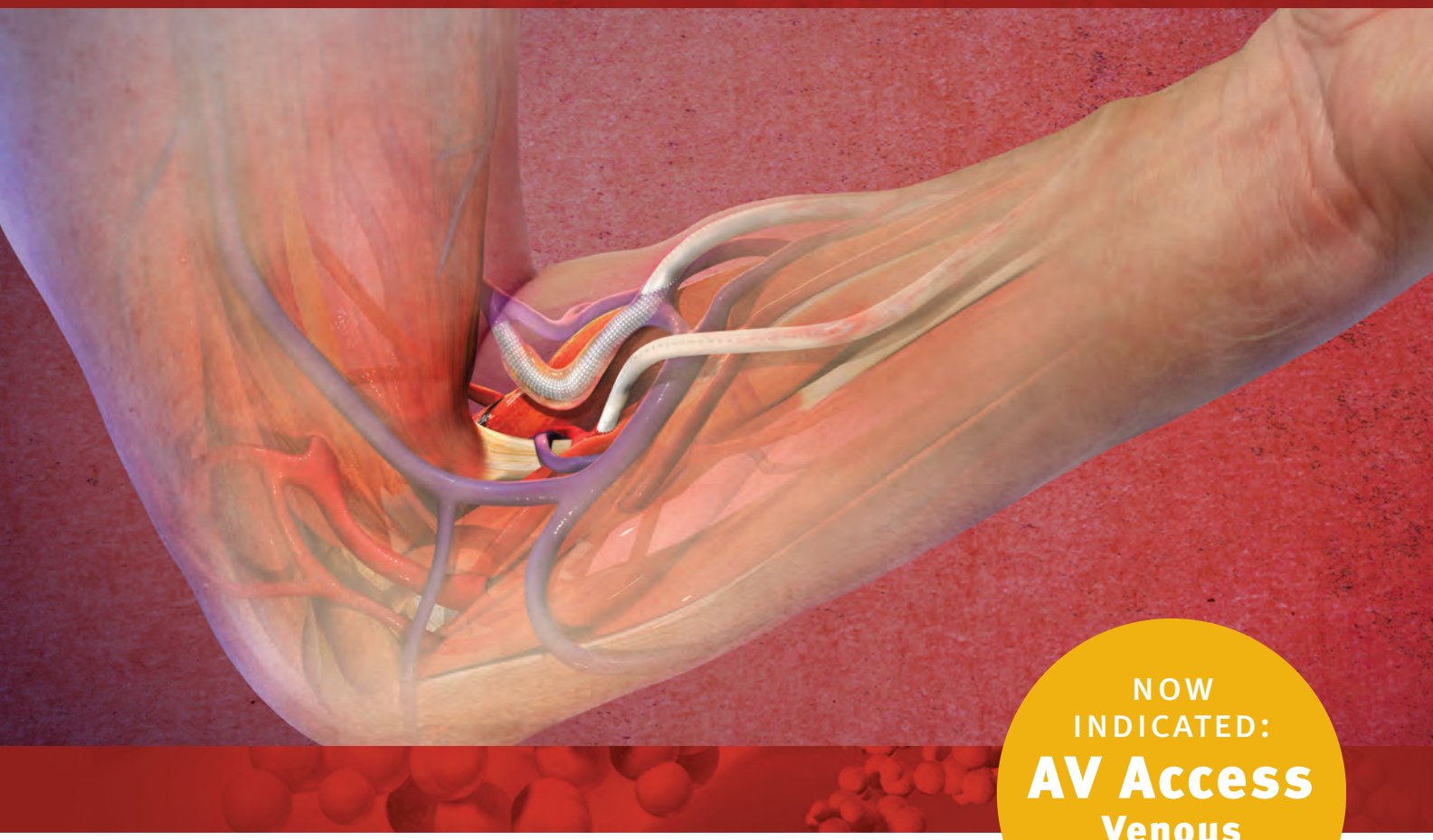
Flexible. Durable. ***Proven.***



NOW INDICATED:
AV Access
Venous Anastomosis

GORE REVISE CLINICAL STUDY

A Multicenter, Prospective, Randomized Controlled Trial

GORE VIABAHN® ENDOPROSTHESIS

PERFORMANCE through data

The Gore REVISE Clinical Study was a multicenter, randomized-controlled trial that demonstrated the safety and effectiveness of the GORE® VIABAHN® Endoprosthesis in treating stenosis or thrombotic occlusions of a synthetic arteriovenous (AV) access graft at the venous anastomosis.

