



GORE® ACUSEAL
Vascular Graft

FREQUENTLY ASKED QUESTIONS



Together, improving life

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GORE® ACUSEAL Vascular Graft Properties

What is the GORE® ACUSEAL Vascular Graft?

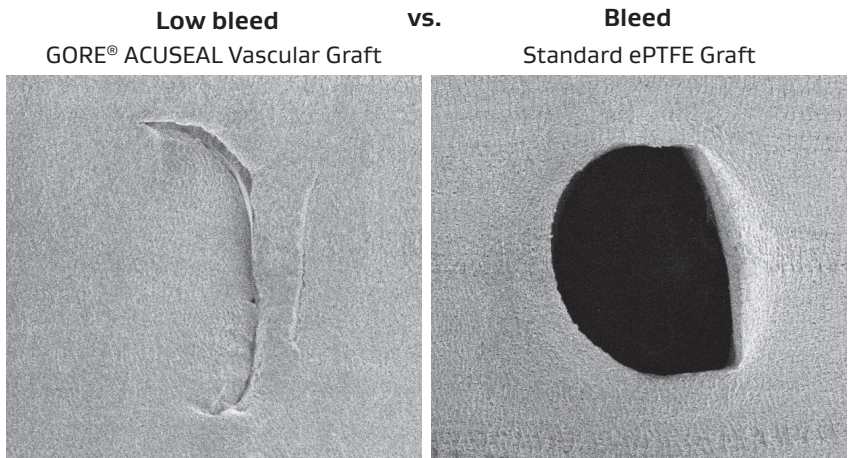
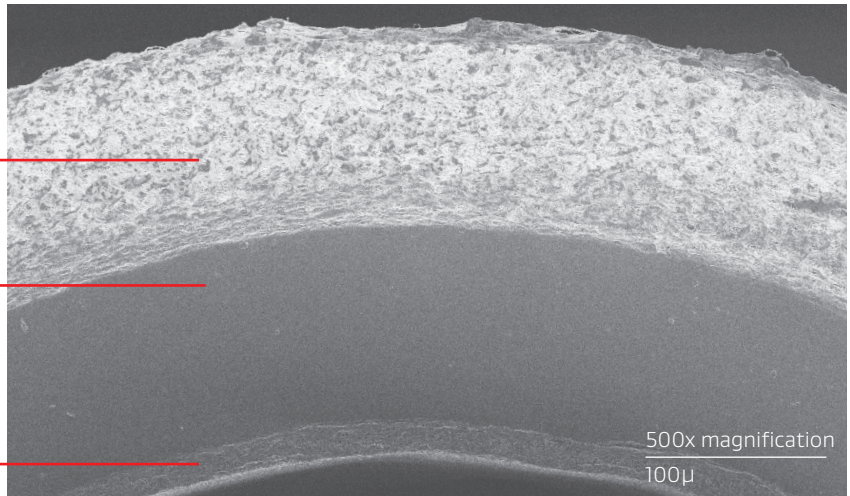
GORE® ACUSEAL Vascular Grafts are intended for use as vascular prostheses in patients requiring vascular access. It is a multi-layer vascular graft which includes an elastomer membrane between the inner and outer layers of expanded polytetrafluoroethylene (ePTFE) graft and is FDA-cleared for vascular access with the claim of early cannulation (within 24 hours of implantation). The lumen of the GORE® ACUSEAL Vascular Graft incorporates the CBAS Heparin Surface which consists of stable, covalent end-point attached heparin of porcine origin. The CBAS Heparin Surface imparts thromboresistant properties to the vascular graft.

