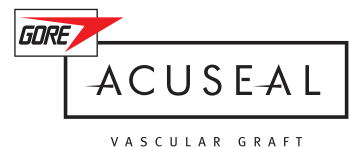




▶ FREQUENTLY ASKED QUESTIONS



PERFORMANCE
through innovation

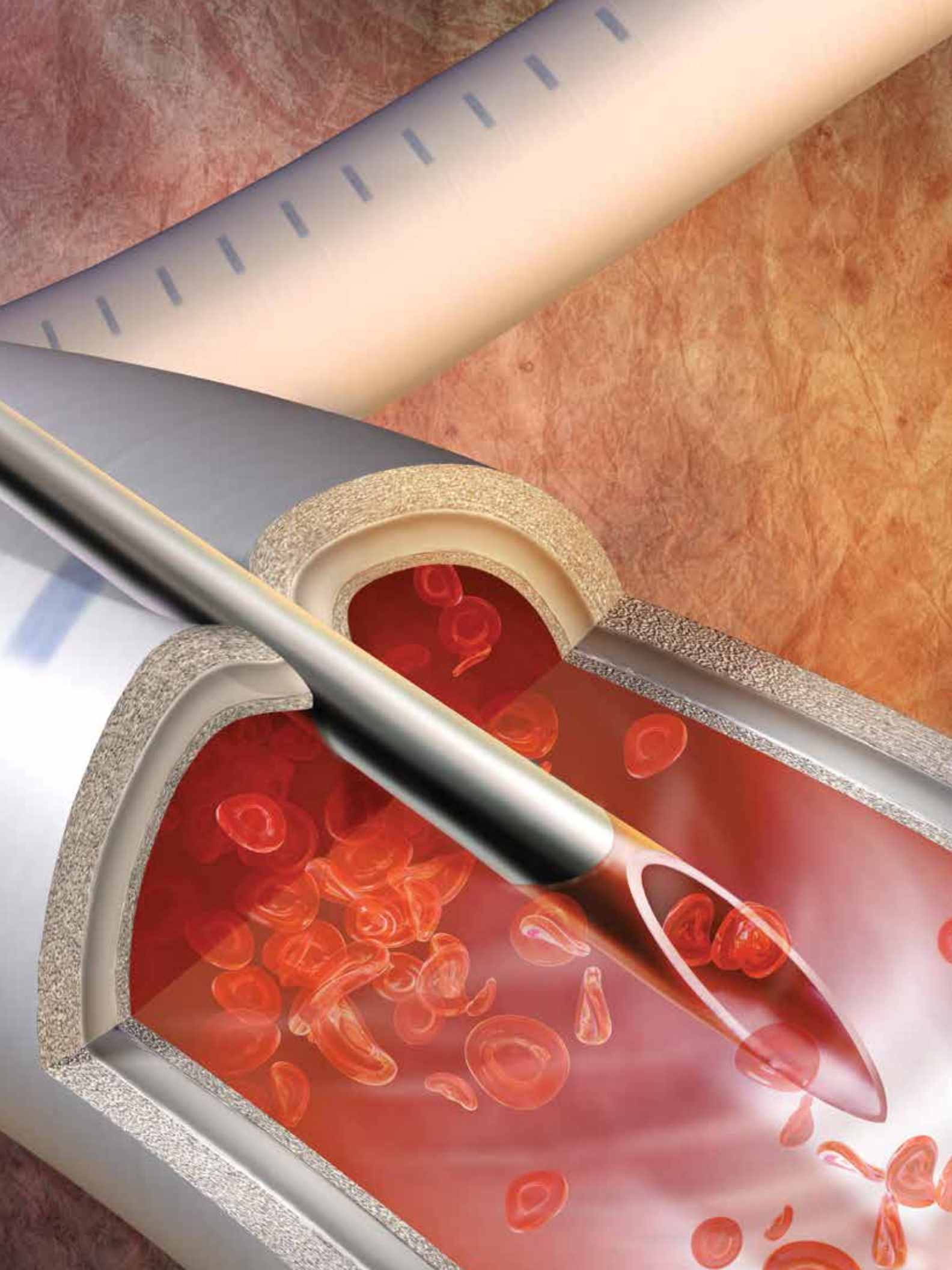


Table of Contents

GORE® ACUSEAL Vascular Graft Properties

What is the GORE® ACUSEAL Vascular Graft?	2
What is unique about the GORE® ACUSEAL Vascular Graft?	3
What are the benefits of the GORE® ACUSEAL Vascular Graft?	3
Are the microstructures of GORE-TEX® Vascular Grafts and GORE® ACUSEAL Vascular Grafts similar?	3

CBAS Heparin Surface and Heparin

Who is Carmeda AB?	4
Does Carmeda AB have a history of working with heparin technology?.....	4
What kind of heparin is bonded on the GORE® ACUSEAL Vascular Graft?.....	4
How long does the heparin last?	4
How many International Units of heparin are on the surface of a GORE® ACUSEAL Vascular Graft?.....	4

Clinical Practice

Implantation

Is the GORE® ACUSEAL Vascular Graft similar to the GORE-TEX® Stretch Vascular Graft? Do I have to tension the graft during implantation?	5
Are there special tunneling techniques for the GORE® ACUSEAL Vascular Graft?	5
Are there special techniques when cutting the GORE® ACUSEAL Vascular Graft?	5
Are there special techniques when sizing the GORE® ACUSEAL Vascular Graft to the anastomosis?	5
What kind of suture can be used with the GORE® ACUSEAL Vascular Graft?	6
Commonly requested GORE-TEX® Sutures reference table.....	6
