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ATRIUM



- Reinforced
- Non-Reinforced
- Multi-Laminate

PTFE

Advanta™

PTFE Vascular Grafts

Instructions For Use

- USA** Polytetrafluoroethylene Vascular Graft
- GB** Prothèse vasculaire en polytétrafluoroéthylène
- F** Polytetrafluoräthylen-Gefäßprothese
- D** Injerto vascular de politetrafluoroetileno
- E** Protesi vascolare in politetrafluoroetilene
- I** Enxerto vascular de politetrafluoroetileno
- P** Vaatprothese, polytetrafluoroethylen (PTFE)
- NL** Karprotese, polytetrafluoroethylen
- DK** Käriltransplantat av polytetrafluoroetylen
- S** Polytetrafluoroetyleni verisuoniproteesi
- FIN** Kartransplantat av polytetrafluoretylen
- N** ATTELAKO MOZXEYMA POLYTIETPAΦOΠOΠEΘYΛENIOY
- GR** Proteza naczyniowe z polytetrafluoroethylenu
- PL** ポリテトラフルオロエチレン人工血管
- J** 聚四氟乙烯尿管移植体
- CN**

STERILE

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 Rev. 2010/04

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Device Tracking Labels

Please complete and return Atrium's Patient Registration/Implant Tracking Report provided. The enclosed Device Tracking Labels should be attached to the patient/hospital records.

Description

Advanta™ PTFE vascular grafts are available in a wide variety of reinforced, non-reinforced and multi-laminate wall constructions made from expanded polytetrafluoroethylene (PTFE) material to form a microporous vascular graft. External ring supported graft models include both removable and NON-removable center ring supported sections made of PTFE monofilament for additional compression resistance. Internal ring supported models include a NON-removable integral support section made of PTFE monofilament layered within the graft wall for additional compression resistance. Products packaged with a blue transfer sleeve, feature a protective handling cover (polyethylene), which is to be removed prior to graft implantation. Products packaged with the Advanta Slider™ Graft Deployment System assembly feature a preattached tunneler tip(s) and a clear, flexible sheath (polyethylene) which must be removed from the graft and patient following graft placement in the tunnel. Advanta PTFE grafts are supplied sterile unless the package has been opened or damaged.

Indications For Use

Advanta PTFE vascular grafts are intended for use in arterial vascular reconstruction, segmental bypass, and for arteriovenous vascular access.

Contraindications

Advanta SST and all thin-wall Advanta PTFE graft models of Advanta VS, Advanta VXT, and Advanta SuperSoft are contraindicated for use in Axillo-femoral bypass, Axillo-bifemoral bypass, or any anatomical location that would include a wide range of body motion. Also, taper, short taper and step taper grafts are not recommended for Axillofemoral or Axillobifemoral bypass, or any anatomical location that would include a wide range of body motion, due to the danger of anastomotic graft disruption during extreme body movement.

Warnings

1. Use only taper point suture needles as taper cut and other cutting needles may damage the graft material and/or host vessel.
2. Do not apply excessive tension to the anastomosis as elongated needle hole formation and/or material disruption may result, causing needle hole bleeding, weeping, and/or localized host vessel damage.
3. Clamping of the graft should be avoided whenever possible and limited to clamps shod with soft material.
4. Do not prewet the Advanta PTFE graft by exposure to organic solvents such as alcohol or force aqueous solutions through the graft wall as the hydrophobic properties of the graft may be effected, which may result in excessive serum leakage and/or perigraft seroma formation.
5. Failure to follow all handling and operative technique warnings and precautions may result in extreme blood loss, loss of limb function, loss of limb, or possible death.
6. Preattached tunneler tip(s), Slider sheath(s), and/or blue transfer sleeve must be removed from the graft and patient prior to wound closure.

7. Do not cut any portion of the graft wall when cutting or separating the Slider sheath in the mid portion of a looping graft.
8. Do not pull, peel, separate or delaminate any portion of the multi-laminate wall or reinforcement layer of the graft.
9. Insufficient animal and clinical data are available at this time to support Advanta PTFE graft use in aortocoronary bypass applications or for use as a patch.

