# The Combination

that lasts







### **Mechanical Solutions**











Transcending Mechanical Solutions

**1975** First GORE-TEX® Vascular Graft

1981 1983 FEP Ringed Thin-walled

**1992** Stretch Technology Thin-walled

**2002** gy GORE INTERING® Vascular Graft

GORE PROPATEN® Vascular Graft

# A NEW CATEGORY in Vascular Bypass.

Gore is the first company to introduce a new category in vascular bypass built on proven elements you can trust — a combination of innovation and a history of clinical success.

- **More than 30,000** successful GORE PROPATEN<sup>®</sup> Vascular Graft implants worldwide.
- **More than 200** scientific papers including numerous clinical studies have demonstrated the safety, efficacy and performance of the end-point covalent heparin bonding technology.
- More than 25 million Gore clinical ePTFE implants worldwide.
- More than 30 years of experience in medical device implants.

### PROPRIETARY END-POINT COVALENT BONDING

Only the end of the heparin molecule is bonded to the graft surface

• The heparin bioactive site remains free to interact with the blood



- luminal surface

  Bioactive site of the heparin molecule bi
- AT-T



heparin molecule binds to antithrombin (AT)

• Heparin molecules are bonded to the graft's

- Antithrombin 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

End-point covalent bonding keeps heparin anchored to the graft surface over time

Proprietary Gore technology





Thin and standard-walled

Removable Rings



## **GORE PROPATEN® Vascular Graft**

#### Sustained bioactivity<sup>1</sup>

- Anchored to the graft surface
- Heparin active sites are not compromised



Sustained Heparin Activity on GORE PROPATEN® Vascular Grafts (in vivo canine aorto-iliac bypasses)



HISTOLOGY Log #

30 40

20

GORE PROPATEN<sup>®</sup> Vascular Graft explant after 239 days (~ 8 months)

- Femoral to anterior tibial bypass
- Substantial heparin bioactivity detected
- In same range as that shown previously in a canine study

GORE PROPATEN<sup>®</sup> Vascular Graft explant after 1111 days (> 3 years)

- Below-knee femoral to tibioperoneal trunk bypass
- Outflow vessel (peroneal artery) occluded
- Substantial heparin bioactivity detected

#### Thromboresistant luminal graft surface that retains the intrinsic bioactive properties of heparin<sup>1</sup>



The bioactive luminal surface of a 3 mm diameter GORE PROPATEN® Vascular Graft (below) remains free of thrombus, while the non-bioactive surface of a control graft (top; 3 mm diameter) is covered with thrombus. Grafts were explanted after two hours in a challenging carotid shunt canine model.

#### Intimal Hyperplasia Reduction

-Lin, et al.<sup>2</sup>



Control ePTFE Graft



GORE PROPATEN® Vascular Graft

Neointimal hyperplasia at the distal anastomoses of an aortoiliac bypass graft model in baboons. Statistically significant reduction in neointimal hyperplasia at the distal anastomosis was observed for the GORE PROPATEN® Vascular Graft as compared to untreated control ePTFE.

A) Distal anastomosis of untreated control ePTFE graft B) Distal anastomosis of the GORE PROPATEN® Vascular Graft. L: Lumen; N: Neointima; G: ePTFE Graft. Collagens are blue, elastin is black, others are red. (Verhoeff-Masson stain; original magnification X40) Images reproduced with permission from Elsevier.

#### Bonded – Does not elute

50

- No systemic heparinization
- Thromboresistance remains over time

# Anything better below-knee would be a vein.



N = Number of Bypasses

Overall weighted average<sup>+</sup> primary patency based on GORE PROPATEN<sup>®</sup> Vascular Graft literature









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- Weighted Average =  $\frac{(N_1 \times Primary Patency_1) + (N_2 \times PP_2) + \dots + (N_n \times PP_n)}{(N_1 \times PP_n)}$ 
  - $N_1 + N_2 + ... + N_n$
- a. References 3 11 were used to calculate the number of patients and patency values.
- References 3 6 and 8 11 were used to calculate the number of patients and patency values. Note that references 5, 6 and 8 reported on clinical series that were predominantly BK Fem-Pop bypasses.
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