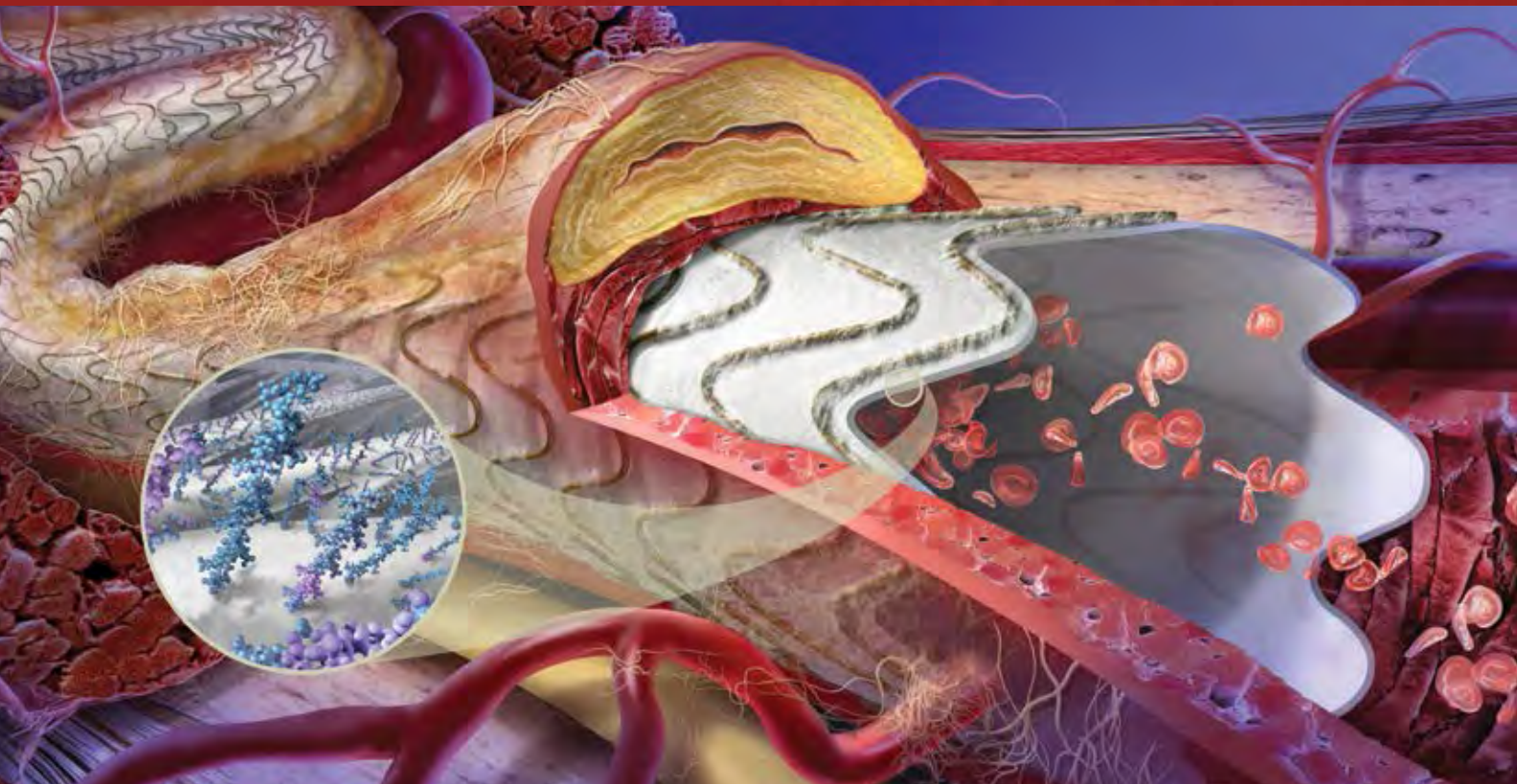


# *Reline*

*with Confidence.*



**PERFORMANCE** through innovation

## THE CONTINUING EVOLUTION OF A REVOLUTIONARY DEVICE

**GORE**

**VIABAHN<sup>®</sup>**  
ENDOPROSTHESIS

HEPARIN  
BIOACTIVE SURFACE

**1996**

Original  
GORE® HEMOBAHN®  
Endoprosthesis  
introduced in Europe

**2007**

GORE® VIABAHN®  
Endoprosthesis with  
Heparin Bioactive Surface  
introduced in US

