### Speaker Slideset



Product with radiopaque markers planned for European availability in 2016.

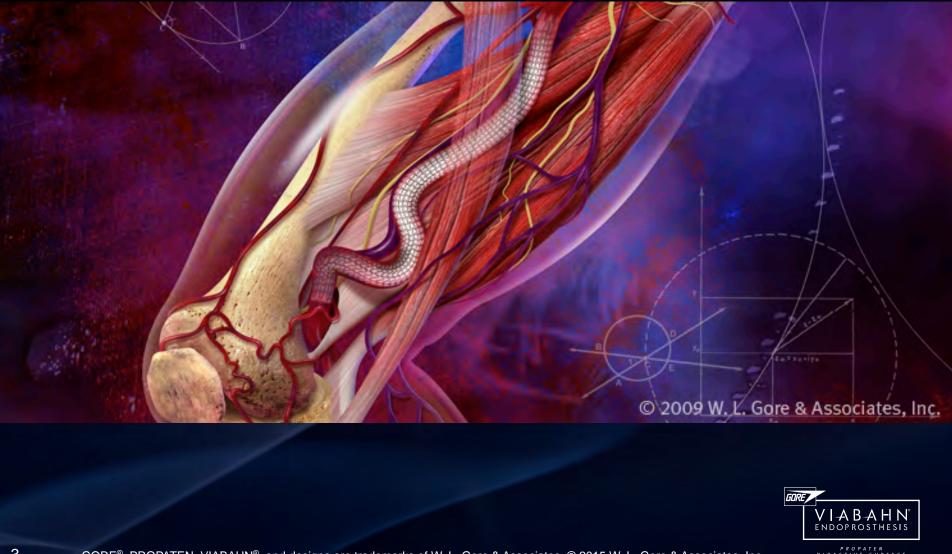


### Table of Contents

- Product Overview
- Mechanical Properties
- Clinical Performance
- Continued Device Evolution
- References and Selected Bibliography
- Image Materials



### **Product Overview**



### **Product Overview**



The GORE® VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal prosthesis for endovascular grafting of peripheral arteries. The GORE® VIABAHN® Endoprosthesis is also indicated for improving blood flow in symptomatic obstructions of peripheral veins.



### **Product Overview**



#### Contraindications

Non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system.

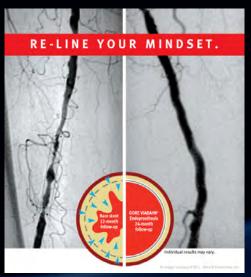
Patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin Induced Thrombocytopenia (HIT) Type II.

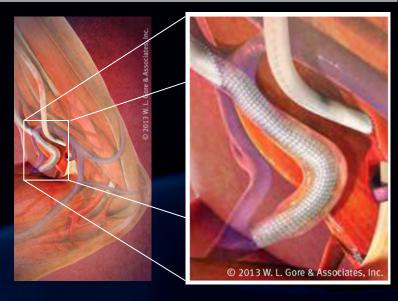
Refer to Instructions for Use at goremedical.com for a complete description of all contraindications, warnings, precautions and adverse events. Ronly



# Total Endoluminal Bypass: Preventing In-Stent Restenosis







Individual results may vary.

The GORE® VIABAHN® Endoprosthesis covers and seals off the diseased and irregular tissue of the vessel wall. In contrast, a bare nitinol stent covers only a small portion of the diseased lumen.



### **Features and Benefits**

- <u>CARMEDA® BioActive Surface (CBAS® Heparin Surface)</u>
  - Intended to provide thromboresistant surface
  - Proprietary covalent bond
  - Sustained bioactivity<sup>1</sup>
- ePTFE Lining
  - Intended to limit in-stent restenosis
- Nitinol Stent
  - Conformable yet durable
- Contoured Proximal Edge
  - May improve flow dynamics as blood enters endoprosthesis



<sup>&</sup>lt;sup>1</sup> See references on slides 47-51.
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### **Endoprosthesis Description**

Contoured proximal edge CBAS® Heparin Surface Ultra-thin wall ePTFE tube Unique, durable bonding film Polished nitinol support Lengths: 2.5, 5, 10, 15, 25 cm Diameters: 5 – 13 mm © 2014 W. L. Gore & Associates, Inc.

Product with radiopaque markers planned for European availability in 2016.

### Endoprosthesis Sizing Table

DEVICE SIZING		2			
Labeled Device Diameter (mm)	RECOMMENDED VESSEL DIAMETER (mm)	Introducer Sheath Size (Fr) Guidewire Diameter 0.035" (0.889 mm)	INTRODUCER SHEATH SIZE (FR) GUIDEWIRE DIAMETER 0.018" (0.460 mm)	AVAILABLE DEVICE LENGTHS <sup>1</sup> (cm)	RECOMMENDED BALLOON DIAMETER FOR DEVICE TOUCH-UP (mm) <sup>2</sup>
5	4.0-4.7	7	6	2.5, 5, 10, 15, 25	5.0
6	4.8-5.5	7	6	2.5, 5, 10, 15, 25	6.0
7	5.6-6.5	8	7	2.5, 5, 10, 15, 25	7.0
8	6.6-7.5	8	7	2.5, 5, 10, 15, 25 <sup>3</sup>	8.0
9	7.6-8.5	9	ė	5, 10, 15	9.0
10	8.6-9.5	114		2.5, 5, 10, 15	10.0
11	9.6-10.5	11	4	2.5, 5, 10	12.0
13	10.6-12.0	12	-	2.5, 5, 10	14.0

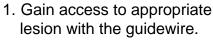
© 2014 W. L. Gore & Associates, Inc.

