

INSTRUCTIONS FOR USE FOR:



GORE-TEX®
V A S C U L A R
G R A F T



GORE-TEX®
S T R E T C H

V A S C U L A R G R A F T



INTERING®

V A S C U L A R G R A F T

en

English

hu

Magyar

bg

Български

it

Italiano

cs

Čeština

lt

Lietuvių

da

Dansk

no

Norsk

nl

Nederlands

pl

Polski

et

Eesti

pt

Português

fi

Suomi

ro

Română

fr

Français

sk

Slovenčina

de

Deutsch

es

Español

el

Ελληνικά

sv

Svenska

INSTRUCTIONS FOR USE FOR GORE-TEX® Vascular Grafts and GORE® INTERING® Vascular Grafts

- I. STERILITY**
- II. INDICATIONS FOR USE**
- III. CONTRAINDICATIONS**
- IV. TO OPEN THE PACKAGE**
- V. TECHNICAL INFORMATION**
- A. CORONARY ARTERY BYPASS PROCEDURES
- B. AXILLOFEMORAL, FEMOROFEMORAL and AXILLOBIFEMORAL BYPASS PROCEDURES
- C. VASCULAR ACCESS
- VI. POSSIBLE COMPLICATIONS WITH THE USE OF ANY VASCULAR PROSTHESIS**
- VII. OPERATIVE TECHNIQUES**
- A. ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS
- B. GORE-TEX® STRETCH VASCULAR GRAFTS
- C. FEP RINGED GORE-TEX® VASCULAR GRAFTS
- D. FEP RINGED GORE-TEX® VASCULAR GRAFTS with REMOVABLE RINGS
- E. GORE® INTERING® VASCULAR GRAFTS
- F. BIFURCATED GORE-TEX® STRETCH VASCULAR GRAFT
- G. FEP RINGED AXILLOBIFEMORAL GORE-TEX® VASCULAR GRAFT with REMOVABLE RINGS and FEP RINGED AXILLOBIFEMORAL GORE-TEX® STRETCH VASCULAR GRAFT with REMOVABLE RINGS
- VIII. STERILITY**
- IX. RESTERILIZATION**
- A. STEAM STERILIZATION
- B. ETHYLENE OXIDE (EtO) GAS STERILIZATION
- C. ALTERNATIVE RESTERILIZATION METHODS
- X. REFERENCES**

- I. STERILITY**
- GORE-TEX® Vascular Grafts are supplied STERILE unless the integrity of the package has been compromised.
- II. INDICATIONS FOR USE**
- GORE-TEX® Vascular Grafts are intended for use as vascular prostheses for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures.
- The FEP Ringed Axillobifemoral GORE-TEX® Vascular Graft with Removable Rings and the FEP Ringed Axillobifemoral GORE-TEX® Stretch Vascular Graft with Removable Rings are intended for use in bypass procedures which reestablish blood supply to the lower extremities.
- III. CONTRAINDICATIONS**
- A. **DO NOT** use GORE-TEX® Vascular Grafts as a patch. If cut and used as a patch, GORE-TEX® Vascular Grafts may lack adequate transverse strength. For cardiovascular procedures requiring patch materials, use the appropriate GORE-TEX® Cardiovascular Patch.
- B. **DO NOT** use any configuration of FEP Ringed GORE-TEX® Vascular Graft, FEP Ringed GORE-TEX® Vascular Graft with Removable Rings, or the GORE® INTERING® Vascular Graft for coronary artery bypass or cerebral reconstruction procedures.

IV. TO OPEN THE PACKAGE

Holding the base of the outer tray, peel back the lid so that the inner tray can be removed by grasping the sealed lip. Beginning at one corner, peel back the inner tray lid and gently remove the GORE-TEX® Vascular Graft. Use clean gloves or atraumatic instruments when handling the graft.

V. TECHNICAL INFORMATION

A. CORONARY ARTERY BYPASS PROCEDURES (Also refer to INDICATIONS FOR USE and CONTRAINDICATIONS)

W. L. Gore & Associates has insufficient clinical and experimental data upon which to base any conclusion regarding the use of non-ringed GORE-TEX® Vascular Grafts in coronary artery bypass procedures.