Is there any difference in perioperative or postoperative bleeding?.....	6
Can the GORE® ACUSEAL Vascular Graft be revised?	6
Does a thrombectomy procedure damage the heparin?	6
What happens if the GORE® ACUSEAL Vascular Graft is clamped – does it damage the CBAS Heparin Surface of the graft?6	

Early Cannulation

How early can the GORE® ACUSEAL Vascular Graft be cannulated?	7
How early has the GORE® ACUSEAL Vascular Graft been cannulated?.....	7
Are there special precautions when cannulating the GORE® ACUSEAL Vascular Graft in the early postoperative period?	7
How long do you hold the cannulation site after the needle has been removed?.....	7
In which clinical situations can the greatest benefit be expected with the GORE® ACUSEAL Vascular Graft?	7

Anticoagulation

Do I have to change my patient’s anticoagulation regimen?	8
Can I change my anticoagulation procedure while using the GORE® ACUSEAL Vascular Graft?	8
What kind of anticoagulation does Gore recommend?	8
Can systemic heparin be reduced while using the GORE® ACUSEAL Vascular Graft?	8
What is the effect of Protamine on the GORE® ACUSEAL Vascular Graft?	8
Can a GORE® ACUSEAL Vascular Graft be implanted in patients with existing heparin-induced thrombocytopaenia (HIT)?	8
What treatment protocol should I follow if a GORE® ACUSEAL Vascular Graft patient develops HIT?	8

