exGraft®

ePTFE Vascular Graft

Instructions for Use

PECAlabs®

Instructions For Use

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Device Description, Indications, Contraindications, Warnings, Precautions and Adverse Reactions

Device Description

exGraft® ePTFE vascular grafts are constructed of expanded polytetrafluoroethylene (ePTFE) and are printed with radiopaque ink on the outer graft walls. exGraft® Carbon ePTFE vascular grafts also contain carbon impregnated into the inner graft walls.

Indications for Use

The exGraft® and exGraft® Carbon ePTFE vascular grafts are indicated for use as vascular prostheses.

The exGraft® and exGraft® Carbon ePTFE vascular grafts are intended for use as vascular prostheses for replacement or bypass of diseased vessels in patients sufering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures.

exGraft® and exGraft® Carbon ePTFE Vascular Grafts are not recommended for use in locations where resistance to kink or compression is desired, exGraft and exGraft Carbon ePTFE Vascular Grafts are not recommended for use as a coronary artery bypass graft.

Contraindications

DO NOT use exGraft® Vascular Grafts as a patch. If cut and used as a patch, exGraft® Vascular Grafts may lack adequate transverse strength. For cardiovascular procedures requiring patch materials, use an appropriate alternative device that is indicated for use as a cardiovascular patch.

Warnings

1. exGraft® ePTFE vascular grafts are supplied sterile and non-pyrogenic unless the package is open or damaged. exGraft® ePTFE vascular grafts are sterilized by ethylene oxide. Each graft is intended for single patient use only. DO NOT RESTERILIZE.
2. This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components - are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious contamination.
3. Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.
4. Do not use after expiration date printed on the label.
5. For Extra-Anatomic procedures, (e.g. Axillofemoral, Femoral Femoral or Axillobifemoral Bypass) the patient should be cautioned that sudden, extreme or strenuous movements should be totally avoided for a period of at least six to eight weeks to allow for proper stabilization of the graft. Routine activities such as raising the arms above the shoulders, reaching out in front, extended reaching, throwing, pulling, striding or twisting should be avoided.
6. Avoid suturing directly through the radiopaque ink when possible.
7. Anastomotic or graft disruption has been associated with Axillofemoral, Femoral Femoral or Axillobifemoral bypass procedures in similar grafts if implanted improperly. Refer to Specific Operative Procedures (Extra-Anatomic Bypass Procedures) for further instructions.
8. When embolectomy or balloon angioplasty catheters are used within the graft, the inflated balloon size must match the inner diameter of the graft. Over-inflation of the balloon or use of an inappropriately sized balloon may dilate or damage the graft.
9. Aggressive and/or excessive graft manipulation when tunneling, or placement within too tight or too small a tunnel, may lead to graft breakage.
10. Agressive and/or excessive rubbing and/or scratching of the graft may remove some of the radiopaque (black) ink. Refer to Other Information (Imaging) for further information.
11. exGraft® ePTFE vascular grafts do not stretch (are non-elastic) in the longitudinal direction. The correct graft length for each procedure must be determined by considering the patient's body weight, posture, and the range of motions across the anatomical area of graft implantation. Failure to cut the grafts to an appropriate length may result in anastomotic or graft disruption, leading to excessive bleeding, and loss of limb or limb function, and/or death.
12. Avoid repeated or excessive clamping at the same location on the graft. If clamping is necessary, use only atraumatic or appropriate vascular smooth jawed clamps to avoid damage to the graft wall.
13. Exposure to solutions (e.g. alcohol, oil, aqueous solutions, etc.) may result in loss of the graft's hydrophobic properties. Loss of the hydrophobic barrier may result in graft wall leakage. Preclotting of the graft is unnecessary.
14. Avoid excessive graft manipulation after exposure to blood or body fluids. Do not forcibly inject any solution through the lumen of the graft, or fill the graft prior to pulling it through the tunnel as loss of the graft's hydrophobic properties may result in graft wall leakage.
15. Do NOT expose exGraft® ePTFE grafts to temperatures greater than 500°F (260°C). PTFE decomposes at elevated temperatures producing highly toxic decomposition products[1].
16. After use, the product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state and federal laws and regulations.
17. During tunneling, create a tunnel that closely approximates the outer diameter of the graft. A tunnel that is too loose may result in delayed healing and may also lead to perigraft seroma formation.