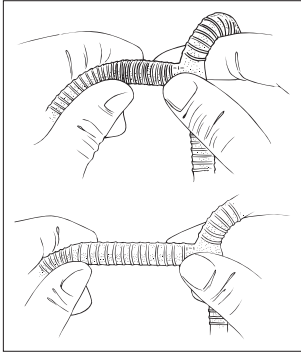
W. L. Gore & Associates cannot recommend using the GORE-TEX® Stretch Vascular Graft in coronary artery bypass procedures.

B. AXILLOFEMORAL, FEMOROFEMORAL, AND AXILLOBIFEMORAL BYPASS PROCEDURES

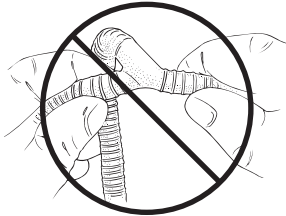
The success of axillofemoral, femorofemoral, and axillobifemoral bypasses depends in large part on the implantation technique. Specific complications associated with improperly implanted GORE-TEX® Vascular Grafts in these positions may include suture hole elongation and mechanical disruption or tearing of the graft, suture line, or host vessel.

Failure to follow these techniques may result in extreme blood loss, loss of limb function, loss of limb, or death. Although experience indicates that the incidence of these complications is extremely low, the following techniques **MUST** be employed if your treatment plan includes one of the above procedures:

- Consider the patient's body weight and posture when determining the lengths of the tissue tunnel and the graft.
- Drape the patient to allow full movement of the arm, shoulder girdle or legs when determining correct graft length.
- Avoid protracted hyperabduction of the arm. Prolonged hyperabduction may lead to brachial plexus injury.
- Allow sufficient length to avoid stressing the axillary or femoral anastomoses throughout the full range of movement of the arm, shoulder girdle, or legs. Surgeons suggest that the graft be placed under both the pectoralis major and pectoralis minor.
- Cutting the non-Stretch graft *slightly* longer than necessary has been reported by some surgeons to reduce further the risk of stressing the graft or the anastomoses.
- For the FEP Ringed Axillobifemoral GORE-TEX® Stretch Vascular Graft, refer to OPERATIVE TECHNIQUES - FEP RINGED AXILLOBIFEMORAL GORE-TEX® VASCULAR GRAFT WITH REMOVABLE RINGS AND FEP RINGED STRETCH AXILLOBIFEMORAL GORE-TEX® VASCULAR GRAFT WITH REMOVABLE RINGS, Section VII. G.
- For the FEP Ringed Axillobifemoral GORE-TEX® Stretch Vascular Graft, moderately tension each component of the graft separately to avoid inadvertently placing excess tension on the graft suture line at the manufactured anastomotic site.



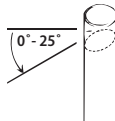
HOLD THE GRAFT AT THE SUTURED ANASTOMOSIS OF THE GRAFT AND TENSION THE LEG OF THE GRAFT.



DO NOT TENSION THE GRAFT BY PULLING ON THE LEGS OF THE GRAFT AS DOING SO MAY LEAD TO SUTURE PULLOUT.

Perpendicular "T" Anastomotic Technique

- When creating a perpendicular "T" anastomosis to the axillary artery, the graft should be cut with a small angle of bevel in order to minimize stress on the graft. The angle of bevel should not exceed 25° relative to the cut edge of the graft.
- Anastomose the graft close to the rib cage on the first portion of the axillary artery. Do not place the anastomosis on the third portion of the axillary artery.

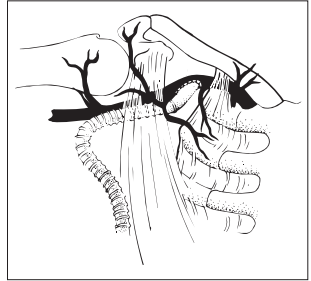


RECOMMENDED ANGLE OF BEVEL

RECOMMENDED ANASTOMOTIC PLACEMENT AND ABDUCTION TEST

Alternative Anastomotic Technique

- An alternative technique reported by some surgeons^{1,2} to further avoid stressing the axillary anastomosis is to route the graft parallel and adjacent to the axillary artery posterior to the pectoralis minor muscle for approximately 8-10 cm before forming a gentle curve to its inferior course.



