Meril Endo Surgery Private Limited
Artwork approval

MERINEUM MESH (IFU)

Date : 24.08.2018

INSTRUCTIONS FOR USE

MERINEUM™ MESH

MANUFACTURED BY

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MERINIUM™ MESH
STERLISED PARTIALLY ABSORBABLE TISSUE SEPARATING DUAL LAYERED SURGICAL MESH

DESCRIPTION

MERINEUM™ MESH is a sterile, tissue separating dual layered partially absorbable surgical mesh consisting of knitted non-absorbable polypropylene mesh and absorbable non-adhesive polylactide-caprolactone film. MERINEUM™ MESH is available in various sizes.

PERFORMANCE

MERINEUM™ MESH is laminated mesh, wherein the non – absorbable Polypropylene mesh is coated with absorbable polylactide – Caprolactone film. Polypropylene mesh provides long term soft tissue enhancement. Polylactide-caprolactone is a biological absorbable high polymer material which acts as an anti-adhesive layer creating a barrier between polypropylene mesh and abdominal organs, thus preventing adhesions during the critical wound healing period. The polylactide-caprolactone shall be absorbed within 3-4 months.

INDICATIONS

MERINEUM™ MESH is intended for use in Laparoscopic Ventral Hernia Repair and other fascial surgical intervention procedures.

CONTRAINDICATIONS

MERINEUM™ MESH is contraindicated where tissue may be contaminated or infected, in infants, children, pregnancy or 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. Though the product shall not give rise to infection, it still needs to be cautiously used for the already contaminated or infected wounds, and operations of intestinal canals damages etc. that possibly leads to the contamination at the operative regions and may lead to the formation

(CONT.)

REVISION
1.General Description is updated. 2.Mfg. Lic. No. is removed.

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of sinus tract or repulsion against the meshes. At this moment, the mesh should be taken out.

3. For the patients with huge incisional hernia, especially the patients with the specific value of hernia sac volume and abdominal volume larger than 15%, pay attention to avoiding the occurrence of abdominal compartment syndrome (ACS).

PRECAUTIONS

1. For the laparoscope repair of the rolled up meshes, make sure the thin film layer is inward, so that when inserting the casing, protect the thin film layer.

2. The product can be only used once, should not be sterilized for use repeatedly.

3. The dimensions of the meshes from all directions shall be 3-5cm larger than the defects.

4. The product is only to be operated by means of the clean gloves or surgical instruments.

5. The product must be permanently fixed; otherwise it shall lead to the migration of the meshes.

6. The product shall not be cut by the hot cutter.

ADVERSE REACTIONS

Adverse reactions associated with the use of MERINEUM™ MESH include, but are not limited to, inflammation, seroma formation, and infection, adhesion, sinus tract formation, repulsion, temporary local stimulations or mechanical disruption of the tissue and/or mesh material.

STERILITY

MERINEUM™ MESH is sterilized by Radiation. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened remaining unused mesh.

STORAGE

Recommended storage condition: below 25ºC, away from moisture and direct heat. Do not use after expiry date!

PACKAGING

MERINEUM™ MESH is available in single packets as sterile flat sheets with blue stripping and one box contains one packet. Peel open the package and remove the MERINEUM™ MESH using sterile technique.

SYMBOLS USED ON LABELLING

= Do not reuse
= Date of Manufacture
= Use by (Use until Year & Month)
STERILE R = Sterilised using Irradiation
LOT = Batch Code (Number)
= Consult Instruction for use
= Do not resterilise
25°C = Upper limit of Temperature (Store below 25°C)
= Keep away from Sunlight
= Keep Dry
= Do not use if Package is Damaged
= Caution
= Manufacturer
EC REP = Authorised Representative in the European Community
CE 1783 = CE mark and Identification number of Notified Body

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