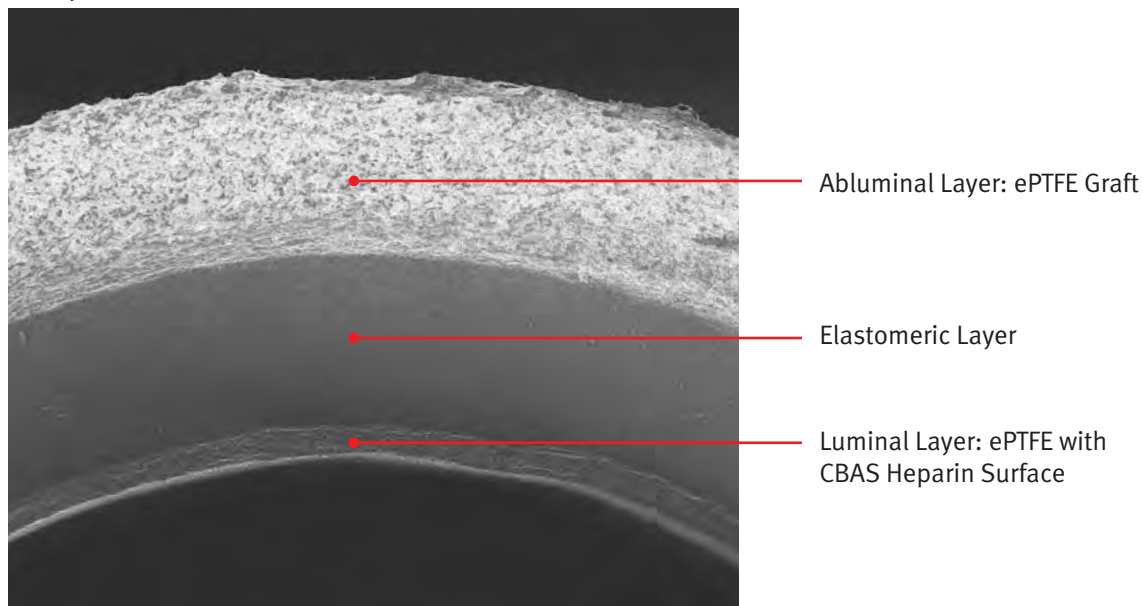
References	9
-------------------------	---

GORE® ACUSEAL Vascular Graft Properties

What is the GORE® ACUSEAL Vascular Graft?

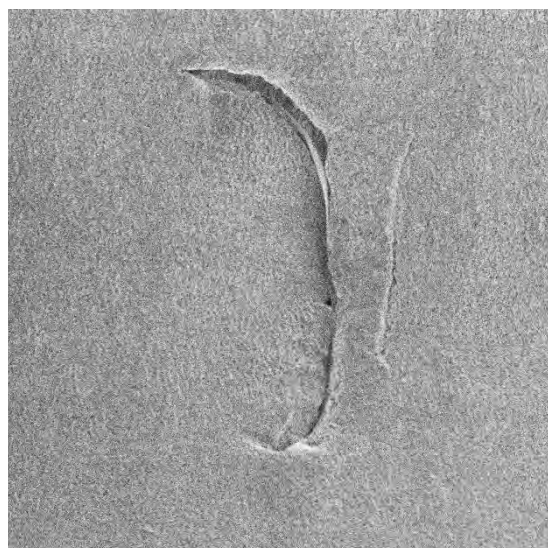
The GORE® ACUSEAL Vascular Graft is a multi-layer vascular graft which includes an elastomer membrane between the inner and outer layers of expanded polytetrafluoroethylene (ePTFE). The lumen of the GORE® ACUSEAL Vascular Graft incorporates the CBAS Heparin Surface which imparts thromboresistant properties to the vascular graft.

Tri-layer construction of a GORE® ACUSEAL Vascular Graft

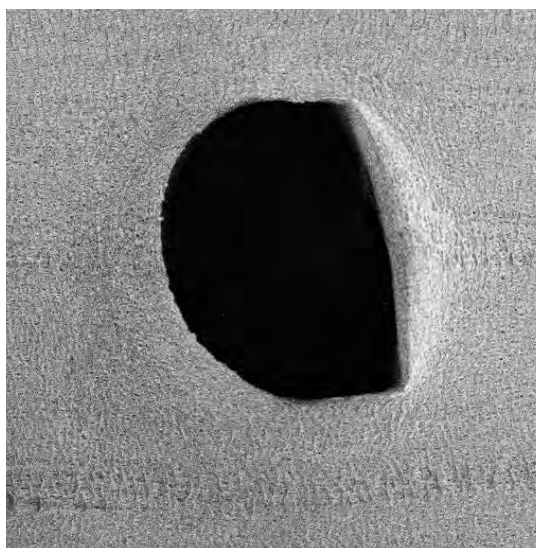


500x magnification
100µ

Low Bleed
GORE® ACUSEAL Vascular Graft



vs
Bleed
Standard ePTFE Graft



*Post cannulation of the luminal surface with a 16 gauge needle
Hold pressure for 10–15 minutes to achieve hemostasis post needle removal.*

Evaluation of GORE® ACUSEAL Vascular Graft in a Benchtop Canine Blood Flow Loop Model



GORE® ACUSEAL Vascular Graft without CBAS Heparin Surface



GORE® ACUSEAL Vascular Graft with CBAS Heparin Surface

What is unique about the GORE® ACUSEAL Vascular Graft?