PATIENT DEMOGRAPHICS

Subject Pre-Enrollment Characteristics

	GORE® VIABAHN® Device Group	PTA Group
Intent-to-Treat Population	n = 145	n = 148
Age (Years)	62 ± 13	61 ± 15
Gender (Female)	52%	51%
Physical Characteristics		
Height (cm)	167 ± 12	165 ± 13
Weight (kg)	84 ± 29	81 ± 26
BMI	30 ± 9	30 ± 9
Medical History		
History of Diabetes	65%	66%
History of Hypertension	99%	97%
Duration of Time Since Starting Hemodialysis (Years)	3.6 ± 3.9	4.1 ± 4.2
Age of Vascular Access Graft (Years)	1.9 ± 1.9	2.3 ± 2.6
Mean Number of Prior Interventions at the Target Lesion	1.9 ± 2.2	1.8 ± 2.3

No statistical values less than 0.05 were detected unless otherwise specified. Means include ± Standard Deviation.
1. Statistical comparison between the two treatment groups reported a p-value of 0.036. 2. Subjects may select multiple races.

Index Procedure Details

	GORE® VIABAHN® Device Group	PTA Group
Intent-to-Treat Population	n = 145	n = 148
Indication for Procedure		
Graft Thrombosis	43%	45%
Low Blood Flow	32%	26%
Elevated Venous Pressure	19%	20%
Prolonged Time to Hemostasis	12%	13%
Arm Swelling	3%	5%
Other	9%	14%
Target Lesion Characteristics		
Percent Stenosed (max)	73 ± 13% (100%)	74 ± 13.0% (100%)
Length Stenosed (max)	22 ± 20 mm (174 mm)	24 ± 22 mm (200 mm)
Percent of Subjects with a Secondary Lesion	24%	21%
GORE® VIABAHN® Device Implantation		
Percent of Subjects Needing Only One Device	97%	NA
Percent Crossed the Antecubital Fossa	17%	NA
Stented Length (max) [1]	57± 20 mm (175 mm)	NA
Procedural Assessments		
Presence of a Palpable, Continuous Thrill	99%	99%
Anatomic Success [2,3]	100%	84%
Clinical Success [3]	98%	98%

1. The 50 mm length devices were the most frequently used at 82%.
2. Statistical comparison between the two treatment groups reported a p-value less than 0.001.
3. Percentages based on effectiveness population for the GORE® VIABAHN® Device group (n = 131) and the PTA group (n = 138).

Pre-Randomization Fistulagram

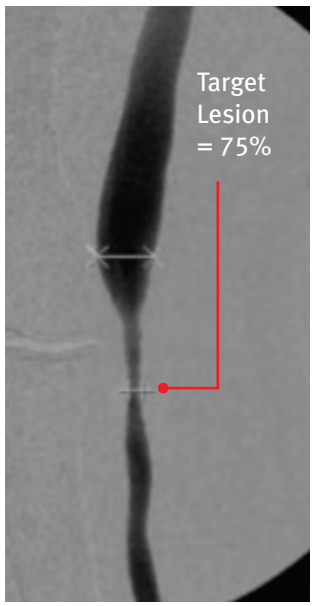


Image 1. Representative example of a target lesion for a thrombotic subject enrolled in the study.