Precautions

1. Only physicians qualified in vascular surgery techniques should use this prosthesis. The healthcare provider is responsible for all appropriate postoperative care instructions to the patient.
2. The healthcare provider must observe aseptic technique during implantation and postoperatively.
3. When suturing, avoid excessive tension on the suture line, inappropriate suture spacing and bites, and gaps between the graft and host vessel. Failure to follow correct suturing techniques may result in suture hole elongation, suture pull-out, anastomotic bleeding, and/or disruption. Refer to "Suturing" for further instructions.
4. To minimize fluid collection around the graft in Extra-Anatomic bypass procedures or in peripheral reconstructive procedures, the lymphatic should be carefully ligated and sealed, especially in the groin area.
5. Consider intraoperative and postoperative patient anti- coagulation therapy for each patient as appropriate.

Adverse Events
Potential complications which may occur with any surgical procedure involving a vascular prosthesis include, but are not limited to: disruption or tearing of the suture line, graft and/or host vessel; suture hole bleeding; graft redundancy; thrombosis; embolic events; occlusion or stenosis; ultrafiltration; seroma formation; swelling of the implanted limb; formation of hematoma or pseudoaneurysm; infection; aneurysm/dilation; blood leakage; hemorrhage; steal syndrome; arrythmia; tachycardia, graft kinking; graft twisting; and/or skin erosion.

Directions For Use

Equipment Required
Tunneler, suture, atraumatic clamp, and/or scissors.

Opening the Package
Proper aseptic technique should be followed when handling the device and sterile packaging. Hold the outer tray in one hand. Peel back the lid. Remove the inner tray. Peel back the inner tray lid slowly and carefully remove the graft using sterile atraumatic instruments or sterile gloves. Protect the graft against damage from sharp or heavy instruments.

| General Operative Techniques

Tunneling Techniques
Prior to utilizing a sheath tunneler, verify that the graft outer dimensions fit the sheath internal dimensions.

Use of a sheath tunneler is recommended as it will minimize graft handling and help maintain graft integrity.

Always follow the instructions for use for the specific tunneler utilized to place the graft.

Create a tunnel that closely approximates the outer diameter of the graft. A tunnel that is too loose may result in delayed healing and may lead to perigraft seroma formation. **Reference WARNING #9 and #17.**

Thrombectomy
Techniques for declotting exGraft® ePTFE vascular grafts include but are not limited to the use of balloon catheters. **Reference WARNING #10.**

Longitudinal Incision: Place stay sutures before introducing the embolectomy catheter. Place a longitudinal incision in the graft that is long enough to accomodate the extraction of a fully dilated thrombectomy catheter balloon. A patch may be considered as an aid to graft closure.

Transverse Incision: No stay sutures are necessary. A horizontal mattress suture is recommended for graft closure.

During the early postoperative period, the natural progression of healing renders the graft translucent in appearance. In this state, a longitudinal incision with stay sutures is recommended. If a transverse incision is performed, a horizontal mattress suture technique and PTFE pledgets may aid in closure.

Angiography
Should angiography be performed at the time of procedure, the artery proximal to the graft should be used for injection if possible.

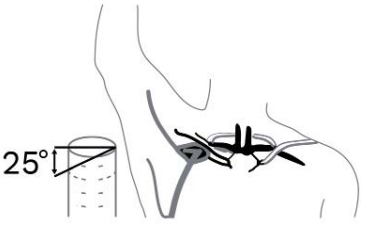
Suturing
Size the graft appropriately to minimize excessive tension at the suture line. Use a tapered, noncutting needle with a nonabsorbable monofilament suture approximately the same size as the needle. Take 2mm suture bites in the graft following the curve of the needle and gently pull the suture at a 90° angle. Proper sizing of the graft length prior to implant will minimize suture hole elongation caused by excessive tension. **Reference WARNING #9 and PRECAUTION #3.**

| Specific Operative Techniques

Extra-Anatomic Bypass Procedures (e.g. Axillofemoral, Femoral Femoral, and Axillobifemoral)
For Extra-Anatomic bypass procedures, careful attention must be given to the following techniques. Failure to follow these technical considerations may result in suture hole elongation, mechanical disruption, or tearing of the graft, suture line or host vessel, thrombosis, extreme blood loss, loss of limb function, loss of limb or death. **Reference WARNING #11 and PRECAUTION #5.**

