Meril Endo Surgery Private Limited
Artwork approval

FILAPROP MESH IFU

Date : 20.02.2018

INSTRUCTIONS FOR USE

FILAPROP™ MESH

MANUFACTURED BY

Endo-Surgery

MERIL ENDO SURGERY PVT. LTD.
THIRD FLOOR, E1-E3 MERIL PARK, SURVEY No.
135/2/B & 174/2 MUKTANAND MARG,
CHALA, VAPI - 396 191, GUJARAT, INDIA
Customer Care No. : 18004194433
E-mail : enquiry.endosurgery@merillife.com
Web. : www.merillife.com

CE 1783

EC REP
OBELIS S.A
Bd. Général Wahis, 53, 1030 Brussels, Belgium
T : +32 2 732 59 54 **F. :** +32 2 732 60 03
E : mail@obelis.net **W. :** www.obelis.net

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FILAPROP™ MESH
STERILE NON-ABSORBABLE SURGICAL POLYPROPYLENE MESH

DESCRIPTION

Surgical FILAPROP™ MESH is a sterile, non- absorbable, knitted monofilament polypropylene mesh for tissue reinforcement.

PERFORMANCE

FILAPROP™ Mesh 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 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 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. To be used by trained medical professional. Surgeon should be familiar with surgical procedures and techniques involving surgical meshes.

2. FILAPROP™ MESH should be shaped, cut to size, and affixed, taking into consideration the patient's posture, weight and anatomical location.

3. Adequate mesh fixation is required to minimize post-operative complications and recurrence.

4. Do not re-sterilise FILAPROP™ MESH that has been in contact with or contaminated by blood or other substances or once opened from the sterile package.

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5. Avoid direct contact with the viscera (intestines) to minimize the possibility of adhesions.

6. Use only non-absorbable sutures, staples or tacker devices with this mesh.

7. Reprocessing of unused mesh which has been removed from the package, or by any other means or condition is not recommended. FILAPROP™ MESH should not be flash autoclaved.

PRECAUTIONS

1. Handling of FILAPROP™ MESH should be with clean, sterile gloves and/or instruments.

2. Careful attention to FILAPROP™ MESH 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 FILAPROP™ MESH include, but are not limited to,inflammation, seroma formation, fistula formation, extrusion, infection or mechanical disruption of the tissueand/or mesh material, possible adhesions when placed indirect contact with the viscera (intestines).

STERILITY

FILAPROP™ MESH 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 is primary packed in Tyvek pouch. Peel open the package and remove the FILAPROP™ MESH 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 resterilise

= 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

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Prepared by	Verified by	Reviewed by QA/RA	Approved by QA/RA
ABHISHEK PALANDE	PANKAJ GURAV	SUBHADRA PATEL	UMESH SHARMA