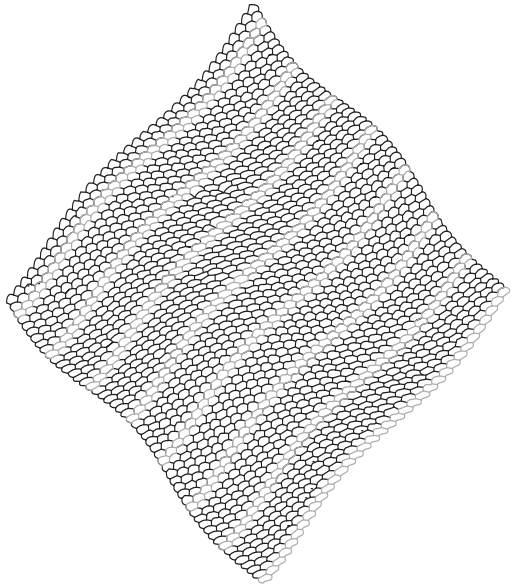
LAB100789244v2

389971E02

PROLENE™ *Soft*

Polypropylene Mesh

Nonabsorbable Synthetic Surgical Mesh



en

Instructions for use

PROLENE™ *Soft*

Polypropylene Mesh
Nonabsorbable Synthetic Surgical Mesh

INTRODUCTION

This package insert is designed to provide instructions for use of PROLENE™ Soft Mesh. It is not a comprehensive reference to surgical technique for repair of abdominal wall hernias.

PROLENE™ Soft Mesh is intended for use only by physicians who are trained in the surgical procedures and techniques required for hernia repairs and the implantation of synthetic meshes. The selection of mesh for any given patient is a function of numerous factors including, but not limited to, the patient's past medical and surgical history, current medical condition (i.e., comorbidities), surgical technique, and size and location of the hernia. The physician is advised to consult the medical literature regarding techniques, complications, and adverse reactions before selecting a mesh.

DESCRIPTION

PROLENE™ Soft Mesh is comprised of nonabsorbable polypropylene filaments. The undyed and dyed (phthalocyanine blue, Color Index No. 74160) polypropylene polymers are identical to the material used in PROLENE™ Suture.

INDICATIONS

PROLENE™ Soft Mesh is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing material to obtain the desired surgical result.

CONTRAINDICATIONS

PROLENE™ Soft Mesh should not be used intraperitoneally.

PROLENE™ Soft Mesh should not be used in patients with the potential for growth (such as infants, children with significant growth potential, and pregnant women), the surgeon should be aware that the device will not stretch significantly as the patient grows.

WARNINGS

- Failure to properly follow instructions may result in improper functioning of the device and could lead to injury. Please read all information carefully.
- If this device is used in patients with the potential for growth or tissue expansion (such as women who may become pregnant), the surgeon should be aware that the device will not stretch significantly as the patient grows.
- This device is indicated for abdominal wall hernia repair and not for gynecologic procedures. Gynecologic procedures should be performed using devices indicated for gynecologic repairs.
- It is recommended that the device not be used in a contaminated field, because contamination of the device may lead to infection that may require removal of the device.
- As with any implant, an acute and permanent foreign body response will occur. In some patients, this response can result in one or more of the adverse reactions listed below.
- The device is a permanent implant that is designed to integrate into the tissue. In cases in which the device needs to be removed, in part or in whole, significant dissection may be required.
- Insufficient overlap on any side of the defect may increase the risk of postoperative complications, including recurrence. Consult Application/Instructions for Use section.
- Insufficient or improper fixation may increase the risk of postoperative complications, including recurrence. Consult Application/Instructions for Use section.

- Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and anyone coming in contact with the device.
- Inspect the mesh carefully before implantation. Do not use the device if it is damaged.

PRECAUTIONS

The safety and effectiveness of pretreating PROLENE™ Soft Mesh with solutions (e.g., saline, medications) prior to implantation have not been studied.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials, including infection, inflammation, seroma formation, acute or chronic pain, foreign body sensation, hematoma, nerve damage, soft tissue injury, adhesion formation, fistula formation, extrusion/erosion, excessive contraction or shrinkage of the tissue surrounding the mesh, and mesh failure/ hernia recurrence.

One or more revision surgeries may be necessary to treat the above-mentioned adverse reactions. Revision surgery may not resolve the adverse reactions and may pose a risk of additional adverse reactions.

APPLICATION / INSTRUCTIONS FOR USE

Sizing and Placement

PROLENE™ Soft Mesh must always be placed extraperitoneally. PROLENE™ Soft Mesh can be trimmed at the surgeon's discretion, but the surgeon should provide the necessary overlap to reduce the risk of recurrence. The use of thermal cutting devices is not recommended, because it has not been tested.

Ventral/Incisional and Inguinal Hernia Repair

In ventral or incisional hernia repair, the mesh should extend at least 3 to 5 cm beyond the margins of the defect, unless at the surgeon's discretion, additional overlap onto healthy tissue is needed. When used in inguinal hernia repair, the mesh should provide sufficient overlap of the fascial defect on all sides. The colored stripes on the mesh can be used for orientation and alignment purposes. Place the mesh so that it lies flat to the tissue.

Fixation

The method of securing the implant (e.g., nonabsorbable/ absorbable sutures or tackers) to provide for adequate mesh fixation and to reduce the risk of recurrence should be determined at the surgeon's discretion, based on the individual patient's needs and the nature of the repair.

Spacing and distribution between fixation points and technique should be determined at the surgeon's discretion to provide adequate mesh fixation, to reduce the risk of mesh migration, and to optimize mesh-to-tissue contact to foster tissue ingrowth.

Preclinical data and reported experience suggest that the fixation points should be at least 1 cm from the edge of the mesh.

PERFORMANCE / ACTIONS

An animal study showed that implantation of PROLENE™ Soft Mesh elicits an inflammatory reaction that stimulates 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 material is not absorbed.

STERILITY

PROLENE™ Soft Mesh is sterilized using ethylene oxide gas. Do not resterilize. Do not use if the package is opened or damaged.

STORAGE

No special storage conditions required. Do not use after expiry date.

HOW SUPPLIED

PROLENE™ Soft Mesh is available in single-use, sterile packets in a variety of sizes.

TRACEABILITY

A traceability label that identifies the type, size, expiry date and batch code of the device is included in every package. This label should be affixed or electronically added to the patient's permanent medical record to clearly identify the device that was implanted.

SYMBOLS USED ON LABELING


Caution


Do not reuse

Do not resterilize


Do not use if package is damaged


Manufacturer

Quantity

Catalogue number

Batch code


Use-by date

Sterilized using ethylene oxide

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo, 00754
Puerto Rico USA
1-877-ETHICON
+1-513-337-6928

Made in U.S.A.
07/2020