Precautions

1. Federal (USA) law restricts this device to sale by or on the order of a physician.
2. Handling of the graft should be minimized and limited to clean sterile gloves.
3. Tunnel forming instruments should be sized to closely match the graft diameter to prevent formation of an oversized tunnel. An oversized tunnel may be a contributing factor in perigraft seroma formation, and may delay or interfere with perigraft tissue attachment and healing. When tunneling for an externally helix supported graft, aggressive graft manipulation or placement within too small or tight tunnel, may lead to separation of the peelable external helix support.
4. Dialysis cannulation through this graft may be instituted with caution, so long as safeguards are taken to prevent or minimize hematoma formation, pseudo-aneurysm, infection and/or material disruption requiring surgical intervention.
5. Vascular access puncture sites must be adequately separated as multiple punctures in the same area may lead to disruption of the graft material and formation of a perigraft hematoma or pseudo-aneurysm requiring revision.
6. Use of any laser, electric, radiofrequency, or heat cautery for tailoring or cutting Advanta PTFE graft material must be avoided.
7. Do not resterilize any Advanta PTFE graft with a blue transfer sleeve or Slider sheath assembly by steam sterilization techniques.
8. Do not resterilize this graft using radiation sterilization techniques.
9. Advanta SST Large Diameter and Advanta SuperSoft PTFE grafts must be fully extended prior to sizing length for implantation.
10. Advanta PTFE grafts should only be cut and trimmed with sharp surgical instruments to avoid reinforcement layer disruption.

Adverse Reactions

Complications that may occur in connection with the use of any vascular graft include, but are not limited to, thrombosis, formation of pseudo-aneurysm due to excessive, localized, multiple and/or large needle punctures, perigraft hematoma formation, perigraft seroma formation or ultrafiltration, excessive needle hole bleeding or weeping, infection, swelling of tissue, suture hole elongation, mechanical disruption, material separation, delamination or tearing of the graft material, suture line or host vessel which may result in extreme blood loss, loss of limb function, loss of limb or possible death.

Open Package

To open sterile package, peel back outer tray lid and remove inner tray. Peel back inner tray lid and carefully remove the Advanta PTFE graft using sterile technique. The outer blue transfer sleeve aids in handling during graft insertion and should be left on the graft until it is ready for tunnel insertion.

Tunneling Advanta PTFE Grafts With The Slider™ Graft Deployment System

Following tunneler instrument insertion through the tissue, remove the threaded bullet tip from the indwelling tunneler rod. Thread the Advanta Slider sheath assembly to the tunneler rod

with at least three, quarter turns. Gently pull back on the tunnel-er instrument, drawing the sheath covered graft into and through the tunnel. As the graft is pulled into the tunnel, hold back the outer, blue transfer sleeve. Once the graft is in position, cut the graft and Slider sheath approximately 2 cm away from the tunnel-er tip(s). Firmly grasp the cut end of the graft with a clean instrument and pull the opposite end of the Slider sheath out from the tunnel and patient. Trim off any portion of the graft material that has been clamped, prior to use. If preferred, the Slider sheath may be partially withdrawn just enough to expose the graft to complete the first anastomosis. After finishing the first anastomosis, remove the entire Slider sheath from the graft and patient. Care must be taken not to place excessive tension on the anastomosis when the Slider sheath is removed after completing the first anastomosis.

