

INSTRUCTIONS FOR USE FOR:



PROPATEN®

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

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English

INSTRUCTIONS FOR USE FOR:

GORE® PROPATEN® Vascular Graft

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I. INDICATIONS FOR USE

GORE® PROPATEN® 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.

II. CONTRAINDICATIONS

- A. **DO NOT** use the GORE® PROPATEN® Vascular Graft in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II.
- B. **DO NOT** use any configuration of GORE® PROPATEN® Vascular Grafts with Removable Rings, Non-Removable Rings or Integrated Rings for coronary artery bypass or cerebral reconstruction procedures.
- C. **DO NOT** use GORE® PROPATEN® Vascular Grafts as a patch. If cut and used as a patch, GORE® PROPATEN® Vascular Grafts may lack adequate transverse strength.

FOR PATCHING APPLICATIONS:

For cardiovascular procedures requiring patch materials, use the appropriate GORE® ACUSEAL Cardiovascular Patch.

III. US CLINICAL EXPERIENCE**Objectives:**

The primary objective of the US clinical study was to evaluate the safety and effectiveness of the GORE® PROPATEN® Vascular Graft and demonstrate substantial equivalence to the GORE-TEX® Stretch Vascular Graft in a peripheral application.

Study Design:

This 200-subject, multi-centered, prospective, randomized, single-blind clinical trial was designed to compare the GORE® PROPATEN® Vascular Graft to the commercially available GORE-TEX® Stretch Vascular Graft for occlusive vascular disease in patients requiring primary above-knee arterial bypass.

The primary efficacy endpoint was primary patency at 12 months, determined by hemodynamic evidence of blood flow. The primary safety endpoint was the major device-related adverse event rate at 12 months.

Study Enrollment:

Eighteen (18) US sites enrolled patients in the study; 101 patients received the GORE® PROPATEN® Vascular Graft while 99 patients received the GORE-TEX® Stretch Vascular Graft. All grafts were thin walled with a 6 mm internal diameter.

Pre-procedure Subject Information:

Demographics and symptom grades were similar between the GORE® PROPATEN® Vascular Graft and GORE-TEX® Stretch Vascular Graft groups. Risk factors were also similar with the exception of diabetes and hyperlipidemia. In the GORE® PROPATEN® Vascular Graft and GORE-TEX® Stretch Vascular Graft groups, respectively, pre-procedure demographics included average age (64.8, 67.3 years) and percent of male subjects (53.5%, 60.6%). In the GORE® PROPATEN® Vascular Graft and GORE-TEX® Stretch Vascular Graft groups, respectively, pre-procedure risk factors included diabetes (27.8%, 14.3%), current tobacco use (55.4%, 49.0%), hypertension (79.2%, 85.7%), and moderately elevated hyperlipidemia controlled through strict diet and medications (58.4%, 43.9%). In the GORE® PROPATEN® Vascular Graft and GORE-TEX® Stretch Vascular Graft groups, respectively, 44.6% and 43.9% of subjects were enrolled with claudication and 55.4% and 56.1% with critical limb ischemia.

Efficacy:

At the end of the 12-month follow-up, primary patency, secondary patency, and limb salvage rates for the GORE® PROPATEN® Vascular Graft were 71.2%, 93.9%, and 95.8%, respectively. Comparatively, the GORE-TEX® Stretch Vascular Graft showed primary patency, secondary patency, and limb salvage rates of 71.0%, 91.7%, and 95.8%, respectively. Long-term data are not available regarding improved patency compared to marketed grafts.

Safety:

Two (2) GORE® PROPATEN® Vascular Graft subjects experienced a total of two major device-related adverse events, both graft infections. Three (3) GORE-TEX® Stretch Vascular Graft subjects experienced a total of four major device-related adverse events, a graft infection with an infected prosthetic mitral valve, a graft infection, and a perigraft hematoma. There were no reported cases of HIT and no unanticipated adverse device effects (UADEs).

Survival at 12 months:

Kaplan-Meier estimates of survival at 12 months were comparable between treatment groups, 92.5% (95% CI: 84.8%, 96.3%) in the GORE® PROPATEN® Vascular Graft group and 95.6% (95% CI: 88.7%, 98.3%) in the GORE-TEX® Stretch Vascular Graft group. No device-related deaths were reported in the study.

