

GORE® VIABAHN® VBX

Balloon Expandable Endoprosthesis
(VBX Stent Graft)

UNIQUE DESIGN
VERSATILE PERFORMANCE
DIFFERENTIATED DATA

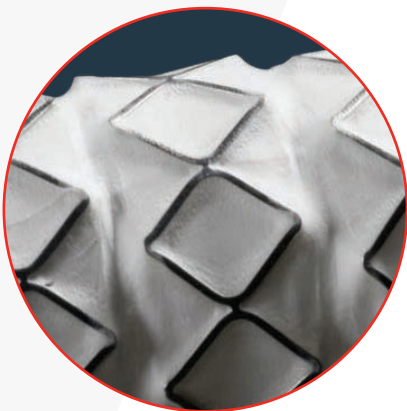


Together, improving life



DESIGNED TO DELIVER PROVEN TO PERFORM

Built to expand to clinical demands, the VBX Stent Graft offers proven procedural success and long-term outcomes¹⁻³ through flexibility, strength and accuracy to treat aortoiliac occlusive disease (AIOD) and complex aneurysmal disease involving the visceral aorta. This includes on-label usage for FEVAR and BEVAR, backed by independently validated, real-world clinical evidence.⁴

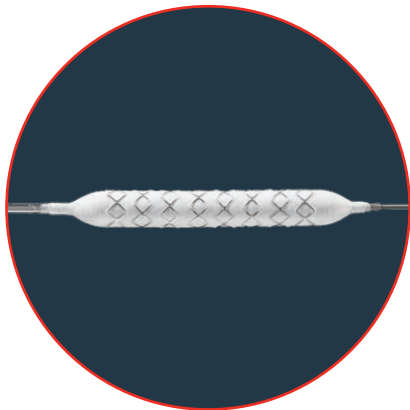


The only balloon expandable (BX) stent graft with stainless steel independent rings⁵⁻⁷

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

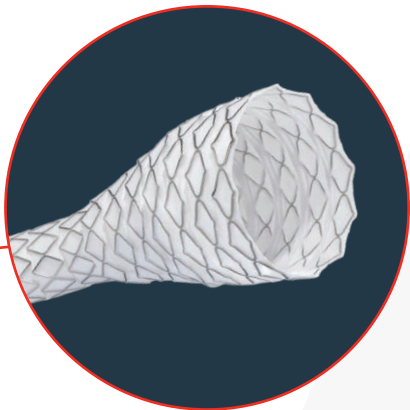
Broadest offering of diameters and lengths⁵⁻⁷

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



The only BX stent graft with a semi-compliant covered balloon⁵⁻⁷

- Improves device retention on the catheter while tracking in tortuous anatomy and tight angles
- Ensures trusted deployment accuracy



