

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 arteries³

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

- Pain
- Tissue loss
- Amputation

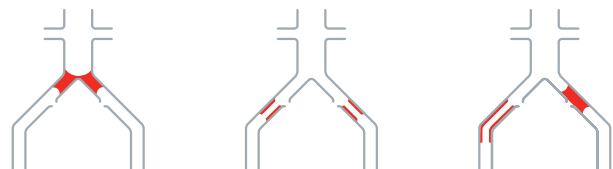
Treatment guidelines

TASC II A and B lesions:

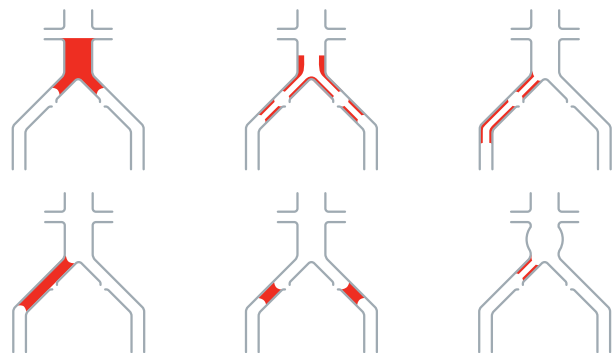
Guidelines recommend an endovascular approach.⁴

TASC II C and 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 stent grafts in instances of severe calcification at risk of vessel rupture.¹⁷

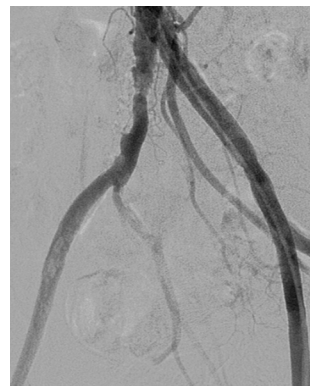
Numerous studies with covered stent grafts have shown excellent outcomes for treating complex aortoiliac occlusive disease



TASC II C and D lesions^{10,14}



Aortic bifurcation lesions (kissing stent technique)^{11,16}



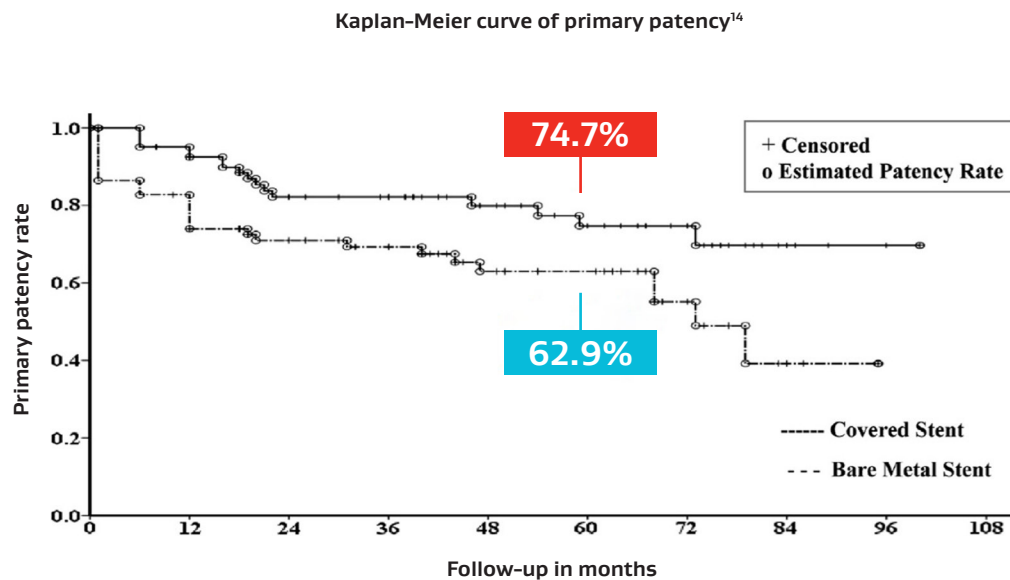
Highly calcified/ difficult-to-dilate lesions^{10,11}



Total occlusions^{10,16,18}

Higher patency rates with covered stents

Comparative studies demonstrate a patency advantage of covered stents versus bare metal^{10,14,15}



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.

