TI Medical Private Limited

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LOTUS™
A Brand of **TI MEDICAL**

INSTRUCTIONS FOR USE

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

LOTUS™
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STERILE NON-ABSORBABLE SURGICAL SUTURES

MONOFILAMENT POLYPROPYLENE SUTURE

Monofilament Polypropylene Suture with Needle (Blue)

Monofilament Polypropylene Suture without Needle (Blue)

BRAND NAME: - PROLUS®

USP Sizes	Metric Size (Gauge No.)	Needle Profile
8-0	0.4	Round-bodied, Reverse cutting, Taper cut, Taper point, spatulated
7-0	0.5	
6-0	0.7	
5-0	1	
4-0	1.5	
3-0	2	
2-0	3	
0	3.5	
1	4	
Needle Curvature: 1/4 circle, 1/2 circle, 3/8 circle and straight		
USP Sizes	**Metric Size (Gauge No.)**	**Needle Profile**
0	3.5	Not Applicable
1	4	
2	5	

DEVICE DESCRIPTION:

This is a monofilament, synthetic non-absorbable, single-use, sterile surgical suture, composed of an isotactic crystalline stereoisomer of Polypropylene, a synthetic linear Polyolefin. The molecular formula is (C3H6)n. The dye used in this suture is solvent blue 104. It is available in a range of gauge sizes, and lengths, attached to stainless steel needles of various types, and sizes, or non-needled. These are wound-in suture cards which are further packed & sealed in Medical Grade paper & poly-film pouch. The primary packing (Medical grade pouch) is terminally which are further packed & sealed in Medical Grade paper & poly-film pouch. The primary packing (Medical grade pouch) is terminally sterilized by ethylene oxide. These pouches are supplied in 12, 24, or 36 units per mono carton along with Instruction for Use (IFU) and such multiple mono cartons are packed in the master cartons. These sutures comply with the requirements of the United States Pharmacopoeia for "Non-Absorbable Surgical Suture" and are intended to use only in a sterile clinical environment like an operating room.

INTENDED PURPOSE:

Monofilament Polypropylene sutures are intended for use in general soft tissue approximation and/or ligation.

INDICATIONS FOR USE:

These sutures are indicated for joining edges of a soft tissue wound or incision by stitching soft tissues and for ligation of tubules including use in micro procedures and hernia repair.

INTENDED PATIENT POPULATION:

Intended for the closure of wounds or surgical incisions on the skin or any other body tissues 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 orthopedics, Gynecologists, Endoscopic surgeons, registered nurses & other medical personnel only.

CLINICAL BENEFITS:

- Excellent Wound Healing
- Minimal Tissue Reactivity
- Minimal postoperative complications
- Easy knot placement
- Ease of handling
- Minimizing the risk of dehiscence or complications
- Secure and long-lasting wound support

PERFORMANCE CHARACTERISTICS:

- Excellent tensile strength
- Good Handling
- Biocompatible
- Good knot security

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 (Wt.%)	Formulation
Polypropylene	≥99.5%	C_3H_6
Solvent Blue 104	≤0.5%	$C_{32}H_{30}N_2O_2$

WARNINGS:

- Do not use tampered or improperly labelled packs.
- Do not use the damaged product that happened during the process of transportation and storage.
- Do not open the pack in a non-sterile environment. Use the product as soon as it is opened and in a sterile condition.
- This suture may be inappropriate in patients suffering from conditions that may delay wound healing.
- Do not use the expired product.
- 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 environmental pollution, needle prick injuries, and any infectious diseases.

PRECAUTIONS:

- Read and follow the instructions 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 the application of surgical instruments such as forceps or needle holders.
- Additional support may be required in the closure of sites undergoing expansion, stretching, or distention.
- Closely monitor 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.
- Incorrect suture technique may lead to Incomplete wound healing/ severe wound dehiscence/ scar formation/ circulation issue / pain/swelling.
- Selection of incorrect type of suture against assessment of patient wound may lead to Failure of surgery / severe injury, pain, irritation, and infection/ Incomplete wound healing.
- Mismanagement of suture at the surgical site by patients may lead to Bleeding, Infection, inflammation, Wound dehiscence & Stitch Abscess.

RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:

- Use of suture on patients who are allergic to polypropylene may lead to Tissue trauma/ edema/Infection/ Inflammation/ Delay in wound healing/ post-surgery infection.
- 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.

STERILITY:

Monofilament Polypropylene sutures are sterilized by using Ethylene Oxide. Do not re-sterilize.

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APPLICATION:

Monofilament polypropylene 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, thus exposing the poly film.

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 suture with the help of the forceps or sterilized glove in a direction parallel to the card with smooth and moderate pull (Suture without needle).
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 Polypropylene 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/10
OTHER REMARK:			REVISION NO.: 03