLEX Clinical Study and is outside of the approved indication — see *Instructions for Use*.

Unmatched versatility[†]

Broadest offering of diameters and lengths⁷⁻⁹

- The longest balloon expandable (BX) stent graft
- The biggest max post-dilated stent diameter BX stent graft[†]
- The most 6 Fr compatible configurations

The only BX stent graft with stainless steel independent rings⁷⁻⁹

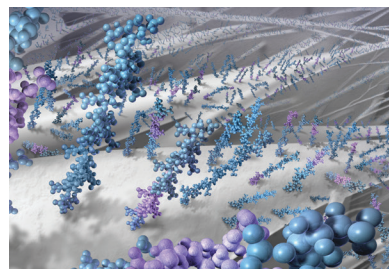
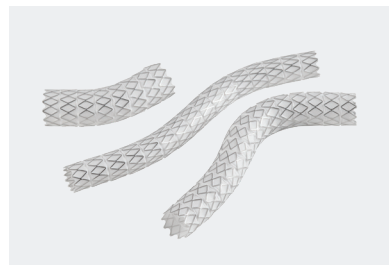
- Enhances flexibility and conformability
- Minimizes foreshortening
- Provides high radial strength

The only BX stent graft with a semi-compliant covered balloon⁷⁻⁹

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

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 thromboresistance¹⁰



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. Holden A, Takele E, Hill A, *et al.* Long-term follow-up of subjects with iliac occlusive disease treated with the Viabahn VBX Balloon-Expandable Endoprosthesis. *Journal of Endovascular Therapy*. In press.
4. W. L. Gore & Associates, Inc. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft). *Clinical evaluation in aortoiliac occlusive disease*. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2022. [Cost calculator]. 22455450-EN.
5. Laird JR, Loja M, Zeller T, *et al.* iCAST balloon-expandable covered stent for iliac artery lesions: 3-year results from the iCARUS multicenter study. *Journal of Vascular & Interventional Radiology* 2019;30(6):822-829.e4.
6. Laird JR. The BOLSTER Study with LIFESTREAM covered stent in iliac lesions: 3-year outcomes. Presented at the Leipzig Interventional Course (LINC) 2019; January 22-25, 2019; Leipzig, Germany.
7. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2023. MD169334.
8. LIFESTREAM® Balloon Expandable Vascular Covered Stent [Instructions for Use]. Tempe, AZ: Bard Peripheral Vascular, Inc; 2019. BAW1345700 Rev. 5 06/19.
9. iCast covered stent system [Instructions for Use]. Merrimack, NH: Atrium Medical Corporation; 2023. AW009603-EN Rev 11.
10. CBAS Heparin Surface. W. L. Gore & Associates website. Accessed August 21, 2023. <https://www.goremedical.com/cbas/references>

 Consult Instructions
for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: 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. Rx only

Products listed may not be available in all markets.

CBAS is a trademark of Carmeda AB, a wholly owned subsidiary of W. L. Gore & Associates, Inc.
GORE, *Together, improving life*, VBX, VBX FLEX, VIABAHN and designs are trademarks of W. L. Gore & Associates.
© 2022, 2023 W. L. Gore & Associates, Inc. 231311008-EN DECEMBER 2023

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 86004 800 437 8181 928 779 2771