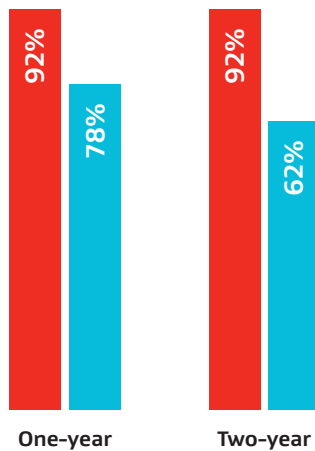
“The five-year results ... demonstrated that the covered stent has an enduring patency advantage over the bare metal stent in both the short and long terms ... and patients who received a covered stent required fewer revascularization procedures.”¹⁴

– Mwipatayi, et al.

Covered stents have demonstrated:

Higher patency rates at the aortic bifurcation¹⁵

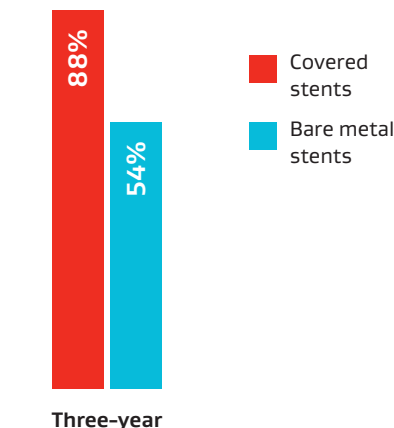
$P = .023$



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

Higher midterm patency for TASC II D lesions¹⁰

$P = .03$



Self-expanding covered stents versus 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 versus baseline

A systematic review and meta-analysis of two randomized controlled trials and four 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

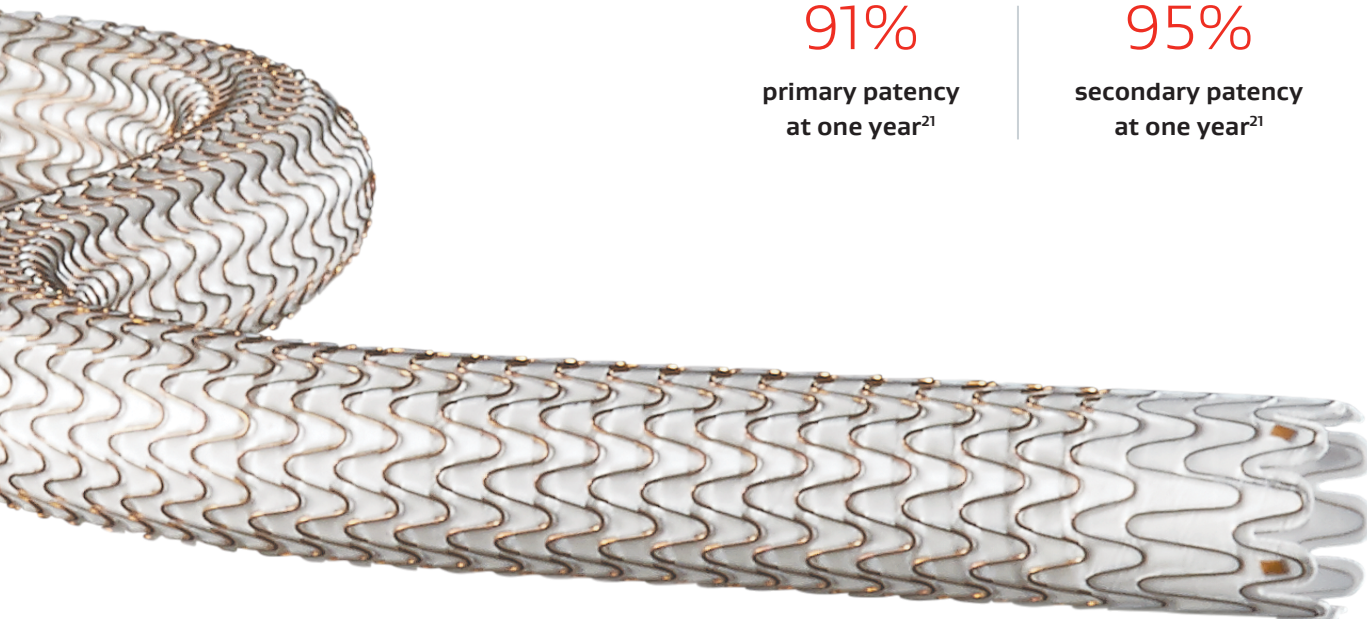
Prospective, multicenter, single-arm study of 53 patients (61 limbs) with iliac artery occlusion or stenosis (mean lesion length: 6.9 cm; 48% of limbs in the external iliac artery)