Post-Randomization Fistulagram

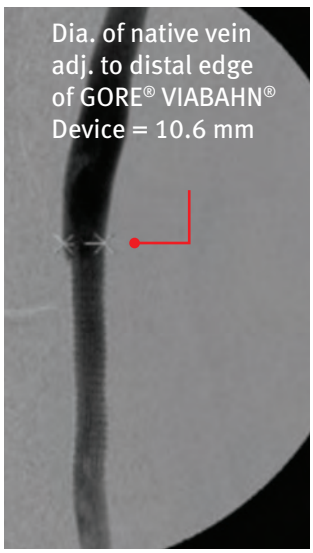
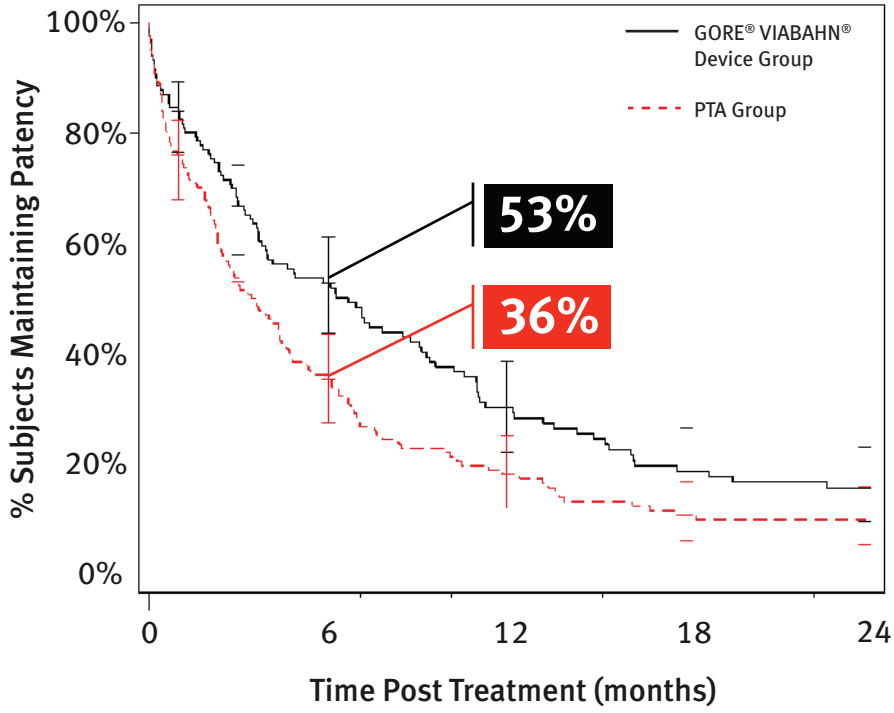


Image 2. Post-device angioplasty for an 8 mm x 5 cm GORE® VIABAHN® Device placed at enrollment.

The GORE® VIABAHN® Device group demonstrated statistical superiority over the PTA group in target lesion primary patency as determined by Kaplan-Meier estimates (p = 0.008).

