INSTRUCTIONS FOR USE

GORE® Hybrid Vascular Graft

I. DEVICE DESCRIPTION
The GORE® Hybrid Vascular Graft is an ePTFE vascular prosthesis that has a section reinforced with nitinol. The nitinol reinforced section is partially constrained to allow for easy insertion and deployment into a vessel. The constraint is made up of an ePTFE fiber which is knitted into a tubular shape. The GORE® Hybrid Vascular Graft has a continuous lumen and has immobilized heparin bonded to the luminal surface.

Figure 1: GORE® Hybrid Vascular Graft with the constrained nitinol reinforced section

II. INDICATIONS FOR USE
GORE® Hybrid 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.

III. CONTRAINDICATIONS
1. DO NOT use the GORE® Hybrid Vascular Graft in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of HIT type II.
2. DO NOT use any configuration of GORE® Hybrid Vascular Grafts for coronary artery bypass or cerebral reconstruction procedures.
3. DO NOT use GORE® Hybrid Vascular Grafts as a patch. If cut and used as a patch, GORE® Hybrid Vascular Grafts may lack adequate transverse strength.

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 and atraumatic barrier and should be used before the labeled “use by” (expiration) date. If the foil pouch has been compromised, the section cannot be used. To open the package, peel open the foil pouch and remove the graft carefully untied prior to use. The deployment line may get entangled, loops or knots prior to use. The deployment line may entangle, loops or knots during shipping and could hinder deployment of the nitinol reinforced section. If observed, deployment line entanglements, loops or knots must be carefully untied prior to use.

Figure 2: GORE® Hybrid Vascular Graft fully deployed

Inspect the device for deployment line entanglements, loops or knots prior to use. The deployment line may get entangled, looped or knotted during shipping and could hinder deployment of the nitinol reinforced section. If observed, deployment line entanglements, loops or knots must be carefully untied prior to use.

V. TECHNICAL INFORMATION
A. The luminal surface of the GORE® Hybrid Vascular Graft is bonded with fractionated active heparin of porcine origin.
B. The presence of heparin on the GORE® Hybrid 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. Effective anticoagulation and antiplatelet therapy should be maintained at a dosage deemed appropriate by physician.
C. 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. DO NOT CUT THE NITINOL REINFORCED SECTION.
D. DO NOT LET THE LUMINAL SURFACE OF THE GORE® HYBRID VASCULAR GRAFT DRY ONCE IT HAS BEEN WETTED.
E. With any vascular procedure, the possibility of HIT may exist. The incidence of HIT type II is extremely low in vascular bypass 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. If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures, including ligation or removal of the graft, may be considered at the discretion of the attending physician.
F. 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® Hybrid Vascular Grafts in coronary artery bypass procedures.
G. AXILLOFEMORAL, FEMOROFEMORAL, AND AXILLOBIFEMORAL BYPASS PROCEDURES
The success of axillofemoral, femorofemoral, and axilllobifemoral bypasses depends in large part on the implantation technique. Specific complications associated with improperly implanted GORE® Hybrid 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 graft slightly longer than necessary has been reported by some surgeons to reduce further the risk of stressing the graft or the anastomoses.
• Correctly bevel the axillary anastomosis. Stress on the graft is minimized when the graft is placed parallel (0°) to the axillary artery. Therefore, the anastomotic angle should be as small as possible and 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.

Figure 3: Recommended Anastomotic Placement and Abduction Test

Figure 4: Recommended Angle of Bevel

0°-25°

• An alternative technique reported by some surgeons 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.

Figure 5: 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 surgeons have reported the use of an axillary counterincision near the third part of the artery.6

• 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. Do not place the nitinol reinforced section in 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 be in the mid-axillary line to minimize kinking when the patient bends forward at the waist.

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.

Routines 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.

H. VASCULAR ACCESS PROCEDURES

Patients should be carefully monitored when using Gore® Hybrid 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. Do not cannulate or puncture the nitinol reinforced section. Cannulating or puncturing the nitinol reinforced section may result in damage to the external nitinol support, resulting in compromised performance or failure. For additional information, 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. If the FEP Ringed Gore® Hybrid Vascular Graft with Removable Rings is used for vascular access, the rings must be removed from any cannulation region prior to implant (See “V. OPERATIVE TECHNIQUES”, Section C, numbered item 4). Do not puncture the graft at or near any FEP ringed section.