5 – 8 mm devices  
decreased in profile by  
one French size

**2008**

GORE® VIABAHN®  
Endoprosthesis approved  
in Taiwan for SFA and  
Iliac artery indications

**2009**

Laser technology enables  
the new contoured edge  
at proximal end

9 – 13 mm devices  
introduced with 0.035"  
guidewire compatibility

**2003**

TIP to HUB  
deployment  
introduced on  
6 – 8 mm devices

Original device introduced in  
US as GORE® VIABAHN®  
Endoprosthesis

**2002**

6 – 8 mm devices  
in US receive FDA  
approval for SFA  
indication

All device sizes receive  
FDA approval for iliac  
artery indication

**2008**

GORE® VIABAHN®  
Endoprosthesis with  
Heparin Bioactive Surface  
and lower profile  
approved by Taiwan FDA

**2015**

**2005**

Gore continues  
to evolve the

GORE® VIABAHN®  
Endoprosthesis,

demonstrating our

commitment to

providing our

customers with

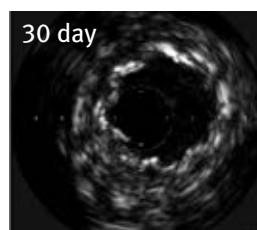
innovative products.



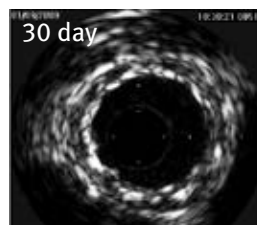
## ▶ A New Beginning for the Proximal End

- New precision laser trimming technology enables manufacturing change
- Excess material at the proximal edge removed
- Contoured edge may improve flow dynamics at proximal end
- The *Instructions for Use*, including sizing and placement recommendations, remain unchanged

### Canine In Vivo IVUS Examples



Non-contoured edge



Contoured edge

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

## ▶ The Endoluminal SFA Bypass

### Cover with Confidence

Covers and excludes the diseased irregular tissue of the arterial wall

### ePTFE Lining

Provides barrier to in-stent restenosis

### Nitinol Stent

Conformable yet durable

### Heparin-Bonded Surface

Intended to provide sustained thromboresistance

## CBAS® Heparin Surface

- Intended to provide a thromboresistant surface
- Sustained bioactivity\*
- Proprietary end-point covalent bonding

Gore® VIABAHN® Endoprosthesis with Heparin Bioactive Surface



*The bioactive luminal surface of a 5 mm diameter Gore® VIABAHN® Endoprosthesis with Heparin Bioactive Surface appears free of thrombus after two hours in an in vitro blood loop model.*

Control Endoprosthesis

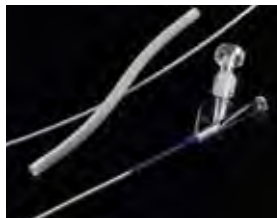


*The non-bioactive luminal surface of a control endoprosthesis (5 mm diameter) appears covered with thrombus after 90 minutes in the same blood loop model (data on file).*

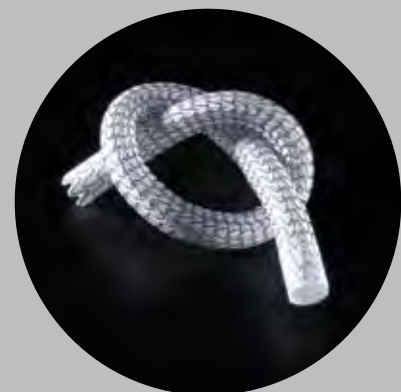
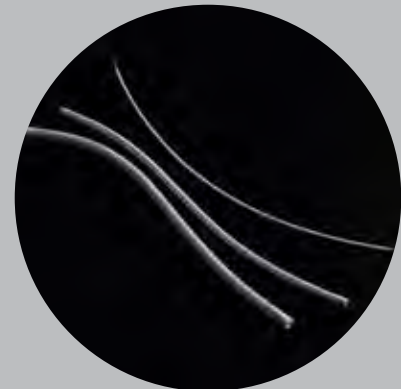
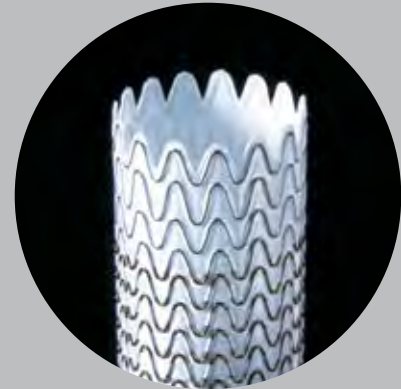
## Smaller Profiles

