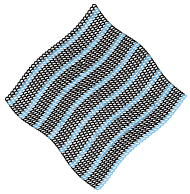
PROLENE™ *Soft*

Polypropylene Mesh

Nonabsorbable Synthetic Surgical Mesh



DESCRIPTION

PROLENE™ Soft Polypropylene Mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE™ Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (Ethicon, LLC). The mesh affords excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE™ monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE™ Polypropylene Mesh. This material, when used as a suture, has been reported to be nonreactive and to retain its strength indefinitely in clinical use.

PROLENE Soft Mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

ACTIONS

PROLENE Soft Mesh is a nonabsorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. Animal studies show that implantation of PROLENE Soft Mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INDICATIONS

This mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

CONTRAINDICATIONS

When this mesh is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows.

PROLENE Soft Mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.

WARNINGS

PROLENE Soft Mesh is provided by Ethicon, LLC as a sterile product. Resterilization of the device is NOT recommended. However, testing has demonstrated that unused PROLENE Soft Mesh that has been removed from the package and reprocessed will not be adversely affected when exposed not more than one time to conventional steam autoclave conditions of 250°F (121°C) for 20 minutes. Processing under any other condition or by any other means is neither recommended nor endorsed by Ethicon, LLC. PROLENE Soft Mesh should not be flash autoclaved.

If this product should become stained with blood or soiled, it should not be resterilized for reuse.

When reprocessed as outlined above, it is the responsibility of the end-user to assure sterility of the product via a validated sterilization process, as Ethicon, LLC has no control over environmental conditions the product may encounter prior to, during or after reprocessing.

PRECAUTIONS

A minimum of 6.5mm (1/4") of mesh should extend beyond the suture line.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

ADVERSE REACTIONS

Potential adverse reactions with PROLENE™ Soft Mesh implantation are those typically associated with surgically implantable materials, including inflammation, seroma formation, adhesion formation, fistula formation, extrusion and potentiation of infection.

INSTRUCTIONS FOR USE

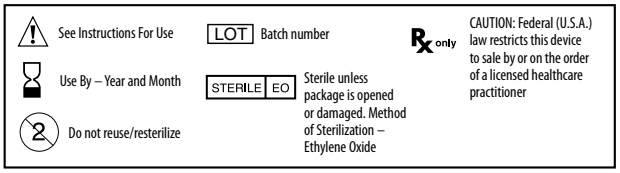
Mesh is implanted according to currently accepted surgical mesh procedures.

Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away.

Adequate mesh fixation is required to minimize post-operative complications and recurrence. The fixation technique, method and products used should follow the current standard of care. Careful attention to fixation and spacing will help prevent excessive tension or disruption between the mesh materials and connective tissue. When fixating with sutures or other mechanical fixation devices, a safe distance from the edge of the mesh of not less than 6.5mm (1/4") must be maintained. 6.5mm to 12.5mm (1/4" to 1/2") should be left between fixation points.

HOW SUPPLIED

PROLENE Soft Mesh is available in single packets as sterile, clear sheets with blue stripes.



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389737R04 STATUS: 06/2010 LAB0010432.3

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