I. MRI SAFETY AND COMPATIBILITY

MR Conditional

No adverse events related to heating effects of the nitinol reinforced section of the Gore® Hybrid Vascular Graft in the MRI environment are known. The effect of heating in the MRI environment for devices with fractured stent struts is not known.
The nitinol reinforced section of the Gore® Hybrid Vascular Graft is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Spatial gradient field of ≤ 720 Gauss / cm
- Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0W / kg for 15 minutes of scanning.

3.0 Tesla Temperature Rise:
The nitinol reinforced section of the Gore® Hybrid Vascular Graft may produce a temperature rise of 2.5°C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 2.8W / kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and when placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 2.8 W / kg.

1.5 Tesla Temperature Rise:
The nitinol reinforced section of the Gore® Hybrid Vascular Graft may produce a temperature rise of 2.4°C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 2.8W / kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris / 4 Software and when placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 1.5 W / kg.

Image Artifact:
An image artifact may extend approximately 2 – 4 mm from the nitinol reinforced section of the Gore® Hybrid Vascular Graft, both inside and outside the device lumen when scanned in non-clinical testing using sequence:

- T1 – weighted, spin echo and gradient echo pulse sequences in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR system with a send-receive RF body coil.

For each vascular device and assembly, the artifacts may appear on MR images as localized signal voids (i.e., signal loss) that are minor in size relative to the size and shape of these implants. The gradient echo pulse sequence may produce larger artifacts than the T1 – weighted, spin echo pulse sequence for the Gore® Hybrid Vascular Graft. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the nitinol reinforced section of the Gore® Hybrid Vascular Graft. Therefore, it may be necessary to optimize the MR imaging parameters to compensate for the presence of this implant.

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. Complications and adverse events can occur when using any device that utilizes nitinol. These complications include, but are not limited to: hematoma; stenosis; thrombosis or occlusion; distal embolism; side branch occlusion; vessel wall trauma and/or rupture; false aneurysm; infection; inflammation; fever and/or pain in the absence of infection; deployment failure; migration; and device failure.

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

VII. OPERATIVE TECHNIQUES

A. ALL GORE® HYBRID VASCULAR GRAFT CONFIGURATIONS

1. To avoid damage or contamination, always use clean gloves andatraumatic instruments when handling the Gore® Hybrid Vascular Graft. Always protect the graft from damage by heavy or sharp objects.

2. In selecting the appropriately sized nitinol reinforced section, a careful assessment of the vessel is necessary. In general, to assure adequate anchoring, the diameter of the nitinol reinforced section should be approximately 5 – 20% larger than the healthy vessel diameter (Table 1).

B. HYBRID VASCULAR GRAFT CONFIGURATIONS

1. The nitinol reinforced section of the Gore® Hybrid Vascular Graft can be introduced into the recipient vessel using either a standard venotomy/arteriotomy or an over the wire technique. When using a standard venotomy/arteriotomy, the direction and length of the venotomy/arteriotomy is the physician's discretion. When using an over the wire technique, a 0.035” guidewire and a peel/tear-away sheath of the appropriate size (Table 1) should be used. The guidewire and peel/tear-away sheath manufacturers’ instructions should be observed. The guidewire access to the vessel is gained using the Seldinger technique. A peel/tear-away sheath is then introduced into the vessel over the guidewire. The dilator is removed, and the nitinol reinforced section of the Gore® Hybrid Vascular Graft is threaded over the guidewire into the peel/tear-away sheath. The peel/tear-away sheath is then carefully peeled away while simultaneously advancing the nitinol reinforced section into the vessel.

2. The nitinol reinforced section of the Gore® Hybrid Vascular Graft should be introduced into the vessel by at least approximately 2.5 cm with the deployment line facing upwards. While stabilizing the nitinol reinforced section, slowly pull the deployment line keeping it as parallel to the vascular prosthesis as possible. Deployment of the nitinol reinforced section will occur from the tip of the delivery constraint toward the non-nitinol reinforced section. If deployed as instructed, the nitinol reinforced section should not appreciably shorten.