- Low bleed barrier
- Elastomeric layer
- ePTFE inner layer
- CBAS Heparin Surface on the blood flow surface
- Outer ePTFE perivascular tissue contact surface
- Uniform structure throughout the length of the graft

What are the benefits of the GORE® ACUSEAL Vascular Graft?

- Hinders suture line bleeding
- Hinders hemodialysis cannulation needle bleeding
- May reduce risk of seroma formation
- Thromboresistance surface
- Kink resistance

Are the microstructures of GORE-TEX® Vascular Grafts and GORE® ACUSEAL Vascular Grafts similar?

The luminal ePTFE layer of the GORE® ACUSEAL Vascular Graft has the same microstructure as a GORE-TEX® Vascular Graft.

CBAS Heparin Surface and Heparin

Who is Carmeda AB?

Carmeda AB, a Swedish company, invented the CBAS Heparin Surface, an end-point attached heparin technology used on the GORE® ACUSEAL Vascular Graft and other medical devices.

In October 2005, Carmeda AB became a wholly owned subsidiary of W. L. Gore & Associates, Inc.

Does Carmeda AB have a history of working with heparin technology?

Carmeda AB is recognized as the world leader in heparin technology with a long history of pioneering research in this field since the company was founded in 1984.

What kind of heparin is bonded on the GORE® ACUSEAL Vascular Graft?

The CBAS Heparin Surface consists of stable, covalent, end-point attached heparin of porcine origin. It is sourced in North America and used in the construction of all GORE® ACUSEAL Vascular Grafts.

How long does the heparin last?

In order to resist thrombus buildup, it is essential that heparin is present on the surface and retains its bioactive function. Graft explants from an in vivo canine model demonstrated the continued presence of heparin on the graft surface and showed sustained heparin bioactivity over a period of 12 weeks.¹ Riesenfeld has reported substantial bioactivity on Berlin Heart Ventricular Assist Device (which uses the same CBAS Heparin Surface technology used on the GORE® ACUSEAL Vascular Graft) removed from a patient after 855 days.² Furthermore, human explants at approximately eight months, three years, four years and eight years post-implantation from medical devices with the CBAS Heparin Surface used for peripheral arterial bypass have demonstrated heparin bioactivity above the level required for thromboresistance in a challenging blood contact model.*

How many International Units of heparin are on the surface of a GORE® ACUSEAL® Vascular Graft?

Heparin activity in solution is typically measured in terms of International Units (IU). Surface bound heparin, on the other hand, is normally measured in terms of picomoles per cm² (pmol / cm²) of antithrombin III (ATIII) uptake. A reasonable estimate of the number of IU on the graft surface can be obtained via theoretical calculations. The total amount of heparin bound to each graft is very low when compared to a common intraoperative dose of heparin. The typical amount of heparin present on a GORE® ACUSEAL Vascular Graft (6 mm x 50 cm) is approximately 60 International Units (IU). This represents 1% of a common intraoperative dose of 5000 IU of heparin administered during vascular surgery.