Tri-layer construction of a GORE® ACUSEAL Vascular Graft

Abluminal layer:
ePTFE graft

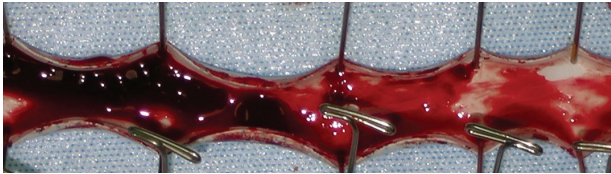
Elastomeric layer

Luminal layer:
ePTFE with CBAS
Heparin Surface

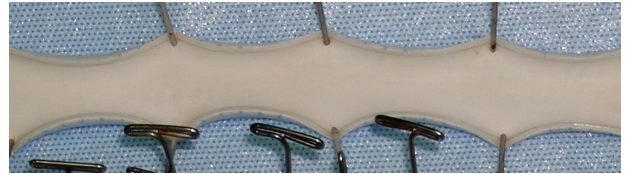


Post cannulation of the luminal surface with a 16 gauge needle. Hemostasis and avoidance of possible hematomas may be achieved by holding constant pressure at the site for 10–15 minutes after needle removal.

Evaluation of GORE® ACUSEAL Vascular Graft in a benchtop canine blood flow loop model.



GORE® ACUSEAL Vascular Graft without the CBAS Heparin Surface is covered with thrombus



GORE® ACUSEAL Vascular Graft with the CBAS Heparin Surface remains free of thrombus

What are the unique features and associated benefits of the GORE® ACUSEAL Vascular Graft?

Unique graft features	Associated benefits
Abluminal layer: ePTFE perivascular tissue contact surface	<ul style="list-style-type: none"> ■ Flexibility without kinking to allow for continued patency
Elastomeric membrane layer	<ul style="list-style-type: none"> ■ Low bleed, enabling early cannulation within 24 hours of implantation ■ Reduces or avoids central venous catheter (CVC) reliance, reducing CVC stenosis, infections and associated costs^{1,2} ■ Hinders hemodialysis cannulation needle and suture line bleeding* ■ May hinder seroma development by minimizing fluid passing through the graft wall
Luminal layer: ePTFE with CBAS Heparin Surface	<ul style="list-style-type: none"> ■ Helps to preserve the site and retain the anticoagulant activity of heparin to resist thrombus formation, contributing to continued patency

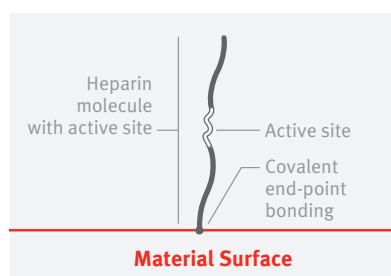
* Post hemodialysis needle removal apply 10-15 minute digital pressure to achieve hemostasis

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.

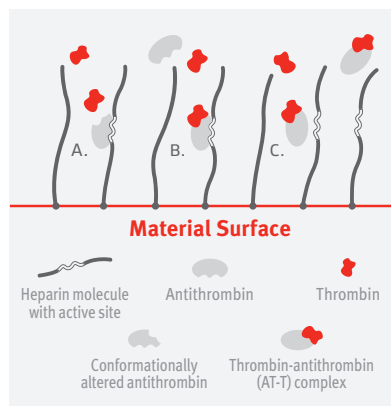
CBAS Heparin Surface and heparin

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.

Mechanism of action



- Bioactive site of the heparin molecule enables antithrombin to bind thrombin
- When antithrombin binds to thrombin, a neutral AT-T complex is formed
- Neutral AT-T complex detaches from the heparin molecule
Active site becomes available to again bind antithrombin

* <http://www.carmeda.se>

What is the CBAS Heparin Surface and how does it work?

CBAS Heparin Surface is the proven heparin bonding technology for lasting thromboresistance. It consists of a proprietary covalent end-point bond that preserves the active site, thus retaining heparin's anticoagulant activity.

Who is Carmeda AB?

Carmeda AB, a Swedish company, is a wholly owned subsidiary of W. L. Gore & Associates, Inc. Carmeda AB developed the CARMEDA® BioActive Surface (also known as the CBAS Heparin Surface), a proprietary end-point attached heparin technology used on the GORE® ACUSEAL Vascular Graft and other Gore medical devices. Carmeda AB is recognized as a world leader in the field of hemocompatible coatings, with a long history of pioneering research in this field since the company was founded in 1984.*

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

The CBAS Heparin Surface consists of stable, covalent, end-point attached heparin of porcine origin.

