GORE® VIABAHN®
Device Family



JOIN THE NEXT GENERATION OF CARE

In the treatment of aortoiliac occlusive disease

Together, improving life

The challenges of treating aortoiliac occlusive disease: An increasingly complex condition

≈10% **U.S. adults (over 60 years old) affected by peripheral arterial disease (PAD)[1,2]**

≈33% **PAD cases involve the iliac arteries[3]**

The incidence of aortoiliac occlusive disease is increasing,[1] leaving more patients vulnerable to a disease that, untreated, can cause:

- Pain
- Tissue loss
- Amputation

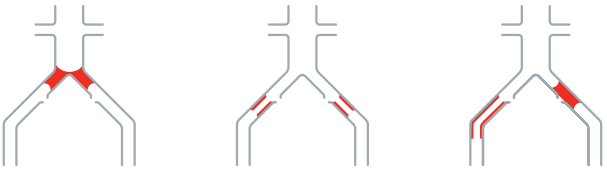
Treatment guidelines

TASC II A & B lesions:

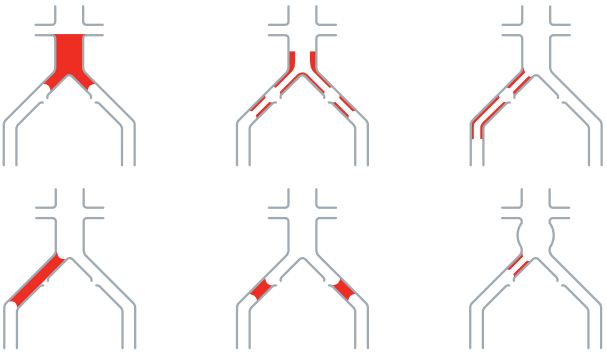
Guidelines recommend an endovascular approach.[4]

TASC II C & D lesions:

Guidelines recommend surgery, although multiple consensus and practice guidelines now generally endorse an endovascular-first strategy in experienced endovascular centers.[4-7]



TASC II C Lesions



TASC II D Lesions

Potential obstacles of endovascular treatment

Challenges:

- Tortuous anatomies
- Severe stenosis
- Highly calcified occlusions

Risks:

- Perforation or rupture of the iliac arteries and aortic bifurcation occurs in nearly 4% of cases and can be a life-threatening complication.[8-11]
- Rupture can be difficult to identify on the final angiogram, and may occur postoperatively, causing acute bleeding and hypotension.[12,13]





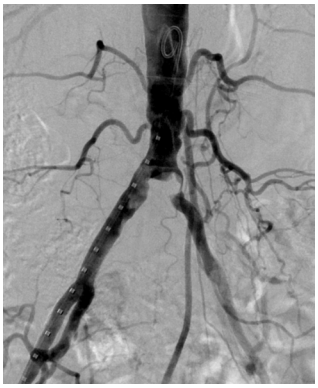
Covered stents offer key advantages

Covered stents help address the shortcomings of bare metal stents[10,14,15] in treating complex aortoiliac occlusive disease:

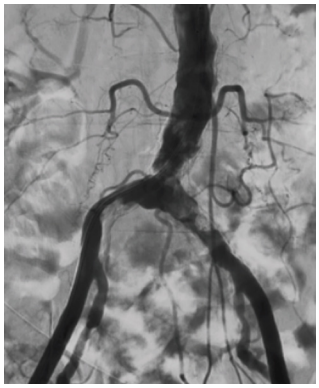
- Exclude plaque.
- Prevent in-stent neointimal hyperplasia.[14-16]
- Decrease the risk of complications caused by distal embolization, perforation, rupture or dissection.[11,17]
- Cover and seal off vessel ruptures.
- Promote hemodynamic flow via a new flow lumen.

