



GORE® VIABAHN® VBX
Balloon Expandable Endoprosthesis

NOW
6Fr
compatible

GREATER
VERSATILITY

TRUSTED PERFORMANCE.
UNMATCHED VERSATILITY.^a



^a Across indication inclusivity and configuration breadth/capability of balloon expandable covered stents.

Together, improving life

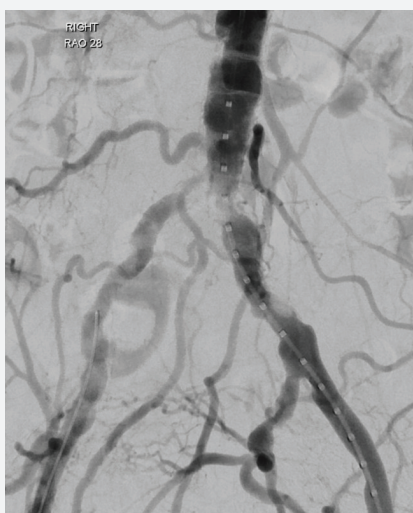
Trusted procedural and clinical performance

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

Procedural outcomes based on usage of legacy GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. (BXA catalogue numbers.)

< 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^b

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

^b 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%

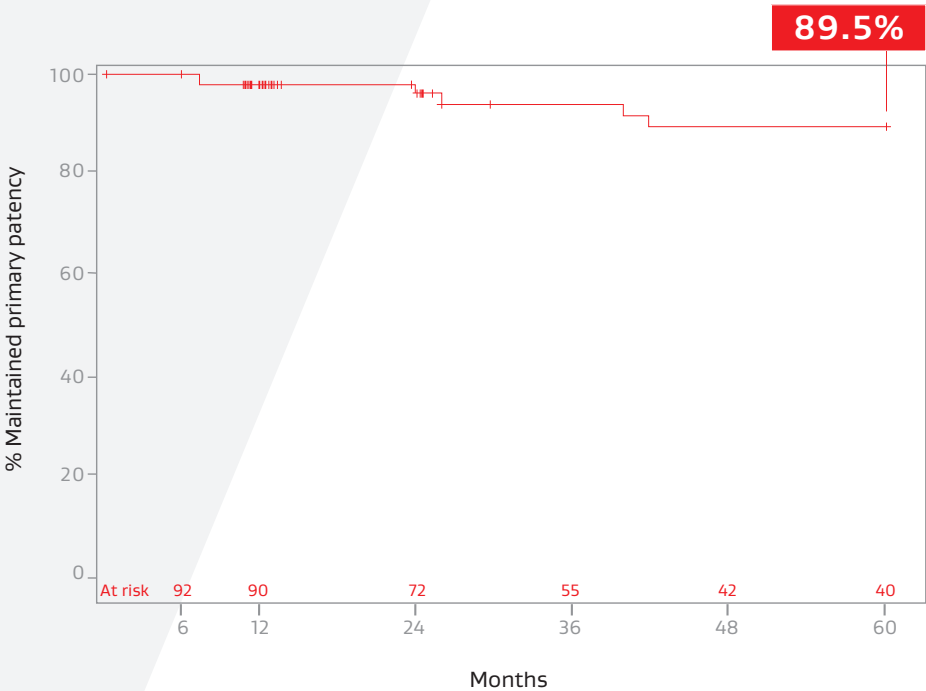
primary
patency per
lesion³

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 .82 to .95) [$P < .001$]³

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

100% of patients improved ≥ 1 Rutherford
category vs. baseline³

Procedural economic value

The VBX Stent Graft delivers an estimated savings of \$5,147/case over 3 years.^{c,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

^c All costs adjusted for inflation to 2023 USD via U.S. Bureau of Labor Statistics (https://www.bls.gov/data/inflation_calculator.htm).

^d Across indication inclusivity and configuration breadth/capability of balloon expandable covered stents.

^e 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^d

Broadest offering of diameters and lengths⁷⁻⁹

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

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

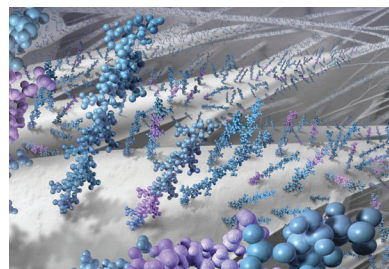
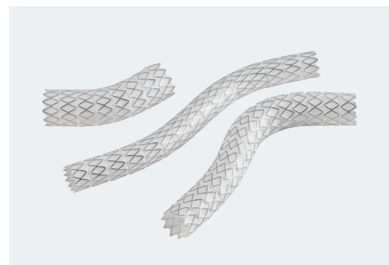
- Enhances flexibility and conformability
- Minimizes foreshortening
- Provides high radial strength

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



Catalogue numbers/size chart

GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis catalogue numbers and available sizes needed for procedures.