- 1. Labeled device lengths are nominal.
- 2. For the 11 and 13 mm diameter devices, balloon inflation pressure should not exceed 8 atm.
- 3. The 8 mm x 25 cm device is not compatible with the 7 Fr COOK® CHECK-FLO® FLEXOR® sheath.
- 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.



### Directions for Use - PAD







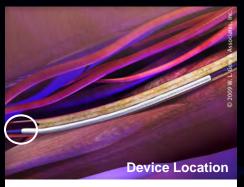
4. Slowly pull deployment knob in a smooth motion.



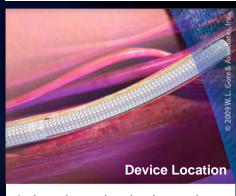
2. Pre-dilate with appropriately sized balloon.



5. Seat balloon well inside device during touch-up.



3. Confirm initial landing zone before deployment.



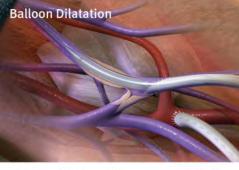
6. Land proximal edge at least 1 cm into healthy vessel.



### Directions for Use – AVR



1. Gain access to appropriate lesion with the guidewire.



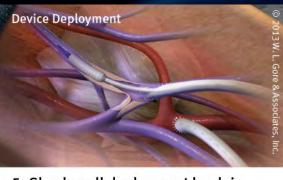
2. Pre-dilate with appropriately sized balloon.



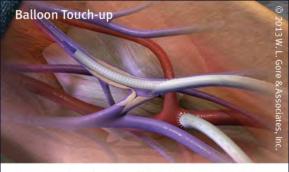
Select device diameter based on the graft diameter.



4. Confirm initial landing zone before deployment.



5. Slowly pull deployment knob in a smooth motion.

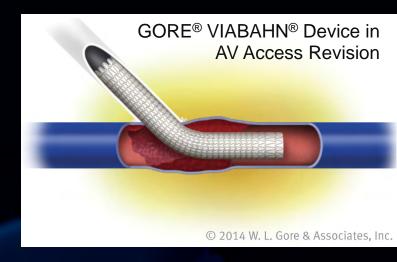


6. Seat balloon well inside device during touch-up.



### Top 10 Technical Considerations

- 1. Avoid excessive oversizing
  - PAD: size to both the inflow and outflow
  - AVR: size to the graft only
- 2. Treat all of the disease
- 3. Prescribe appropriate antiplatelet therapy
- 4. Assure adequate inflow and outflow
- 5. Landing zones
  - PAD: Place in 1 cm in healthy tissue proximal and distal to the lesion
  - AVR: Place at least 1 cm of the device in graft and 1 cm into healthy vein
- 6. Overlap devices by at least 1 cm
- 7. Post-dilate
- 8. Do not use PTA outside of the device
- 9. Regular duplex ultrasonography follow-up
- 10. Treat progressing disease





## **Mechanical Properties**

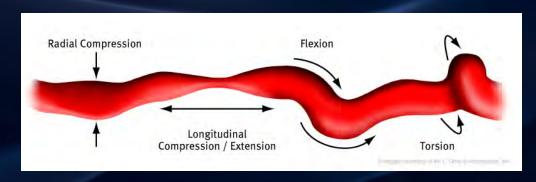






## Compliant with the Mechanical Forces within the Native Vasculature

- More than 500,000 GORE® VIABAHN® Endoprostheses sold worldwide
- Very low incidence of reported fractures
  - < 0.015% reported commercially\*
  - None reported in the 24-month
     Gore REVISE Clinical Study,
     including across the elbow
- Capable of longitudinal compression with little residual force
- Superb flexibility





## Compliant with the Mechanical Forces within the Native Vasculature

#### Flexion

- "The curvature of the femoral vessels was studied and quantified in stretched and flexed positions...
   Three or more small curves were seen proximal to the knee joint in all volunteers".<sup>2</sup>
- Outstanding bending and flexibility

### Durability

- "One premise is that the SFA ... undergo[es] unique and severe conformational changes that can literally pull apart a metal device (stent)." 3
- Very low incidence of reported fractures (< 0.015%)</li>



Product with radiopaque markers planned for European availability in 2016.



### Mechanical Forces: Flexion

#### Flexion

"The curvature of the femoral vessels was studied and quantified in stretched and flexed positions...
 Three or more small curves were seen proximal to the knee joint in all volunteers."



CORDIS® S.M.A.R.T.® CONTROL® Stent



Covidien PROTÉGÉ® EVERFLEX® Stent



GORE® VIABAHN® Endoprosthesis



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BARD® LIFESTENT® Vascular Stent



IDEV® SUPERA® Stent



BARD® FLUENCY® Plus Stent

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PROTÉGÉ® and EVERFLEX® are trademarks of Covidien. IDEV® and SUPERA® are trademarks of IDEV Technologies, Inc.



<sup>&</sup>lt;sup>2</sup> See references on slides 47-51.

### Mechanical Forces: Flexion (continued)



Abbott ABSOLUTE PRO® LL Stent



OptiMed SINUS-SUPERFLEX Stent



COOK® ZILVER® PTX® Stent



BARD® LUMINEXX® Stent



## Mechanical Forces: Longitudinal Compression

The GORE® VIABAHN® Endoprosthesis is capable of longitudinal compression with little residual force.

