TI Medical Private Limited

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LOTUS™
A Brand of **TI MEDICAL**

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/12, Issue No.: 02, Rev. No.: 03, Rev. Dt.: 10/05/2026)

LOTUS™
A Brand of TI MEDICAL

STERILE NON-ABSORBABLE SURGICAL SUTURES

BRAIDED COATED POLYESTER SUTURE

Braided coated Polyester Suture with Needle (Green)
Braided coated Polyester Suture without Needle (Green)
Braided coated Polyester Suture with Needle (White)
Braided coated Polyester Suture without Needle (White)
Braided coated Polyester Suture with Needle (Green & White)

BRAND NAME: - ESTERLUS®

USP Sizes (with Needle)	Metric Size (Gauge No.)	Needle Profile
5-0	1	Taper point, Micro point spatulated, Taper cut, Diamond point, Reverse cutting, Reverse round bodied heavy, circle cutting.
4-0	1.5	
3-0	2	
2-0	3	
0	3.5	
1	4	
2	5	
5	7	
Needle Curvature: 1/4 circle, 1/2 circle and 5/8 circle		
USP Sizes-without Needle	**Metric Size (Gauge No.)**	**Needle Profile**
4-0	1.5	Not Applicable
3-0	2	
2-0	3	
0	3.5	
1	4	
2	5	

DEVICE DESCRIPTION:
This is a non-absorbable, sterile, single-use surgical suture, composed of fine filaments of polyethylene terephthalate. The fine polyester fibers are braided to produce a suture that remains soft & pliable. The device is coated with silicon which helps in easy passage through the tissue without irritation. It is available in dyed green color(D & C green No.6) that can be attached to various needle types, shapes, and lengths or non-needled. These are packed in a suture card which is further packed & sealed. Based on the number of sutures(10,4,1) wound in the suture card and packed in the Medical Grade paper & poly-film pouch (1 suture) and Tyvek pouch (10 and 4 sutures). However, the primary packing (Medical grade pouch) is terminally sterilized by ethylene oxide. These pouches are supplied in 6, 12, 24, or 36 units per box packing configuration along with Instruction for Use (IFU) and such multiple mono cartons are packed in the master carton. These sutures comply with the requirements of the United States Pharmacopoeia for "Non-Absorbable Surgical Suture". These sutures are intended to be used only in a sterile clinical environment like the operating room.

INTENDED PURPOSE:
Braided coated polyester suture is intended for use in general soft tissue approximation and/or ligation.

INDICATIONS FOR USE:
These sutures are indicated for repairing or joining the soft tissues of wounds or incisions through approximation and for ligation of tubal structures, during gynecological surgery orthopedic surgery, ophthalmic surgery, hernia repair, and prosthetic implantations.

INTENDED PATIENT POPULATION:
This is intended for the closure of wounds or surgical incisions on the skin or any other body tissue and ligation of tubules in patients of varying age groups in line with the intended use, indication, and contraindication.

INTENDED USERS:
Used by trained & experienced orthopedic surgeons, gynecologists, registered nurses & other medical personnel only.

CLINICAL BENEFITS:
- Excellent Fracture healing
- Minimal tissue reactivity
- Patient Comfort & Satisfaction
- Reduction in the rate of wound complications
- Favorable Handling Characteristics

PERFORMANCE CHARACTERISTICS:
- Outstanding knot security
- Excellent tissue support

TYPE OF USE:
This device is for single use only. Reuse of the device can lead to cross-contamination causing severe consequences to the patient.

CONTRAINDICATIONS:
Do not expose the suture to prolonged contact with the salt solution such as those found in the urinary and biliary tract which may result in calculus formation.

LIMITATIONS:
There is no evidence of limitations.

OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION:

Raw Material	Composition	Formulation
Braided coated Polyester Suture - Green		
Polyethylene terephthalate	> 98%	$(C_{10}H_8O_4)n$
D&C No. 6 Green	< 0.75%	Cn
Nu-Sil MED-2174 Elastomer	1-2%	$(R_2SiO)x$
Braided coated Polyester Suture - White		
Polyethylene terephthalate	> 98%	$(C_{10}H_8O_4)n$
Nu-Sil MED-2174 Elastomer	1-2%	$(R_2SiO)x$

WARNINGS:
- Do not use tampered or improperly labelled pack.
- Do not use the damaged product happened during the process of transportation and storage.
- Do not open the pack in a non-sterile environment.
- This suture may be inappropriate in patients suffering from conditions that may delay wound healing.
- Do not use the expired product.
- Do not dispose of the waste in a normal bin. To be disposed of as per the user's country disposal regulations and hospital/ clinic protocol. If not disposed of properly it may lead to enviro-nmental pollution, needle pricks, and infectious diseases.