Note: Once deployment has started, repositioning of the nitinol reinforced section should not be attempted.
5. After deployment, the nitinol reinforced section may be smoothed and seated against the vessel wall by inflating an angioplasty balloon within it. The balloon manufacturers’ instructions should be observed. Touch-up balloon diameter should be selected according to Table 1. It should be inflated to the desired diameter along the entire length of the nitinol reinforced section. If the nitinol reinforced section length exceeds that of the balloon, multiple inflations may be needed. Failure to post-dilate along the entire length of the nitinol reinforced section may lead to restenosis and graft failure. After the balloon is inflated throughout the nitinol reinforced section, attention is required to ensure complete deflation of the balloon prior to cautious removal of the balloon catheter to prevent displacement of the nitinol reinforced section. Do not extend balloon dilatation beyond the ends of the device and into healthy vessel as this may also induce restenosis and subsequent graft failure.

6. Two longitudinal stay sutures must be placed through the vessel wall and the nitinol reinforced section, spaced approximately 180° apart, in order to provide additional anchoring to the vessel wall.

7. At the end of the procedure, the deployed nitinol reinforced section may be evaluated by using a fluoroscope and further balloon inflations may be necessary if residual folds or invaginations are visualized in the nitinol reinforced section.

8. Care must be taken to implant approximately three centimeters of the graft adjacent to the nitinol reinforced section in a straight orientation.

9. When applying clamps, care should be taken to avoid mechanical damage to, or disruption of, the graft. Use the appropriate atraumatic or guarded (i.e., rubber shod) clamps. Avoid repeated, localized clamping or excessive clamping on any section of the graft.

10. It is not necessary to precut the GORE® Hybrid Vascular Graft.

11. 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.

12. 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.

13. Failure to correctly cut the GORE® Hybrid 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 CUT THE NITINOL REINFORCED SECTION. 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.

14. 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.
15. 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.

16. 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.

17. 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.

18. The physician should ensure that the patient has been informed as to appropriate postoperative care. This design allows the surgeon to remove rings without damaging or compromising the mechanical integrity of the graft, host vessel, and/or suture lines.

B. OPERATIVE TECHNIQUES - TENSIONING

1. When handling or tensioning the Gore® Hybrid Vascular Graft, avoid using excessive force or high rates of force which could lead to graft disruption.

2. Even though the Gore® Hybrid Vascular Graft affords some extensibility, the graft must still be cut to the correct length.

3. After completing the anastomosis at the nitinol reinforced section end, carefully apply moderate tension to the non-nitinol reinforced section while holding the nitinol reinforced section in order to remove the extremity. Care must be taken while tensioning the non-nitinol reinforced section to avoid dislodging the nitinol reinforced section from the vessel. Ensure that moderate tension is transmitted from the nitinol reinforced section end of the graft to the other end immediately prior to cutting the graft to length. Blue orientation markers can aid in determining moderate tension.

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

Figure 8a: Figure 8b:

- RELAXED
- MODERATE TENSION
- TENSION
- RELAXED
- TENSION

C. OPERATIVE TECHNIQUES – GORE® HYBRID VASCULAR GRAFT WITH REMOVABLE RINGS

1. Gore® Hybrid Vascular Grafts with Removable Rings consist of a reinforced expanded PTFE 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). If the reinforcing layer appears frayed or damaged, that segment of the graft should not be used.

2. 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 approximates the graft diameter, and allows free passage of FEP rings. A tissue tunnel that is too tight may disrupt ring attachment.

3. To prevent ring detachment when passing a graft through an incision, avoid catching the rings on the edge of the incision or tunneler.

4. 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).

5. Reference, “V. TECHNICAL INFORMATION”, Sections F and G, and “VII. OPERATIVE TECHNIQUES”, Sections A and B.

VIII. STERILITY

Gore® Hybrid 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® HYBRID VASCULAR GRAFT.

X. REFERENCES


DEFINITIONS

Use By
Caution
Consult Instructions for Use
Do Not Resterilize
Do Not Reuse
Catalogue Number
Batch Code
Serial Number
Authorised Representative in the European Community
MR Conditional

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

STERILE Sterile
STERILE LO Sterilized using Ethylene Oxide
Do Not Use if Package is Damaged
Keep Dry
Store in a Cool Place
Diameter
Fibril Length Radial Support 5 Microns (Nominal)
Length
Manufacturer