When a looped graft is to be placed with a single-ended Slider sheath assembly, graft insertion will require a two step tunneling technique. First, the graft must be pulled through the first anastomotic incision, out through a second "mid loop incision", and disconnected from the tunneler instrument. The original bullet tip must be reattached to the tunneler instrument and passed from a third incision and out through the mid loop incision. Following bullet tip removal, the graft slider assembly must be reattached to the tunneler and drawn through and out the third incision. Following graft positioning in the looped tunnel, carefully cut the clear Slider sheath in the mid portion of the loop so that each end of the sheath can be removed separately from the first and third incisions. **Do not cut any portion of the graft wall when cutting or separating the Slider sheath in the mid portion of a looping graft.**

When a looped graft is to be placed with a double-ended Slider sheath assembly, graft insertion will require a two step tunneling technique. First, a "mid-incision" must be made at the base of the loop. The tunneler instrument should be passed from the first anastomotic incision to the mid-incision. The bullet tip must be removed from the tunneler. Thread one of the Advanta Slider sheath assemblies to the tunneler rod. Gently pull back on the tunneler holding the outer blue transfer sleeve. Once the graft is in position, detach the Slider sheath assembly and reattach the bullet tip to the tunneler. Pass the tunneler through the second anastomotic incision to the mid-incision. Detach the bullet tip. Remove the blue transfer sleeve, thread the second Advanta Slider sheath assembly and pull through the tunnel. Once the graft is in position, remove the Slider sheath from both ends of the graft. Note: For select sizes, the Slider sheath of a double-ended Slider sheath assembly is in two separate pieces. Therefore it is not necessary to cut the sheath in the middle.

Aortic Application

For aortic procedures such as aortobifemoral bypasses, or aortic aneurysm repair, careful attention must be made to the following technique precautions:

- Do not clamp, cut, separate or delaminate any portion of the bifurcated flow divider section or continuous ring supported limb sections.
- The graft must be cut to the correct length regardless of its extensibility characteristics.
- Due to the extensibility of the graft, moderate tension must be applied to the entire length of the graft before or after completing the proximal anastomosis. Care should be taken not to subject the bifurcation area to excessive tension.
- Avoid extreme lateral angulation of the graft limbs at the flow divider to prevent material disruption and/or kinking of the graft.

- To minimize stress on the graft and to create a smooth graft-vessel transition for an end-to-side anastomosis, special care and matching of suturing is required for the size and type of suture needle being used.
- Special care should be taken to avoid damaging the aortic, flow divider, or limb sections with surgical instruments.
- See "Warnings" and "Precautions".

Axillofemoral, Axillobifemoral, And Femoral-Femoral Applications

For extra-anatomical bypass procedures such as in Axillofemoral, Axillobifemoral, or Femoral-Femoral locations, careful attention must be made to the following technique precautions:

- The patient's weight and range of limb motion should be included when determining sufficient graft length, tunnel location, and tunnel length required, so as to avoid extreme stress on the anastomosis and possible graft material disruption.
- Stress at the Axillary anastomosis may be minimized by anastomosing the graft essentially perpendicular to the Axillary artery. This can be facilitated with a 0°-25° angle of bevel, depending upon the position of the Axillary artery.
- It is recommended that the graft be anastomosed as close to the rib cage as possible, on the first Axillary artery section. Attachment to the third section of the Axillary artery is not recommended.
- For Axillofemoral and Axillobifemoral procedures it is recommended that the graft be positioned under both the pectoralis major and minor muscles.
- Prolonged hyperabduction of the arm during surgery must be avoided as this could lead to brachial plexus complication or injury following surgery.
- The patient must be advised against making sudden or strenuous movements of the arm, shoulder, or leg during the first eight week period following surgery. Raising of the arms above the shoulders, extended reaching, and abrupt pulling or twisting should also be strongly advised against during the initial postoperative eight week period.
- Do not clamp, cut, separate or delaminate any portion of the axillobifemoral flow divider section or continuous ring supported limb sections.
- Avoid extreme lateral angulation of the graft limbs at the axillobifemoral flow divider to prevent material disruption and/or kinking of the graft.
- Special care should be taken to avoid damaging the axillobifemoral flow divider and ring supported sections with surgical instruments.
- See contraindications.