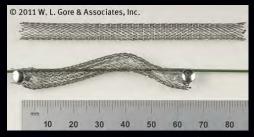
- Longitudinal compression
  - "From the supine position to the fetal position, the SFA shortened
     13% ± 11% (P < .001)."4</li>



GORE® VIABAHN® Endoprosthesis



BARD® LIFESTENT® Vascular Stent



Cordis S.M.A.R.T.® CONTROL® Stent



Covidien PROTEGE® EVERFLEX® Stent



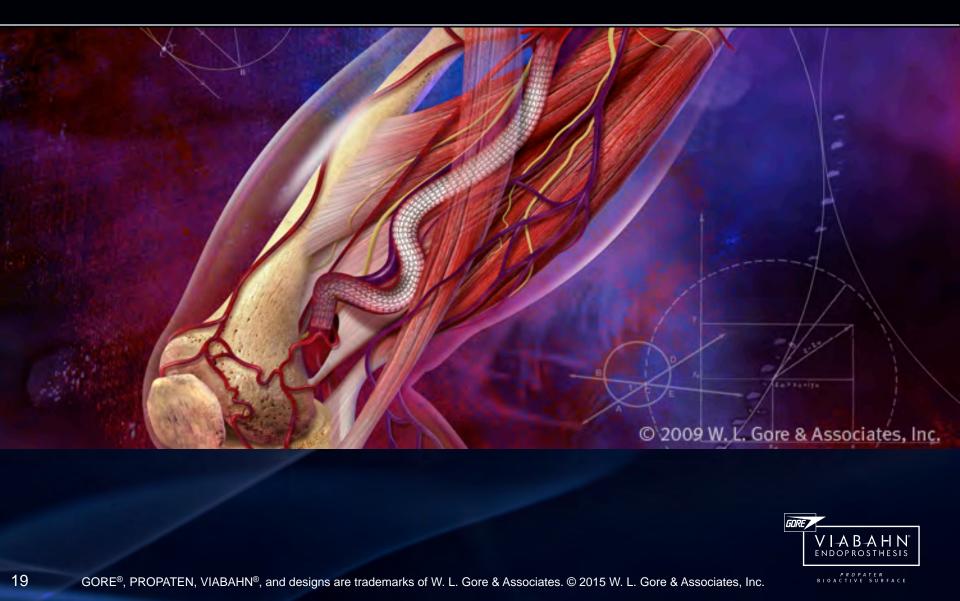
FLUENCY® Plus Stent

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<sup>&</sup>lt;sup>4</sup> See references on slides 47-51.

### Clinical Performance



# Reported Patencies of GORE® VIABAHN® Endoprosthesis in the SFA (1,338 Limbs, 17 Studies)

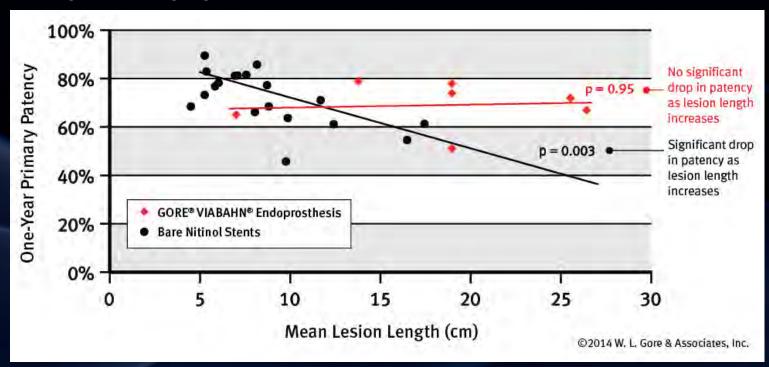
Average /	Total		1,338	16.4	58	76	67	61	55
Saxon Geraghty Lammer	2013 2013 2013	J Vasc Interv Radiol. 2013;24(2):165-173. <sup>19</sup> J Vasc Surg. 2013;58(2):386-395.e4. <sup>20</sup> J Am Coll Cardiol. 2013;62(15):1320-1327. <sup>21</sup>	119 72 66	19.0 19.0 19.0	56 60 79	73 51 78	41	27	
ensvelt ohnston	2012 2012	J Vasc Surg. 2012;56(1):118-125. <sup>17</sup> J Vasc Surg. 2012;56(4):998-1007.e1. <sup>18</sup>	56 65	18.5 26.0	58	76 57			
McQuade Fritschy	2010 2010	J Vasc Surg, 2010;52(3):584-591. <sup>15</sup> J Cardiovasc Surg, 2010;51(6):783-790. <sup>16</sup>	50 96	25.6		72 76	63 70	63 67.7	59
Djelmami- Hani Saxon*	2008	J Am Coll Cardiol. 2008;51(10)Supplement 2:B796 <sup>13</sup> J Vasc Interv Radiol. 2008;19(6):823-832. <sup>14</sup>	132 97	7.0	39 21	80 65			
Fischer Saxon* Alimi	2006 2007 2008	J Endovasc Ther. 2006;13(6):281-290. <sup>10</sup> J Vasc Interv Radiol. 2007;18(11):1341-1350 <sup>11</sup> Eur J Vasc Endovasc Surg. 2008;35(3):346-352 <sup>12</sup>	59 87 102	10.7 14.2 11.7	87 42	67 76 74	58 65 71	57 60 71	52 55
Chopra Coats	2006	14th Annual AIMS; November 13-16, 2006; New York, NY. Page II 2.1.8 Endovascular Today 2006;5(9):76-78.9	70 83	20.0	71 47	93 89	87	72	
ammer ahnke Bleyn	2000 2003 2004	Radiology. 2000;217(1):95-104.5 J Vasc Interv Radiol. 2003;14(1):41-51.6 Controversies & Updates in Vascular & Cardiac Surgery. 2004;14:87-91.7	80 52 67	13.8 8.5 14.3	83 100	79 78 82	74 73	62 68	54
Author	YEAR	JOURNAL PUBLICATION / PRESENTATION	No. of Limbs	LESION LENGTH (cm)	% Occlusions	1		PATENCY s / %)	4

<sup>5-21</sup> See references on slides 47-51.