GRAFT TO AXILLARY ARTERY END-TO-SIDE ANASTOMOSIS. THE GRAFT IS PLACED PARALLEL TO THE AXILLARY ARTERY POSTERIOR TO THE PECTORALIS MINOR MUSCLE FOR 8 TO 10 CM BEFORE GENTLY CURVING TOWARD THE PROPOSED ANASTOMOTIC SITE.

- To aid in proper parallel placement of the graft in relation to the axillary artery, some surgeons¹ have reported the use of an axillary counterincision near the third part of the artery.
- Begin implantation by pulling the graft from the axillary counterincision to the first portion of the axillary artery. The graft **must** be placed under both the pectoralis major and the pectoralis minor muscles. The anastomosis **must** be performed in the first portion of the axillary artery, proximal to the thoracoacromial trunk. This entails dissection and proximal control at the axillary-subclavian junction under the clavicle. Correct placement in this area prevents excessive movement of the artery/graft junction. **Do not** place the anastomosis on the second or third portion of the axillary artery. **Rotate the axillary artery with clamps so that the arteriotomy is made on its inferior border, placing the arteriotomy as close as possible to the first rib to minimize subsequent movement.** Correctly bevel the axillary anastomosis. Stress on the anastomosis is minimized when the graft is placed parallel to the axillary artery.
- Continue the procedure by pulling the graft from the axillary counterincision to the femoral incision with use of an appropriate tunneling instrument. **The graft should lie in the mid-axillary line to minimize kinking when the patient bends forward at the waist.**

FOR ALL TECHNIQUES: CAUTION THE PATIENT AGAINST EXTREME OR ABRUPT MOVEMENTS OF THE ARM, SHOULDER, OR LEGS DURING A CONVALESCENT PERIOD OF SIX TO EIGHT WEEKS TO ALLOW FOR ADEQUATE HEALING. ROUTINE ACTIVITIES SUCH AS REACHING OUT IN FRONT, RAISING ARMS ABOVE THE SHOULDER LEVEL, THROWING, PULLING, STRIDING, OR TWISTING SHOULD BE AVOIDED.

FAILURE TO FOLLOW THESE PROCEDURES MAY RESULT IN EXTREME BLOOD LOSS, LOSS OF LIMB FUNCTION, LOSS OF LIMB, OR DEATH.

C. VASCULAR ACCESS

Patients should be carefully monitored when using GORE-TEX® 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, refer to the brochure *GORE-TEX® Vascular Grafts for Hemodialysis: Techniques for the Care and Cannulation of A-V Fistulas*, available from W. L. Gore & Associates.

FEP RINGED GORE-TEX® VASCULAR GRAFTS

Most of the configurations of the FEP Ringed GORE-TEX® Vascular Graft should not be used as vascular access devices because of the possibility of the dialysis needle dislodging the rings. (See "OPERATIVE TECHNIQUES - FEP RINGED GORE-TEX® VASCULAR GRAFT" Section VII. C.) However, surgeons may choose configurations with a 5 cm to 15 cm ringed section that may help to prevent kinking at the apex of the loop, or to resist compression when crossing the antecubital fossa.

If the FEP Ringed GORE-TEX® Vascular Graft with Removable Rings is used for vascular access, the rings must be removed from any cannulation region prior to implant. (See "OPERATIVE TECHNIQUES - FEP RINGED GORE-TEX® VASCULAR GRAFT WITH REMOVABLE RINGS" Section VII. D.) Do not puncture the graft at or near any FEP ringed section.

VI. POSSIBLE COMPLICATIONS WITH THE USE OF ANY VASCULAR PROSTHESIS

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.

VII. OPERATIVE TECHNIQUES

A. ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS

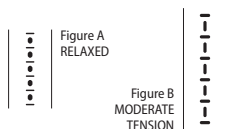
1. To avoid damage or contamination, always use clean gloves and atraumatic instruments when handling a GORE-TEX® Vascular Graft. Always protect the graft from damage by heavy or sharp objects.
2. When applying clamps, care should be taken to avoid mechanical damage to or disruption of the graft. Use the appropriate atraumatic or guarded (for example, rubber shoe) clamps. Avoid repeated, localized clamping or excessive clamping on any section of the graft.
3. It is not necessary to preclot GORE-TEX® Vascular Grafts.