PROVEN TO INCREASE TIME TO NEXT INTERVENTION

Kaplan-Meier Analysis of the Target Lesion Primary Patency

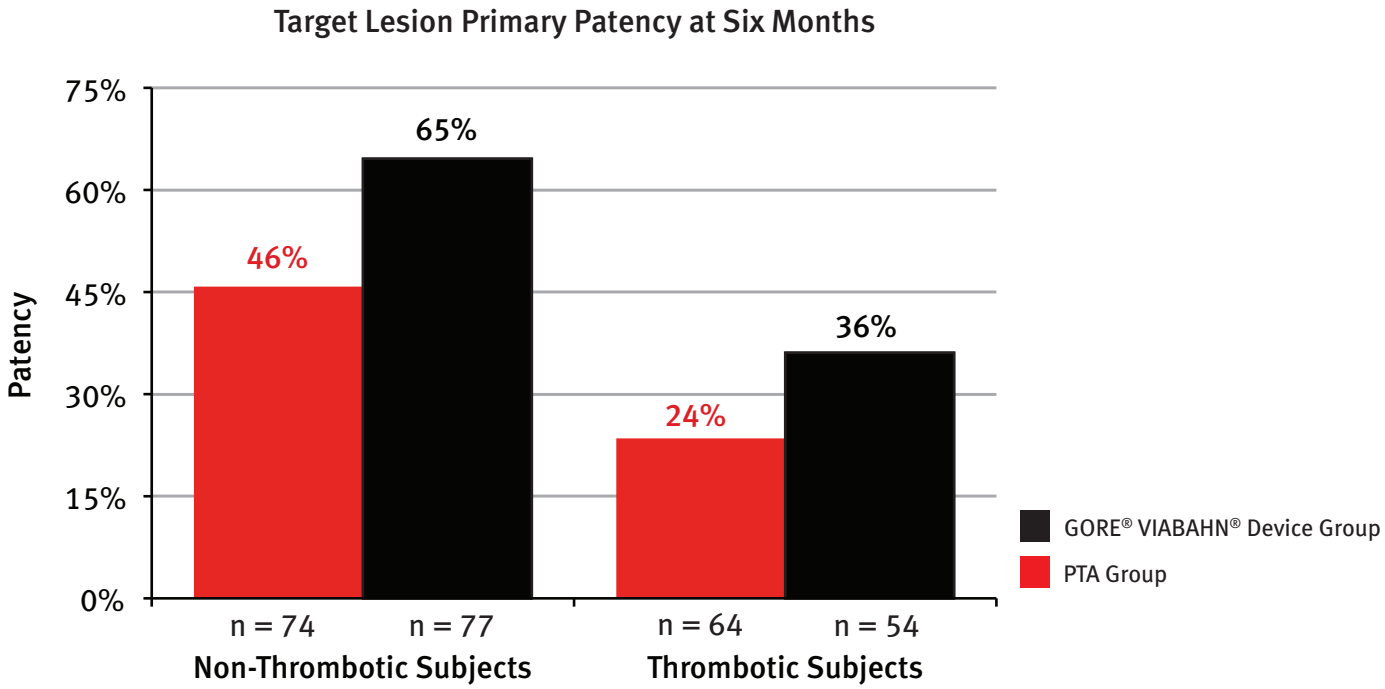


	GORE® VIABAHN® Device Group				PTA Group			
Effectiveness Population [1]	n = 131				n = 138			
Time	3 mo	6 mo	12 mo	24 mo	3 mo	6 mo	12 mo	24 mo
Primary Endpoint								
Target Lesion Primary Patency [2]	67%	53%	30%	16%	53%	36%	18%	10%
Additional Assessments								
Circuit Primary Patency [3]	61%	43%	21%	10%	49%	29%	15%	7%
Access Secondary Patency [4]	95%	91%	83%	69%	88%	87%	79%	67%

1. Effectiveness Population is the per protocol population or the group of subjects available for analysis without significant protocol deviations as determined by the Data Safety Monitoring Board.
2. Statistical comparison between the two treatment groups reported a p-value of 0.008. A similar statistical analysis for the intent-to-treat population reported a p-value of 0.006.
3. Statistical comparison between the two treatment groups reported a p-value of 0.035 and the location of the loss of patency was more often occurred outside the target lesion for the GORE® VIABAHN® Device group (80% vs 54%, p < 0.001).
4. Secondary patency was maintained with 61 additional stents or stent grafts in the PTA group and 35 additional stents or stent grafts in the GORE® VIABAHN® Device group.

The GORE® VIABAHN® Device group demonstrated a similar treatment benefit for both thrombotic and non-thrombotic subjects.

PROVEN TO RE-ESTABLISH FLOW OF OCCLUDED GRAFTS



Outcomes of Thrombotic and Non-Thrombotic Subjects

	GORE® VIABAHN® Device Group				PTA Group			
Effectiveness Population	n = 131				n = 138			
Time	3 mo	6 mo	12 mo	24 mo	3 mo	6 mo	12 mo	24 mo
Non-Thrombotic Subjects	n = 77				n = 74			
Target Lesion Primary Patency[1]	80%	65%	37%	20%	66%	46%	23%	13%
Circuit Primary Patency[2]	71%	50%	25%	10%	59%	36%	19%	9%
Access Secondary Patency	99%	97%	92%	76%	97%	96%	88%	79%
Thrombotic Subjects	n = 54				n = 64			
Target Lesion Primary Patency[1]	48%	36%	21%	9%	39%	24%	13%	6%
Circuit Primary Patency[2]	48%*	34%	17%	9%	39%	22%	11%	4%
Access Secondary Patency	89%	83%	70%	60%	77%	75%	68%	52%