VIABAHN ENDOPROSTHESIS

# GORE® VIABAHN® Endoprosthesis in Long Lesions

 The GORE® VIABAHN® Endoprosthesis exhibits proven performance in long, challenging SFA lesions.



Prospective Randomized or Prospective Multi-Center (> 2 sites) SFA studies included. <sup>5, 14, 15, 19-30, 32-37</sup> Registry studies not included. Patency definitions may vary: where Kaplan-Meier estimates with a PSVR of ≥ 2.5 are available, these were used for comparison. P-values indicate results of t-test on slope of weighted linear regression compared to zero. Note that McQuade *et. al,* 2010 reported stented length, not lesion-length.



<sup>5, 14, 15, 19-30, 32-37</sup> See references on slides 47-51.

### Competitive Data – BMS

Author	STUDY	YEAR	Device	MADE BY	N (LIMBS)	LESION LENGTH (Cm)	One-year Primary Patency	STUDY TYPE*
Krankenberg et al 27	FAST	2007	LUMINEXX Device	C. R. Bard, Inc.	123	4.5	68%	R
Dake et al 28	ZILVER PTX	2011	Bare ZILVER® Stent	Cook Medical	59	5.3	73%	R
Dake et al 28	ZILVER PTX	2011	ZILVER® PTX® Device	Cook Medical	61	5.3	90%	R
Dake et al 28	ZILVER PTX	2011	ZILVER® PTX® Device	Cook Medical	236	5.4	83%	R
Zeller et al 25	FACT	2008	CONFORMEXX Device	C. R. Bard, Inc.	110	5.9	77%	SAS
Medtronic 32	Complete SE	2013	COMPLETE® SE Stent	Medtronic	196	6.1	78%	SAS
Laird et al <sup>24</sup>	RESILIENT	2010	LIFESTENT® Device	C. R. Bard, Inc.	134	7.1	81%	R
Bosiers 33	4-EVER	2013	Pulsar – 18 Stent	Biotronik	120	7.2	81%	SAS
Cordis 34	STROLL	2013	S.M.A.R.T.® CONTROL® Stent	Cordis	250	7.7	82%	SAS
Dick et al 29	ASTRON	2009	ASTRON® Device	Biotronik	34	8.2	66%	R
Soukas 35	SUPERB	2013	SUPERA® Stent	IDEV Techonogies, Inc.	264	8.3	86%	SAS
Matsumura et al 26	Durability II	2012	EVERFLEX Device	Covidien	287	8.9	77%	SAS
Lammer et al 36	STRIDES	2011	DYNALINK® Stent with Everolimus	Abbott Laboratories	109	9.1	68%	SAS
Banerjee et al 37	COBRA - Control Arm	2012	Multiple	Multiple	45	10.0	44%	R
Schillinger et al 26	VIENNA (Absolute)	2006	DYNALINK® Device / ABSOLUTE® Device	Abbott Laboratories	51	10.1	63%	R
Banerjee et al 37	COBRA – Cryoplasty Arm	2012	Multiple	Multiple	45	12.0	77%	R
Duda et al 30	SUPER-SL	2009	S.M.A.R.T.® Device / LUMINEXX Device	Cordis / C. R. Bard, Inc.	199	12.8	60%	R
Lammer et al 21	VIASTAR (BMS Arm)	2013	Multiple	Multiple	63	17.0	54%	R
Geraghty <sup>20</sup>	VIBRANT (BMS Arm)	2013	Multiple	Multiple	76	18.0	61%	R
					0	2013 W. L. G	ore & Associates	s, Inc.

<sup>20, 21, 23-30, 32-37</sup> See references on slides 47-51.

<sup>\*</sup> Prospective randomized or prospective multi-center (>2 centers) SFA studies included. Registry studies not included. Patency definitions may vary: where Kaplan-Meier estimates with a PSVR of ≥ 2.5 are available, these were used for comparison. GORE®, PROPATEN, VIABAHN®, and designs are trademarks of W. L. Gore & Associates. © 2015 W. L. Gore & Associates, Inc.



### Key Studies: McQuade 2010

Randomized comparison of percutaneous GORE® VIABAHN® Endoprosthesis versus prosthetic femoral-popliteal bypass in the treatment of superficial femoral arterial occlusive disease<sup>15</sup>

	GORE® VIABAHN® E	NDOPROSTHESIS (N = 50)	EPTFE OR DACRON	® GRAFT BYPASS (N = 50)
Diameter	5	5.7 mm		.4 mm
Length	25.6 cm		H H	
TASC II A and B	n	n = 39		1 = 35
TASC II C and D	n = :	11 (22%)	n =	15 (30%)
	PRIMARY	SECONDARY	PRIMARY	SECONDARY
1 Year Patency	72%	83%	76%	86%
2 Year Patency	63%	74%	63%	76%
3 Year Patency	63%	74%	63%	76%
4 Year Patency	59%	74%	58%	71%
			© 2014	W. L. Gore & Associates, Inc.



<sup>&</sup>lt;sup>15</sup> See references on slides 47-51.