4. Blood or plasma leakage may occur if appropriate handling techniques are not observed. 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.
5. 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.
6. Failure to correctly cut the GORE-TEX® Vascular Graft may damage the outer reinforcing layer and may result in aneurysmal dilatation or reduced suture retention strength. When cutting the graft, gently pull the graft taut and determine the correct length. Cut the graft with a *sharp* surgical instrument. **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.**
7. Use a tunneler, such as the GORE® Tunneler, to 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.
8. Anastomotic angles vary with the vascular procedure being performed. Use of an appropriate anastomotic angle may minimize undue stresses that may lead to mechanical disruptions of the graft, host vessel, and/or suture lines.
9. 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 can damage the graft.
10. Undue anastomotic bleeding may occur if excessive tension causes suture holes to elongate or tear, if the needle-to-suture diameter ratio is too great, or 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.

B. OPERATIVE TECHNIQUES - GORE-TEX® STRETCH VASCULAR GRAFT

1. When handling or tensioning a GORE-TEX® Stretch Vascular Graft, avoid using excessive force or high rates of force that could lead to graft disruption.
2. Even though the GORE-TEX® Stretch Vascular Graft affords some extensibility, the graft must still be cut to the correct length.

- After completing the proximal anastomosis, apply **moderate** tension to the entire length of the GORE-TEX® Stretch Vascular Graft in order to remove the extensibility. Ensure that moderate tension is transmitted from the distal end of the graft to the proximal (first) anastomosis immediately prior to cutting the graft to length. Blue orientation markers can aid in determining moderate tension.
- Reasonable assurance of moderate tension is provided when the blue orientation markers, illustrated in the following two figures, change configuration from Figure A to Figure B at the proximal and distal anastomotic sites.



- Reference, "TECHNICAL INFORMATION," Section V. A., "CORONARY ARTERY BYPASS PROCEDURES," and "OPERATIVE TECHNIQUES: ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.

C. OPERATIVE TECHNIQUES - FEP RINGED GORE-TEX® VASCULAR GRAFT

- DO NOT loosen or remove the FEP rings from the graft. Removal of the rings will loosen or fray the outer reinforcing layer of the graft. (See "OPERATIVE TECHNIQUES - ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS" Section VII. A.) If removal of rings is necessary, only grafts with removable rings should be used; refer to, "OPERATIVE TECHNIQUES: FEP RINGED GORE-TEX® VASCULAR GRAFTS WITH REMOVABLE RINGS."
- Use a tunneler, such as the GORE® Tunneler, to create a tissue tunnel that closely approximates the graft diameter, and allows free passage of FEP rings. A tissue tunnel that is too tight may disrupt ring attachment.
- Reference, "CONTRAINDICATIONS," Section III. B., and "TECHNICAL INFORMATION," Section V. C. and "OPERATIVE TECHNIQUES: ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.

D. OPERATIVE TECHNIQUES - FEP RINGED GORE-TEX® VASCULAR GRAFT WITH REMOVABLE RINGS

- FEP Ringed GORE-TEX® Vascular Grafts with Removable Rings consist of a reinforced ePTFE GORE-TEX® Vascular Graft and an additional thin film to which rings are attached. This design allows the surgeon to remove rings without damaging or compromising the mechanical integrity of the graft. Following ring removal, portions of the additional thin film are normally visible on the graft and removed ring(s).
- Use a tunneler to create a tissue tunnel that closely approximates the graft diameter, and allows free passage of FEP rings. A tissue tunnel that is too tight may disrupt ring attachment.

- To prevent ring detachment when passing a graft through an incision, avoid catching the rings on the edge of the incision or tunneler.
- RING REMOVAL:** To avoid damaging the graft, do **NOT** use surgical blades or sharp instruments. Care should be taken not to damage the reinforcing layer immediately beneath the additional thin film to which the rings are attached. Following ring removal, portions of the additional thin film are normally visible on the graft and removed ring(s). IF THE REINFORCING LAYER APPEARS FRAYED OR DAMAGED, THAT SEGMENT OF THE GRAFT SHOULD NOT BE USED.

To remove rings from the end of a ringed section or before suturing: Hold the graft firmly with one gloved hand. With the other hand, gently grasp and lift a ring(s) with gloved fingers or atraumatic instrument and slide it off the end of the graft.

