

## FLEXIBLE STRENGTH. PROVEN SUCCESS.

Proven procedural success and durable clinical outcomes through 3 years

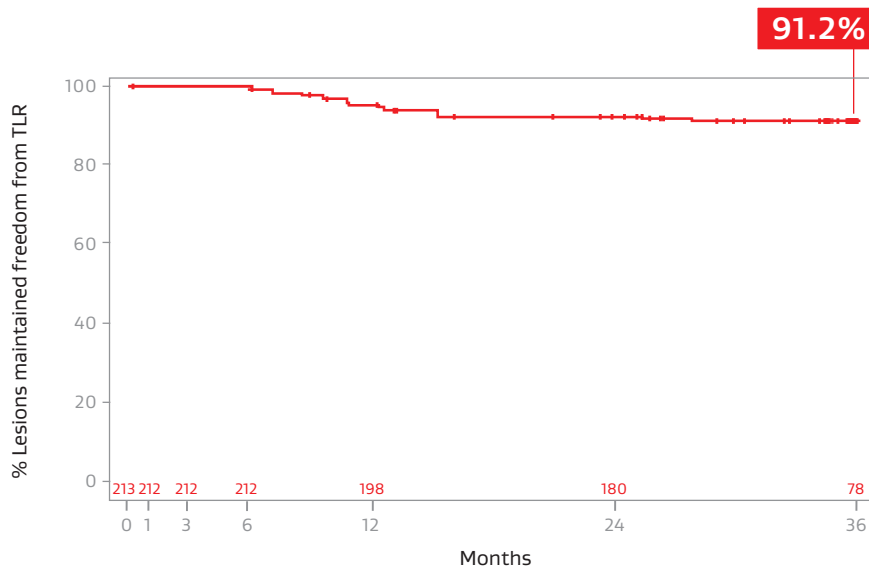
**Proven procedural success:**

- 100% restoration of lumen diameter<sup>1</sup>
- 100% delivery to target lesion with no device dislodgement<sup>1</sup>
- 96.9% primary patency at nine months<sup>1</sup>

**Sustained clinical effectiveness through 3 years:**

- 91.2% freedom from target lesion revascularization (fTLR)<sup>2</sup>

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)



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

# DURABLE PATIENT BENEFIT VERSUS BASELINE THROUGH 3 YEARS<sup>2</sup>

**92%** of patients with improvement  
in Rutherford category<sup>2</sup>

**.17** improvement in mean resting ankle-brachial  
index (ABI) ( $P < .001$ , .93 mean ABI)<sup>\*,2</sup>

2-3x improvement in median WIQ measures<sup>†</sup>


|                  | 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)  |

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

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

## 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/10.1177/15266602817720463>.
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*. In press. <https://journals.sagepub.com/doi/10.1177/15266602820920569>

**INDICATIONS FOR USE IN THE U.S., AUSTRALIA, NEW ZEALAND, CANADA AND LATIN AMERICA:** 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](http://eifu.goremedical.com) for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. 

 Consult Instructions  
for Use  
[eifu.goremedical.com](http://eifu.goremedical.com)

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