### Clinical Performance – AVR



### Bare Metal Stent Outcomes Similar to PTA

CITATION	AUTHOR	N	STUDY TYPE	6 мо
J Vasc Interv Radiol. 2004;15(10):1051-1060.	Vogel and Parise 38	53	Retrospective	51%
J Vasc Interv Radiol. 2005;16(12):1619-1626.	Vogel and Parise 39	25	Prospective	67%
Korean J Radiol. 2006;7(2):118-124.	Liang et al <sup>40</sup>	23	Observational	41%
Kidney Int. 2006;69(5):934-937.	Maya and Allon 41	14	Prospective	19%
Clin J Am Soc Nephrol. 2008;3(3):699-705.	Chan et al 42	211	Retrospective	25%
Int J Nephrol. 2011; 2011: 464735.	Hatakeyama et al 43	25	Prospective	28%
J Korean Soc Radiol. 2012;66(6):519-526.	Yoon et al 44	11	Prospective	29%
Cardiovasc Intervent Radiol. 2012;35(4):832-838.	Kim et al <sup>45</sup>	32	Retrospective	41%
			Weighted Average	33%
CIRCUIT PRIMARY PATENCY OF PTA IN TRI	EATING DYSFUNCTION	AL AVGS F	rom Randomized Con	TROLLE
CITATION	STUDY NAME	N	STUDY TYPE	6 мо
J Vasc Interv Radiol. 2005;16(12):1593-1603.	Cutting Balloon Study <sup>46</sup>	167	Prospective	36%
N Engl J Med. 2010;362(6):494-503.	Bard FLAIR® Pivotal Study <sup>47</sup>	93	Prospective	20%
Data on File, not yet published	Gore REVISE Clinical Study 48	138	Prospective	29%
© 2014 W. L. Gore & Associates, Inc. FLAIR® is a	trademarks of C.P. Bard	line	Weighted Average	30%

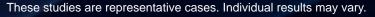


# Diffuse In-stent Stenosis is the Common Failure Mode of Bare Metal Stents



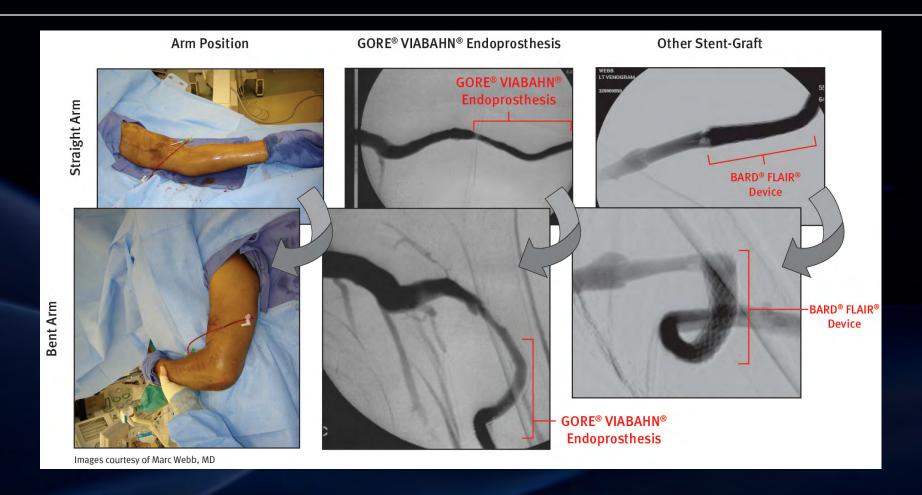


<sup>&</sup>lt;sup>44</sup> See references on slides 47-51.





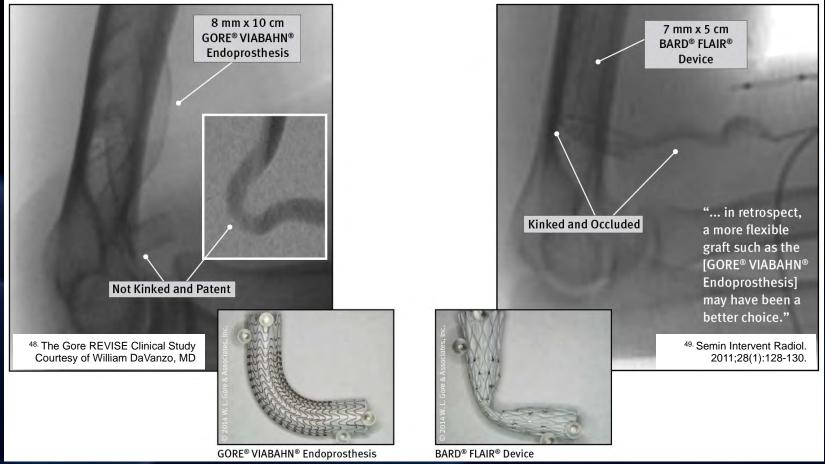
### Flexibility to Conform with the Anatomy







### Flexibility to Conform with the Anatomy



48,49 See references on slides 47-51.

These studies are representative cases. Individual results may vary.

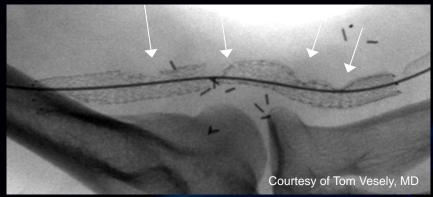
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### Durability to Last Under Mechanical Strain



### BMS across elbow with multiple fractures

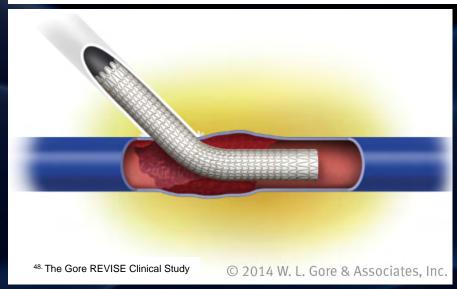


No reported fractures in the 24-month study period in Gore REVISE Clinical Study

<sup>&</sup>lt;sup>48</sup> See references on slides 47-51.

