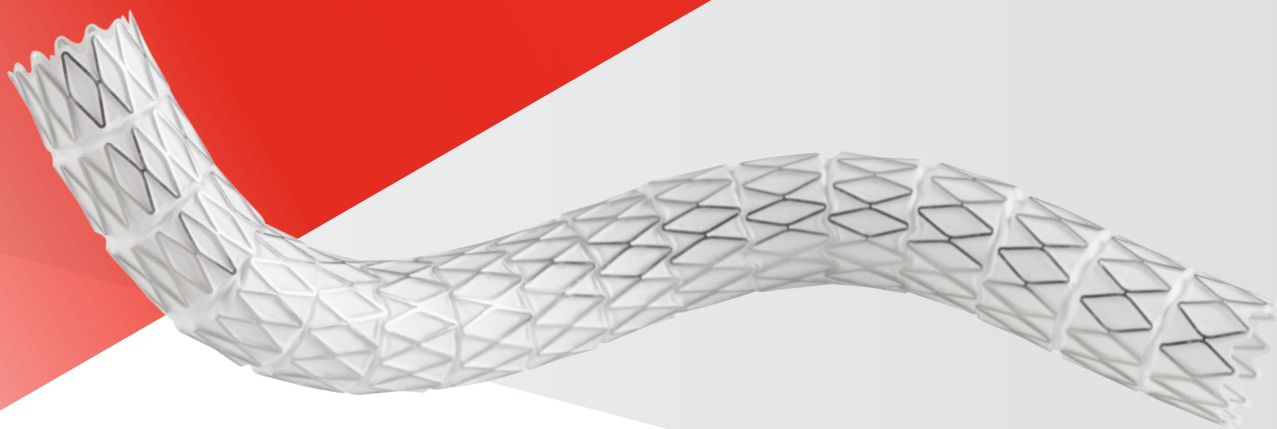
GORE® VIABAHN® VBX
Balloon Expandable Endoprosthesis

FLEXIBLE STRENGTH.
PROVEN SUCCESS.



Together, improving life

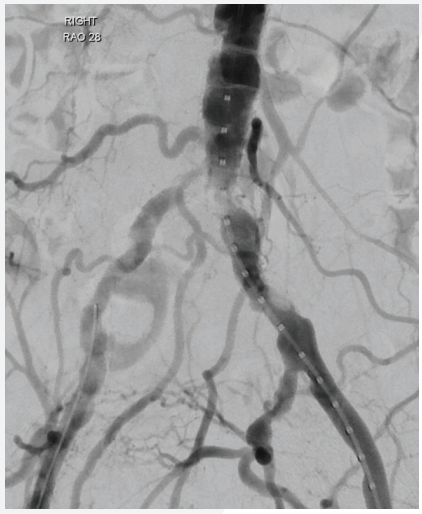
Proven procedural and clinical success

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 & D, 42.5% kissing stent).

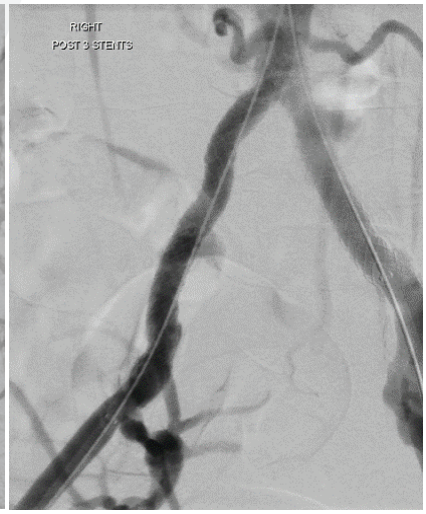
In the study, 234 devices were delivered; 50% bilateral treatment, 18% contralateral deliveries and predilitation was not required.

100%

restoration of lumen diameter[1]



Before



After

≤ 30% residual stenosis due to high radial strength, even in highly calcified and non-compliant lesions[1]

100% delivery to target lesion with no device dislodgement[1]

100% stent retention[1]

100% deployment at the target site[1]

Proven patency and patient benefit

1-year outcomes

94.5%
primary patency[2]

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

99.5% secondary patency[2]

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. baseline[2]

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

Clinically proven results[3]

GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (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.