To remove rings from within a ringed section or after suturing: Hold the graft firmly with one gloved hand. With the other hand, loosen a ring(s) by gently grasping and lifting with an atraumatic instrument. Carefully cut each ring with blunt-nosed scissors and peel off the severed ring(s).

- Reference, "CONTRAINDICATIONS," Section B; "TECHNICAL INFORMATION," Sections B. and C; and, "OPERATIVE TECHNIQUES: ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.

E. OPERATIVE TECHNIQUES - GORE® INTERING® VASCULAR GRAFT

- GORE® INTERING® Vascular Grafts consist of a reinforced ePTFE GORE-TEX® Vascular Graft with integrated ePTFE radial support within the wall of the graft.
- The GORE® INTERING® Vascular Graft is available in both Stretch and Non-Stretch configurations. Reference, "OPERATIVE TECHNIQUES: ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.
- The ePTFE radial support is NOT removable. The GORE® INTERING® Vascular Graft is a unibody design incorporating continuous ePTFE microstructure between radial support and non-radial support sections of the graft. Attempting to remove the radial support will damage the graft.
- The ePTFE radial support sections of the GORE® INTERING® Vascular Graft can be incorporated into the anastomosis.
The integrated radial support can be cut and sewn through using appropriate cutting and suturing techniques.
Reference, "OPERATIVE TECHNIQUES: ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.
- When applying clamps, care should be taken to avoid mechanical damage or disruption to the GORE® INTERING® Vascular Graft. Use the appropriate atraumatic or guarded (for example, rubber shoe) clamps. Avoid repeated, localized clamping or excessive clamping on any section of the graft.

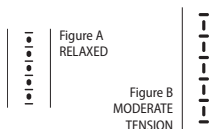
- Reference, "TECHNICAL INFORMATION," Section V. A., "CORONARY ARTERY BYPASS PROCEDURES," and "OPERATIVE TECHNIQUES: ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.

F. OPERATIVE TECHNIQUES - BIFURCATED GORE-TEX® STRETCH VASCULAR GRAFT

- When clamping, cutting or suturing the graft, care should be taken to avoid damage to the suture line of the bifurcation area.
- Even though the Bifurcated GORE-TEX® Stretch Vascular Graft affords some extensibility, the graft must still be cut to the correct length.
- After completing the proximal anastomosis, apply moderate tension to the entire length of the Bifurcated GORE-TEX® Stretch Vascular Graft in order to remove the extensibility. Ensure that moderate tension is transmitted from the distal end of the graft to the proximal (first) anastomosis immediately prior to cutting the graft to length. Blue orientation markers can aid in determining moderate tension.

If removal of graft extensibility is desired prior to performing the proximal anastomosis, care should be taken to moderately tension each component of the graft separately to avoid inadvertently placing excess tension on the graft suture line at the bifurcation area.

- Reasonable assurance of moderate tension is provided when the blue orientation markers, illustrated in the following two figures, change configuration from Figure A to Figure B at the proximal and distal anastomotic sites.



- Avoid extreme lateral angulation of the graft limbs to prevent potential kinking.
- For end-to-side anastomoses, the anastomotic bevel should be approximately two or three times as long as the graft diameter. This will minimize the stress on the graft and allow a smooth vessel-graft transition.
- Reference, "OPERATIVE TECHNIQUES: ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.

G. OPERATIVE TECHNIQUES - FEP RINGED AXILLOBIFEMORAL GORE-TEX® VASCULAR GRAFT WITH REMOVABLE RINGS AND FEP RINGED STRETCH AXILLOBIFEMORAL GORE-TEX® VASCULAR GRAFT WITH REMOVABLE RINGS

- The FEP Ringed Axillobifemoral GORE-TEX® Vascular Graft with Removable Rings and FEP Ringed Axillobifemoral GORE-TEX® Stretch Vascular Graft with Removable Rings are not elastic. The grafts should never be too short.
- Even though the FEP Ringed Stretch Axillobifemoral GORE-TEX® Vascular Graft with removable Rings affords some extensibility, the graft must still be cut to the correct length.

