



GORE<sup>®</sup> VIABAHN<sup>®</sup> VBX Balloon Expandable Endoprosthesis

### TRUSTED PERFORMANCE. UNMATCHED VERSATILITY.\*



\* Across indications and configurations of covered stents.

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<sup>1</sup>



Before

After

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

## 100% 100% 100%

delivery to target lesion with no device dislodgement<sup>1</sup> stent retention<sup>1</sup>

deployment at the target site<sup>1</sup>

\* Based on prior clinical data. New evaluation of reduced profile delivery is underway.

# Proven patency and patient benefit\*

1-year outcomes



96.1% primary patency in TASC C and D lesions at 1 year<sup>2</sup>

99.5% secondary patency<sup>2</sup>

#### 3-year outcomes

92%

91.2% freed revas

freedom from target lesion revascularization (fTLR)<sup>2</sup>

+.17 improvement in mean resting ABI  $(P < .001, .93 \text{ mean ABI})^{\dagger,2}$ 

of patients improved ≥ 1 Rutherford category versus baseline<sup>2</sup>

\* Based on prior clinical data. New evaluation of reduced profile delivery is underway.

+ (*P* < .001) Statistically significant change from pre-procedure.

#### Clinically proven results<sup>\*,3</sup>



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

#### Additional patient benefits versus baseline<sup>\*,3</sup>

Follow-up of patients treated with the VBX Stent Graft

#### 5-year outcomes

+.15

improvement in mean resting ankle-brachial index (ABI) (from .76 to .95)  $[P < .001]^{\dagger}$ 

3x

improvement in median WIQ measures

 $\frac{100\%}{100\%} \quad \begin{array}{l} \text{of evaluated (n=28) patients} \\ \text{improved} \geq 1 \text{ Rutherford category} \end{array}$ from baseline<sup>‡,3</sup>

\* Based on prior clinical data. New evaluation of reduced profile delivery is underway.

+ (P < .001) Statistically significant change from pre-procedure.

<sup>\$ 59</sup> subjects participated and 28 were available through the end of the study at 5-year follow-up.

# Physician initiated 5 year follow-up elevates BX stent graft long-term data<sup>\*</sup>



Note: Key differences in study design and patient population hinder a direct comparison of results from COBEST and physician-initiated study.

\* Based on prior clinical data. New evaluation of reduced profile delivery is underway.

# Advanced technology and unique design

Broadest offering of diameters and lengths<sup>5-9</sup>:

- The longest BX stent graft
- Broadest range of diameter adjustability in a single device\*
- The most 6 Fr compatible configurations

The only BX stent graft with stainless steel independent rings<sup>5–9</sup>:

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

The only BX stent graft with a covered semicompliant balloon<sup>5-9</sup>:

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

Proven leader in stent graft technology:

- Twenty years of peripheral stent graft clinical experience
- Leverages the stent graft technology of the GORE<sup>®</sup> VIABAHN<sup>®</sup> Endoprosthesis
- Featuring Gore's CBAS<sup>®</sup> Heparin Surface, the proven heparin bonding technology for lasting thromboresistance<sup>10</sup>









#### References

- Bismuth J, Gray BH, Holden A, et al; 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
- 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
- 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. 2023;0(0). doi:10.1177/15266028231165723
- 4. Mwipatayi BP, Sharma S, Daneshmand A, *et al*; COBEST co-investigators. Durability of the balloon-expandable covered versus bare-metal stents in the Covered versus Balloon Expandable Stent Trial (COBEST) for the treatment of aortoiliac occlusive disease. *Journal of Vascular Surgery* 2016;64(1):83-94.e1.
- 5. Gore Medical Products Instructions for Use (IFU). W. L. Gore & Associates, Inc. Accessed September 10, 2024. https://eifu.goremedical.com/
- 6. BeGraft Peripheral Plus Stent Graft System [Instructions for Use]. Hechingen, Germany: Bentley InnoMed GmbH. BeGraft Peripheral Stent Graft System [Instructions for Use]. Hechingen, Germany: Bentley InnoMed GmbH.
- 7. BD<sup>®</sup> LIFESTREAM<sup>®</sup> Balloon Expandable Vascular Covered Stent [Instructions for Use]. Tempe, AZ: Bard Peripheral Vascular, Inc; 2016. PK1345700 Rev. 4 07/16.
- 8. Advanta V12 balloon expandable Covered Stent [Instructions for Use]. Merrimack, NH; Atrium Medical Corporation.
- 9. iCover Peripheral balloon expandable PTFE covered stent system [Instructions for Use]. Barcelona, Spain. iVascular S.L.U.
- 10. CBAS® Heparin Surface. W. L. Gore & Associates website. Accessed June 21, 2024. https://www.goremedical.com/eu/cbas



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