Reduced delivery profile for 5 – 8 mm devices

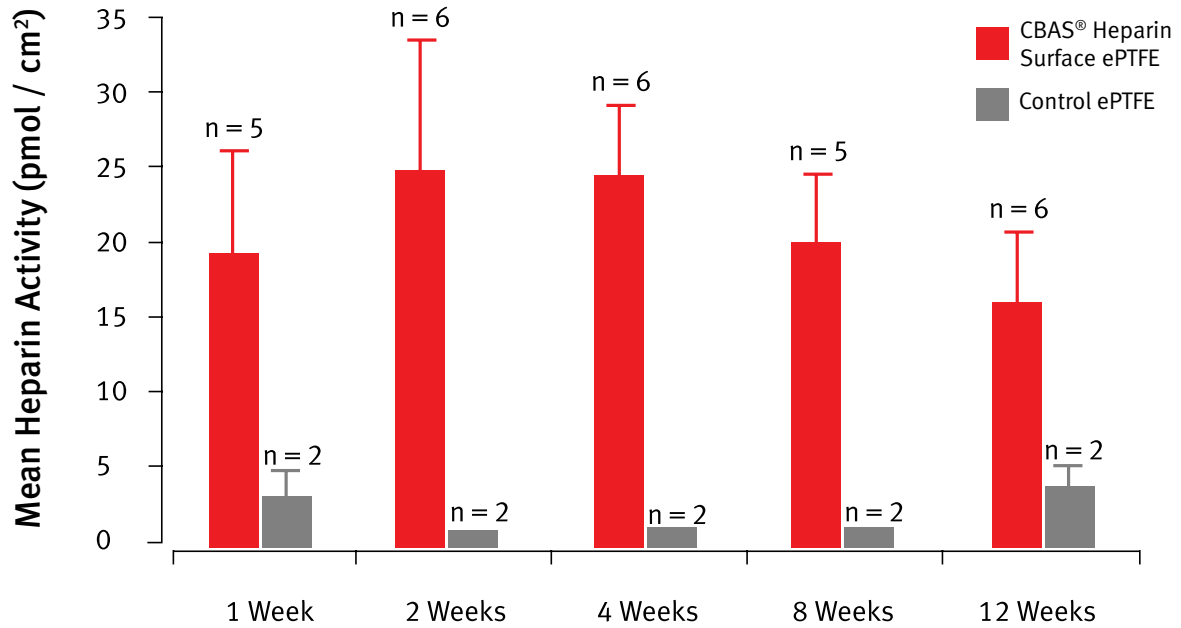
DIAMETER (mm)	PROFILE (Fr)	GUIDEWIRE
5	6	0.014" or 0.018"
6	6	0.014" or 0.018"
7	7	0.014" or 0.018"
8	7 <sup>4</sup>	0.014" or 0.018"



New catheter design maintains pushability and trackability of previous generation



