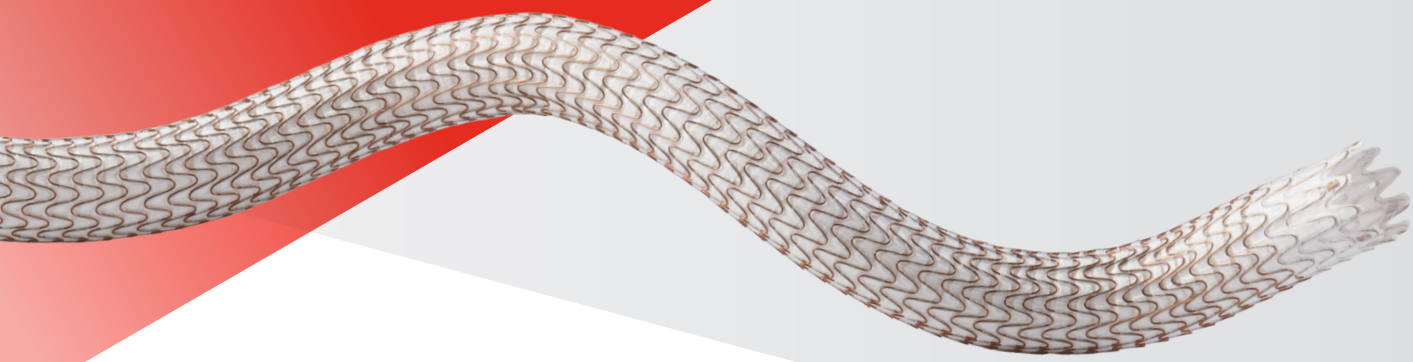
GORE® VIABAHN®
Endoprosthesis
with Heparin Bioactive Surface*

DATA-DRIVEN SOLUTIONS TO OPTIMIZE ARTERIOVENOUS (AV) ACCESS MAINTENANCE OUTCOMES



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

Together, improving life

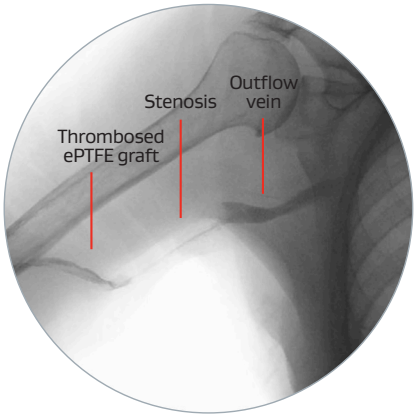
Key VIABAHN® Device applications for optimizing outcomes in AV access revision

The Kidney Disease Outcomes Quality Initiative (KDOQI) 2019 guidelines call for avoidance of unnecessary access-related procedures and complications.[1]

VIABAHN® Device enables optimized outcomes aligned to KDOQI guideline recommendations.[1]

- Goal of ≤ 3 interventions annually to maintain the access.
- Avoid use of bare metal stents for the treatment of significant arteriovenous graft (AVG) lesions.
- Stent graft use in preference to angioplasty alone for recurrent clinically significant stenotic and recurrent thrombotic AVG lesions.

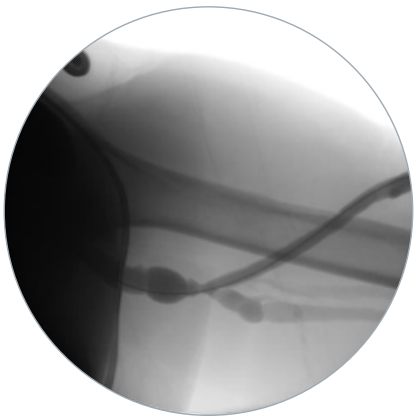
Consider VIABAHN® Device advantages at the AVG venous anastomosis in these clinical applications:



40% fewer reinterventions in thrombosed AVGs[2]

In **thrombosed AVGs**, the VIABAHN® Device demonstrated a 40% reduction in reinterventions and 18% total lesion treatment cost savings over two years versus percutaneous transluminal angioplasty (PTA).[2]

Image courtesy of Daniel Patel, M.D. Used with permission.