The Society for Vascular Surgery recommends covered stents in instances of severe calcification at risk of vessel rupture.[17]

Numerous studies with covered stents have shown excellent outcomes for treating complex aortoiliac occlusive disease



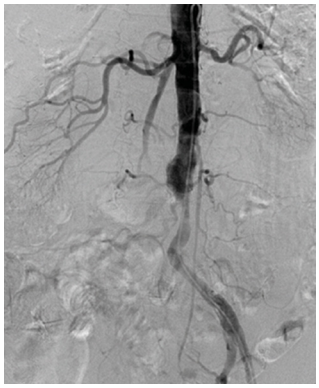
TASC II C & D lesions[10,14]



Aortic bifurcation lesions (kissing stent technique)[11,16]



Highly calcified/ difficult-to-dilate lesions[10,11]

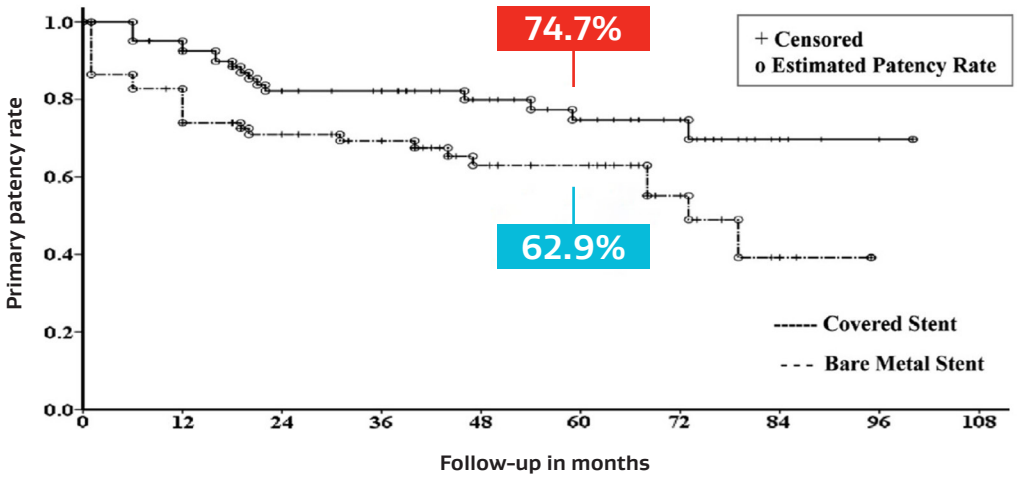


Total occlusions[10,16,18]

Higher patency rates with covered stents

Comparative studies demonstrate a patency advantage of covered stents vs. bare metal[10,14,15]

Kaplan-Meier curve of primary patency[14]



Kaplan-Meier curve of overall primary patency rates of both stent groups. The overall patency rate was 74.7% in the covered stent (CS) group vs. 62.9% in the bare metal stent (BMS) group at 60 months of follow-up (log-rank test, *P* = .01). n at risk, number of stents at risk of severe restenosis.

"The 5-year results ... demonstrated that the covered stent has an enduring patency advantage over the bare metal stent in both the short and long terms ... and patients who received a covered stent required fewer revascularization procedures."[14]

– Mwipatayi, et al.

Covered stents have demonstrated:

Higher patency rates at the aortic bifurcation[15]

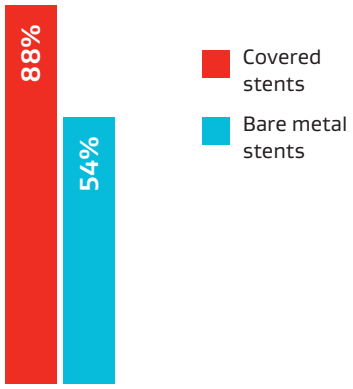
P = .023



Balloon expandable covered iliac kissing stents vs. bare metal stents at the aortic bifurcation

Higher midterm patency for TASC II D lesions[10]

P = .03



Self-expanding covered stents vs. bare metal stents in iliac artery occlusions

"In a subcategory of TASC II D, lesions with long-segment severe stenosis of both the common and external iliac arteries, covered stents should be considered as the primary line of treatment."[19]

– Piazza, et al.