Thrombectomy

It is recommended that a radial or transverse incision be used for all Advanta PTFE thrombectomy procedures, followed by a horizontal mattress suture technique for graft closure. If and when a longitudinal incision is made for a thrombectomy, it is recommended to place a stay suture at each end of the longitudinal incision prior to balloon catheter use. Do not apply excessive tension on the implanted Advanta PTFE graft during inflated balloon catheter withdrawal. Overinflation of an embolectomy balloon or use of an inappropriate sized catheter may cause damage to the graft and anastomosis. Extreme care must be exercised with the use of all mechanical water jet thrombectomy and mechanical rotary brush devices so as to not disrupt or damage the Advanta PTFE graft material, prior vascular access holes and/or suture line.

Restertilization

Should the original sterile package be inadvertently opened or damaged prior to use, Advanta PTFE vascular grafts may be restertilized using either validated steam or ETO sterilization methods, up to a maximum of one (1) time. Suitable lot number traceability must accompany the product through all phases of handling, repackaging, and sterilization. Do not restertilize or reuse any graft that has been in contact or contaminated by blood or other substances. Avoid placing heavy or sharp objects on or in direct contact with the graft material during any part of handling, repackaging, and/or sterilization process. Advanta PTFE grafts should never be exposed to temperatures greater than 482°F (250°C). Sterility and fitness of restertilized product will be the sole responsibility of the hospital. Sterilization recommendations provide no assurance for the sterility of the restertilized product and serve only as a guide. Do not restertilize this graft using radiation sterilization techniques.

Steam Sterilization

If an Advanta PTFE graft must be restertilized, place it in a separate container suitable for use with steam sterilization. Do not steam or flash autoclave any Advanta PTFE graft with the blue transfer sleeve or with a Slider sheath assembly. No part of the original package should be in direct contact with the graft during steam sterilization. For gravity displacement and/or prevacuum (flash) steam sterilizers, autoclave at or above the minimum temperature requirements of 270°F (132°C) for 4 minutes at 30 PSI (2Kg/cm²).

Ethylene Oxide (ETO) Gas Sterilization

Place the Advanta PTFE graft (including transfer sleeve/Slider sheath assembly) in a container or package suitable for use with ETO sterilization. Selection of a specific, validated, ETO sterilization cycle and aeration requirements are the responsibility of the hospital. After ETO sterilization, it is essential that the Advanta PTFE graft be adequately aerated prior to use either by an ambient shelf method or mechanical aeration.

Model Selection

Advanta PTFE vascular grafts are available in a wide variety of reinforced, non-reinforced and multi-laminate PTFE constructions to address many different anatomical and clinical performance requirements. Most models are available with and without Atrium's exclusive Slider Graft Deployment System in a wide selection of diameters, externally supported lengths, and tapered shapes.

Advanta SST Reinforced Grafts

Multi-laminate design offers thin wall handling with variable pore size wall construction. (10 micron pore intrawall reinforcement film, 60/30 micron pore size wall)

Advanta VXT Reinforced Grafts

Softwrap reinforcement provides strength and handling with a variable pore size wall construction. (60 micron pore reinforcement film, 60/20 micron pore size wall)










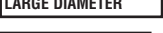




Advanta SuperSoft Reinforced Grafts

Conventional pore size wall construction with Softwrap reinforcement provides softer feel and flexibility. (60 micron pore reinforcement film, 30/20 micron pore size wall)

Advanta VS Non-Reinforced Grafts

One-piece design offers variable pore size wall construction with preferred kink and compression resistance. (60/20 micron pore size wall)

SYMBOLS USED ON PRODUCT LABELS

 REF	CODE NUMBER	 LOT	LOT NUMBER
 STERILE	STERILE		
	SEE PACKAGE INSERT		SINGLE USE ONLY
	EXPIRATION DATE	 RX ONLY	PRESCRIPTION ONLY
 DIM	DIMENSIONS	 RINGED	RINGED
 LARGE DIAMETER	LARGE DIAMETER		
 STANDARD WALL	STANDARD WALL		
 THIN WALL	THIN WALL		
 SLIDER™ GDS	GRAFT DEPLOYMENT SYSTEM		
 REINFORCED	REINFORCED-POROUS PTFE WRAP		

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