### Outflow Vein Wall Apposition Not Necessary

GREA	TER THAN THE GORE®	VIABAHN® ENDOPROS	sthesis 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%



<sup>&</sup>lt;sup>48</sup> See references on slides 47-51.
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# Stents / Stent-Grafts to Maintain Secondary Patency

SECONDAR	Y PATENCY OF THE	PTA GROUP IN TI	HE GORE REVISE CL	INICAL STUDY 48	
n = 138	3 months	6 months	12 months	24 months	$\Delta$ at 24 months
With Stents / Stent-Grafts	88%	87%	79%	67%	F 20/
Without Stents / Stent-Grafts	74%	65%	51%	35%	- 52%

Access secondary patency was maintained in the PTA group by implanting 61 stents / stent- grafts (53 GORE® VIABAHN® Endoprosthesis) during a subsequent intervention. In this analysis, the impact of stent / stent-grafts on access secondary patency in the PTA group were assessed by considering the implantation of a device as a loss of patency similar to a surgical bypass or abandonment.

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### Key Study: Gore REVISE Clinical Study 48

A 24-month multi-center, RCT demonstrating the safety and effectiveness of the GORE® VIABAHN® Device in treating stenosis or thrombotic occlusions at the AV graft venous anastomosis.

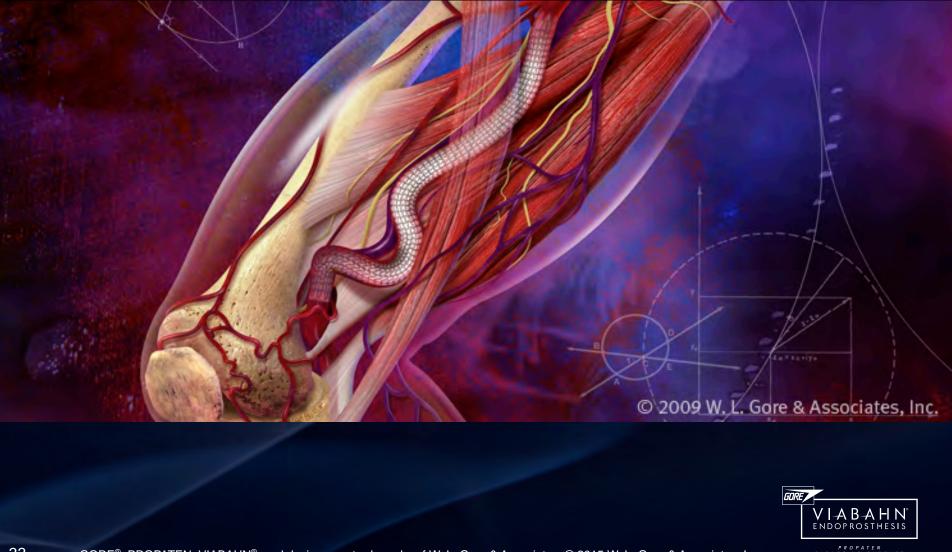
GORE® VIABAHN® Device (n = 131)	53%	65%	69%
	6-month Primary Patency	Non-Thrombatic 6-month PP	24-month Secondary Patency
PTA Group (n = 138)	36%	46%	67%ª

#### **Key findings:**

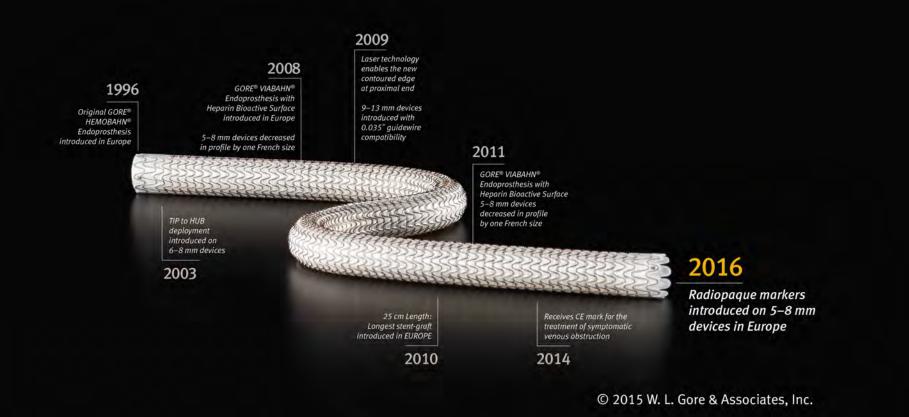
- Device benefits both stenotic and thrombotic occlusion patients (exceeds KDOQI expectations)
- Reduces the frequency of repeat interventions to maintain patency
- Successful while crossing the elbow



## Continued Device Evolution



### Continued Device Evolution



Product with radiopaque markers planned for European availability in 2016.

The GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface is sold in some markets as the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface.

VIABAHN° ENDOPROSTHESIS

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## 25 cm GORE® VIABAHN® Endoprosthesis Longest Stent or Stent-Graft Available

Go Long.



Extend Your Options.

© 2013 W. L. Gore & Associate, Inc.