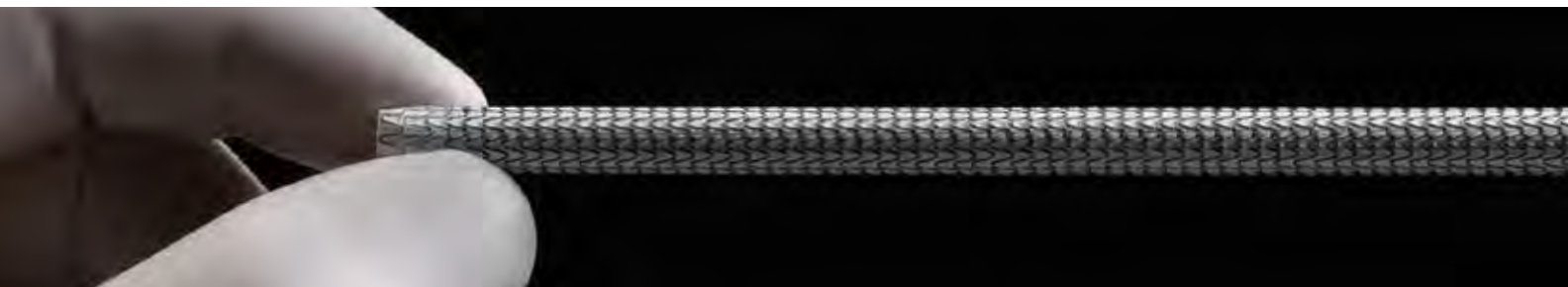
## ▶ Sustained Bioactivity



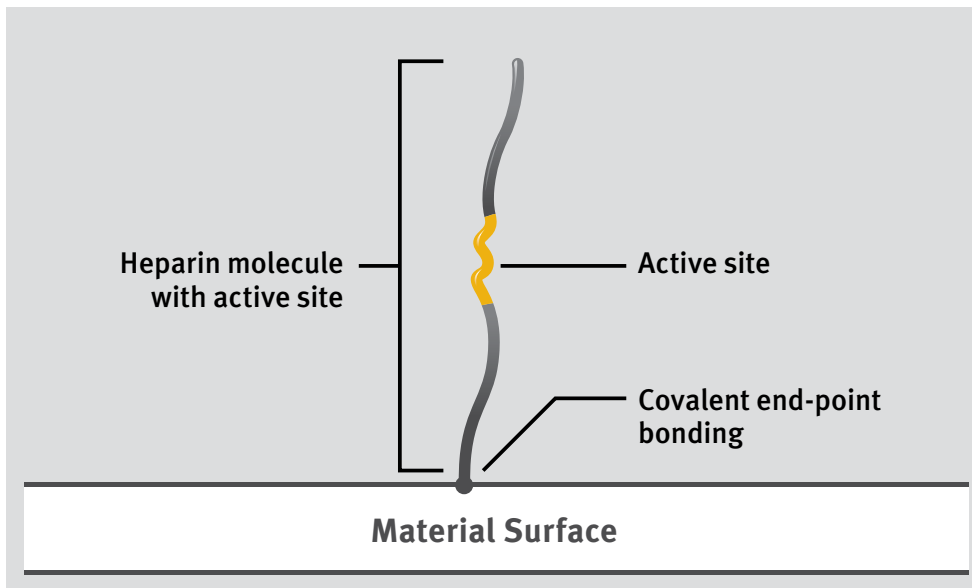
### Postoperative Week

Long-term Heparin Activity of Explanted Heparin-bonded ePTFE Vascular Grafts in a Canine Model\*

\* Begovac PC, Thomson RC, Fisher JL, Hughson A, Gällhagen A. Improvements in GORE-TEX® Vascular Graft performance by Carmeda® bioactive surface heparin immobilization. *European Journal of Vascular and Endovascular Surgery* 2003;25(5):432-437.