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 or store the graft if the foil pouch has been compromised.

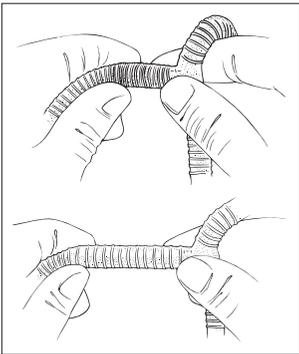
To open the package, peel open the foil pouch and remove the tray. Beginning at one corner, peel back the tray lid and gently remove the graft. Use clean gloves or atraumatic instruments when handling the graft.

V. TECHNICAL INFORMATION

- A. The CBAS® Heparin Surface on the GORE® PROPATEN® Vascular Graft consists of stable, covalent, end-point attached heparin of porcine origin.
- B. The presence of heparin on the GORE® PROPATEN® 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.
- 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.
- D. **DO NOT LET THE LUMINAL SURFACE OF THE GORE® PROPATEN® 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 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.
- F. The total graft length printed on the package is the usable length when the graft is placed under moderate tension. (Refer to OPERATIVE TECHNIQUES - TENSIONING, Section VII. B.)
- 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® PROPATEN® Vascular Grafts in coronary artery bypass procedures.
- H. **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® PROPATEN® 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.
- For the pre-configured GORE® PROPATEN® Vascular Graft Removable Ring Axillobifemoral, refer to OPERATIVE TECHNIQUES - GORE® PROPATEN® VASCULAR GRAFT REMOVABLE RING AXILLOBIFEMORAL, Section VII. E.
- For the pre-configured GORE® PROPATEN® Vascular Graft Removable Ring Axillobifemoral, moderately tension each component of the graft separately to avoid inadvertently placing excess tension on the graft suture line at the manufactured anastomosis site.

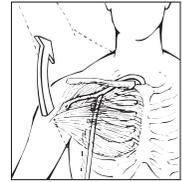


HOLD THE GRAFT AT THE SUTURED ANASTOMOSIS OF THE GRAFT AND TENSION THE LEG OF THE GRAFT.

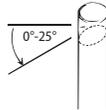


DO NOT TENSION THE GRAFT BY PULLING ON THE LEGS OF THE GRAFT AS DOING SO MAY LEAD TO SUTURE PULLOUT.

- 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.

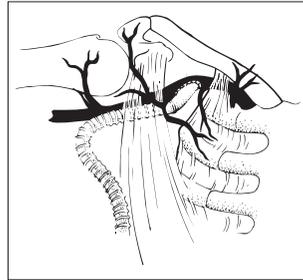


RECOMMENDED ANASTOMOTIC PLACEMENT AND ABDUCTION TEST



RECOMMENDED ANGLE OF BEVEL

- An alternative technique reported by some surgeons^{3,4} 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 AXILARY ARTERY END-TO-SIDE ANASTOMOSIS. THE GRAFT IS PLACED PARALLEL TO THE AXILARY 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 surgeons⁵ have reported the use of an axillary counterincision near the third part of the artery.
- The axillofemoral portion of the graft should lie in the mid-axillary line to minimize kinking when the patient bends forward at the waist.
- For the pre-configured GORE® PROPATEN® Vascular Graft Removable Ring Axillobifemoral, begin implantation by pulling the graft to the axillary counterincision with the 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.**
- Pull 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.

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.

I. VASCULAR ACCESS PROCEDURES

Patients should be carefully monitored when using GORE® PROPATEN® 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.

If the GORE® PROPATEN® Vascular Graft with Removable Rings is used for vascular access, the rings must be removed from any cannulation region prior to implant (Reference, "OPERATIVE TECHNIQUES - GORE® PROPATEN® VASCULAR GRAFT WITH REMOVABLE RINGS," Section VII.C.4.). Do not puncture the graft at or near any ringed section.

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. E on previous page).**

VII. OPERATIVE TECHNIQUES

A. ALL GORE® PROPATEN® VASCULAR GRAFT CONFIGURATIONS

- To avoid damage or contamination, always use clean gloves and atraumatic instruments when handling the GORE® PROPATEN® Vascular Graft. Always protect the graft from damage by heavy or sharp objects.
- 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.
- It is not necessary to preclot the GORE® PROPATEN® Vascular Graft.
- 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.
- 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.
- Failure to correctly cut the GORE® PROPATEN® 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.
- Use a 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.

