exGraft™

ePTFE Vascular Graft

Instructions for Use

PECA labs®

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.

Indications for Use

exGraft® ePTFE vascular grafts are indicated for the repair or reconstruction of peripheral arteries.

Contraindications

None known.

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. 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.
6. Aggressive and/or excessive graft manipulation when tunneling, or placement within too tight or too small a tunnel, may lead to graft breakage.
7. 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.
8. 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.
9. 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.
10. 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.
11. 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.
12. 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].
13. 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.
14. 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.
15. The exGraft is not indicated for use as blood access graft

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 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; skin erosion; arrhythmia; tachycardia; graft twisting; and/or graft kinking.

Directions For Use

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

Opening the Package
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, protect the ink on the outer wall 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 #8 and # 16.**

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 #8 and PRECAUTION #3.**

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.

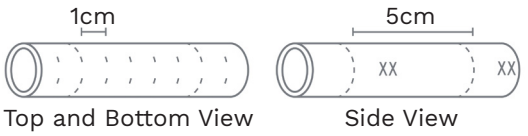
Angiography
Should angiography be performed at the time of procedure, the artery proximal to the graft should be used for injection if possible.

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 all exGraft® Models.

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

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

PECA labs®

CE 0459 EC REP
Authorized Representative in the European Community
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Manufacturer:
PECA Labs, Inc.
4424 Penn Avenue
STE 201
Pittsburgh, PA 15224
USA
TEL: 1.412.482.3755
1.877.842.2873
FAX: 1.412.228.5868
1.877.581.9945
www.PECALabs.com

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