

INSTRUCTION FOR USE-NON ABSORBABLE MONOFILAMENT POLYPROPYLENE SURGICAL MESH

Dolphin Mesh® STERILE NON-ABSORBABLE MONOFILAMENT POLYPROPYLENE SURGICAL MESH

DESCRIPTION

Dolphin Mesh® is a monofilament synthetic non – absorbable, sterile surgical Mesh composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The molecular formula is $(C_3H_6)_n$.

INTENDED USE

Dolphin mesh is used in hernia repair and weak tissue support.

SELECTION CRITERIA

The Mesh should be selected and implanted depending on patient's condition, surgical experience, surgical technique, and wound size.

PERFORMANCE

Dolphin Mesh elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. Dolphin Mesh is not absorbed nor is it subjected to degradation or weakening by the action of tissue enzymes. Due to its relative biological inertness it is recommended for use where the least possible suture reaction is desired. As a mono – filament it has been successfully employed in surgical wound which subsequently become infected or contaminated where it can minimize later sinus formation and suture extrusion

CONTRAINDICATIONS

The use of this Mesh is contraindicated in patients with known sensitivities or allergies to polypropylene.

WARNINGS

- a. Surgeons should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Dolphin Mesh® for wound closure, as the risk of wound dehiscence may vary with the site of application and the Mesh material used.
- b. In surgery of the urinary or biliary tract, care should be taken to avoid prolonged contact of this or any other Mesh with salt solution, to prevent calculus formation.
- c. For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury or illness.
- d. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- e. Contamination of the device may lead to injury, illness of the patient.

PRECAUTIONS

- a. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- b. In handling this mesh material, care should be taken to avoid damaging the surface of the material with surgical instruments as this could lead to fracture of the material in use.
- c. Care should be taken to avoid damage while handling surgical mesh.

ADVERSE REACTIONS

Adverse reactions associated with the use of Dolphin Mesh® include transitory local irritation at the wound site or transitory inflammatory foreign body response. Like all foreign bodies Dolphin Mesh® may potentate an existing infection.

STERILITY

Dolphin Mesh® meshes are sterilized by ethylene oxide. Do not re – sterilize! Do not use if package is opened or damaged! Discard opened unused meshes.

STORAGE

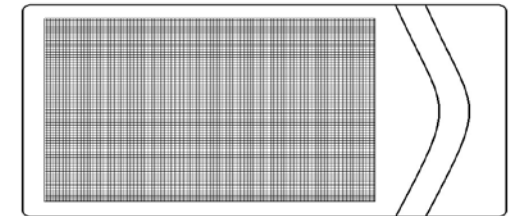
Recommended storage condition 10°C-35°C, away from moisture and direct heat. Do not use after expiry date.

DISPOSAL

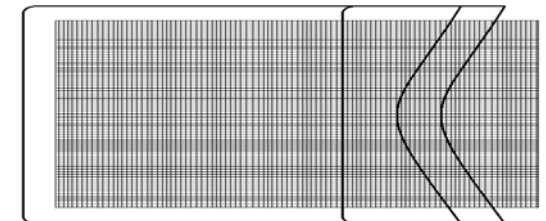
Discard used meshes contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

INSTRUCTION FOR USE

1. Hold the pack in a horizontal/ vertical manner.

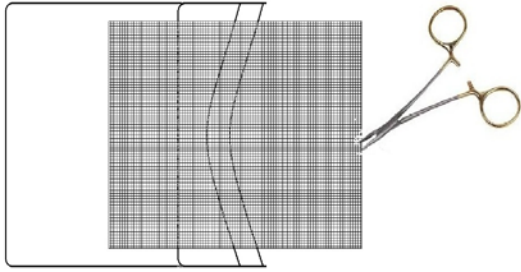


2. Hold the protruded portions of the paper poly pouch and peel open to see the mesh.



3. With the help of sterilized forceps pull out the mesh.

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SYMBOLS USED ON THE LABELS

	Do not reuse		Batch number
	Date of manufacture		CE logo
	Date of expiry		Registered
	Sterilized by ethylene oxide		EU REPRESENTATIVE
	Temperature limitation		Do not resterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture



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