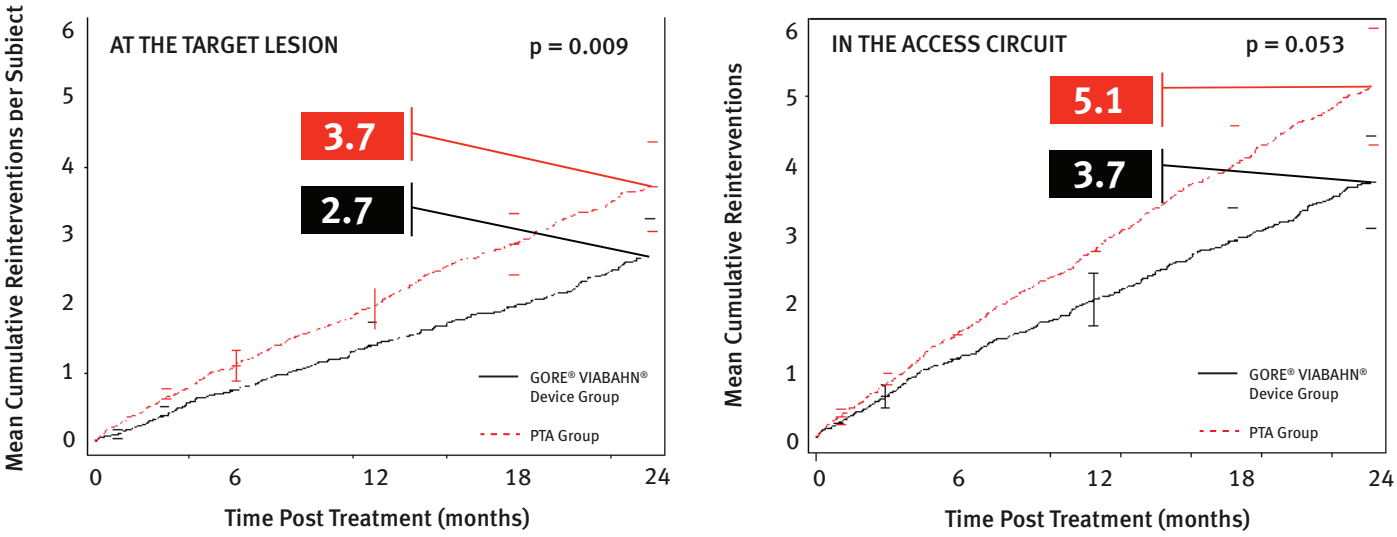
1. A statistical comparison between non-thrombotic and thrombotic subjects in terms of the treatment effect of the GORE® VIABAHN® Device reported a p-value of 0.792.
2. A statistical comparison between non-thrombotic and thrombotic subjects in terms of the treatment effect of the GORE® VIABAHN® Device reported a p-value of 0.768.

*** Circuit primary patency exceeded the KDOQI Guideline expectation of 40% primary patency at 3 months (Guideline 6.8.2).**

GORE® VIABAHN® Device Group demonstrated a reduction in the number of repeat interventions per patient as compared to PTA.

