2020 SCAI* GUIDELINES FOR AORTO-ILIAC ARTERIAL INTERVENTIONS[1]

* Society for Cardiovascular Angiography & Intervention.

Together, improving life

GORE

Covered BX stent grafts garnered five Class I recommendations — more than any other treatment modality.

Lesion characteristics	Class I
Aorto-iliac bifurcation	■
Focal CIA lesion	■
Diffuse CIA lesion	■
Moderate to severe calcified focal lesion	■
Moderate to severe calcified diffuse lesion	■

SCAI guidelines on device selection in aorto-iliac arterial interventions[1]

Class of recommendation (COR)* and level of evidence (LOE) for device selection as the intended definitive therapy in the aorto-iliac arterial intervention†

	PTA		Specialty balloons		Drug coated balloons		BMS (Self-expanding)		BMS (Balloon-expandable)		Covered stents (Self-expanding)		Covered stents (Balloon-expandable)		Drug eluting stents		Atherectomy	
	COR	LOE	COR	LOE	COR	LOE	COR	LOE	COR	LOE	COR	LOE	COR	LOE	COR	LOE	COR	LOE
Aorto-iliac bifurcation	**IIb** (Weak)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)	**IIa** (Moderate)	**B** (Randomized)	**I** (Strong)	**B** (Randomized)	**IIb** (Weak)	**C** (Limited data)	**I** (Strong)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (Harm)	**C** (Expert opinion)
Focal CIA lesion	**IIa** (Moderate)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)	**IIa** (Moderate)	**B** (Randomized)	**I** (Strong)	**B** (Randomized)	**IIb** (Weak)	**C** (Limited data)	**I** (Strong)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (Harm)	**C** (Expert opinion)
Diffuse CIA lesion	**IIb** (Weak)	**B** (Non-randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)	**I** (Strong)	**B** (Non-randomized)	**I** (Strong)	**B** (Non-randomized)	**IIb** (Weak)	**C** (Limited data)	**I** (Strong)	**B** (Non-randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (Harm)	**C** (Expert opinion)
Focal EIA lesion	**IIa** (Moderate)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)	**I** (Strong)	**B** (Randomized)	**IIa** (Moderate)	**B** (Randomized)	**IIb** (Weak)	**C** (Limited data)	**IIa** (Moderate)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (Harm)	**C** (Expert opinion)
Diffuse EIA lesion	**IIb** (Weak)	**B** (Non-randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)	**I** (Strong)	**B** (Non-randomized)	**IIa** (Moderate)	**B** (Non-randomized)	**IIa** (Moderate)	**C** (Limited data)	**IIa** (Moderate)	**C** (Limited data)	**III** (No benefit)	**C** (Expert opinion)	**III** (Harm)	**C** (Expert opinion)
Moderate to severe calcified focal lesion	**IIb** (Weak)	**B** (Non-randomized)	**III** (No benefit)	**C** (Limited data)	**III** (No benefit)	**C** (Expert opinion)	**IIa** (Moderate)	**C** (Limited data)	**IIa** (Moderate)	**C** (Limited data)	**IIa** (Moderate)	**C** (Limited data)	**I** (Strong)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)
Moderate to severe calcified diffuse lesion	**IIb** (Weak)	**B** (Non-randomized)	**III** (No benefit)	**C** (Limited data)	**III** (No benefit)	**C** (Expert opinion)	**IIa** (Moderate)	**B** (Non-randomized)	**IIa** (Moderate)	**B** (Non-randomized)	**IIa** (Moderate)	**C** (Limited data)	**I** (Strong)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)
Chronic total occlusion, focal lesion	**IIb** (Weak)	**C** (Limited data)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)	**IIa** (Moderate)	**B** (Randomized)	**IIa** (Moderate)	**B** (Randomized)	**IIa** (Moderate)	**C** (Limited data)	**IIa** (Moderate)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (Harm)	**C** (Expert opinion)
Chronic total occlusion, diffuse lesion	**IIb** (Weak)	**C** (Limited data)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)	**IIa** (Moderate)	**B** (Randomized)	**IIa** (Moderate)	**B** (Non-randomized)	**IIa** (Moderate)	**C** (Expert opinion)	**IIa** (Moderate)	**B** (Randomized)	**III** (No benefit)	**C** (Expert opinion)	**III** (Harm)	**C** (Expert opinion)
In-stent restenosis, focal lesion	**IIa** (Moderate)	**C** (Limited data)	**III** (No benefit)	**C** (Expert opinion)	**IIb** (Weak)	**C** (Expert opinion)	**IIb** (Weak)	**C** (Limited data)	**IIb** (Weak)	**C** (Limited data)	**IIa** (Moderate)	**C** (Limited data)	**IIa** (Moderate)	**C** (Limited data)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)
In-stent restenosis, diffuse lesion	**IIa** (Moderate)	**C** (Limited data)	**III** (No benefit)	**C** (Expert opinion)	**IIb** (Weak)	**C** (Expert opinion)	**IIb** (Weak)	**C** (Limited data)	**IIb** (Weak)	**C** (Limited data)	**IIa** (Moderate)	**C** (Limited data)	**IIa** (Moderate)	**C** (Limited data)	**III** (No benefit)	**C** (Expert opinion)	**III** (No benefit)	**C** (Expert opinion)

* Colors were assigned based on class of recommendation.

† Lesion length is defined as focal when ≤ 4 cm and as diffuse when > 4 cm.

Flexible strength. Proven success.

GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

The only BX stent graft with stainless steel independent rings[2,3]

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

The only BX stent graft with a semi-compliant covered balloon[2,3]

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

The only BX stent graft with heparin coating[2,3]

- Proven heparin bonding technology for lasting thromboresistance[4]

Broadest offering of diameters and lengths[2,3]

- The longest BX stent graft
- The largest max post-dilated stent diameter BX stent graft*

Proven leader in stent graft technology

- Twenty years of peripheral stent graft clinical experience
- Leverages the stent graft technology of the GORE® VIABAHN® Endoprosthesis

* Expansion beyond 13 mm is outside of the indication — see *Instructions For Use*.

1. Feldman DN, Armstrong EJ, Aronow HD, *et al*. SCAI guidelines on device selection in aorto-iliac arterial interventions. *Catheterization & Cardiovascular Interventions* 2020;96(4):915-929.
2. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2019. MD172914.
3. LifeStream™ Balloon Expandable Vascular Covered Stent [Instructions for Use]. Tempe, AZ: Bard Peripheral Vascular, Inc; 2016. PK1345700 Rev. 4 07/16.
4. CBAS Heparin Surface. W. L. Gore & Associates Web site. Accessed October 27, 2020. https://www.goremedical.com/cbas/references.

Consult Instructions for Use
eifu.goremedical.com

INTENDED USE/INDICATIONS: 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 for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. $\mathrm{R}_{\mathrm{X\ Only}}$

Products listed may not be available in all markets.

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