Additional patient benefits vs. baseline

A systematic review and meta-analysis of 2 randomized controlled trials and 4 retrospective cohort studies (N = 744) compared outcomes with covered and uncovered stents when treating aortoiliac occlusive disease.[20]

The covered stent group demonstrated:

+.08 higher ankle-brachial index (ABI)
(Mean difference: .08, 95% CI .07 to .09, P < .001)

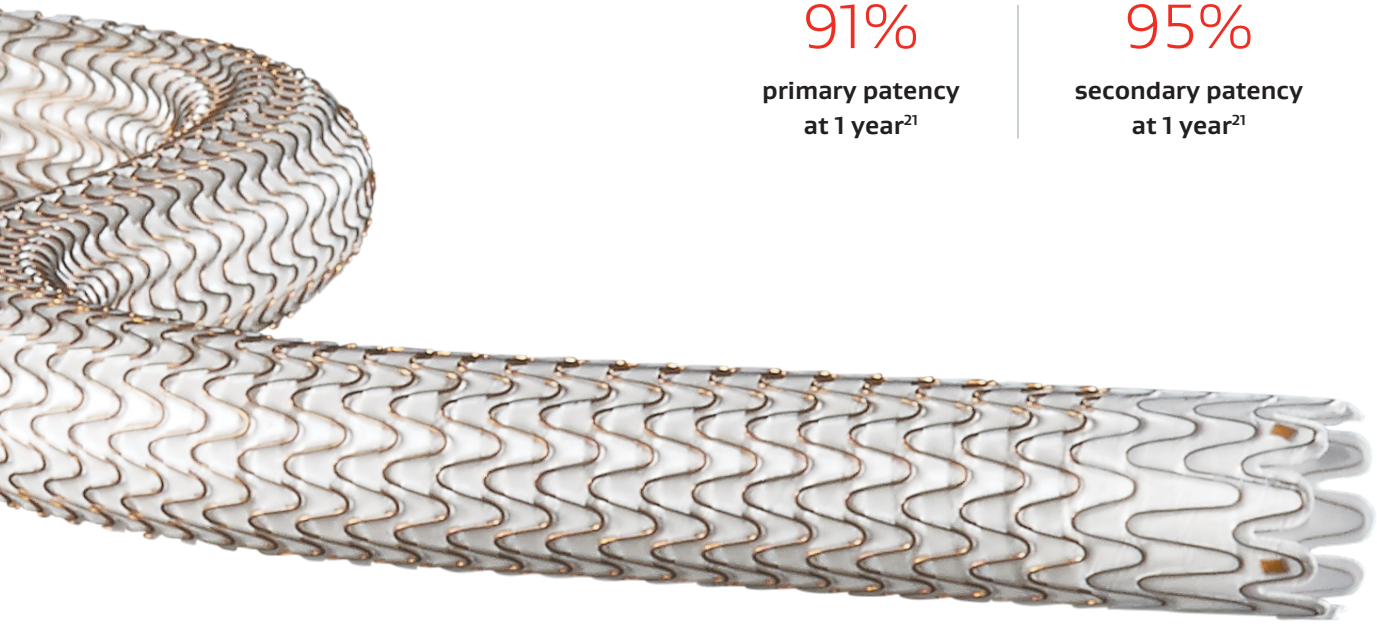
81% lower odds of reintervention
(Odds ratio: .19, 95% CI .09 to .42, P < .001)

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VIABAHN® Device outcomes in iliac occlusive disease
Prospective, multicenter, single-arm study of 53 patients (61 limbs) with iliac artery occlusion or stenosis (mean lesion length: 6.9 cm; 48% of limbs in the external iliac artery)

91%
primary patency at 1 year[21]

95%
secondary patency at 1 year[21]



The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface*

* As used by Gore, Heparin Bioactive Surface refers to Gore's proprietary CBAS® Heparin Surface.

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



VBX Stent Graft outcomes in iliac occlusive disease

Gore VBX FLEX Clinical Study: Prospective, multicenter, single-arm study of 134 patients with aortoiliac occlusive disease (32.1% TASC II C & D, 42.5% kissing stent)

1-year outcomes

100%
technical success[16]

94.5%
primary patency[22]

99.5%
secondary patency[22]

3-year outcomes

91.2%
freedom from target lesion revascularization (fTLR)[22]

+.17
improvement in mean resting ABI (*P* < .001, .93 mean ABI)[22]

92%
of patients improved ≥ 1 Rutherford category versus baseline[22]

The GORE® VIABAHN® Device family of covered stents offer the flexibility and conformability to safely and confidently address even the most complex cases.[†,10,22]

† The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis indication includes de novo or restenotic lesions in iliac arteries, including those at the aortic bifurcation. The GORE® VIABAHN® Endoprosthesis indication includes lesions in the iliac arteries only. Product indications on last page.