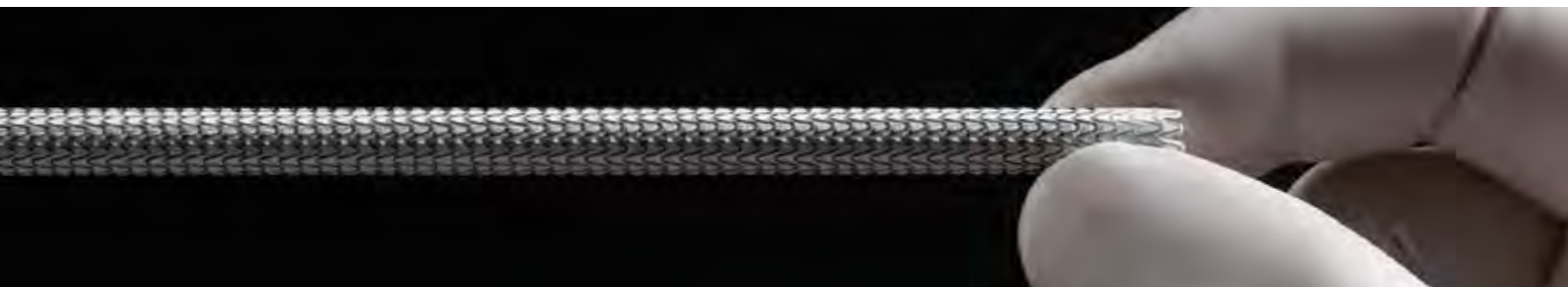


## Proprietary Covalent End-point Bonding



*Covalent end-point bonding allows the heparin to extend into the bloodstream, keeping the active site bioavailable, unlike a non-permanent bond that can be washed away in the bloodstream.*

- The anticoagulant function of heparin is dependent on the bioavailability of an active site within the molecule.
- Some methods of covalent heparin bonding damage and / or obstruct the active site, and hence destroy the heparin's anticoagulant activity.
- The CBAS<sup>®</sup> Heparin Surface of the GORE<sup>®</sup> PROPATEN<sup>®</sup> Vascular Graft consists of a proprietary covalent end-point bond that preserves the active site, thus retaining heparin's anticoagulant activity.



## ➤ Sizing Table

### 0.035" Guidewire Compatibility

Device Sizing		Introducer Sheath (Fr)				RECOMMENDED BALLOON DIAMETER FOR DEVICE TOUCH-UP <sup>3</sup> (mm)
ENDOPROSTHESIS LABELED DIAMETER <sup>1</sup> (mm)	RECOMMENDED VESSEL DIAMETER <sup>2</sup> (mm)	2.5 cm DEVICE LENGTH <sup>1</sup>	5 cm DEVICE LENGTH <sup>1</sup>	10 cm DEVICE LENGTH <sup>1</sup>	15 cm DEVICE LENGTH <sup>1</sup>	
5	4.0 – 4.7	7	7	7	7	5
6	4.8 – 5.5	7	7	7	7	6
7	5.6 – 6.5	8	8	8	8	7
8	6.6 – 7.5	8	8	8	8	8
9	7.6 – 8.5	–	9	9	9	9
10	8.6 – 9.5	11 <sup>4</sup>	11 <sup>4</sup>	11 <sup>4</sup>	11 <sup>4</sup>	10
11	9.6 – 10.5	11	11	11	–	12
13	10.6 – 12.0	12	12	12	–	14

### 0.018" Guidewire Compatibility

Device Sizing		Introducer Sheath (Fr)				RECOMMENDED BALLOON DIAMETER FOR DEVICE TOUCH-UP <sup>3</sup> (mm)
ENDOPROSTHESIS LABELED DIAMETER <sup>1</sup> (mm)	RECOMMENDED VESSEL DIAMETER <sup>2</sup> (mm)	2.5 cm DEVICE LENGTH <sup>1</sup>	5 cm DEVICE LENGTH <sup>1</sup>	10 cm DEVICE LENGTH <sup>1</sup>	15 cm DEVICE LENGTH <sup>1</sup>	
5	4.0 – 4.7	6	6	6	6	5
6	4.8 – 5.5	6	6	6	6	6
7	5.6 – 6.5	7	7	7	7	7
8	6.6 – 7.5	7	7	7	7	8

<sup>1</sup> Labeled device diameters and lengths are nominal.

<sup>2</sup> Recommended endoprosthesis compression within the vessel is approximately 5 – 20%.

<sup>3</sup> For the 11 and 13 mm diameter devices, balloon inflation pressure should not exceed 8 atm.

<sup>4</sup> 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.



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\* Begovac PC, Thomson RC, Fisher JL, Hughson A, Gällhagen A. Improvements in GORE-TEX® Vascular Graft performance by Carmeda® bioactive surface heparin immobilization. *European Journal of Vascular and Endovascular Surgery* 2003;25(5):432-437.

Products listed may not be available in all markets.

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