GB

CAPROLEN-MESH

Instruction for Use

POLYPROPYLENE/ POLY(GLYCOLIDE-CO-CAPROLACTONE)
STERILE SYNTHETIC PARTIALLY ABSORBABLE COMPOSITE
SURGICAL MESH

INTRODUCTION
This package insert is designed to provide instructions for use of Caprolen-Mesh. It is not a comprehensive reference to surgical technique for repair of abdominal wall hernias.
Caprolen Mesh is intended for use only by physicians who are trained in the surgical procedures and techniques required for 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
Caprolen Mesh partially absorbable composite mesh is made from bicomponent monofilament composed of a Poly(glycolide-co-caprolactone, 75/25) and polypropylene segments, and warp-knitted with dyed and undyed monofilament. When dyed, only in PGA-PCL (PGCL) portion, FDA-approved color additives such as D&C Violet No. 2 are used. The Poly(glycolide-co-caprolactone, 75/25) is identical to the material used in Monokaprol Suture. After absorption of the Poly(glycolide-co-caprolactone, 75/25) component, only the polypropylene mesh remains. The remaining polypropylene mesh stretches to a greater degree perpendicular to the blue stripes.

INDICATIONS
Caprolen-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
Caprolen-Mesh should not be used intraperitoneally.
Caprolen-Mesh must not be used following planned intraoperative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh, which may lead to infection that may require removal of the mesh.

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 infants, children, or 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 gynaecologic procedures. Gynaecologic procedures should be performed using devices indicated for gynaecologic 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 pre-treating Caprolen 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
Caprolen Mesh must always be placed extraperitoneally. Caprolen Mesh can be trimmed at the surgeon's discretion, while providing the necessary overlap to reduce the likelihood of recurrence. The use of thermal cutting devices is not recommended, because it has not been tested.
Ventral/ Incisional and Inguinal Hernia Repair
Ensure that the Caprolen-Mesh, when used in ventral/ incisional repair, is large enough to extend at least 3 to 5 cm beyond the margins of the hernia 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 purple 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 a adequate mesh fixation and to reduce 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
Implantation of PGCL/PP 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. Caprolen Mesh was found to have 70% of its original burst strength remaining after fourteen days in vitro.The absorbable component is essentially absorbed within 91 days, whereas the polypropylene material is not absorbed.

STERILITY
Caprolen-Mesh is sterilized using ethylene oxide gas. Do not resterilize. Do not use if the package is opened or damaged.

STORAGE
Caprolen Mesh should be stored under controlled conditions (5°C - 25°C) and keep away from sunlight. Protect from humidity. Do not use after expiry date.

HOW SUPPLIED
Caprolen-Mesh is available in single-use, sterile packets in a variety of sizes.

SYMBOLS USED ON LABELLING

Do not re-use	STERILE EO Sterile EO: Ethylene oxide	Protect from humidity
Do not resterilize	LOT Batch Number	Recyclable pack
Do not use if package is damaged	REF Catalogue Number	Attention, See instruction for use
Manufacturer	5°C 25°C Temperature Limit	Consult instructions for use
YYYY - MM Date of manufacture, year-month		CE 2292
YYYY-MM Expiry Date, year-month	Keep away from sunlight	

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