Unique design enables diameter and flare customization

- Maintains durability to preserve seal integrity

LEADER IN STENT GRAFT TECHNOLOGY

**600,000+ VBX
SOLD WORLDWIDE IN
OVER 50 COUNTRIES⁸**

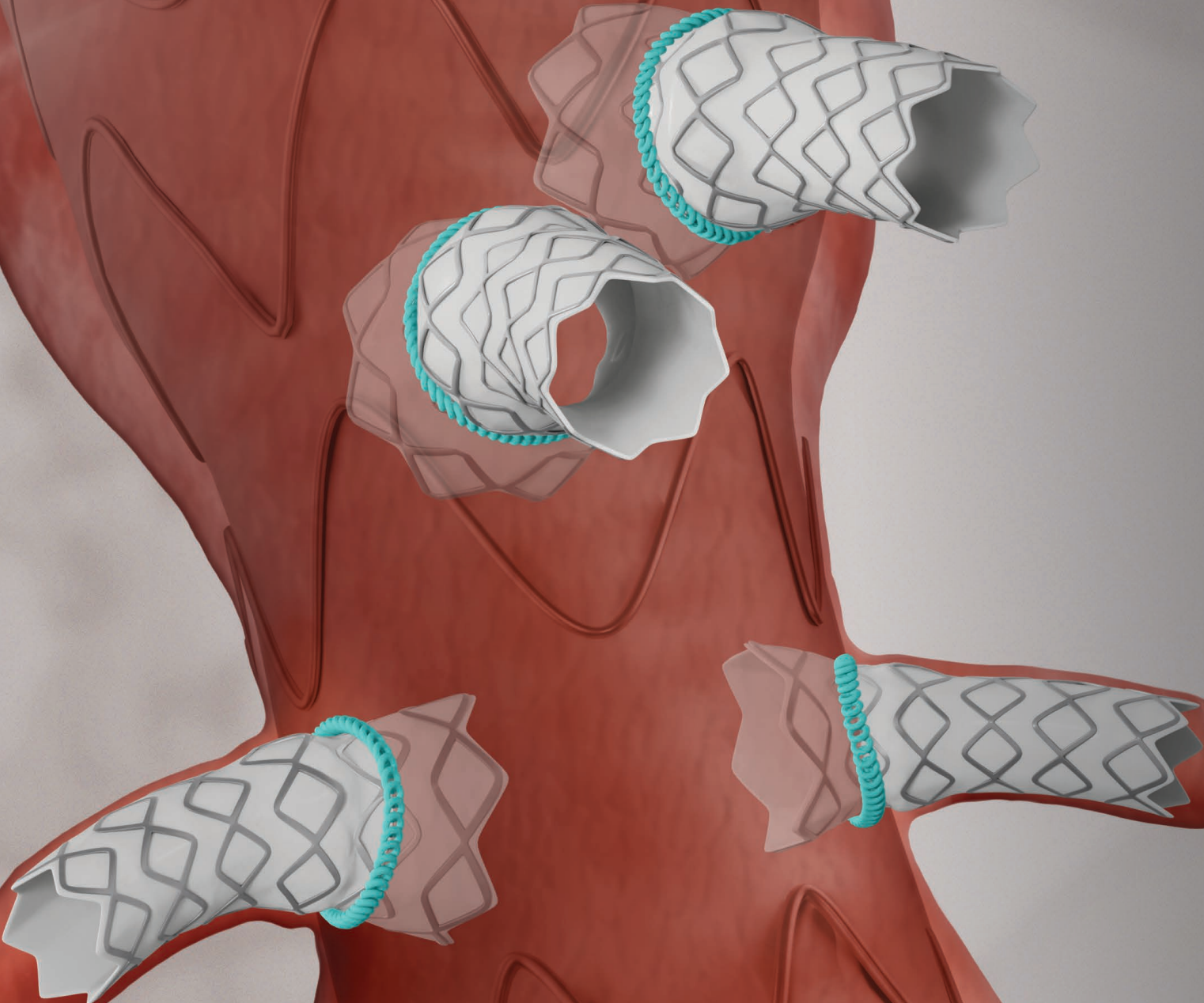
Physicians in over 50+ countries place their trust in the VBX Stent Graft

**GORE
TECHNOLOGY**

Built on 20+ years of peripheral stent graft clinical experience

**CBAS[®]
HEPARIN
SURFACE**

Designed for lasting thromboresistance



PROVEN IN FEVAR AND BEVAR

The VBX Stent Graft is backed by core lab analyzed clinical evidence you can trust. It has delivered proven procedural and clinical success in hundreds of FEVAR and BEVAR patients in the Gore EMBRACE and EXPAND Registries and as noted in multiple publications.⁹⁻¹⁴

THE DIFFERENCE IS IN OUR DATA⁴



BROAD INCLUSION MINIMAL EXCLUSION

Criteria representing real-world patient demographics



CORE LAB ANALYZED

Independently validated to increase accuracy and reduce bias



MULTICENTER REGISTRY DESIGN

Strategically increasing the real-world population being studied



MIX OF COMPLEX ANEURYSMS

The EMBRACE Registry shows consistently strong clinical results in complex cases

BECAUSE DATA REPRESENTS MORE THAN JUST NUMBERS

EMBRACE REGISTRY ¹⁵	FEVAR		BEVAR	
Target vessel technical success ^a	100%		99.6%	
	1-YEAR OUTCOMES	3-YEAR OUTCOMES	1-YEAR OUTCOMES	3-YEAR OUTCOMES
Primary patency	99.4%	97.5%	98.9%	94.0%
Freedom from target vessel instability (FTVI)	96.6%	93.9%	94.5%	88.4%

Treated vessels: FEVAR = 208, BEVAR = 454

EXPAND REGISTRY ¹⁵	FEVAR		BEVAR	
Target vessel technical success ^a	100%		100%	
	1-YEAR OUTCOMES	3-YEAR OUTCOMES	1-YEAR OUTCOMES	3-YEAR OUTCOMES
Primary patency	100.0%	96.5%	96.0%	93.4%
Freedom from target vessel instability (FTVI)	100.0%	96.5%	96.0%	92.7%

Treated vessels: FEVAR = 97, BEVAR = 223

ANEURYSM TYPES STUDIED IN EMBRACE

Consistent strong clinical results were seen across a mix of complex aneurysm types

	FEVAR ¹⁶	BEVAR ¹⁷
TAAA Type I-III	24%	61%
TAAA Type IV	12%	24%
Pararenal aneurysm	20%	11%
Juxtarenal aneurysm	19%	4%
Infrarenal aneurysm	24%	0%



The Gore EMBRACE Registry is a multicenter, single-arm retrospective and prospective study of 259 patients with aortic aneurysms involving the renal-mesenteric arteries.¹³

The Gore EXPAND Registry is a post-market registry, evaluating the safety and performance data of the VBX Stent Graft in peripheral vessels in patients who require interventional treatment.¹⁴

Explore the data

a. Based on previously collected clinical data. Evaluation of the reduced-profile delivery system is ongoing.

