

Polypropylene Monofilament Surgical Mesh

Device Tracking Labels

The enclosed Device Tracking Labels should be attached to the patient/hospital records.

Description

Atrium Polypropylene Monofilament Surgical Mesh is a sterile, non-absorbable, knitted polypropylene monofilament mesh material for tissue reinforcement.

Indications For Use

Polypropylene Mesh is intended for use in hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a non-absorbable supportive material.

Contraindications

Atrium Mesh is contraindicated where tissue may be contaminated or infected and in infants, children or pregnancy where future growth may be compromised by its use.

Warnings

1. Do not re-sterilize surgical mesh that has been in contact with or contaminated by blood or other substances.
2. Avoid direct contact with the viscera (intestines) to minimize the possibility of adhesions.
3. Use only non-absorbable sutures, staples or tacker devices with this mesh.

Precautions

1. Handling of mesh should be with clean, sterile gloves and/or instruments.
2. Careful attention to surgical mesh handling, suture, staple or tacker fixation is required in the presence of nerves and vessels in the surgical field.

Adverse Reactions

Complications that may occur with the use of any surgical mesh include, but are not limited to, inflammation, infection or mechanical disruption of the tissue and/or mesh material, possible adhesions when placed in direct contact with the viscera (intestines).

Open Sterile Package

Peel open the package and remove the Atrium Mesh using sterile technique.

Handling And Operative Technique

Atrium mesh should be shaped, cut to size, and affixed, taking into consideration the patient's posture, weight and anatomical location. Careful attention to suture/staple/tacker placement and spacing will help prevent excessive tension or disruption between the mesh material and connective tissue. It is recommended that suture/staple/tackers be placed 1/4 in. or 6.5 mm from the edge of the mesh material for best results.

Self-Forming Mesh Plugs

Insertion of the Atrium Self-Forming Mesh Plug is accomplished by grasping the center tab with clean, sterile forceps, centering the mesh over the defect, and gently pushing the center tab portion of the multilayered plug into the internal ring to a desired depth. Once inserted, the mesh plug should fill the defect, with the outer edge remaining flush to the external surface of the defect. The mesh plug should then be further secured in position by selectively suturing, stapling or tacking a portion of the mesh in position.

For direct hernias, the defect should be circumscribed at its base and the contents fully reduced prior to plug insertion. For femoral hernias, the sac should be reduced prior to securing the mesh plug into position. When the Self-Forming

Mesh Plug is used for groin hernias, the flat preshape onlay patch provided can be placed directly over the inserted plug and sutures, stapled or tacked in position as required. For recurrent hernias, the flat preshape onlay may not be required.

To shorten plug depth, reduce the overall size of the circular multilayered mesh prior to insertion by trimming the outer edge of the circular mesh plug to a smaller diameter. Material can also be removed between the weld seams from the top 2 layers of the multilayered mesh plug (center tab and inner layer only) to reduce the bulk width of the plug. Do not cut or trim away any portion of a weld seam or forcibly delaminate any mesh layer when reducing the overall size or depth of the mesh plug.

Resterilization

Should the original sterile package be inadvertently opened or damaged prior to use, Atrium Mesh may be resterilized using validated ETO or steam sterilization methods no more than one time. Suitable lot number traceability must accompany product through all phases of handling, repackaging and sterilization. Atrium Mesh should never be exposed to temperatures greater than 250°F (121°C). Sterility and fitness of resterilized product will be the sole responsibility of the hospital. Do not sterilize this mesh using radiation techniques.

SYMBOLS USED ON PRODUCT LABELS

REF CODE NUMBER

LOT LOT NUMBER

STERILE **EO** STERILE. STERILIZED BY ETHYLENE OXIDE.

 SEE PACKAGE INSERT

 SINGLE USE ONLY

 EXPIRATION DATE

Rx ONLY PRESCRIPTION ONLY

DIM DIMENSIONS



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