Clinically proven results

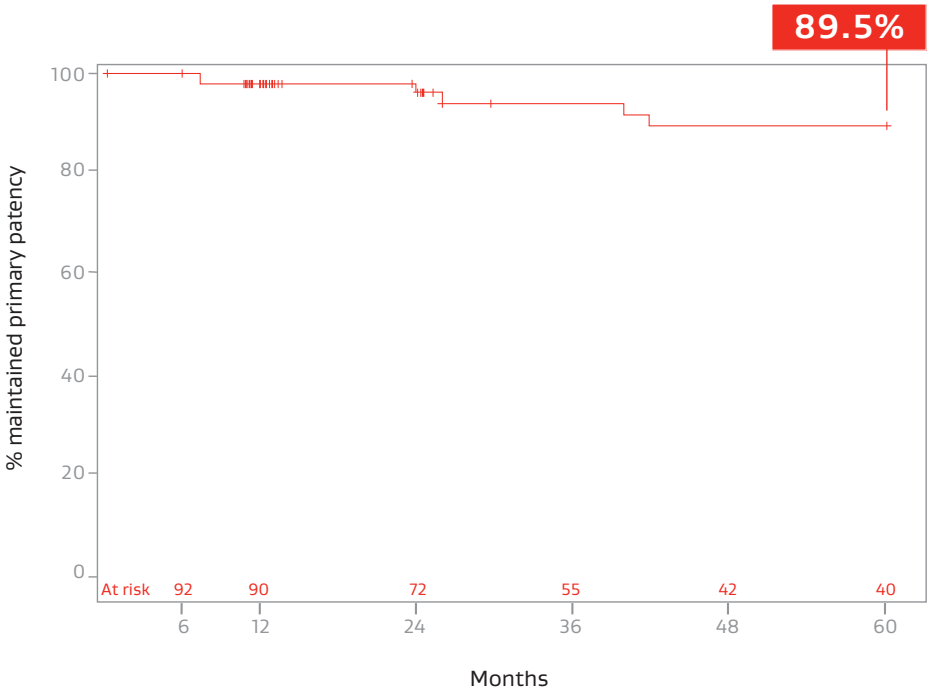
Physician-initiated **5-year** follow-up of patients from 3 centers participating in the VBX FLEX Study

5-year outcomes

89.5%
primary patency per lesion[23]

96.1%
primary assisted patency per lesion[23]

89.1%
fTLR per subject[23]



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

Additional patient benefits vs. baseline

Follow-up of patients treated with the **VBX Stent Graft**

5-year outcomes

+.15 improvement in mean resting ABI (from .82 to .95) [$P < .001$][23]

3x improvement in median WIQ measures[23]

100% of patients improved ≥ 1 Rutherford category vs. baseline[23]



Lesions for consideration:

Aortoiliac bifurcation (kissing stent technique) lesions

Common challenges

- Plaque shift
- Embolization concerns
- Flow dynamics
- Tapered anatomy
- Rupture risk

The VBX Stent Graft delivers:

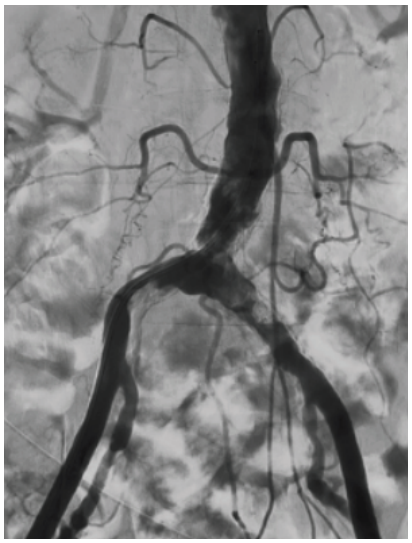
fTLR in kissing stents (N = 118)*



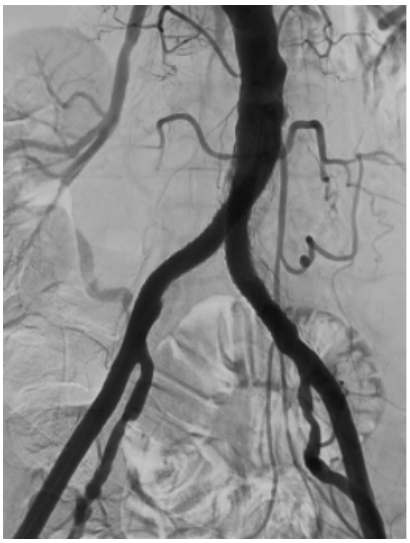
fTLR at 5-year follow-up (N = 59)†,23



Before



After



* Data on file 2020; W. L. Gore & Associates, Inc; Flagstaff, AZ.
† 5-year follow-up subjects (N = 59) with 47.5% kissing stents.

Moderate to severely calcified focal or diffuse lesions

Common challenges

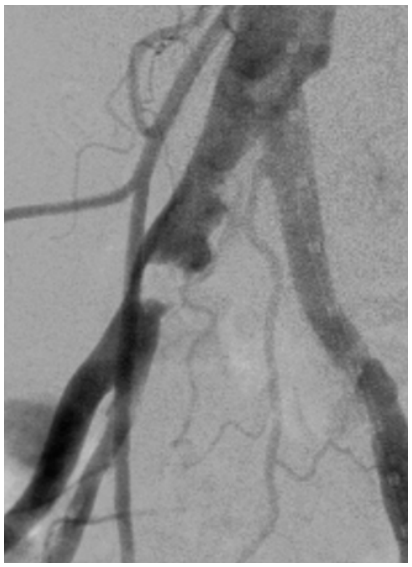
- Sufficient radial strength
- Embolization concerns
- Need for reintervention
- Rupture risk

The VBX Stent Graft delivers:

fTLR in TASC II C & D lesions (N = 77)*



Before



After



Lesions for consideration:

Focal or diffuse common iliac artery lesions

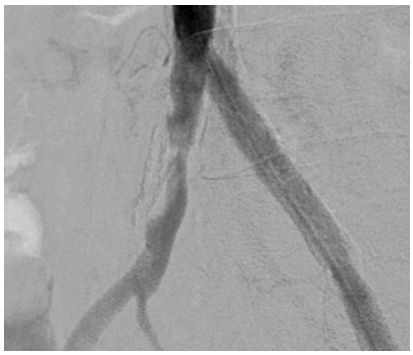
Common challenges

- Embolization concerns
- Conformability
- Need for reintervention (e.g., neointimal hyperplasia)
- Rupture risk

The VBX Stent Graft delivers:

- Independent stainless steel ring designed for flexibility and conformability.
- Highly flexible stent and catheter facilitate deployment.
- Graft covers and excludes disease (fluoropolymer including ePTFE).

Before



After





Focal or diffuse external iliac artery lesions

Common challenges

- Deployment accuracy
- Tortuosity
- Vessel movement
- Embolization concerns

The VIABAHN® Device delivers:

- Single wire nitinol frame for flexibility, trackability and fracture resistance.
- CBAS® Heparin Surface for lasting thromboresistance.[24]
- ePTFE graft covers and excludes disease.

Before



After



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24. CBAS® Heparin Surface. W. L. Gore & Associates, Inc. Accessed May 22, 2024. https://www.goremedical.com/cbas/references

INDICATIONS FOR USE IN THE U.S.: 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 also indicated for use with thoracoabdominal and pararenal branched devices indicated with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a branch component.* **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 market where this product is available. ℞ Only

* Not applicable to Reduced Profile GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. (BXB catalogue numbers.)

INDICATIONS FOR USE IN THE U.S.: The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 7.5 mm. The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 6.5 mm. The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0 – 12 mm. The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts. **CONTRAINDICATIONS:** The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is contraindicated for non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface 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. ℞ Only

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