INSTRUCTIONS FOR USE FOR:

GORE ACUSEAL

VASCULAR GRAFT

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GORE® ACUSEAL Vascular Graft

I. INDICATIONS FOR USE

GORE® ACUSEAL Vascular Grafts are intended for use as a vascular prosthesis in patients requiring vascular access.

II. CONTRAINDICATIONS

A. **DO NOT** use the GORE® ACUSEAL Vascular Graft in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II.

B. **DO NOT** use GORE® ACUSEAL Vascular Grafts as a patch. If cut and used as a patch, GORE® ACUSEAL Vascular Grafts may lack adequate transverse strength.

III. US CLINICAL EXPERIENCE

Objectives:

The primary objective of the US clinical study was to evaluate the safety and effectiveness of the GORE® ACUSEAL Vascular Graft compared to historical published literature controls.

Study Design:

This 138-subject, multi-centered, prospective, single arm clinical trial was designed to compare the GORE® ACUSEAL Vascular Graft to historical controls in patients requiring arteriovenous access grafts for hemodialysis.

The primary efficacy endpoint was cumulative patency at 6 months, determined by hemodynamic evidence of blood flow. The primary safety endpoint was freedom from bleeding at 6 months defined as percent of subjects free from major or minor bleeding including hematoma, incision site bleeding, gastrointestinal bleeding, rectal bleeding, and hemoptysis. The study also documented the time to first hemodialysis access and first three consecutive hemodialysis sessions.

Study Enrollment:

Ten (10) US sites enrolled patients in the study. All grafts were 6 mm internal diameter.

Pre-procedure Subject Information:

Demographics and medical history were similar between the GORE® ACUSEAL Vascular Graft and the historical control group except for percentage of males and number of subjects. Risk factors between groups were also similar with the exception of cerebral vascular disease. In the GORE® ACUSEAL Vascular Graft and historical control group, respectively, pre-procedure demographics included average age (63, 58 years), percent of male subjects (49%, 38 %), percentage of blacks (55%, 70%), and patients with cerebral vascular disease (28%, 16%). In the GORE® ACUSEAL Vascular Graft and historical control group, respectively, preprocedure risk factors included diabetes (60%, 60%), current tobacco use (23%, 17%), cardiovascular disease (51%, 42%), and peripheral vascular disease (17%, 15%). In the GORE® ACUSEAL Vascular Graft and historical control group, respectively, 83% and 74% of subjects were enrolled with a prior history of hemodialysis. A greater number of subjects in the GORE® ACUSEAL Vascular Graft presented for surgery with a central venous catheter (89%) compared to the subjects in the historical control group (66%).

Efficacy:

At the end of the 6-month and 12–month follow-up, the primary endpoint of cumulative patency for the GORE® ACUSEAL Vascular Graft was 84% and 78% compared to the historical control of 75% and 66%. The secondary endpoint of primary unassisted patency for the GORE® ACUSEAL Vascular Graft was 45% and 33% compared to the historical control of 41% and 23%.

Safety:

At the end of the 6-month and 12-month follow-up, freedom from bleeding (defined as any occurrence of reported bleeding from any source including but not limited to gastrointestinal bleeds, hemoptysis, extravasations, incision site bleeds, etc) was 88% and 84% in the GORE® ACUSEAL Vascular Graft group compared to 78% and 66% in the historical control group. Out of 135 study grafts cannulated, only two cannulation related hematomas were reported on days 107 and 169 postoperative. One resolved without treatment and one was revised due to infection. There were no device related adverse events or device related deaths reported in the study. There were also no reported cases of heparin induced thrombocytopenia (HIT) and no unanticipated adverse device effects (UADEs) in the GORE® ACUSEAL Vascular Graft group.

Early Access for Cannulation:

As part of a secondary endpoint of the GORE® ACUSEAL Vascular Graft clinical study, the time from initial graft implantation of the graft to the time of first cannulation was collected and analyzed. This data is summarized below:

Table 1: Time to First Cannulation Post Graft Implantation

Time till Graft Cannulation	Number of ACUSEAL Grafts Cannulated
24 Hours	N=30/135 (22.2%)
48 Hours	N=48/135 (35.6%)
72 Hours	N=54/135 (40.0%)
7 Days	N=70/135 (51.9%)

Three ACUSEAL Grafts were not cannulated.
The median days to first cannulation through the study graft was 5 days with a range of 0-116 days. For patients cannulated within the first 24 hours, the median time to first cannulation of the study graft was 21 hours with a range of 2 hours to 24 hours.