1-YEAR OUTCOMES IN AIOD

TRUSTED PROCEDURAL AND CLINICAL
PERFORMANCE IN AIOD

100% technical
success¹⁸

Delivery to target lesion
with no device dislodgement | Stent
retention | Deployments with
residual stenosis ≤ 30%

95% primary patency¹

96% primary patency
in TASC II C & D lesions¹⁹

100% secondary patency¹

5-YEAR OUTCOMES IN AIOD

PHYSICIAN INITIATED 5-YEAR FOLLOW-UP ELEVATES
BX STENT GRAFT LONG-TERM DATA

100%
of patients improved ≥ 1
Rutherford category vs. baseline²

90% primary patency
per lesion²

89% fTLR per subject²

96% primary assisted
patency per lesion²

THE GORE VBX FLEX CLINICAL STUDY¹⁸

Prospective, multicenter,
single-arm study of 134
patients with complex AIOD

32.1% TASC II C & D
42.5% kissing stent

234

DEVICES
DELIVERED

50%

BILATERAL
TREATMENT

18%

CONTRALATERAL
DELIVERIES

*Predilatation
was not required*

ADDITIONAL PATIENT BENEFITS VS. BASELINE²

+.15

improvement in
mean resting ankle
brachial index (ABI)
from baseline
[*P* < .001]

3x

improvement in median
walking impairment
questionnaire
(WIQ) measures

KEY ADVANTAGES OF COVERED STENTS

How covered stents help address the shortcomings of bare metal stents in treating complex AIOD²⁰⁻²²:

- Exclude plaque
- Prevent in-stent neointimal hyperplasia^{18,21,22}
- Decrease the risk of complications caused by distal embolization, perforation, rupture or dissection^{23,24}
- Cover and seal off vessel ruptures
- Promote hemodynamic flow via a new flow lumen

The Society for Vascular Surgery recommends covered stents in instances of severe calcification at risk of vessel rupture.²³

GORE IS WORKING TO ADVANCE EVIDENCE IN COMPLEX AIOD

The **FORWARD Clinical Study** is an ongoing prospective, multicenter randomized controlled trial evaluating the VBX Stent Graft versus bare metal stents in patients with complex AIOD.

Numerous studies with covered stents have shown excellent outcomes for treating complex AIOD including those with:



TASC II C & D lesions^{20,21}



Aortic bifurcation lesions (kissing stent technique)^{18,24}



Highly calcified/difficult-to-dilate lesions^{20,24}



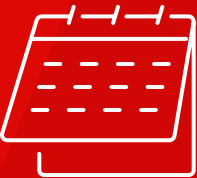
Total occlusions^{18,20,25}



GLOBAL
MULTICENTER
STUDY



RANDOMIZED
CONTROLLED
DESIGN



5-YEAR
FOLLOW-UP

PROCEDURAL ECONOMIC VALUE



Fewer devices

Long (79 mm) lengths may reduce the total number of devices needed²⁶



Fewer dislodgements

Reliable delivery with no device dislodgements^{a,18}



Fewer reinterventions

Relative to competitive devices as demonstrated in 3-year outcomes data^{1,25,27}



Fewer errors

Accurate placement^a helps avoid need for additional stent grafts¹⁸

a. Based on previously collected clinical data. Evaluation of the reduced-profile delivery system is ongoing.

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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 markets where this product is available. Rx_{Only}

INDICATIONS FOR USE IN THE US: 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 indicated to maintain visceral artery perfusion as a bridging stent in:

- fenestrated endovascular aortic aneurysm repair with 6-8 mm diameter fenestrations
- branched endovascular aortic aneurysm repair with 6-8 mm diameter branches (e.g. portals, cuffs, or directional branches) that are at least 10 mm in length

Bridging stent use is limited to aortic endovascular graft systems wherein safety and effectiveness has been demonstrated.

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. Patients with known sensitivities or allergies to the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis materials including expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP), stainless steel, and heparin.

Products listed may not be available in all markets.

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