PRECAUTIONS:
- Ensure the package is intact before opening.
- Read the labelling instructions thoroughly on the package before opening it.
- Read and follow the instruction before performing the surgery.
- Sutures should be handled by trained professionals.
- Only trained surgeons must perform the approximation procedure.
- Care should be taken to avoid damage from handling surgical needles.
- Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holder.
- Avoid off-label use and misuse of the suture.
- Allergy tests must be recommended for patients of unknown sensitivities.
- Additional support may be required in the closure of sites undergoing expansion, stretching, or distention.
- Closely monitoring the wound and suture site for signs of infection or microbial adhesion.
- Suture should be removed after the wound is healed, to prevent any complications.
- Improper handling of suture may lead to unnecessary infections and bleeding.
- Mismanagement of suture at the surgical site by patients may lead to bleeding, infection, inflammation, wound dehiscence and/or stitch abscess.
- Early removal of suture post-surgery may lead to bleeding, infection, and/or wound dehiscence.

RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:
- Use of Polyester sutures on patients who have an unknown clinical history of allergy may lead to allergic reactions, rashes or inflammation.
- As a non-absorbable suture, it may act transiently as a foreign body. As with any foreign material in the presence of the foreign body, bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

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STERILITY:
Braided-coated Polyester sutures are sterilized by Ethylene Oxide. Do not re-sterilize the product.

APPLICATION:
These sutures should be selected and implanted depending on the patient's condition, surgical history, surgical technique, and wound size.

HANDLING OF THE DEVICE:

1. Hold the foil in the left hand and grasp the foil flap between the thumb and index finger of the right hand.

2. Grasp transparent poly film with the thumb and index finger of the left hand, gripping the pack between knuckles thus exposing it to a sterile card.
3. Project the sterile card onto the sterile table only after peeling apart the peelable foil completely.

4. Arm the needle with an appropriate needle holder using the no-touch technique. Remove the needled suture with a smooth and moderate pull in a direction parallel to the card. (Suture with needle).

5. Remove the needled suture with a smooth and moderate pull in a direction parallel to the card. If resistance is observed while removing, then relax the suture and pull again. Please do not pull against the swaged end of the suture.
6. If resistance is observed while removing. Then relax the suture and pull again. Please do not pull against the swaged end of the suture.

STORAGE:
Recommended storage condition is to store at a temperature below 26°C, away from moisture & direct sunlight. Do not use it after the expiry date.

DISPOSAL:
Discard used sutures and needles contaminated with blood in the container meant for "infectious waste". Unused expired pouches should be incinerated.

EXPLANATION OF SYMBOLS	
Symbol	**Title**
CE 2975	CE Logo with Notified Body Number
	Manufacturer
EU REP	Authorized Representative in the European Community/ European Union
	Date of Manufacture
STERILE EO	Sterilized using Ethylene Oxide
	Do not re-use
	Do not re-sterilize
LOT	Batch code
	Use-by Date
REF	Catalogue Number
	Caution
	Do not use if package is damaged and consult instructions for use
	Keep away from Sunlight
UDI	Unique Device Identifier
25°C	Upper limit of temperature

STERILE EO	Single Sterile Barrier System used in combination with Sterilized using ethylene oxide
	Single Sterile Barrier System with protective packaging outside
MD	Medical device
	Consult instructions for use or consult electronic instructions for use
	Importer
	Distributor
	Keep dry

CE 2975

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Mfg. Lic. No.: MFG/MD/2024/000202

MANUFACTURER NAME:	TI Medical Private Limited		USE COLOR:
PRODUCT:	IFU for Polyester Suture		PANTONE RED PANTONE BLACK
DIMENSION:	220mm L x110mm W +/- 2mm		
WEIGHT(GSM):	60 +/- 5% GSM		
PREPARED BY:	VERIFIEDBY:	APPROVED BY:	
"DESIGNER"	"D&D EXECUTIVE"	"D&D HEAD"	ARTWORK DOC. NO.: TI/IFU/12
OTHER REMARK:			REVISION NO.: 03