Time to Potential Central Venous Catheter Removal:

An additional secondary endpoint of the GORE® ACUSEAL Vascular Graft clinical study, for the subjects presenting with a central venous catheter (CVC), the time from initial graft implantation to the third consecutive use of the graft for hemodialysis was collected and analyzed. *(Note: the third consecutive cannulation was a surrogate endpoint for time to catheter removal; typically, catheter removal is generally ordered after the third consecutive cannulation.)*

Within 28 days of graft implantation 75.6% of the implanted GORE® ACUSEAL Vascular Grafts had been successfully cannulated 3 consecutive times and allowing for the potential for the CVC catheter to be removed.

IV. PACKAGE HANDLING

Store in a cool dry place. This product has an expiration date and should be used before the labeled "use by" (expiration) date marked on the box. The foil pouch is both a moisture barrier and a sterile barrier. DO NOT use if the foil pouch has been compromised.

To open the package, peel open the foil pouch and remove the tray. Beginning at one corner of the tray, peel back the tray lid and gently remove the graft. Use clean sterile gloves or atraumatic sterile instruments when handling the graft.

V. TECHNICAL INFORMATION

A. The GORE® ACUSEAL Vascular Graft is a multi-layer vascular graft with a low bleed layer between the inner and outer layers of expanded polytetrafluoroethylene.

B. The CBAS® Heparin Surface on the GORE® ACUSEAL Vascular Graft consists of stable, covalent, end-point attached heparin of porcine origin.

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

D. In the event of graft occlusion, established vascular prosthesis revision procedures should be considered. Appropriate revision procedure selection should be determined by the physician based on the specific case requirements.

E. DO NOT LET THE LUMINAL SURFACE OF THE GORE® ACUSEAL VASCULAR GRAFT DRY ONCE IT HAS BEEN WETTED.

F. With any vascular procedure, the possibility of HIT may exist. The incidence of HIT type II is extremely low in vascular patients receiving 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.[1, 2]

If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures, including ligation or removal of the device, may be considered at the discretion of the attending physician.

G. CORONARY ARTERY BYPASS PROCEDURES

(Also refer to INDICATIONS FOR USE and CONTRAINDICATIONS) W. L. Gore & Associates, Inc., has insufficient clinical and experimental data upon which to base any conclusion regarding the use of GORE® ACUSEAL Vascular Grafts in coronary artery bypass procedures.

H. VASCULAR ACCESS PROCEDURES

The GORE® ACUSEAL Vascular Graft can be cannulated early (within 24 hours after implantation). Patients should be carefully monitored when using GORE® ACUSEAL Vascular Grafts for vascular access. Puncture sites must be adequately separated when repeated needle punctures of the graft are necessary. Multiple punctures in the same area may lead to disruption of the graft material or formation of a perigraft hematoma or pseudoaneurysm. For additional information on early cannulation and vascular access, refer to the brochure "*GORE-TEX® Vascular Grafts for Hemodialysis: Techniques for the Care and Cannulation of A-V Grafts*", available from W. L. Gore & Associates.

I. SPECIAL CONSIDERATIONS FOR EARLY CANNULATION

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

- Local anesthesia
- Graft movement prevented during cannulation
- Swift, clean puncture with a small (17- gauge) needle
- Reduced blood flow (200-250 ml/min) for the entire session during the first week
- Administration of low-dose heparin for the first week

If cannulating the GORE® ACUSEAL Vascular Graft within two weeks of implantation hold pressure for 10-15 minutes to achieve hemostasis.

VI. POSSIBLE COMPLICATIONS WITH THE USE OF ANY VASCULAR PROSTHESIS

A. Complications which may occur in conjunction with the use of any vascular prosthesis include but are not limited to: redundancy; infection; ultrafiltration or perigraft seroma; thrombosis; mechanical disruption or tearing of the suture line, graft, and/or host vessel; excessive suture hole bleeding; formation of pseudoaneurysms due to excessive, localized, or large needle punctures; or perigraft hematomas.