- Covers more lesion with one device
- May reduce the need for overlapping devices



## GORE® VIABAHN® Endoprosthesis Lowest Profile Stent-Graft



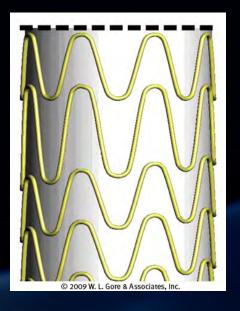
- Reduced profile on 5 8 mm devices
  - -5-6 mm at **6 Fr**
  - -7-8 mm at **7 Fr**
- Catheter compatible with 0.018" or 0.014" guidewire
- Stiffer catheter material maintains pushability and trackability



# GORE® VIABAHN® Endoprosthesis with Contoured Edge



Product with radiopaque markers planned for European availability in 2016.





- Precision laser trimming technology enables manufacturing change
- Excess graft material is removed
- Contoured trim is on *proximal* edge only



#### Reason for Contoured Edge Modification

- Manufacturing process change enables excess graft material removal at proximal margin of device
- Contoured edge may improve flow dynamics at proximal edge



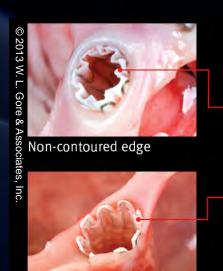
Product with radiopaque markers planned for European availability in 2016.



#### Contoured Edge: Canine Model

Contoured proximal edge — precision laser trimming technology enables manufacturing change. Post-mortem dissection demonstrates device apposition to artery.

#### **Animal acute examples**

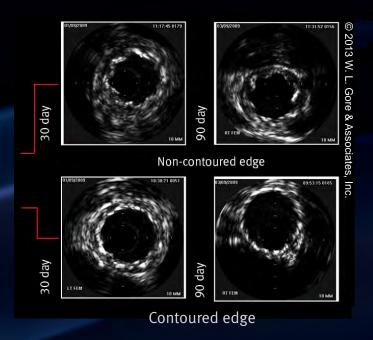


Contoured edge

Excess material removed at the device margin of the contoured edge compared to a non-contoured edge

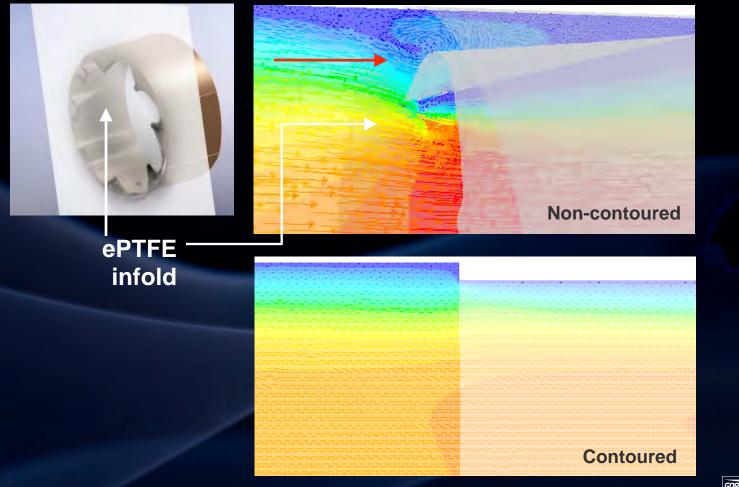
Intravascular ultrasound (IVUS) demonstrates device apposition to artery in canine model.

#### Canine in vivo IVUS Examples





### Flow Dynamics Simulation





V (m/s)

1.56

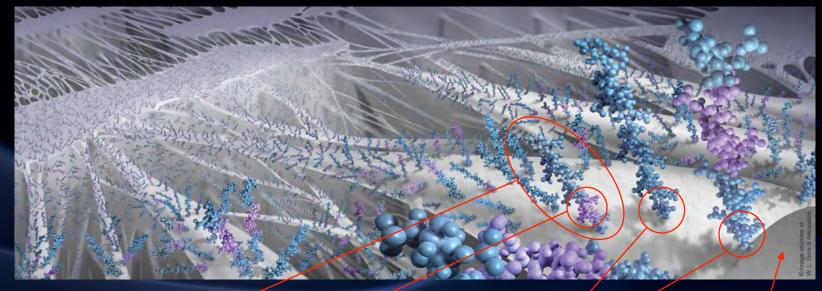
# CBAS® Heparin Surface: Unique Bioactive Heparin Bonding Technology

- Proprietary end-point covalent bonding
  - CBAS® Heparin Surface technology allows for retention of bioactivity
- Sustained bioactivity<sup>1</sup>
  - Heparin active site catalytically facilitates antithrombin-thrombin complex formation and then becomes available to repeat the reaction
- Intended to provide a thromboresistant surface
  - Long-term, safe, clinical history of the CBAS® Heparin Surface



# Unique Bioactive Heparin Bonding Technology

#### Inside the microstructure



Heparin molecule

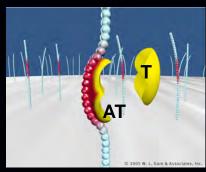
**Bioactive heparin site** 

Heparin molecules are bonded via **end-point linkage** mechanism to the surface of the endoprosthesis while retaining heparin's anticoagulant activity.

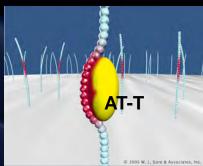


ePTFE fibril

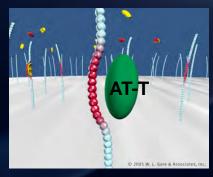
#### Mechanism of Action



- Heparin molecules are bonded to the endoprosthesis surface.
- Bioactive site of the heparin molecule binds to antithrombin (AT).