91%

primary patency
at one year²¹

95%

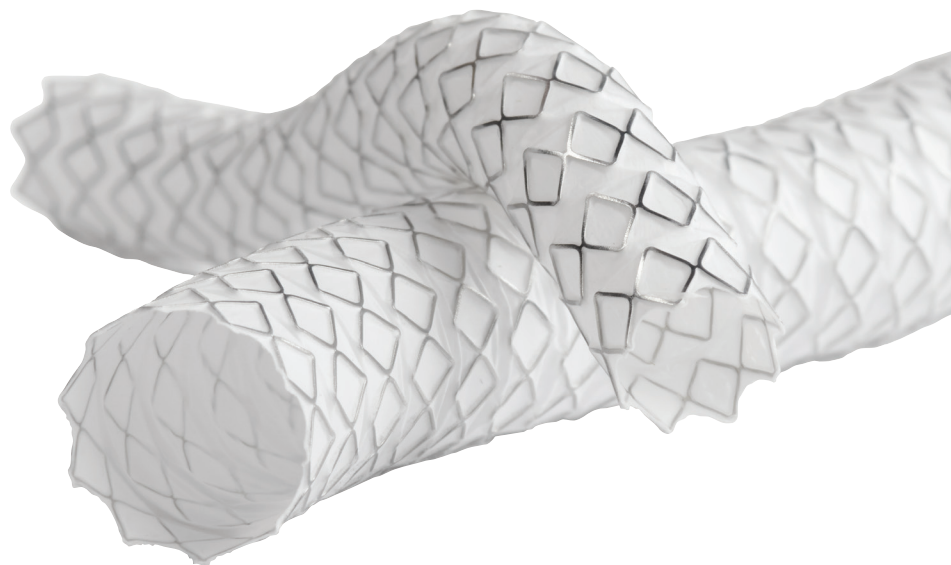
secondary patency
at one year²¹



**The GORE® VIABAHN® Endoprosthesis
with Heparin Bioactive Surface* (VIABAHN® Device)**

* 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 and D, 42.5% kissing stent)

One-year outcomes

100%	94.5%	99.5%
technical success ¹⁶	primary patency ²²	secondary patency ²²

Three-year outcomes

91.2%	+.17	92%
freedom from target lesion revascularization (fTLR) ²²	improvement in mean resting ABI ($P < .001$, .93 mean ABI) ^{†,22}	of patients improved ≥ 1 Rutherford category versus baseline ²²

The GORE® VIABAHN® Device Family of covered stent grafts. Offering the flexibility and conformability to safely and confidently address even the most complex cases.^{‡,10,22}