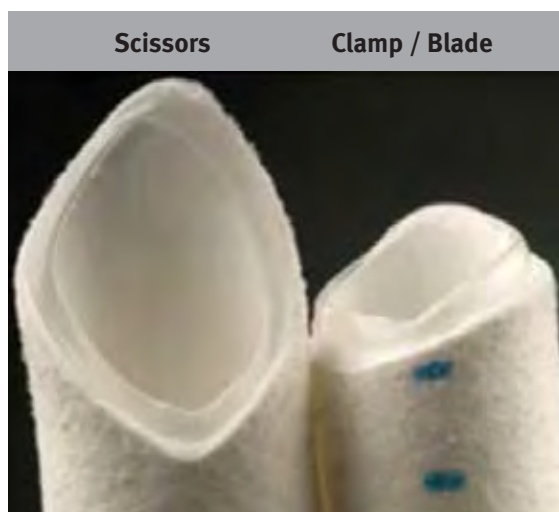
* Data on file

Clinical Practice

Implantation

Is the GORE® ACUSEAL Vascular Graft similar to the GORE-TEX® Stretch Vascular Graft?
Do I have to tension the graft during implantation?

The GORE® ACUSEAL Vascular Graft does not need to be pretensioned prior to implantation. While the graft affords a small amount of longitudinal extensibility, it should not be in a state of excessive tension when implanted.



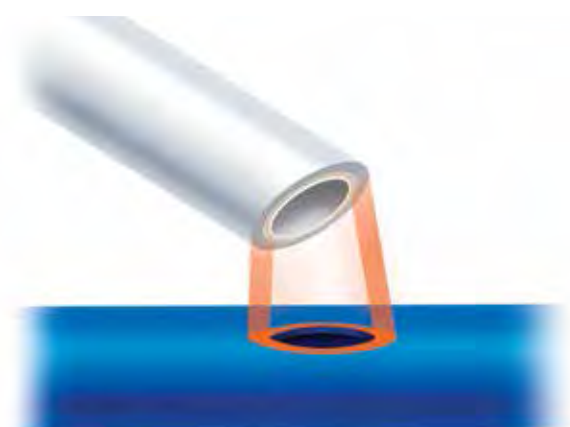
Are there special tunneling techniques for the GORE® ACUSEAL Vascular Graft?

Standard tunneling techniques can be used with the GORE® ACUSEAL Vascular Graft. Create a tissue tunnel that closely approximates the outer graft diameter. The 6 mm GORE® ACUSEAL Vascular Graft has an outer diameter of 8.8 mm. The 4–7 mm graft has an outer diameter of 9.4 mm.

Are there special techniques when cutting the GORE® ACUSEAL Vascular Graft?

Always cut the GORE® ACUSEAL Vascular Graft with a sharp surgical instrument. A different appearance is seen when cutting the GORE® ACUSEAL Vascular Graft

with scissors versus a clamp and blade. Sharp scissors create a smooth appearance to the wall of the vascular graft. A clamp and blade cut causes compression of the ePTFE microstructure and retraction of the ePTFE layers, creating a different appearance in the wall of the vascular graft. Either technique is acceptable. When suturing, be sure to pass the needle and thread through all three layers of the GORE® ACUSEAL Vascular Graft.



Are there special techniques when sizing the GORE® ACUSEAL Vascular Graft to the anastomosis?

Care must be taken when sizing the GORE® ACUSEAL Vascular Graft to the arteriotomy or venotomy. Match the inner diameter of the graft wall with the outer perimeter of the opening of the vessel.

GORE® ACUSEAL Vascular Graft Sizing		
INTERNAL DIAMETER	WALL THICKNESS	OUTER DIAMETER
6 mm	1.4 mm	8.8 mm
4–7 mm		
4 mm	1.2 mm	5.4 mm
7 mm	1.2 mm	9.4 mm

What kind of suture can be used with the GORE® ACUSEAL Vascular Graft?

Either GORE-TEX® Suture (Table 1) or polypropylene suture can be used with the GORE® ACUSEAL Vascular Graft.