VBX Stent Graft catalogue number	Reduced profile VBX Stent Graft catalogue number	Stent labeled/nominal diameter (mm)	Maximum post-dilated stent diameter (mm) ^f	Stent length (mm)	Catheter length (cm)	Guidewire diameter (in)	Introducer sheath size (Fr)
BXA051501A	BXB051501A	5	8	15	80	.035	6
BXA051901A	BXB051901A	5	8	19	80	.035	6
BXA052901A	BXB052901A	5	8	29	80	.035	6
BXA053901A	BXB053901A	5	8	39	80	.035	6
BXA055901A	BXB055901A	5	8	59	80	.035	6
BXA057901A	BXB057901A	5	8	79	80	.035	6
BXA061501A	BXB061501A	6	8	15	80	.035	6
BXA061901A	BXB061901A	6	8	19	80	.035	6
BXA062901A	BXB062901A	6	8	29	80	.035	6
BXA063901A	BXB063901A	6	8	39	80	.035	6
BXA065901A	BXB065901A	6	8	59	80	.035	6
BXA067901A	BXB067901A	6	8	79	80	.035	6
BXA071501A	BXB071501A	7	11	15	80	.035	6
BXA071901A	BXB071901A	7	11	19	80	.035	6
BXA072901A	BXB072901A	7	11	29	80	.035	6
BXA073901A	BXB073901A	7	11	39	80	.035	6
BXA075901A	BXB075901A	7	11	59	80	.035	6
BXA077901A	BXB077901A	7	11	79	80	.035	6
BXA082901A	BXB082901A	8	11	29	80	.035	7
BXA083901A	BXB083901A	8	11	39	80	.035	7
BXA085901A	BXB085901A	8	11	59	80	.035	7
BXA087901A	BXB087901A	8	11	79	80	.035	7
BXA092901A	BXB092901A	9	13	29	80	.035	7
BXA093901A	BXB093901A	9	13	39	80	.035	7
BXA095901A	BXB095901A	9	13	59	80	.035	7
BXA097901A	BXB097901A	9	13	79	80	.035	7
BXA102901A	Unchanged	10	13	29	80	.035	8
BXA103901A	Unchanged	10	13	39	80	.035	8
BXA105901A	Unchanged	10	13	59	80	.035	8
BXA107901A	Unchanged	10	13	79	80	.035	8
BXA112901A	Unchanged	11	16 ^g	29	80	.035	8
BXA113901A	Unchanged	11	16 ^g	39	80	.035	8
BXA115901A	Unchanged	11	16 ^g	59	80	.035	8
BXA117901A	Unchanged	11	16 ^g	79	80	.035	8

^f Secondary balloon required to post-dilate the stent beyond its nominal deployed diameter (Secondary balloon not included).

^g 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*.

VBX Stent Graft catalogue number	Reduced profile VBX Stent Graft catalogue number	Stent labeled/ nominal diameter (mm)	Maximum post-dilated stent diameter (mm)^f	Stent length (mm)	Catheter length (cm)	Guidewire diameter (in)	Introducer sheath size (Fr)
BXAL082901A	BXBL082901A	8	16 ^g	29	80	.035	7
BXAL083901A	BXBL083901A	8	16 ^g	39	80	.035	7
BXAL085901A	BXBL085901A	8	16 ^g	59	80	.035	8
BXAL0857901A	BXBL0857901A	8	16 ^g	79	80	.035	8
BXA051502A	BXB051502A	5	8	15	135	.035	6
BXA051902A	BXB051902A	5	8	19	135	.035	6
BXA052902A	BXB052902A	5	8	29	135	.035	6
BXA053902A	BXB053902A	5	8	39	135	.035	6
BXA055902A	BXB055902A	5	8	59	135	.035	6
BXA057902A	BXB057902A	5	8	79	135	.035	6
BXA061502A	BXB061502A	6	8	15	135	.035	6
BXA061902A	BXB061902A	6	8	19	135	.035	6
BXA062902A	BXB062902A	6	8	29	135	.035	6
BXA063902A	BXB063902A	6	8	39	135	.035	6
BXA065902A	BXB065902A	6	8	59	135	.035	6
BXA067902A	BXB067902A	6	8	79	135	.035	6
BXA071502A	BXB071502A	7	11	15	135	.035	6
BXA071902A	BXB071902A	7	11	19	135	.035	6
BXA072902A	BXB072902A	7	11	29	135	.035	6
BXA073902A	BXB073902A	7	11	39	135	.035	6
BXA075902A	BXB075902A	7	11	59	135	.035	6
BXA077902A	BXB077902A	7	11	79	135	.035	6
BXA082902A	BXB082902A	8	11	29	135	.035	7
BXA083902A	BXB083902A	8	11	39	135	.035	7
BXA085902A	BXB085902A	8	11	59	135	.035	7
BXA087902A	BXB087902A	8	11	79	135	.035	7
BXA092902A	BXB092902A	9	13	29	135	.035	7
BXA093902A	BXB093902A	9	13	39	135	.035	7
BXA095902A	BXB095902A	9	13	59	135	.035	7
BXA097902A	BXB097902A	9	13	79	135	.035	7
BXA102902A	Unchanged	10	13	29	135	.035	8
BXA103902A	Unchanged	10	13	39	135	.035	8
BXA105902A	Unchanged	10	13	59	135	.035	8
BXA107902A	Unchanged	10	13	79	135	.035	8
BXA112902A	Unchanged	11	16 ^g	29	135	.035	8
BXA113902A	Unchanged	11	16 ^g	39	135	.035	8
BXA115902A	Unchanged	11	16 ^g	59	135	.035	8
BXA117902A	Unchanged	11	16 ^g	79	135	.035	8
BXAL082902A	BXBL082902A	8	16 ^g	29	135	.035	7
BXAL083902A	BXBL083902A	8	16 ^g	39	135	.035	7
BXAL085902A	BXBL085902A	8	16 ^g	59	135	.035	8
BXAL087902A	BXBL087902A	8	16 ^g	79	135	.035	8

^f Secondary balloon required to post-dilate the stent beyond its nominal deployed diameter (Secondary balloon not included).

^g 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*.

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; 2024. [Cost calculator]. 24PR1034-EN01.
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 (IFU). W. L. Gore & Associates, Inc. Accessed August 6, 2025. <https://eifu.goremedical.com/>
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 July 8, 2024. <https://www.goremedical.com/cbas/references>



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. The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is also indicated for use with thoracoabdominal and pararenal branched devices indicated with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a branch component. **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. R_x only

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