



**FLIXENE™**  
Vascular Graft

**USA**

**GB** Vascular Graft

**F** Prothèse vasculaire

**D** Gefäßprothese

**E** Injerto vascular

**I** Protesi vascolare

**P** Enxerto vascular

**NL** Vaatprothese

**DK** Karprotese

**S** Kärtransplantat

**FIN** Verisuoniproteesi

**N** Kartransplantat

**GR** Αγγειακό μόσχευμα

**PL** Proteza naczyniowa

**J** 人工血管

**CN** 血管



**FLIXENE™**  
Vascular Graft

**Instructions  
For Use**



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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**

Flixene™ is a tri-laminate vascular graft made from expanded polytetrafluoroethylene (PTFE) material. External ring supported graft models include both removable and NON-removable center ring supported sections made of PTFE monofilament for additional compression resistance. On some models a NON-removable integral support section made of PTFE monofilament layered within the graft wall is provided 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 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. Flixene grafts are supplied sterile unless the package has been opened or damaged.

**Indications For Use**

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

**Contraindications**

Thin-wall graft models 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 Flixene 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 loop-ing 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 Flixene 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 peri-graft hematoma or pseudo-aneurysm requiring revision.
6. Use of any laser, electric, radiofrequency, or heat cautery for tailoring or cutting Flixene graft material must be avoided.
7. Do not resterilize any Flixene 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. Grafts must be fully extended prior to sizing length for implantation.
10. Flixene 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 Flixene 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 Flixene 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 Slider sheath assembly to the tunneler rod with at least three, quarter turns. Gently pull back on the tunneler 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 2cm away from the tunnel 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 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 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.

## When Placing the Flixene with IFG

The Flixene with IFG can be implanted in one of two ways, 1) by creating an end to end anastomosis or 2) by inserting the graft within the vessel.

Option 1) The Flixene with IFG can be implanted by creating an end to end anastomosis. The two ends of the IFG section can be sutured in a traditional end to end anastomosis to the native vessel.

(1a)



Option 2) The FLIXENE with IFG can be inserted within the vessel, by making a standard arteriotomy or venotomy (2a) and inserting the IFG within the vessel (2b). If the IFG section needs to be trimmed care should be taken not to cut the internal reinforcement or junction. Compress the IFG segment and insert within the venotomy. Suture the venotomy closed around the IFG segment (2c).

2a)



2b)



2c)



Following insertion of the IFG segment, tunnel the proximal segment and proceed with the proximal anastomosis. Care must be taken not to place excessive tension on the anastomosis when tunneling.

### 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 Flixene graft 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 stitch at each end of the longitudinal incision prior to balloon catheter use. Do not apply excessive tension on the implanted Flixene 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 Flixene graft material, prior vascular access holes and/or suture line.

## Resterilization

Should the original sterile package be inadvertently opened or damaged prior to use, Flixene vascular grafts may be resterilized 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 resterilize 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. Flixene grafts should never be exposed to temperatures greater than 482°F (250°C). Sterility and fitness of resterilized product will be the sole responsibility of the hospital. Sterilization recommendations provide no assurance for the sterility of the resterilized product and serve only as a guide. Do not resterilize this graft using radiation sterilization techniques.
















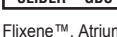
## Steam Sterilization

If a Flixene graft must be resterilized, place it in a separate container suitable for use with steam sterilization. Do not steam or flash autoclave any Flixene 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/cm<sup>2</sup>).

## Ethylene Oxide (ETO) Gas Sterilization

Place the Flixene 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 Flixene graft be adequately aerated prior to use either by an ambient shelf method or mechanical aeration.

## SYMBOLS USED ON PRODUCT LABELS

 REF	CODE NUMBER	 LOT	LOT NUMBER
 STERILE	STERILE	 DIM	DIMENSIONS
	SEE PACKAGE INSERT		SINGLE USE ONLY
	EXPIRATION DATE		PRESCRIPTION ONLY
 IFG	INTRALUMINAL FLOW GUARD		RINGED
 GW	GRADUATED WALL		GRADUATED WALL TAPER
 GWT - GW	GRADUATED WALL TAPER WITH GRADUATED WALL		
 GW - TRMP	GRADUATED WALL WITH TRUMPET TAPER		
 GWT - TRMP	GRADUATED WALL TAPER WITH TRUMPET TAPER		
 SLIDER™ GDS	GRAFT DEPLOYMENT SYSTEM		

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