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

‡ 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 results²³

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

Five-year outcomes

89.5%

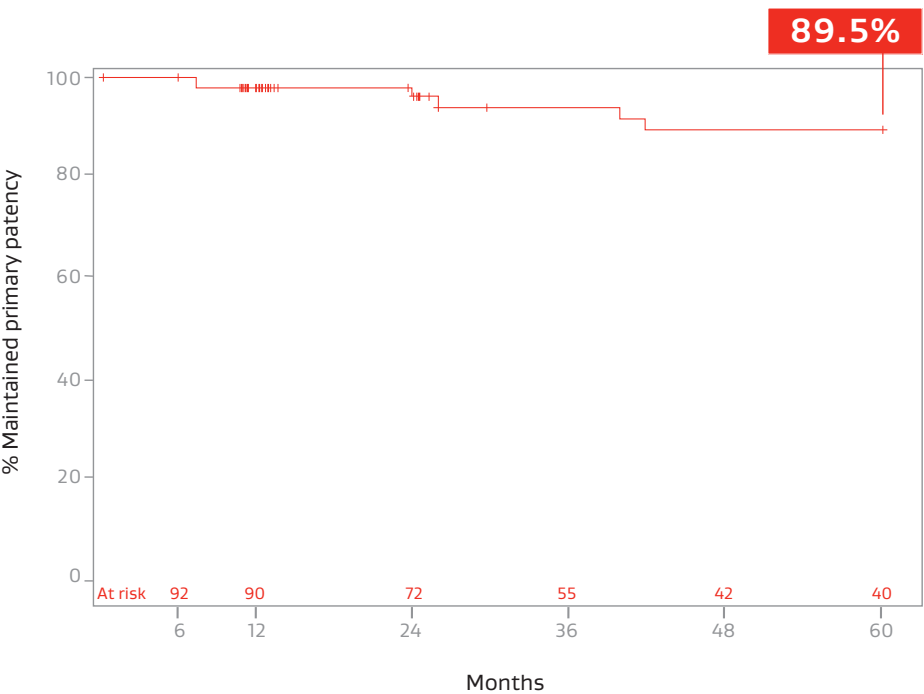
primary patency
per lesion

96.1%

primary assisted
patency per lesion

89.1%

ftLR per subject



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

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

Additional patient benefits versus baseline²³

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

Five-year outcomes

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

3x improvement in median
WIQ measures

89% of patients improved
≥ 1 Rutherford category
versus baseline



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:

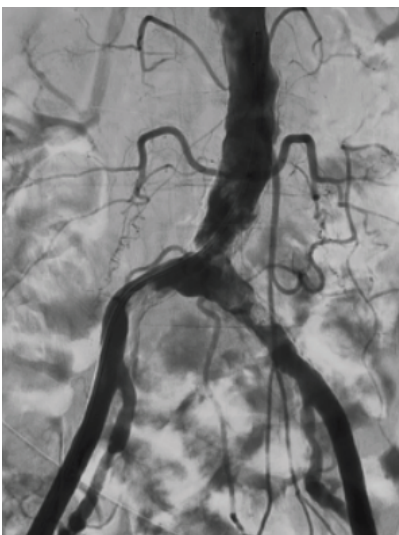
FTLR in kissing stents (N = 118)*



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 and D lesions (N = 77)*

1-year	97.4%
2-year	96.1%
3-year	94.5%

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

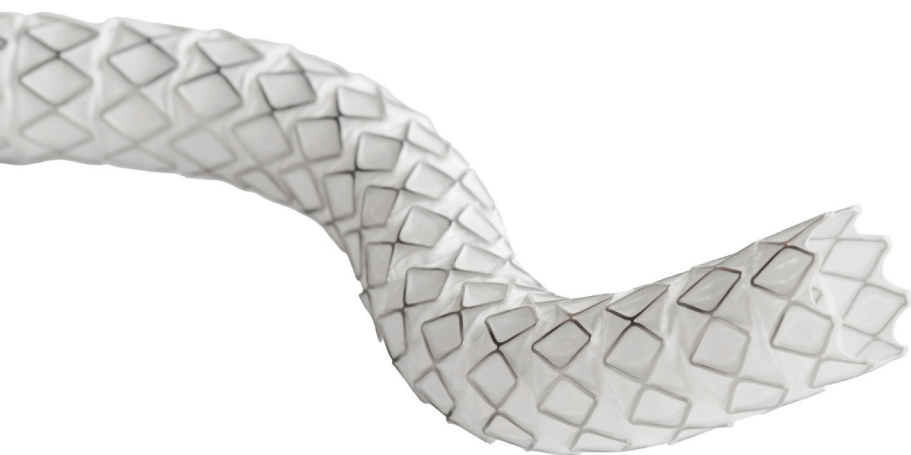
The VBX Stent Graft delivers:

- Independent stainless steel ring design for flexibility and conformability.
- Highly flexible stent and catheter facilitates deployment.
- ePTFE graft covers and excludes disease.