How long does the heparin last?

In order to resist thrombus formation, it is essential that heparin is present on the graft surface and retains its bioactive function. Graft explants from two controlled animal studies demonstrated the continued presence of heparin on the graft surface and showed sustained bioactivity over a period of 12 weeks³ and two years.⁴ Furthermore, human explants at approximately 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.⁵

How much heparin is on the surface of the GORE® ACUSEAL Vascular Graft?

The total amount of heparin covalently bound to the GORE® ACUSEAL Vascular Graft surface is extremely small in comparison to a common therapeutic intraoperative dose of heparin administered during vascular surgery (data on file 2017; W. L. Gore & Associates, Inc; Flagstaff, AZ.). End-point covalent bonding keeps the heparin anchored to the surface of the GORE® ACUSEAL Vascular Graft and does not have a systemic effect.

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. Refer to the table for GORE® ACUSEAL Vascular Graft sizing.

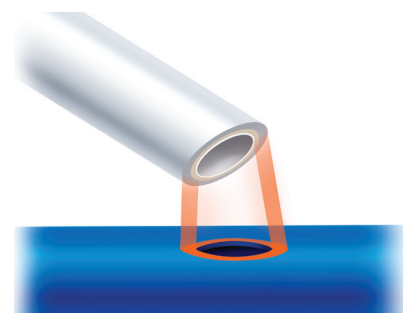
Are there special techniques when cutting the GORE® ACUSEAL Vascular Graft?

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; however, scissors are preferred. 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	Outer diameter
5 mm	7.6 mm
6 mm	8.8 mm
4–6 mm	
4 mm	6.4 mm
6 mm	8.4 mm
4–7 mm	
4 mm	6.4 mm
7 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
CV-6	TTc-9	61	6K06
CV-6	TTc-9	76	6M02
CV-6	TTc-12	61	6K10
CV-6	TTc-12	76	6M10
CV-6	TTc-13	46	6J04
CV-6	TTc-13	61	6K04
CV-6	TTc-13	76	6M04
CV-6	TTc-13	91	6N04
CV-7	TTc-9	46	7J02
CV-7	TTc-9	61	7K02
CV-7	TTc-9	76	7M02
CV-8	TTc-9	46	8J02
CV-8	TTc-9	61	8K02
CV-8	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.

Does a thrombectomy procedure damage the CBAS Heparin Surface?

In vitro tests have shown that the CBAS Heparin Surface is still functional even after an inflated thrombectomy balloon was pulled through the graft three times (data on file 1999; W. L. Gore & Associates, Inc; Flagstaff, AZ.).

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 functional after repeated in vitro pseudo-balloon thrombectomy procedures. The CBAS Heparin Surface is very stable and is not easily removed by mechanical methods. 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.

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.⁶ This patient did not have a CVC. By implanting the GORE® ACUSEAL Vascular Graft and permitting early cannulation, the patient did not require a CVC.

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.⁷

- 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 without a mature fistula who are in short term need of hemodialysis, or are not ideal fistula candidates, can avoid or dramatically shorten use of CVC with a GORE® ACUSEAL Vascular Graft. If the patient has a CVC, the catheter can be removed sooner if the GORE® ACUSEAL Vascular Graft is implanted instead of a non-early cannulation vascular graft.

Anticoagulation/Antiplatelet regimens

Do I have to change my patient's anticoagulation and/or antiplatelet regimens?

It is not necessary to change the patient's anticoagulation and/or antiplatelet regimens. 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.⁸

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

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

What kind of anticoagulation/antiplatelet therapy does Gore recommend?

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

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

The presence of the CBAS Heparin Surface on the GORE® ACUSEAL Vascular Graft is not intended to

serve as an alternative to the physician's chosen intraoperative or postoperative anticoagulation and/or antiplatelet regimens. 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.⁸

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

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

Can a GORE® ACUSEAL Vascular Graft be implanted in patients with a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II?

The GORE® ACUSEAL Vascular Graft is contraindicated for use in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (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.^{9,10} If symptoms persist, alternative procedures can be considered at the discretion of the attending physician.

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