- 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.
- 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.
- 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.
- The physician should ensure that the patient has been informed as to appropriate postoperative care.

B. OPERATIVE TECHNIQUES - TENSIONING

- When handling or tensioning the GORE® PROPATEN® Vascular Graft, avoid using excessive force or high rates of force which could lead to graft disruption.
- Even though the GORE® PROPATEN® 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® PROPATEN® 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.



C. OPERATIVE TECHNIQUES - GORE® PROPATEN® VASCULAR GRAFT WITH REMOVABLE RINGS

- GORE® PROPATEN® 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).
- 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 II. B.; "TECHNICAL INFORMATION," Section V. F., G., and H.; and, "OPERATIVE TECHNIQUES: ALL GORE® PROPATEN® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.

D. OPERATIVE TECHNIQUES - GORE® PROPATEN® VASCULAR GRAFT WITH INTEGRATED RINGS

- GORE® PROPATEN® Vascular Grafts with Integrated Rings consist of a reinforced ePTFE GORE-TEX® Vascular Graft with integrated ePTFE radial support within the wall of the graft.
- The ePTFE radial support is NOT removable. The GORE® PROPATEN® Vascular Graft with Integrated Rings 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® PROPATEN® Vascular Graft with Integrated Rings 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® PROPATEN® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.
- When applying clamps, care should be taken to avoid mechanical damage or disruption to the GORE® PROPATEN® Vascular Graft with Integrated Rings. Use the appropriate atraumatic or guarded (for example, rubber shod) clamps. Avoid repeated, localized clamping or excessive clamping on any section of the graft.
- Reference, "Technical Information," Section V. G., "Coronary Artery Bypass Procedures," and "OPERATIVE TECHNIQUES: ALL GORE® PROPATEN® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.

E. OPERATIVE TECHNIQUES - GORE® PROPATEN® VASCULAR GRAFT REMOVABLE RING AXILLOBIFEMORAL

- The GORE® PROPATEN® Vascular Graft Removable Ring Axillobifemoral is not elastic. The graft should never be too short.
- Even though the GORE® PROPATEN® Vascular Graft Removable Ring Axillobifemoral affords some extensibility, the graft must still be cut to the correct length.
- Failure to correctly cut the GORE® PROPATEN® Vascular Graft Removable Ring Axillobifemoral 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. H., "AXILLOFEMORAL, FEMOROFEMORAL, AND AXILLOBIFEMORAL BYPASS PROCEDURES."
- Reference, "OPERATIVE TECHNIQUES: ALL GORE® PROPATEN® VASCULAR GRAFT CONFIGURATIONS," Section VII. A.; and, "OPERATIVE TECHNIQUES - GORE® PROPATEN® VASCULAR GRAFT WITH REMOVABLE RINGS," Section VII. C.

VIII. STERILITY

GORE® PROPATEN® 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® PROPATEN® VASCULAR GRAFT.

REFERENCES

- 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:e4955-e5305.
- 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.
- Landry GJ, Moneta GL, Taylor LM Jr, Porter JM. Axillobifemoral bypass. *Annals of Vascular Surgery* 2000;14(3):296-305.
- Taylor LM Jr, Park TC, Edwards JM, et al. Acute disruption of polytetrafluoroethylene grafts adjacent to axillary anastomoses: a complication of axillofemoral grafting. *Journal of Vascular Surgery* 1994;20(4):520-528.
- Bunt TJ, Moore W. Optimal proximal anastomosis / tunnel for axillofemoral grafts. *Journal of Vascular Surgery* 1986;3(4):673-676.

DEFINITIONS

 Authorised 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

 Serial Number

 Sterile

 Sterilized using Ethylene Oxide

 Store in a Cool Place

 Use By

 Angle

 Axillobifemoral

 Diameter

 Fibril Length 25 Microns (Nominal)

 Fibril Length Radial Support 5 Microns (Nominal)

 Integrated Rings

 Length

 Non-Removable Rings

 Removable Rings

 Ring Section

 Standard Wall

 Thin Wall



20027094



Manufacturer

W. L. GORE & ASSOCIATES, INC.

1505 North Fourth Street

Flagstaff, Arizona 86004

UNITED STATES

Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763

Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

For international contact and additional product information,
visit **www.goremedical.com**

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