

FILAPROP MESH SOFT (IFU)

(62 x 200)mm

Date : 25.03.2023

INSTRUCTIONS FOR USE

FILAPROP™ MESH SOFT

MANUFACTURED BY



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Endo-Surgery

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FILAPROP™ MESH SOFT
STERILE NON-ABSORBABLE SURGICAL POLYPROPYLENE
SOFT MESH

DESCRIPTION
Surgical FILAPROP™ MESH SOFT is a sterile, non- absorbable, knitted monofilament polypropylene mesh for tissue reinforcement. FILAPROP™ MESH SOFT has polypropylene filament diameter less than that of FILAPROP™ MESH; thus making it more flexible.

PERFORMANCE
FILAPROP™ MESH SOFT is a non-absorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. 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.

INDICATION
FILAPROP™ MESH SOFT is intended for use for the repair of hernias or other fascial defects that requires the addition of a reinforcing or bridging material to obtain the desired surgical result.

CONTRAINDICATIONS
FILAPROP™ MESH SOFT 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

- To be used by trained medical professional. Surgeon should be familiar with surgical procedures and techniques involving surgical meshes.
- FILAPROP™ MESH SOFT should be shaped, cut to size, and affixed, taking into consideration the patient's posture, weight and anatomical location.
- Adequate mesh fixation is required to minimize post-operative complications and recurrence.
- Do not re-sterilise FILAPROP™ MESH SOFT that has been in contact with or contaminated by blood or other substances or once opened from the sterile package.

(CONT.)

- Avoid direct contact with the viscera (intestines) to minimize the possibility of adhesions.
- Use only non-absorbable sutures, staples or tacker devices with this mesh.

PRECAUTIONS

- Handling of FILAPROP™ MESH SOFT should be with clean, sterile gloves and/or instruments.
- Careful attention to FILAPROP™ MESH SOFT with Suture, staple or tacker fixation, 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.

ADVERSE REACTIONS
Complications that may occur with the use of any FILAPROP™ MESH SOFT include, but are not limited to, inflammation, seroma formation, fistula formation, extrusion, infection or mechanical disruption of the tissue and/or mesh material, possible adhesions when placed in direct contact with the viscera (intestines).

STERILITY
FILAPROP™ MESH SOFT is sterilised by ethylene oxide as indicated on the package. Do not resterilize. Do not use if package is opened or damaged. Discard opened unused mesh!

STORAGE
Recommended storage conditions: Below 25°C, away from moisture and direct heat. Do not use after expiry date.

PACKAGING
FILAPROP™ MESH SOFT is primary packed in Tyvek pouch. Peel open the package and remove the FILAPROP™ MESH SOFT using sterile technique.

SYMBOLS USED ON LABELLING

	= Do not reuse
	= Date of Manufacture
	= Use by (Use until Year & Month)
	= Sterilised using Ethylene Oxide
	= Batch Code (Number)
	= Consult Instruction for use
	= Do not reesterilise
	= Upper limit of Temperature (Store below 25°C)
	= Keep away from Sunlight
	= Keep Dry
	= Do not use if Package is Damaged
	= Caution
	= Manufacturer
	= Authorised Representative in the European Community
	= CE mark and Identification number of Notified Body

PANTONE SHADE	
	BLACK
	PANTONE-278

ARTWORK No.	REV.
ME/IFU/103	04

REVISION
1.CE No and OBELIS address has been added