GORE® VIABAHN® Device family

Join the next generation of care in the treatment of aortoiliac occlusive disease

The latest generation of covered stent grafts

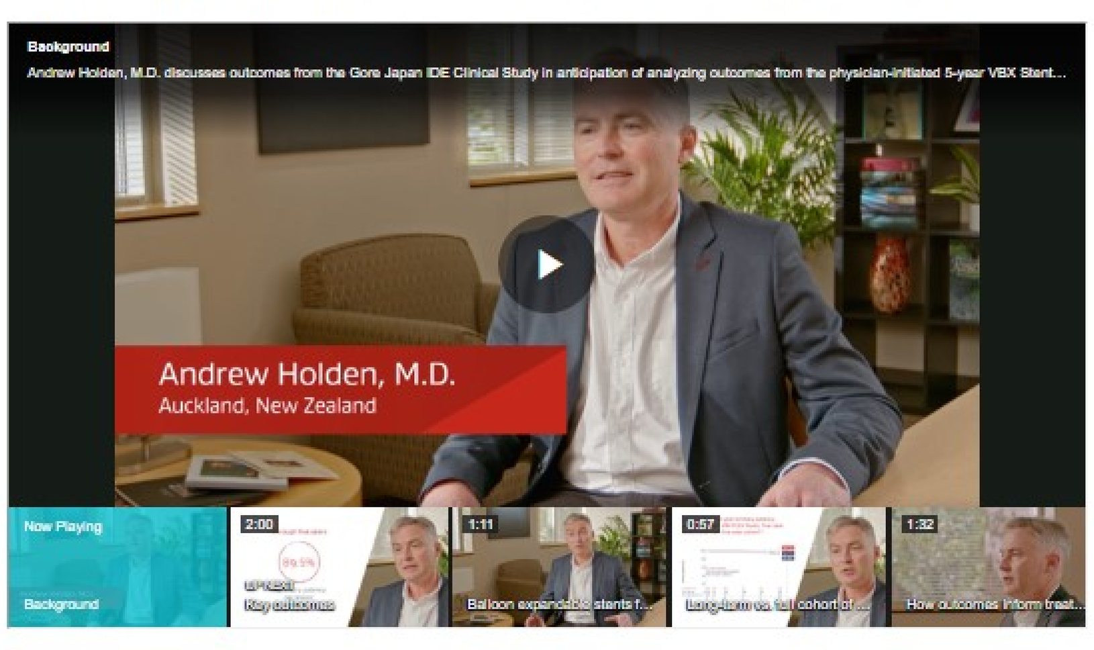
GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft)

Decide with data

The Gore VBX FLEX Clinical Study 3-year follow-up found the VBX Stent Graft to be a robust and durable treatment option for AIOD.[1] Now, sustained patient benefit and durability are demonstrated **through 5 years**.

Investigator Insights

Andrew Holden, M.D. discusses the background, outcomes and implications of this 5-year long-term data.



Physician-initiated 5-year VBX Stent Graft follow-up

Objective and methodology[2]

- This physician-initiated study enrolled 59 patients from 3 participating centers that were representative of the VBX FLEX Study 3-year follow-up cohort. Twenty-eight patients completed the 5-year follow-up.
- The primary durability endpoint was long-term primary patency.

DURABLE CLINICAL OUTCOMES THROUGH 5 YEARS[2]:

89.5%
primary patency per lesion

96.1%
primary assisted patency per lesion

89.1%
freedom from target lesion revascularization per subject

SUSTAINED PATIENT BENEFIT THROUGH 5 YEARS[2]:

89%
of patients improved ≥ 1 Rutherford category from baseline

.15
improvement in mean resting ankle-brachial index (ABI) ($P < .001$, .95 mean ABI)*

3x
improvement in median WIQ measures

The case for long-term durable clinical outcomes:

Case study 1: Treating severe aortoiliac occlusive disease (AIOD) at the aortic bifurcation
Case study 2: Restoring flow to a patient with stenosis at the aortoiliac bifurcation
Case study 3: Restoring flow in a patient with severe claudication and focal iliac calcification

Go deeper into the data

5-year data highlights >

Full 5-year follow-up data >

Visit the VBX Stent Graft product page. >

GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface†

Proven patency with unmatched versatility‡

Visit the VIABAHN® Device product page. >

VIABAHN® DEVICE OUTCOMES IN ILIAC OCCLUSIVE DISEASE

Prospective, multicenter, single-arm study

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[3]

95%
secondary patency at 1 year[3]

* ($P < .001$) Statistically significant change from pre-procedure.
† As used by Gore, Heparin Bioactive Surface refers to Gore's proprietary CBAS® Heparin Surface.
‡ Across indication inclusivity, and configuration breadth/capability of balloon expandable covered stents.

1. Panneton JM, Bismuth J, Gray BH, Holden A. Three-year follow-up of patients with iliac occlusive disease treated with the Viabahn Balloon-Expandable Endoprosthesis. *Journal of Endovascular Therapy* 2020;27(5):728-736.
2. Holden A, Takele E, Hill A, *et al.* Long-term follow-up of subjects with iliac occlusive disease treated with the Viabahn VBX Balloon-Expandable Endoprosthesis. *Journal of Endovascular Therapy*. In press.
3. Lammer J, Dake MD, Bleyn J, *et al.* Peripheral arterial obstruction: prospective study of treatment with a transluminally placed self-expanding stent graft. *Radiology* 2000;217(1):95-104.

Consult Instructions for Use
eifu.goremedical.com

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_{only}

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