Within 28 days of graft implantation 75.6% of the implanted GORE® ACUSEAL Vascular Grafts had been successfully cannulated 3 consecutive times. The median time to first cannulation through the study graft was 21 hours with a range of 2 hours to 24 hours. 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. Three ACUSEAL Grafts were not cannulated.

<table>
<thead>
<tr>
<th>Time Till Graft Cannulation</th>
<th>Number of ACUSEAL Grafts Cannulated</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 Hours</td>
<td>N=30/135 (22.2%)</td>
</tr>
<tr>
<td>48 Hours</td>
<td>N=48/135 (35.6%)</td>
</tr>
<tr>
<td>72 Hours</td>
<td>N=54/135 (40.0%)</td>
</tr>
<tr>
<td>7 Days</td>
<td>N=70/135 (51.9%)</td>
</tr>
</tbody>
</table>

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.
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 oratraumatic 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 CRAS® 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

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 orpseudoaneurysm. 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: 1

• 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 pseudoaneuysms 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

A. 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 andatraumatic 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 appropriateatraumatic 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 BETAINE® 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

DEFINITIONS

Authorized Representative in the European Community
Batch Code
Catalogue Number
Caution
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
Sterile
Sterilized using Ethylene Oxide
Store in a Cool Place
Use By
Diameter
Fibril Length 25 Microns (Nominal)
Length