

FUTURA SURGICARE PVT LTD
INFORMATION FOR USE (IFU)
Brand name: DOLPHIN MESH

Material: Knitted polypropylene mesh (Undyed)

Non – absorbable 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 $(C_3H_6)_n$. Dolphin Mesh is available only in undyed manner.

Entire detail of the product range is contained in the catalogue.

Indications:

A Dolphin Mesh is suitable for use in general soft tissue approximation and/or ligation, including use in cardiovascular & general closure. It is mainly used in hernia repair.

Applications:

Suture should be selected and implanted depending on the 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.

Contra – indications:

None known.

Warnings:

User should be familiar with surgical procedure and techniques involving non – absorbable sutures before employing Dolphin Mesh for hernia repair and wound closure as a risk of wound dehiscence may vary with the site of application and the mesh material used.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

Precautions:

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. Avoid crushing or crimping damage due to surgical instruments such as forceps or needle holders.

Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. Dolphin Mesh should be properly sutured to the

skin or with a round body needle only, usage of any kind of cutting/ taper cutting/ reverse cutting needle may damage the mesh.

Adverse reactions:

Adverse reactions associated with the use of this device include: minimal initial inflammatory tissue reaction and transient local irritation at the wound site. Like all foreign bodies Dolphin Mesh may potentate an existing infection.

Sterility:

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

Storage:

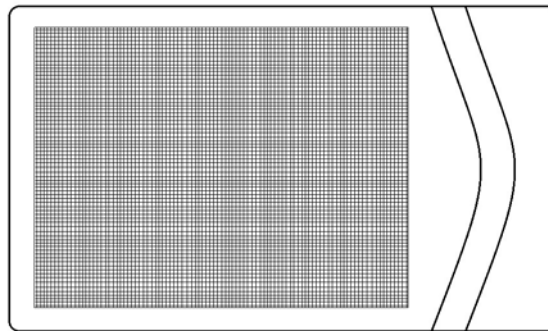
Recommended storage condition 10 – 35 °C, away from moisture and direct heat. Do not use after expiry date.

Disposal:

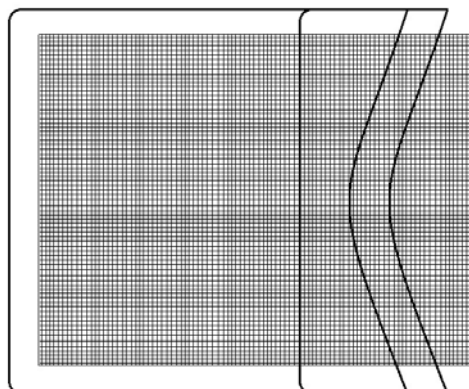
Discard used mesh, sutures and needles contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

Technique for opening the peel open pouch.

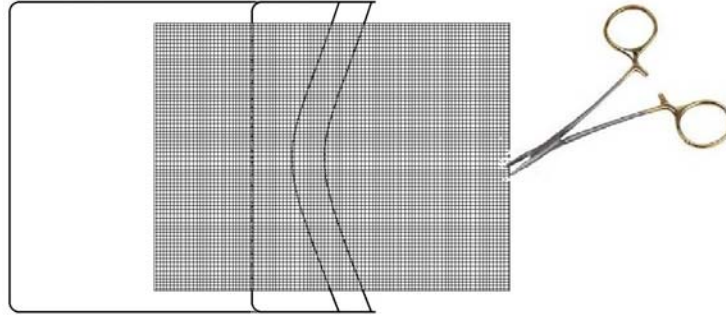
1. Hold the pack in a horizontal/ vertical manner.



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.



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 re-sterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture

Manufacturer: Futura Surgicare Pvt Ltd, 86/C2, 3rd Main, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore – 560022, India. Mfg Lic No: KTK/28/273/1995

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