- Failure to correctly cut the FEP Ringed Axillobifemoral GORE-TEX® Vascular Graft with Removable Rings or the FEP Ringed Axillobifemoral GORE-TEX® Stretch Vascular Graft with Removable Rings may damage the outer reinforcing layer and may result in aneurysmal dilatation or reduced suture retention strength. When cutting the graft, gently pull the graft taut and determine the correct length. Cut the graft with a sharp surgical instrument. 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.
- Reference, "TECHNICAL INFORMATION," Section V. B., "AXILOFEMORAL, FEMOROFEMORAL, AND AXILLOBIFEMORAL BYPASS PROCEDURES."
- Reference, "OPERATIVE TECHNIQUES: ALL GORE-TEX® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.; and, "OPERATIVE TECHNIQUES - FEP RINGED GORE-TEX® VASCULAR GRAFT WITH REMOVABLE RINGS," Section VII. D.

VIII. STERILITY

GORE-TEX® Vascular Grafts are supplied STERILE. Provided that the integrity of the package is not compromised in any way, the package will serve as an effective barrier for a minimum of five years from the date of sterilization. There is no expiration date for product function or characteristics.

IX. RESTERILIZATION

GORE-TEX® Vascular Grafts may be resterilized (if necessary) up to three times, using either steam or EtO techniques with no loss of mechanical or chemical integrity. Only clean, unused, undamaged portions of the graft should be resterilized. Do not handle the graft with ungloved hands at any time. Do not expose GORE-TEX® Vascular Grafts to temperatures greater than 482° F (250° C).

Sterility of the resterilized product is the responsibility of the health care institution.

DO NOT STERILIZE THE GRAFT USING RADIATION TECHNIQUES. DO NOT STERILIZE THE GRAFT IN THE ORIGINAL PACKAGING MATERIALS. THE GRAFT MUST BE REPACKAGED IN MATERIALS APPROPRIATE FOR THE TYPE OF STERILIZATION USED IN YOUR INSTITUTION. PROTECT THE GRAFTS FROM HEAVY OR SHARP OBJECTS IN THE STERILIZER.

A. STEAM STERILIZATION

USING A VALIDATED GRAVITY DISPLACEMENT STEAM STERILIZER, autoclave at or above these minimum requirements: 250° F (121° C) for 30 minutes or 270° F (132° C) for 15 minutes. USING A VALIDATED PRE-VACUUM (ALSO KNOWN AS HIGH VACUUM STEAM STERILIZER), autoclave at or above these minimum requirements: 270° F (132° C) for 4 minutes.

B. ETHYLENE OXIDE (ETO) GAS STERILIZATION

EtO gas sterilization equipment varies. The choices and validation of specific cycle and aeration parameters are the responsibility of the health care institution.


























C. ALTERNATIVE RESTERILIZATION METHODS

W. L. Gore & Associates has not validated other resterilization methods, such as gas plasma, formaldehyde gas, hydrogen peroxide vapor, etc., and cannot make any recommendations regarding the use of these or other methods to resterilize GORE-TEX® Vascular Grafts. Sterility of the resterilized product is the responsibility of the health care institution.

X. REFERENCES

1. Landry GJ, Moneta GL, Taylor Jr. LM, Porter JM. Axillobifemoral bypass. *Annals of Vascular Surgery* 2001;14(3):296-305.
2. Taylor Jr. LM, Park TC, Edwards JM, Yeager RA, McConnell DC, Moneta GA, Porter JM. Acute disruption of polytetrafluoroethylene grafts adjacent to axillary anastomoses: a complication of axillofemoral grafting. *Journal of Vascular Surgery* 1994;20:520-528.
3. Bunt TJ, Moore W. Optimal proximal anastomosis/tunnel for axillofemoral grafts. *Journal of Vascular Surgery* 1986;3:673-676.

DEFINITIONS

-  Use By
-  Caution
-  Consult Instructions for Use
-  Catalogue Number
-  Batch Code
-  Authorised Representative in the European Community
-  CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.
-  Sterile
-  Sterilized using Steam or Dry Heat
-  Do Not Use if Package is Damaged
-  Manufacturer
-  Angle
-  Axillobifemoral
-  Diameter
-  Fibril Length 25 Microns (Nominal)
-  Fibril Length Radial Support 5 Microns (Nominal)
-  Length
-  Non-Removable Rings
-  Non-Stretch
-  Removable Rings
-  Ring Section
-  Standard Wall
-  Stretch
-  Thin Wall
-  Thin Wall Limbed