SURGIMESH PRO

Instructions for Use

POLYPROPYLENE MESH

DESCRIPTION

SURGIMESH PRO is a sterile, transparent, non-absorbable, pre-shaped, extruded biocompatible knitted polypropylene monofilament with low weight.
SURGIMESH PRO does not have any derived products from human or animal origin.
SURGIMESH PRO is Packaged in a medical pouches in a certified clean room and sterilized by ETO according to a validated process.

INDICATIONS

SURGIMESH PRO is a non-absorbable mesh used to repair hernia defects that require reinforcement with a non-absorbable supportive material.

CONTRA INDICATIONS

SURGIMESH PRO is contraindicated in infants, children or pregnancy with future growth potential, as this product will not stretch significantly.
SURGIMESH PRO contraindicated in contaminated or infected wounds as infection may require removal of the mesh.

WARNINGS

SURGIMESH PRO is provided by SURGIMEDIC as a sterile product. Re-sterilization of the device is NOT allowed.
Use only non-absorbable staples; suture clips sutures with SURGIMESH PRO.
SURGIMEDIC rejects any responsibility regarding the use of fixation devises which can be chosen freely by the surgeons.
Avoid direct contact with the viscera intestines to avoid the possibility of adhesions.

PRECAUTIONS

Handling of SURGIMESH PRO should be with sterile technique and avoid any contact with cutting or sharp instruments since it can deteriorate the mesh.
A minimum of 7mm of mesh should extend beyond the suture line.

ADVERSE REACTIONS

No side effect due to the mesh is known.
Complications that may occur due to implantation of any surgical mesh include, but are not limited to, infection, inflammation, fistula formation, extrusion and adhesion formation (when placed in direct contact with the intestine).

INSTRUCTIONS FOR USE

It is recommended that staples, suture clips or non-absorbable sutures be placed 7mm to 13mm from the edge of the SURGIMESH PRO material for best results.

STANDARD PACKAGING

SURGIMESH PRO is available in medical pouches as sterile and 3 pouches per box.

STORAGE

It is recommended to be stored in dark, dry, clean place at the room temperature.

SYMBOLS USED ON THE PRODUCT LABELS

CE 2803	CE symbol and identification number of the notified body.
LOT	Lot number (batch)
	"Use by" expiration date (year-month)
	Date of manufacture (year-month)
	Do not use if package is damaged
	Single use
	consult instruction for use on
	Do not resterilize
	Manufacturer
REF	Product code
	Store below 25 C
	Keep away from sunlight
	protect from humidity
	Double sterile barrier system
MD	Medical Device
STERILE EO	Package is sterile when not damaged or opened. EO sterilization method -Ethylene oxide.

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It is very important to check the external integrity of the package and the expiration date.
In compliance with the European Directive 93/42/EEC, this product MUST BE handled and/or implanted by qualified persons.