Commonly Requested GORE-TEX® Sutures Table 1			
THREAD SIZE	NEEDLES	THREAD LENGTH (cm)	CATALOGUE NUMBER
CV-6	TTc-9	46	6J02
	TTc-9	61	6K06
	TTc-9	76	6M02
	TTc-12	61	6K10
	TTc-12	76	6M10
	TTc-13	46	6J04
	TTc-13	61	6K04
	TTc-13	76	6M04
	TTc-13	91	6N04
CV-7	TTc-9	46	7J02
	TTc-9	61	7K02
	TTc-9	76	7M02
CV-8	TTc-9	46	8J02
	TTc-9	61	8K02
	TTc-9	76	8M02

Is there any difference in perioperative or postoperative bleeding?

The GORE® ACUSEAL Vascular Graft is designed to provide heparin function at the graft surface; systemic anticoagulation remains unaffected. Because the GORE® ACUSEAL Vascular Graft has an elastomeric middle layer, perioperative and postoperative bleeding is hindered.

Can the GORE® ACUSEAL Vascular Graft be revised?

All standard revision procedures can be performed on the GORE® ACUSEAL Vascular Graft, including lytic therapy and balloon thrombectomy. The CBAS Heparin Surface remains intact even after repeated in vitro pseudo-balloon thrombectomy procedures.* When applying clamps, care should be taken to avoid mechanical damage to, or disruption of, the graft. Use the appropriate atraumatic or guarded (for example, rubber shod) clamps. Avoid repeated, localized clamping or excessive clamping on any section of the graft.

Does a thrombectomy procedure damage the CBAS Heparin Surface?

In vitro tests have shown that the CBAS Heparin Surface is still intact even after an inflated thrombectomy balloon was pulled through the graft three times.*

What happens if the GORE® ACUSEAL Vascular Graft is clamped — does it damage the CBAS Heparin Surface of the graft?

Graft clamping, according to recommended procedure, has no effect on the CBAS Heparin Surface or elastomeric layer. The CBAS Heparin Surface is very stable and is not easily removed by mechanical methods. As with any prosthetic vascular graft, atraumatic or guarded clamps should be used and repeated, localized clamping of the same graft section should be avoided.

* Data on file

Early Cannulation

How early can the GORE® ACUSEAL Vascular Graft be cannulated?

The GORE® ACUSEAL Vascular Graft can be cannulated within 24 hours after implantation. See the special considerations described below for optimal patient outcomes.

How early has the GORE® ACUSEAL Vascular Graft been cannulated?

As of this publication, the earliest a GORE® ACUSEAL Vascular Graft has been cannulated for hemodialysis is two hours post-implantation. This patient did not have a central venous catheter. By implanting the GORE® ACUSEAL Vascular Graft and permitting early cannulation, the patient did not require a central venous catheter.

Are there special precautions when cannulating the GORE® ACUSEAL Vascular Graft in the early postoperative period?

Yes. Adherence to aseptic technique is important. It is advised to wear sterile gloves since surgical incisions have not had sufficient time to heal. Certain sites have used the following practices for cannulation in the early postoperative period.³

- Local anesthesia
- Prevent graft movement during cannulation
- Swift, clean puncture with a small (17 gauge) needle
- Reduced blood flow of 200–250 ml / min
- Administration of a lower dose of heparin if bleeding from incision sites

How long do you hold the cannulation site after the needle has been removed?

In the early postoperative period and beyond, it is recommended to hold digital pressure at the needle exit site for 10–15 minutes, as for any healed, conventional vascular graft. Not applying constant pressure for 10–15 minutes can cause blood to leak out of the cannulation site and into the subcutaneous tunnel, potentially causing a hematoma.

In which clinical situations can the greatest benefit be expected with the GORE® ACUSEAL Vascular Graft?

Patients in need of hemodialysis who do not have a central venous catheter are the ideal candidates for a GORE® ACUSEAL Vascular Graft. If the patient has a central venous catheter, the catheter can be removed sooner if the GORE® ACUSEAL Vascular Graft is implanted instead of a non-early cannulation vascular graft.

Anticoagulation

Do I have to change my patient's anticoagulation regimen?

It is not necessary to change the patient's anticoagulation regimen. The thromboresistant effect of the CBAS Heparin Surface on a GORE® ACUSEAL Vascular Graft is limited to the device surface and does not have a systemic anticoagulant effect.⁴

Can I change my anticoagulation procedure while using the GORE® ACUSEAL Vascular Graft?