PROVEN TO REDUCE THE NUMBER OF INTERVENTIONS NECESSARY TO MAINTAIN ACCESS PATENCY

Mean Cumulative Function Estimates of Reinterventions per Subject



Repeat Interventions Necessary to Maintain Secondary Patency

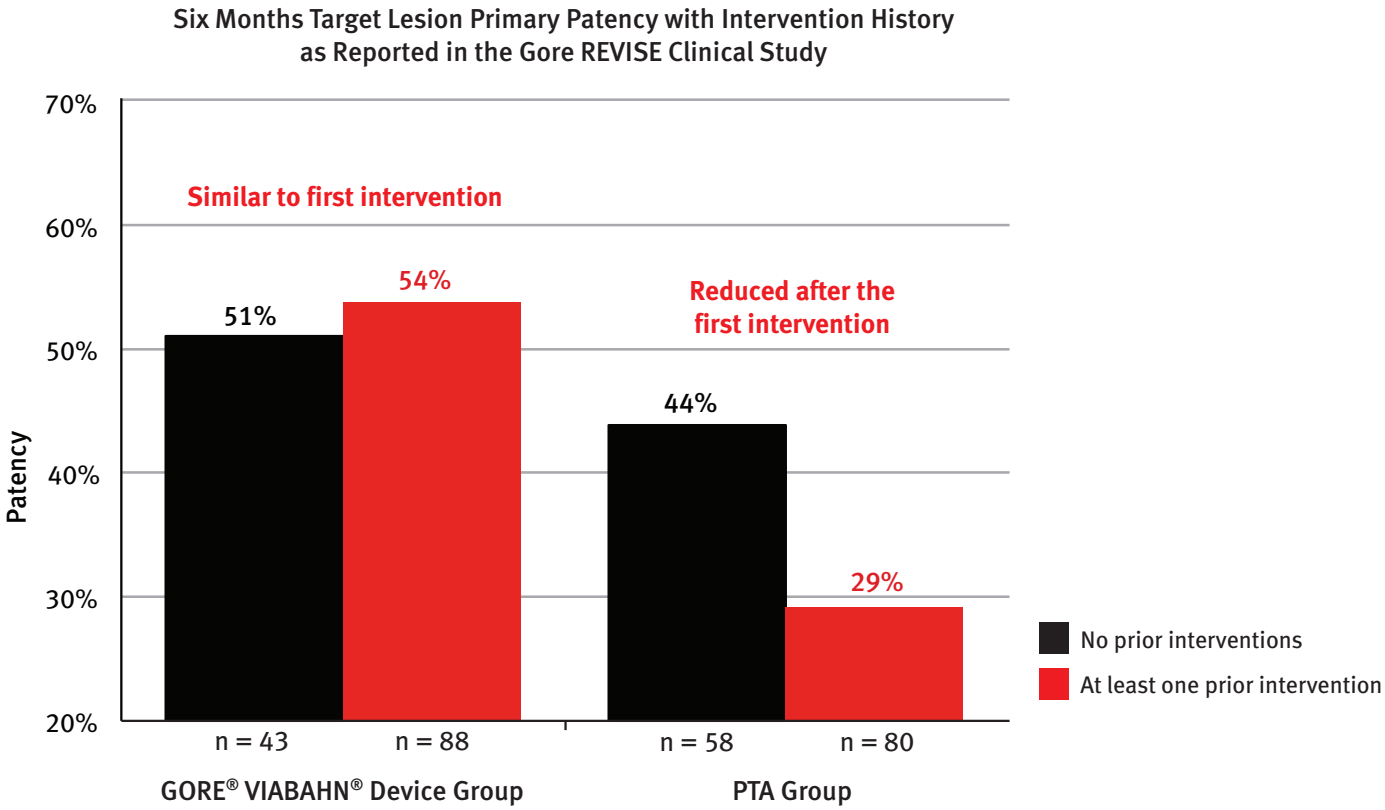
	GORE® VIABAHN® Device Group		PTA Group	
Effectiveness Population	n = 131		n = 138	
	Mean Number per Subject at 24 mo	Count	Mean Number per Subject at 24 mo	Count
Repeat Interventions at the Target Lesion [1]	2.7	246	3.7	343
Repeat Interventions of the AV Access Circuit [2]	3.7	346	5.1	471
By Intervention Type				
PTA	3.3	305	4.8	435
Thrombectomy / Thrombolysis	2.2	212	2.7	253
Stent or Stent-Graft	0.4	35	0.6	61
Surgical Revision	0.1	8	0.2	19
For Thrombotic Subjects [3]	2.2	214	2.8	265

1. Statistical comparison between the two treatment groups reported a p-value of 0.009.
2. Statistical comparison between the two treatment groups reported a p-value of 0.053.
3. Results based on effectiveness population for thrombotic subjects in the GORE® VIABAHN® Device group (n = 54) and the PTA group (n = 64).

Key Considerations When Selecting the GORE® VIABAHN® Device for AV Access Revision.

EFFECT OF INTERVENTION HISTORY

The GORE® VIABAHN® Device demonstrated similar outcomes regardless of intervention history, while PTA outcomes were lower after the first intervention.

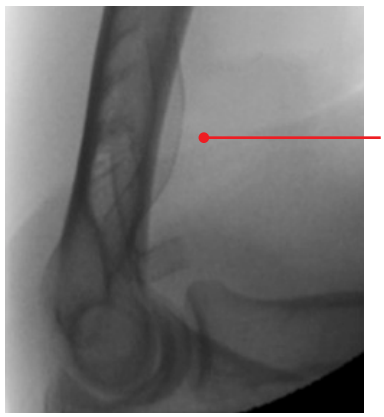


CROSSING POINTS OF FLEXION

Sub-set analysis from the Gore REVISE Clinical Study demonstrated quality outcomes relative to the entire study cohort when the device is placed across the elbow.

Patency Outcomes Crossing the Elbow (n = 22)	3 months	6 months	12 months	24 months
Target Lesion Primary Patency	72%	72%	56%	32%
Circuit Primary Patency	72%	67%	39%	22%
Access Secondary Patency	95%	95%	95%	83%

No fractures of the GORE® VIABAHN® Device were reported over the two-year period.