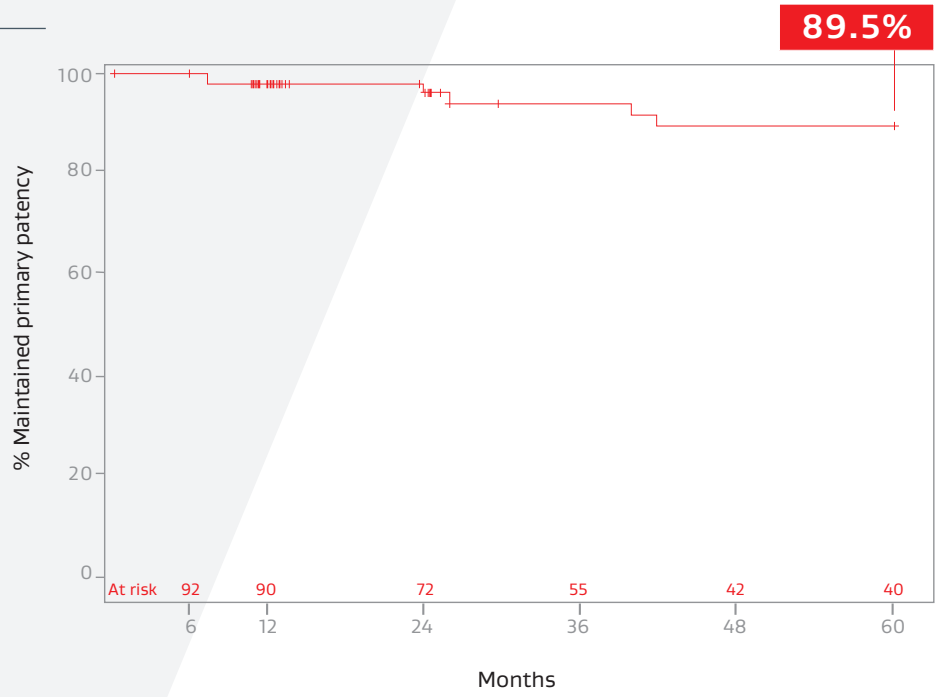
Physician-initiated **5-year** follow-up of patients from 3 centers participating in the VBX FLEX Study

5-year outcomes

89.5%
primary patency per lesion[3]

96.1%
primary assisted patency per lesion[3]

89.1%
fTLR per subject[3]



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) measures[3]
100%	of patients improved ≥ 1 Rutherford category vs. baseline[3]

Procedural economic value of the VBX Stent Graft

Fewer devices
Long (79 mm) available lengths may reduce the total number of devices needed[4]

Fewer reinterventions
Relative to competitive devices as demonstrated in 3-year outcomes data[2,5,6]

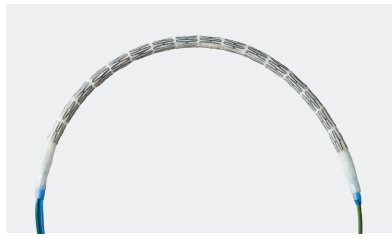
Fewer dislodgements
Reliable delivery with no device dislodgements[1]

Fewer errors
Accurate placement helps avoid need for additional stent grafts[1]

Advanced technology and unique design

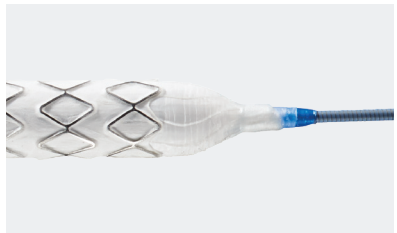
The only balloon expandable (BX) stent graft with stainless steel independent rings[7–11]

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



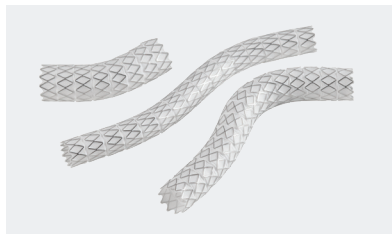
The only BX stent graft with a semi-compliant covered balloon[7–11]

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



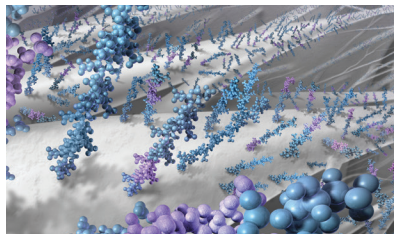
A broad offering of diameters and lengths[7–11]

- The longest BX stent graft
- Maximum post-dilated diameter up to 16 mm with 8L or 11 mm devices*



Proven leader in stent graft technology

- Twenty years of peripheral stent graft clinical experience
- Leverages the stent graft technology of the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface†,‡
- Featuring Gore's CBAS® Heparin Surface, the proven heparin bonding technology for lasting thromboresistance[12]



* Latin America/Brazil: 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*.

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

‡ Also referred to as the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in some regions.

References

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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.
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11. BeGraft Peripheral Stent Graft System [Instructions for Use]. Hechingen, Germany: Bentley InnoMed GmbH.
12. 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

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the market where this product is available. ℞ Only

Products listed may not be available in all markets.

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