- Antithrombin (AT) binds to thrombin
   (T) a neutral AT-T complex is formed.
- Thrombin loses its ability to catalyze the conversion of fibrinogen to fibrin.

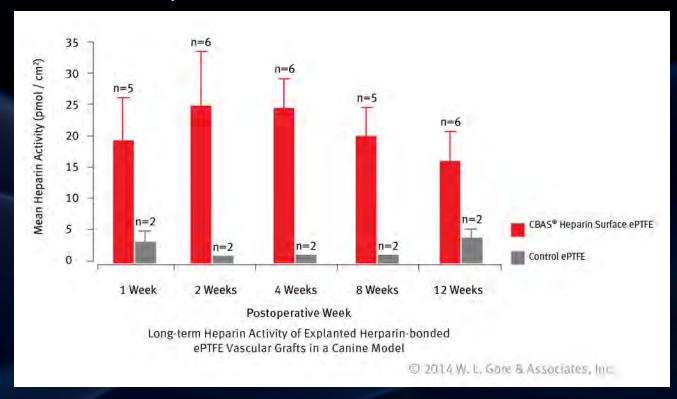


- Neutral AT-T complex detaches from the heparin molecule.
- Heparin bioactive site becomes available to again bind antithrombin.



#### Sustained Heparin-bonded Bioactivity<sup>1</sup>

- Anchored to the endoprosthesis surface
- Bonded heparin does not elute (data on file)
- Intended to provide sustained thromboresistance



<sup>&</sup>lt;sup>1</sup> See references on slides 47-51.



#### **Acute Thromboresistance**

 Illustration of thromboresistant characteristics exhibited by the CBAS® Heparin Surface



GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface

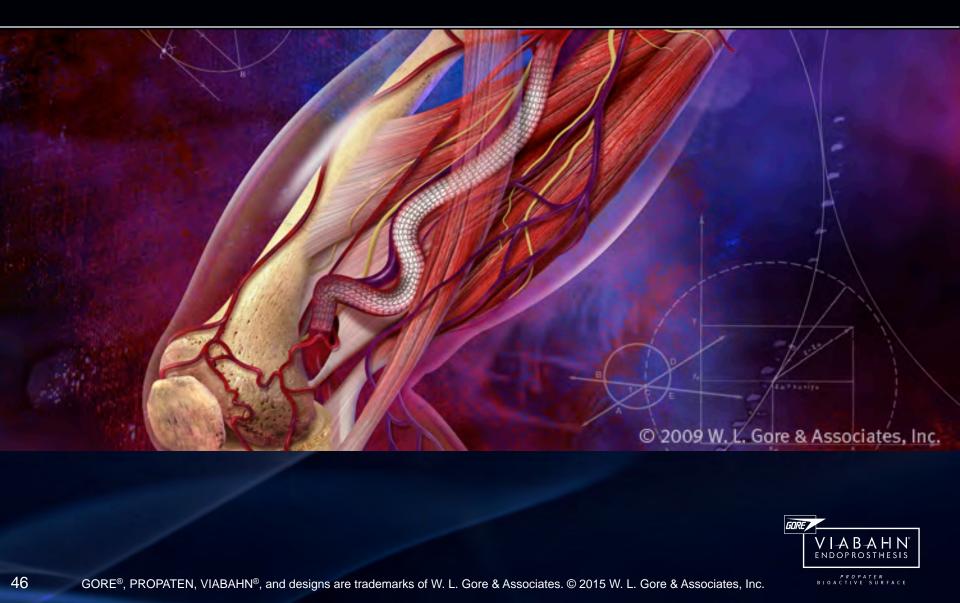


Control Endoprosthesis

The bioactive luminal surface of a 5 mm diameter GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface appears free of thrombus after two hours in an *in vitro* blood loop model. The non-bioactive luminal surface of a control endoprosthesis (5 mm diameter) appears covered with thrombus after 90 minutes in the same blood loop model. *(data on file)* 



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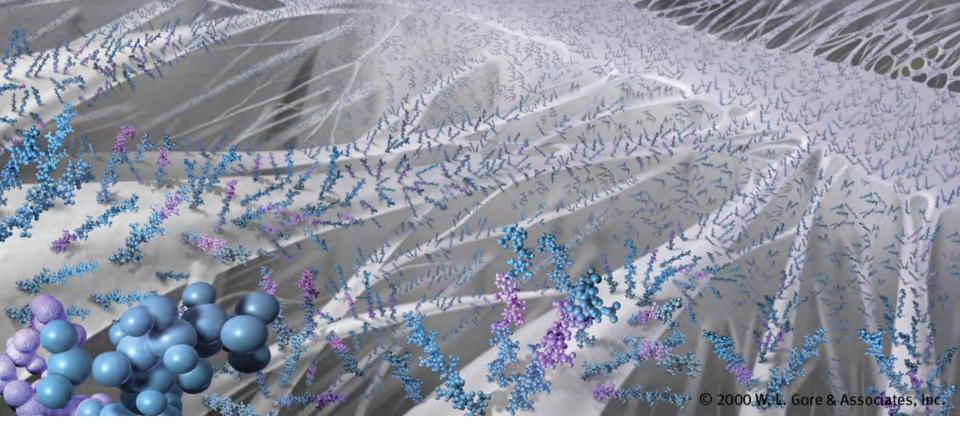


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#### W. L. GORE & ASSOCIATES, INC.

Flagstaff, AZ 86004

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

goremedical.com

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