INSTRUCTIONS FOR USE

STERILENE MESH™

DESCRIPTION :

Sterilene Mesh is constructed of knitted filaments of Non Absorbable Monofilament Polypropylene material.

INTENDED USE :

Sterilene Mesh is indicated for the surgical reconstruction of tissues defects for incisional/ventral, umbilical, epigastric and inguinal hernia.

STERILIZATION :

- Sterilene Mesh is sterilized by Ethylene Oxide (EtO) only.
- Do not use if the packaging is damaged. Single use, Sterile product, Non resterilizable

CONTRAINDICATION :

Sterilene Mesh is contraindicated in infants, children or pregnancy with future growth potential, as this product will not stretch significantly. Sterilene Mesh is contra indicated in gynecological procedure and urogenital prolapse.

TRACEABILITY :

Identification labels included in each pack to ensure product traceability . Use as required by current regulations.

PRECAUTIONS / WARNING :

- Before employing Polypropylene mesh, users should be familiar with surgical procedures and techniques involving non-absorbable mesh. If there is any prior infection at the application site then that should be treated before application of Mesh. Although polypropylene doesn't cause infection, however depending upon the site of application it can aggravate the same.
- In handling this or any other mesh material, care should be taken to avoid damage from handling.
- Avoid crushing damage due to application of surgical instruments such as forceps or needle holders.
- Do not place the mesh in contact with the intestinal loops.
- Once the sterile pack containing the mesh has been opened, it cannot be resterilized or reused.
- Use of the device is restricted to specialist personnel.
- The surgeon and his co-worker must carry out a visual inspection of the packaged device to check that the sterile barrier has not been damaged.
- Do not reuse/resterilize, may cause infection.
- Only Qualified surgeons shall use the mesh and follow approved surgical practice during management of contaminated or infected wounds.
- Mesh, if required, shall be disposed as per best practices and applicable law.

ADVERSE REACTIONS:

Adverse reaction associated with the use of Poly propylene mesh may include minimal initial inflammatory tissue reaction, transient local irritation at the wound site, pain, infection, hernia recurrence, adhesion, Bowel obstruction, Migration, bleeding, fistula, seroma, perforation, contraction.

INSTRUCTION FOR USE :

Surgeon should follow national clinical guidelines or best accepted surgical mesh procedure.

Sterilene mesh is available in single use, sterile packets in different size. The Device needs to be implanted permanently.

TECHNIQUE FOR OPENING OVERWRAP.

Hold pack in left hand, seize foil flap between right hand thumbs and finger, hence exposing transparent plastic flap.

Separate the transparent plastic flap and paper flap with thumbs and fingers of both hands gripping pack between knuckles.

Apply constant pressure between knuckles and roll thumb outward to separate the flaps, exposing the sterile primary pouch.

Now the scrub nurse removes the sterile Primary pouch pack with sterile forceps or with sterile gloved hand.

Symbols used on labeling :-

	Do not reuse.
/ Mfg.	Manufacturing year + Month.
/ Exp.	Use until Year + Month.
LOT	Batch Number.
STERILE EO	Sterile unless package is opened or damaged. Method of Sterilization- Ethylene Oxide Sterilization.
	Caution
REF	Product code.
	Consult Instructions for use.
	Do not resterilize.
	Do not use if package is damaged.
32°C 15°C	Temperature Limitation.
EC REP	Authorized European Representative.
70% 60%	Moisture Limitation.
	Keep away from sunlight.
	Keep away from moisture.
	Non-pyrogenic
SBS	Sterile Barrier System
MD	Medical device
	Patient information website
CE 2460	CE- mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.

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Peters SURGICAL

STERILENE MESH™

EC REP

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