GORE® VIABAHN® VBX
Balloon Expandable Endoprosthesis
(VBX Stent Graft)

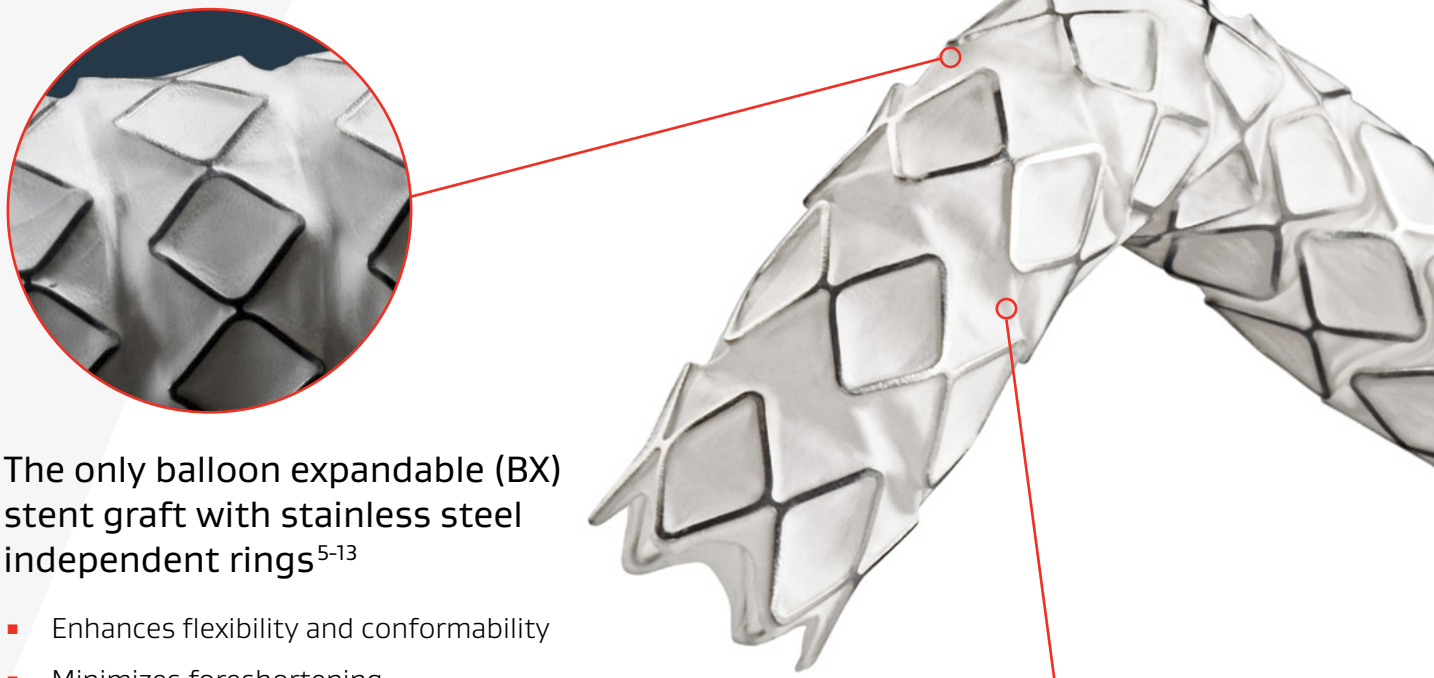
UNIQUE DESIGN
VERSATILE PERFORMANCE
DIFFERENTIATED DATA



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 outcomes[1-3] 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]



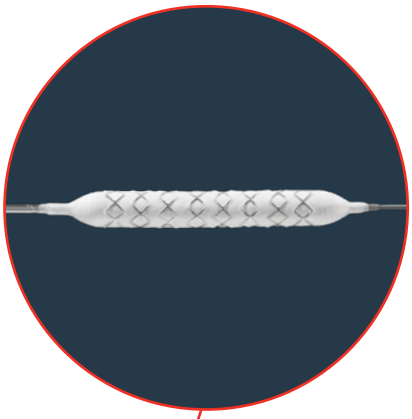
The only balloon expandable (BX) stent graft with stainless steel independent rings[5-13]