B. A possible complication which may occur in conjunction with the use of any heparin-containing product: HIT type II (see section V. F.).

VII. OPERATIVE TECHNIQUES

ALL GORE® ACUSEAL VASCULAR GRAFT CONFIGURATIONS

1. 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.
2. When handling the GORE® ACUSEAL Vascular Graft, avoid using excessive force or high rates of force which could lead to graft disruption.
3. To avoid damage or contamination, always use clean sterile gloves and atraumatic sterile instruments when handling the GORE® ACUSEAL Vascular Graft. Always protect the graft from damage by heavy or sharp objects.
4. 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.
5. It is not necessary to preclot the GORE® ACUSEAL Vascular Graft.
6. Do not allow the graft to contact organic solvents such as alcohol or BETADINE® Solution. Avoid excessive manipulation of the graft in contact with tissue fluids or blood, as well as forcing irrigating solutions through the graft wall or filling the graft with blood prior to passing it through the tissue tunnel.
7. The correct graft length for each procedure must be carefully determined, taking into consideration the patient's body weight and posture, and the range of motions likely to be encountered across the anatomical area of the graft implantation. The graft should never be too short.
8. Failure to correctly cut the GORE® ACUSEAL Vascular Graft may damage the outer reinforcing layer and may result in aneurysmal dilatation or reduced suture retention strength. When cutting the graft, ensure that the graft is neither in tension nor has excessive slack and determine the correct length. Cut the graft with a sharp surgical instrument preferably scissors. DO NOT PULL OR PEEL THE OUTER REINFORCING LAYER FROM ANY AREA OF THE GRAFT. IF THE OUTER REINFORCING LAYER BECOMES FRAYED AT THE END OF THE GRAFT, CAREFULLY TRIM THAT PORTION OF THE GRAFT WITH A SHARP SURGICAL INSTRUMENT.
9. Standard tunneling techniques can be used with the GORE® ACUSEAL Vascular Graft. Create a tissue tunnel that closely approximates the graft diameter. A tissue tunnel that is too loose may result in delayed or insufficient perigraft tissue attachment, and may be a contributing factor to perigraft seroma formation. When using a sheath tunneler, such as the GORE® Tunneler, the graft should be pulled, rather than pushed, through the tunneler sleeve for greater ease of use (see GORE® Tunneler Instructions For Use).
10. Anastomotic angles vary with the vascular procedure being performed. Use of an appropriate anastomotic angle may minimize undue stresses which may lead to mechanical disruptions of the graft, host vessel, and / or suture lines.
11. Use only nonabsorbable, monofilament sutures, such as GORE-TEX® Suture, of a size appropriate for the nature of the reconstruction. Do not use a full radius cutting needle as it may damage the graft.
12. Undue anastomotic bleeding may occur if gaps occur between the graft and the host vessel. Use appropriate suture placement and bites and avoid undue tension on the suture line. Hemostatic agents such as topical thrombin and SURGICEL® Absorbable Hemostat may be used to minimize anastomotic bleeding. The manufacturers' instructions for these products should be observed.
13. When suturing through the GORE® ACUSEAL Vascular Graft, suture bites must pass through all layers of the graft wall.
14. The physician should ensure that the patient has been informed as to appropriate postoperative care.

VIII. STERILITY

GORE® ACUSEAL Vascular Grafts are supplied STERILE unless the integrity of the package has been compromised. The sterilization method is marked on the box. Sterility will be maintained until the labeled "use by" (expiration) date marked on the box.

IX. RESTERILIZATION

DO NOT RESTERILIZE THE GORE® ACUSEAL VASCULAR GRAFT.

REFERENCES

1. 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.
2. 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.
3. Hudson PC. Early cannulation of vascular access sites for dialysis. *Dialysis & Transplantation* 1996;25(8):523-526.

DEFINITIONS

EC REP Authorised Representative in the European Community

LOT Batch Code

REF Catalogue Number

Caution

℞ Only CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

Consult Instructions for Use

Date of Manufacture

Do Not Resterilize

Do Not Reuse

Do Not Use if Package is Damaged

Keep Dry

Manufacturer

SN Serial Number

STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

Store in a Cool Place

Use By

Diameter

FL Fibril Length 25 Microns (Nominal)

x Length

20028179

Manufacturer

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For international contact and additional product information,
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