- To avoid extreme stress on the anastomosis and the graft, include the patient's weight and range of limb motion when determining graft length, tunnel length and location.
- To determine the correct graft length, drape the patient to allow full movement of the arm, shoulder girdle or legs.
- Avoid protracted hyperabduction of the arm, during the surgical procedure. Prolonged hyperabduction may lead to brachial plexus injury.
- Allow sufficient graft length to avoid stressing of axillary or femoral anastomosis throughout the full range of movement of the arm, shoulder girdle, or legs. The graft should be placed under both the pectoralis major and pectoralis minor. **Reference Figure 1.**

Figure 1



- Cutting the graft slightly longer than necessary has been reported by some surgeons to reduce further the risk of stressing the graft or the anastomosis.
- Correctly bevel the axillary anastomosis. Stress on the graft is minimized when the graft is placed perpendicular 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.
- Place the graft anastomosis close to the rib cage on the first portion of the axillary artery[2]. Do not place the anastomosis on the third portion of the axillary artery.
- Notify the patient that sudden, extreme or strenuous movements of the arm, shoulder or leg should be totally avoided for a period of at least six to eight weeks to allow for proper stabilization of the graft. Routine activities such as raising the arms above the shoulders, reaching out in front, extended reaching, throwing, pulling, striding, or twisting should be avoided. **Reference WARNING #5, #6, and #11.**

Blood Access Procedures

Leave the graft in place for approximately two weeks prior to use. There is an increased risk of hematoma formation if the graft is punctured prior to complete healing.

1. Insert the blood access needle at a 20˚ to 45˚ angle, with the bevel up. When the graft is penetrated, advance the needle parallel to the graft.
2. ROTATE (CHANGE) THE CANNULATION SITES.
3. Do not repeat cannulation in the same area. Repeat cannulation may lead to formation of a hematoma or a pseudoaneurysm. Do NOT cannulate within the dialysis needle's length of the proximal and distal anastomosis.
4. Strictly adhere to aseptic technique to minimize infection.
5. Apply moderate digital pressure to the cannulation site after needle withdrawal. This compression assists in hemostasis.

Note: There should always be a pulse or thrill of near equal intensity proximal and distal to the area of compression.

Instruct the patient as to proper postoperative care.

MRI Safety Information

MR Conditional

Non-clinical testing has indicated that the exGraft® ePTFE vascular grafts are MR Conditional.

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3.0T
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the exGraft® ePTFE vascular grafts are expected to produce a maximum temperature rise of less than 4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artificat caused by the device extends approximately 2mm from the exGraft® when imaged with a gradient echo pulse sequence and a 3.0T MRI System.

Other Information

Imaging

exGraft® ePTFE vascular grafts contain radiopaque ink on the outer graft walls. The radiopaque ink is black to the naked eye. The radiopaque ink is visible under exposure to x-rays. **Reference WARNING #9 and Figure 2.**

Note: The blue lines are not radiopaque and are not shown in the Figure 2.

Figure 2

Note: "XX" Shown on the side view is replaced with the Internal Diameter of the graft on exGraft® Models 4mm or above. exGraft models with Internal Diameters of 3mm and 3.5mm have the following symbols:

References

1. Guide to the Safe Handling of Fluoropolymer Resins, 4th Edition, The Fluoropolymers Division of the Society of The Plastics Industry, Inc.
2. Victor M. Bernhard, M.D. and Jonathan B. Towne, M.D., Editors, Complications in Vascular Surgery, Second Edition, Grune and Stratton, Inc. (Harcourt Brace Jovanovich; Publishers), Orlando, 1985, 56.
3. "Perigraft Seromas, Complicating Arterial Grafts", Robert M. Blumenberg, M.D., et al, Surgery, Vol. 97, No. 2, February 1985.

Warranty

PECA Labs warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in PECA Labs' sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact PECA Labs to see if additional product information is available.

Catalogue Number

Lot Number

Use By

D: Internal Diameter

L: Length

Contents

Consult Instructions For Use

Single Use

Do Not Resterilize

Non-Pyrogenic

Manufacturer

Lift Here

Sterilized Using Ethylene Oxide

Do Not Use If Package Is Damaged

Not Made With Natural Rubber Latex

MR Conditional

Federal (U.S.A) Law Restrics This Device To Sale By Or On The Order Of A Physician

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