

ABSOMESH IFU (62X300)mm

Date : 19.01.2023

INSTRUCTIONS FOR USE	
ABSOMESH™	
<p style="text-align: center;">MANUFACTURED BY</p> <div style="text-align: center;">  <p>Meril Endo-Surgery</p> </div> <p style="text-align: center;">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</p> <p style="text-align: center;">Document No. : ME/IFU/047 Rev.04 Rev. Dt. 2023/01</p>	<p>maintained from the edge of the mesh and between two fixation points to prevent risk of mesh migration or recurrence of hernia.</p> <p>3. Avoid direct contact with the viscera (intestines) to minimize the possibility of adhesions.</p> <p>ADVERSE REACTIONS</p> <p>Adverse reactions associated with the use of ABSOMESH™ include, but are not limited to, inflammation, seroma formation, fistula formation, extrusion and infection or mechanical disruption of the tissue and/or mesh material.</p> <p>STERILITY</p> <p>ABSOMESH™ is sterilized by ethylene oxide. Do not resterilize. Do not use if package is opened or damaged. Discard opened remaining unused mesh.</p> <p>STORAGE</p> <p>Recommended storage condition: below 25°C, away from moisture and direct heat. Do not use after expiry date!</p> <p>PACKAGING</p> <p>ABSOMESH™ is primary packed in Tyvek pouch and further in single aluminium packets as sterile flat sheets. Peel open the package and remove the ABSOMESH™ using sterile technique.</p> <p>SYMBOLS USED ON LABELLING</p> <p> = Do not reuse</p> <p> = Date of Manufacture</p>
<p style="text-align: center;">ABSOMESH™ PARTIALLY ABSORBABLE MONOFILAMENT KNITTED MESH STERILISED POLY (GLYCOLIDE-CO-CAPROLACTONE) AND POLYPROPYLENE MESH</p> <p>DESCRIPTION</p> <p>ABSOMESH™ is a sterile, partially absorbable mesh consisting of knitted non-absorbable polypropylene and absorbable poly(glycolide-co-caprolactone) mesh material, dyed with D&C Violet No. 2. ABSOMESH™ is available in various sizes.</p> <p>PERFORMANCE</p> <p>ABSOMESH™ Mesh is used for permanent stabilization of the abdominal wall, e.g., in hernia repair. The absorbable poly (glycolide-co-caprolactone) portion of the mesh provides required firmness to the mesh; thus making the implantation of the mesh easier. Due to the wide pore construction of ABSOMESH™ Mesh, during healing, a strong three-dimensional collagen fiber network is formed. The residual polypropylene mesh does not hinder this process, thereby avoiding excessive connective tissue deposition and deleterious scar formation. The tissue in growth occurs through the pores with simultaneous absorption of poly (glycolide-co-caprolactone). After absorption of poly (glycolide-co-caprolactone), the tissue ingrowth continues to occur through the residual polypropylene which provides enough support to the defect area. The purpose of using absorbable poly (glycolide-co-caprolactone) along with non-absorbable polypropylene material is to subsequently reduce the foreign material in the body at the same time provide required support to the defect area (Poly(glycolide-co-caprolactone) shall absorb within 90 to 120 days)</p> <p>INDICATIONS</p> <p>ABSOMESH™ is intended for use for the repair of hernias or other abdominal fascial defects that requires the addition of a reinforcing or bridging material to obtain the desired surgical result.</p>	<p> = Use by (Use until Year & Month)</p> <p> = Sterilised using Ethylene Oxide</p> <p> = Batch Code (Number)</p> <p> = Consult Instruction for use</p> <p> = Do not resterilise</p> <p> = Upper limit of Temperature (Store below 25°C)</p> <p> = Keep away from Sunlight</p> <p> = Keep Dry</p> <p> = Do not use if Package is Damaged</p> <p> = Caution</p> <p> = Manufacturer</p>
<p>CONTRAINDICATIONS</p> <p>ABSOMESH™ is contraindicated where tissue may be contaminated or infected, in infants, children, pregnancy or where future growth may be compromised by its use. ABSOMESH™ must always be separated from the abdominal cavity by peritoneum. ABSOMESH™ as flat mesh is not suitable for insertion into inguinal canal.</p> <p>WARNINGS</p> <ol style="list-style-type: none"> To be used by trained medical professional. Surgeon should be familiar with surgical procedures and techniques involving surgical meshes. Adequate mesh fixation is required to minimize post operative complications and recurrence. The fixation technique, method and other products used (including sutures, tacks, staples or other means) is left to the discretion of the surgeon to optimize clinical outcomes. ABSOMESH™ can be shaped, cut to size, and affixed, taking into consideration the patient's posture, weight and anatomical location providing a sufficient overlap to cover all sides of the defect. Careful attention to suture/staple/tacker placement and spacing will help prevent excessive tension or disruption between the mesh material and connective tissue. Take special care while fixing mesh in the presence of nerves or vessels to avoid injury. ABSOMESH™ in a contaminated or infected wound can lead to fistula formation and/or rejection of the mesh. Foreign body reactions may occur in some patients. <p>PRECAUTIONS</p> <ol style="list-style-type: none"> Handling of ABSOMESH™ should be with clean, sterile gloves and/or instruments. While fixing the mesh, adequate distance should be <p style="text-align: right;">(CONT.)</p>	

PANTONE SHADE	
	BLACK
	C 7 M 24 Y 45 K 0

Revision
1. CE No. OBELIS address has been removed.

ARTWORK No.	REV.
ME/IFU/047	04