The clinician should consider the need for intraoperative and / or postoperative anticoagulation therapy based on the pharmacological requirements and medical history of the patient. The presence of CBAS Heparin Surface on the GORE® ACUSEAL Vascular Graft is not intended to serve as an alternative to the surgeon's chosen intraoperative or postoperative anticoagulation regimens.

What kind of anticoagulation does Gore recommend?

The clinician should determine the appropriate anticoagulation therapy based on the pharmacological requirements and medical history of the patient. The presence of CBAS Heparin Surface on the GORE® ACUSEAL Vascular Graft is not intended to serve as an alternative to intraoperative or postoperative anticoagulation.

Can systemic heparin be reduced while using the GORE® ACUSEAL Vascular Graft?

The presence of CBAS Heparin Surface on the GORE® ACUSEAL Vascular Graft is not intended to serve as an alternative to intraoperative or postoperative anticoagulation. The thromboresistant effect of the CBAS Heparin Surface on a GORE® ACUSEAL Vascular Graft is limited to the device surface and does not have a systemic anticoagulant effect.⁴

What is the effect of Protamine on the GORE® ACUSEAL Vascular Graft?

Although Protamine reverses the anticoagulant activity of heparin, its effect is transitory. Protamine can only remain bound to heparin when it is present in sustained excess quantities. Since Protamine is rapidly removed from the circulation, any effect is short-lived.

Can a GORE® ACUSEAL Vascular Graft be implanted in patients with existing heparin-induced thrombocytopenia (HIT)?


The GORE® ACUSEAL Vascular Graft is contraindicated for use in patients with known hypersensitivity to heparin, including those patients who have had a previous or existing incident of HIT type II.

What treatment protocol should I follow if a GORE® ACUSEAL Vascular Graft patient develops HIT?

The incidence of HIT type II is extremely low in vascular patients receiving systemic heparin over a period of several days. If HIT type II is diagnosed, established procedures for the treatment of this condition, including immediate cessation of systemic heparin administration, should be followed.^{5,6} If symptoms persist, alternative procedures can be considered at the discretion of the attending physician.

References

1. 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.
2. Riesenfeld J, Ries D, Hetzer R. Analysis of the heparin coating of an EXCOR® Ventricular Assist Device after 855 days in a patient. Abstract presented at the 32nd Society for Biomaterials Annual Meeting. April 18-21, 2007. Chicago, IL. Abstract 180.
3. Hudson P. Early cannulation of vascular access sites for dialysis. *Dialysis & Transplantation* 1996;8:523-526.
4. Heyligers JMM, Lisman T, Verhagen HJM, Weeterings C, de Groot PG, Moll FL. A heparin-bonded vascular graft generates no systemic effect on markers of hemostasis activation or detectable heparin-induced thrombocytopenia-associated antibodies in humans. *Journal of Vascular Surgery* 2008;47(2):324-329.
5. Linkins LA, Dans AL, Moores LK, Bona R, Davidson BL, Schulman S, Crowther M; American College of Chest Physicians. Treatment and prevention of heparin-induced thrombocytopenia: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141(2)Supplement:e495S-e530S.
6. Warkentin TE. Heparin-coated intravascular devices and heparin-induced thrombocytopenia. In: Warkentin TE, Greinacher A, eds. *Heparin-Induced Thrombocytopenia*. 5th ed. New York, NY: Informa Healthcare USA; 2012;(20):573-590.

 Consult Instructions for Use



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.

GORE®, GORE-TEX®, ACUSEAL, PERFORMANCE THROUGH INNOVATION, PROPATEN®, and designs are trademarks of W. L. Gore & Associates.

CBAS is a trademark of Carmeda AB, a wholly owned subsidiary of W. L. Gore & Associates, Inc.

© 2011, 2013, 2015 – 2016 W. L. Gore & Associates, Inc. AQ0107-EN5 APRIL 2016