50% higher primary patency when treating significant AVG stenosis[3]

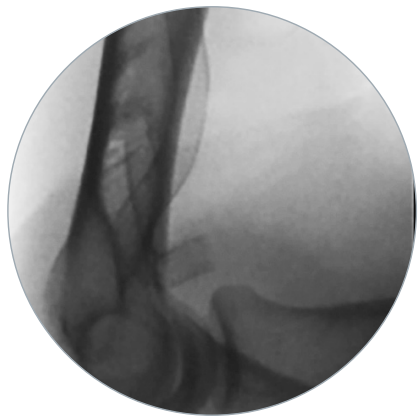
In treatment of **> 50% stenosis**, the VIABAHN® Device increased primary patency of both the target lesion and the circuit by ~ 50% when compared to PTA at six months.[3]

Image courtesy of Nicolas Mouawad, M.D. Used with permission.

83% secondary patency in lesions across the elbow[4]

Thanks to its ability to flex and conform to anatomy without kinking, the VIABAHN® Device demonstrated secondary patency **across the elbow** at two years of 83% with zero reported fractures.[4]

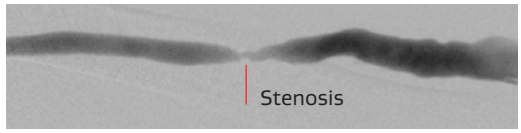
Image courtesy of William DaVanzo, M.D. Used with permission.



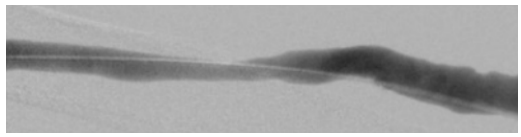
63% of venous elastic recoil occurs within five minutes[5]

Venous elastic recoil after PTA of stenoses in hemodialysis access circuits is common, with 63% occurring within FIVE minutes post-procedure.[5] If recoil is diagnosed at the venous anastomosis of an AV graft in a follow-up angiogram, consider utilizing the VIABAHN® Device.

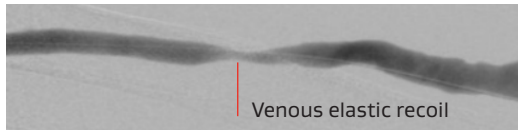
Images courtesy of John Ross, M.D. Used with permission.



Pre-angioplasty



Immediately post-angioplasty



~15 minutes post-angioplasty

VIABAHN® Device sizing techniques for optimal outcomes

ZERO migrations[3]

Zero device migrations observed over a two-year study when device diameter was 5–20% larger than the AV graft inner diameter.[3]

60% target lesion primary patency (TLPP)[4]

Undersizing the device relative to the outflow vein trended toward increased target lesion primary patency (TLPP; 60% at 6 months) compared to apposing the stent graft to the outflow vein (47% TLPP at 6 months).[4]

References

1. Lok CE, Huber TS, Lee T, *et al;* KDOQI Vascular Access Guideline Work Group. KDOQI Clinical Practice Guideline for Vascular Access: 2019 update. *American Journal of Kidney Diseases* 2020;75(4) Supplement 2:S1-S164.
2. Mohr BA, Sheen AL, Roy-Chaudhury P, Schultz SR, Aruny JE; REVISE Investigators. Clinical and economic benefits of stent grafts in dysfunctional and thrombosed hemodialysis access graft circuits in the REVISE Randomized Trial. *Journal of Vascular & Interventional Radiology* 2019;30(2):203-211.e4.
3. Vesely T, DaVanzo W, Behrend T, Dwyer A, Aruny J. Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts. *Journal of Vascular Surgery* 2016; 64(5):1400-1410.e1.
4. W. L. Gore & Associates, Inc. GORE® VIABAHN® Endoprosthesis versus Percutaneous Transluminal Angioplasty (PTA) to Revise Arteriovenous Grafts at the Venous Anastomosis in Hemodialysis Patients. (GORE REVISE Study, AVR 06-01). Flagstaff, AZ: W. L. Gore & Associates, Inc; 2012. [IDE Final Clinical Study Report]. G070069.
5. Rajan DK, Sidhu A, Noel-Lamy M, Mahajan A, Simons ME, Sniderman KW, Jaskolka J, Tan KT. Elastic Recoil after Balloon Angioplasty in Hemodialysis Accesses: Does It Actually Occur and Is It Clinically Relevant? *Radiology*. 2016 Jun;279(3):961-7. doi: 10.1148/radiol.2015150991. Epub 2015 Dec 22. PMID: 26694051.

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® VIABAHN® Endoprosthesis 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 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 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 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

Products listed may not be available in all markets.

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