Before



After



Focal or diffuse external iliac artery lesions

Common challenges

- Deployment accuracy
- Tortuosity
- Vessel movement
- Embolization concerns

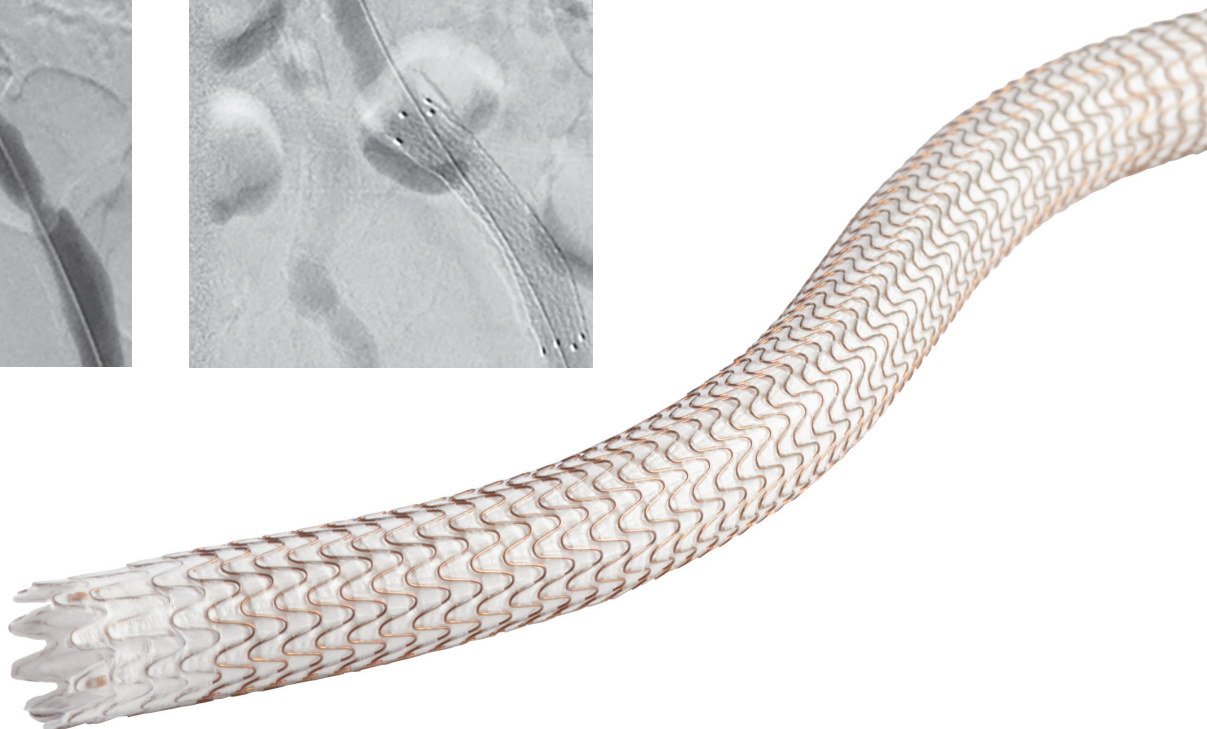
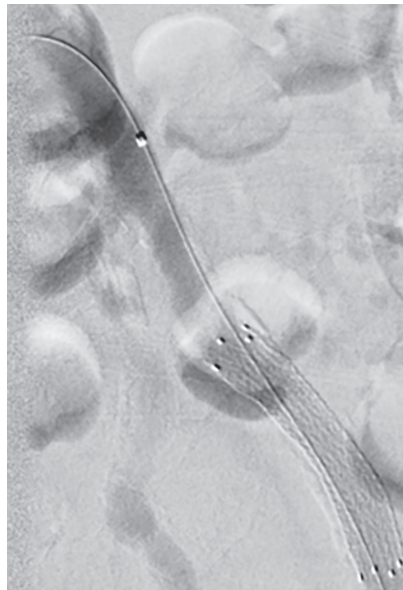
The VIABAHN® Device delivers:

- 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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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. **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. R_x Only

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. R_x Only

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