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

Broadest offering of diameters and lengths[5-13]

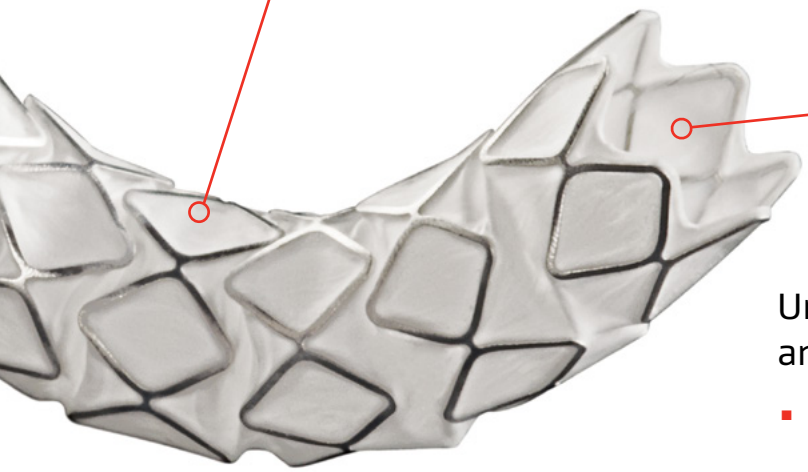
- The longest BX stent graft
- The most 6 Fr compatible configurations
- Broadest range of diameter adjustability in a single device

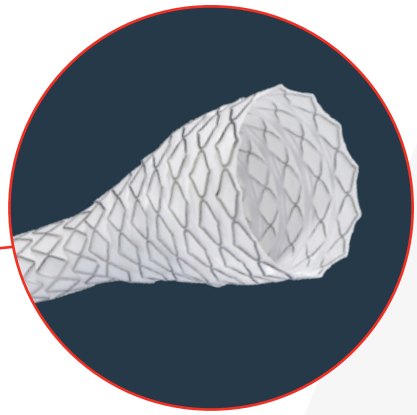




The only BX stent graft with a semi-compliant covered balloon[5-13]

- 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 COUNTRIES[14]