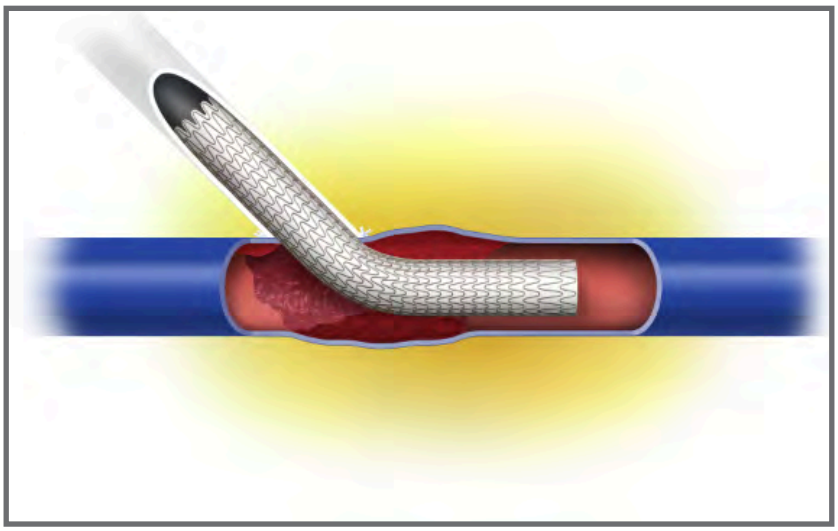
Key Considerations When Selecting the GORE® VIABAHN® Device for AV Access Revision.

DECIDING ON OUTFLOW WALL APPOSITION

The Gore REVISE Clinical Study reported quality outcomes when outflow wall apposition was not achieved.

Outcomes when the Outflow Vein Diameter is 1 mm Greater than the GORE® VIABAHN® Device Diameter (n = 49)				
Patency	3 months	6 months	12 months	24 months
Target Lesion Primary Patency	77%	62%	44%	22%
Circuit Primary Patency	69%	48%	34%	16%
Access Secondary Patency	98%	94%	89%	77%

NOTE: This patient population included thrombosis patients.



Note: The GORE® VIABAHN® Device should always be sized 5% to 20% greater than the AV graft diameter per the *Instructions for Use*.

Sizing Table

TIP to HUB Device Deployment – 0.014" or 0.018" Guidewire Compatibility (With radiopaque markers)

Device Sizing		Introducer Sheath (Fr)					
Endoprosthesis Labeled Diameter [1] (mm)	Recommended Vessel Diameter [2] (mm)	2.5 cm Device Length [1]	5 cm Device Length [1]	10 cm Device Length [1]	15 cm Device Length [1]	25 cm Device Length [1]	Recommended Balloon Diameter for Device Touch-up [3] (mm)
5	4.0 – 4.7	6	6	6	6	6	5
6	4.8 – 5.5	6	6	6	6	6	6
7	5.6 – 6.5	7	7	7	7	7	7
8	6.6 – 7.5	7	7	7	7	7[4]	8

TIP to HUB Device Deployment – 0.035" Guidewire Compatibility (Radiopaque markers on 5–8 mm devices)

Device Sizing		Introducer Sheath (Fr)					
Endoprosthesis Labeled Diameter [1] (mm)	Recommended Vessel Diameter [2] (mm)	2.5 cm Device Length [1]	5 cm Device Length [1]	10 cm Device Length [1]	15 cm Device Length [1]	25 cm Device Length [1]	Recommended Balloon Diameter for Device Touch-up [3] (mm)
5	4.0 – 4.7	7	7	7	7	7	5
6	4.8 – 5.5	7	7	7	7	7	6
7	5.6 – 6.5	8	8	8	8	8	7
8	6.6 – 7.5	8	8	8	8	8	8
9	7.6 – 8.5	–	9	9	9	–	9
10	8.6 – 9.5	11[4]	11[4]	11[4]	11[4]	–	10
11	9.6 – 10.5	11	11	11	–	–	12
13	10.6 – 12.0	12	12	12	–	–	14

1 Labeled device diameters and lengths are nominal.
2 Recommended endoprosthesis compression within the vessel is approximately 5 – 20%.
3 For the 11 and 13 mm diameter devices, balloon inflation pressure should not exceed 8 atm.
4 The 10 mm diameter device is compatible with the following 10 Fr introducer sheaths: CORDIS® AVANTI® Sheath Introducer, Boston Scientific SUPER SHEATH Introducer Sheath, B. Braun INTRADYN Tear-Away Introducer Sheath. The 8 mm x 25 cm device is not compatible with the 7 Fr COOK® CHECK-FLO® FLEXOR® Sheath.

GORE
Creative Technologies Worldwide

W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)
00800.6334.4673 (Europe)
800.437.8181 (United States)
928.779.2771 (United States)

goremedical.com

Products listed may not be available in all markets.