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

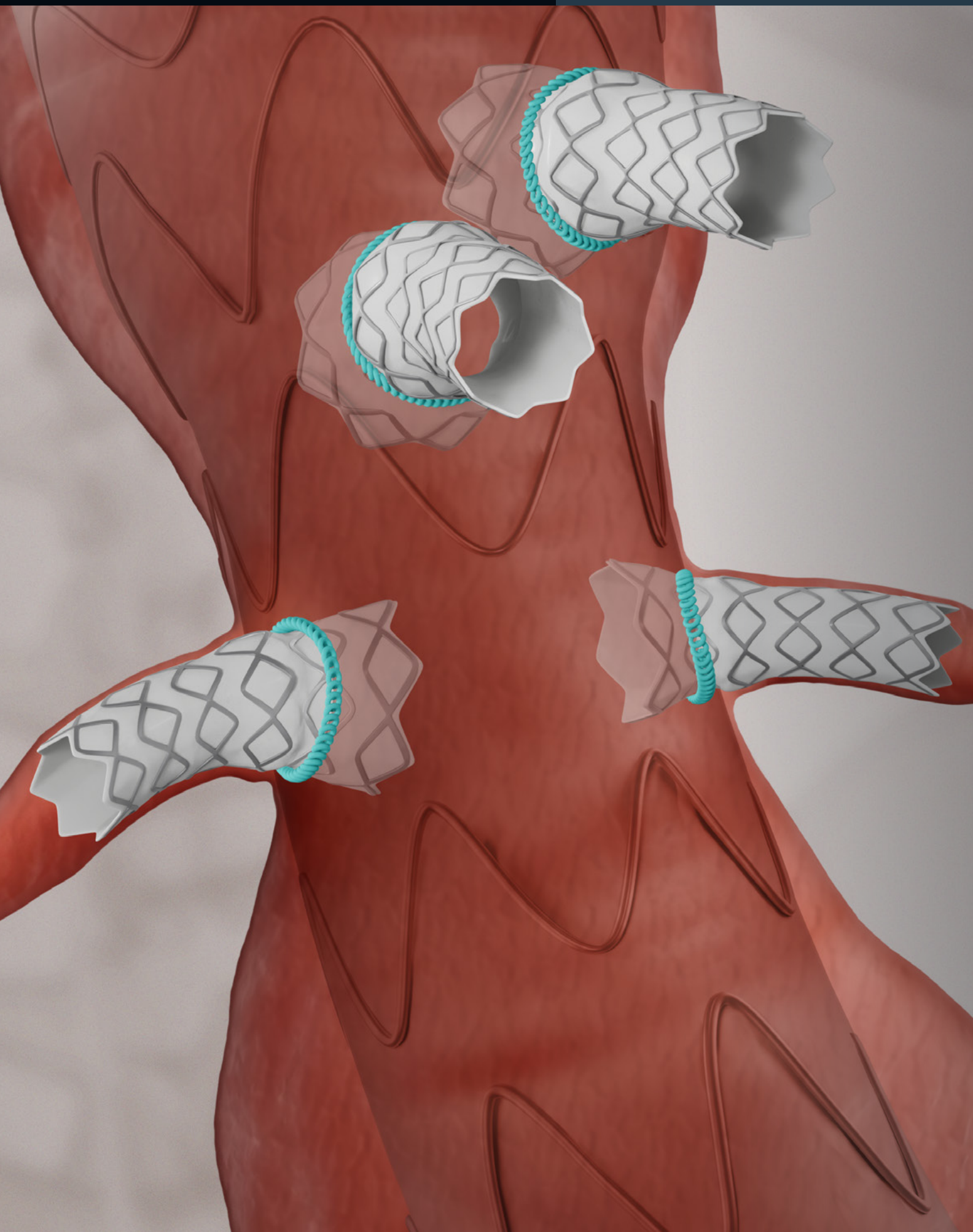
GORE TECHNOLOGY

Built on 20+ years of peripheral stent graft clinical experience

CBAS® HEPARIN SURFACE

Designed for lasting thromboresistance

VBX STENT GRAFT IN FEVAR AND BEVAR





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.[15-20]

THE DIFFERENCE IS IN OUR DATA[4]

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[21]	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

ANEURYSM TYPES STUDIED IN EMBRACE

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

	FEVAR[22]	BEVAR[22]
TAAA Type I-III	24%	61%
TAAA Type IV	12%	24%
Pararenal aneurysm	20%	11%
Juxtarenal aneurysm	19%	4%
Infrarenal aneurysm	24%	0%

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

EXPAND REGISTRY[21]	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



The Gore EMBRACE Registry is a multicenter, single-arm retrospective and prospective study of 259 patients with aortic aneurysms involving the renal-mesenteric arteries.[19]

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.[20]

1-YEAR OUTCOMES IN AIOD

TRUSTED PROCEDURAL AND CLINICAL PERFORMANCE IN AIOD

100% technical success[23]

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

95% primary patency[1]

96% primary patency in TASC II C & D lesions[24]

100% secondary patency[1]

THE GORE VBX FLEX CLINICAL STUDY[23]

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

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. baseline[2]

90%	primary patency per lesion[2]
89%	fTLR per subject[2]
96%	primary assisted patency per lesion[2]

ADDITIONAL PATIENT BENEFITS VS. BASELINE[2]

+.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 AIOD[25-27]:

- Exclude plaque
- Prevent in-stent neointimal hyperplasia[23,26,27]
- Decrease the risk of complications caused by distal embolization, perforation, rupture or dissection[28,29]
- Cover and seal off vessel ruptures
- Promote hemodynamic flow via a new flow lumen

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



TASC II C & D lesions[25,26]



Aortic bifurcation lesions (kissing stent technique)[23,29]



Highly calcified/ difficult-to-dilate lesions[25,29]

The Society for Vascular Surgery recommends covered stents in instances of severe calcification at risk of vessel rupture.[28]



Total occlusions[23,25,30]

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.

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 needed[31]

Fewer dislodgements
Reliable delivery with no device dislodgements[a,23]

Fewer reinterventions
Relative to competitive devices as demonstrated in 3-year outcomes data[1,30,32]

Fewer errors
Accurate placement[a] helps avoid need for additional stent grafts[23]

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

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