TI Medical Private Limited

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LOTUS™
A Brand of **TI MEDICAL**

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/09, Issue No.: 02, Rev. No.: 03, Rev. Dt.: 10/05/2026)

LOTUS™
A Brand of TI MEDICAL

STERILE NON-ABSORBABLE SURGICAL SUTURES

MONOFILAMENT POLYAMIDE SUTURE

Monofilament Polyamide Suture with Needle (Black)

Monofilament Polyamide Suture without Needle (Black)

Monofilament Polyamide Suture with Needle (Blue)

Monofilament Polyamide Suture without Needle (Blue)

BRAND NAME: - NYLUS®

USP Sizes (Black)	Metric Size (Gauge No.)	Needle Profile
11-0	0.1	Straight cutting, Reverse cutting, Taper point, Taper cutting, Reverse cutting precision point, round-bodied, spatulated cutting, Micro point cutting
10-0	0.2	
9-0	0.3	
8-0	0.4	
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	
2	5	
Needle Curvature: Straight 1/2 circle, and 3/8		
USP Sizes (Blue)	**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 synthetic non-absorbable, sterile, single-use, monofilament surgical suture, composed of long chain-aliphatic polymers, Polyamide 6, and Polyamide 6.6. It is available as dyed black to enhance the visibility in tissue. It is available in a range of gauge sizes and lengths, attached to stainless steel needles of varying types and sizes, and non-needled. The finished sutures are packed in a medical-grade paper and poly-film pouch and then sealed. These primary packs are sterilized by using ETO and 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 be used only in a sterile clinical environment like an operating room.

INTENDED PURPOSE:

Monofilament Polyamide Suture is intended for use in general soft tissue approximation and/or ligation.

INDICATIONS FOR USE:

This Suture is indicated for repairing or joining the soft tissues of wounds or incisions through approximation and for ligation of tubal structures, during ophthalmic, orthopedic, plastic, microsurgeries, and ligament/tendon repairs.

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 & and experienced surgeons, registered nurses & other medical personnel only.

CLINICAL BENEFITS:

- Better healing of the wounds
- Patient Satisfaction
- Better tissue healing
- Low risk of wound complications
- Low rate of tissue reactivity
- Minimum Inflammatory reaction

PERFORMANCE CHARACTERISTICS:

- Good knot security
- Excellent handling
- Better tensile strength stability

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:

- Use of this suture to prolonged contact with the salt solution such as those found in the urinary and biliary tract can result in calculus formation.
- This suture may be inappropriate in patients suffering from conditions that may delay wound healing.

LIMITATIONS:

Monofilament Polyamide sutures should not be used in Cardio-vascular surgery, Urinary tract surgery, Biliary tract surgery, and Gastrointestinal surgery.

OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION:

Sl. No.	Raw Material	Composition	Formulation
Monofilament Polyamide Suture (Black)			
1	Polyamide 6-6.6	≥ 99.5%	PA-6: NH-$(CH_2)_5$CO PA-6.6: $C_{12}H_{22}N_2O_2$
2	Pigment Black 7	≥ 0.5%	Cn
Monofilament Polyamide Suture (Blue)			
1	Polyamide 6-6.6	≥ 99.5%	PA-6: NH-$(CH_2)_5$CO PA-6.6: $C_{12}H_{22}N_2O_2$
2	Copper Phthalocyanine	≥ 0.5%	$C_{32}H_{16}CuN_8$

WARNINGS:

- Do not use tampered or damaged products that happened during the process of transportation and storage.
- Do not use improperly labelled pack.
- Do not open the pack in a non-sterile environment.
- Discard open, unused packs.
- Do not use the expired product.
- Do not expose the pack to chemical disinfectants containing oxidizing agents like Hydrogen Peroxide or other similar chemicals, this may affect the product quality.
- 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 pricks, and infectious diseases.

PRECAUTIONS:

- Read and follow the instruction before performing the surgery.
- Sutures should be handled by trained professionals familiar with surgical procedures & techniques.
- 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 holder.
- As this is a non-absorbable suture, the surgeon in the closure of sites undergoing expansion, stretching or distention, which may require additional support, should consider the use of supplemental non absorbable suture. Under some circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.
- Closely monitoring the wound and suture site for signs of infection or microbial adhesion.
- Improper handling of sutures may lead to unnecessary infections and bleeding.
- Mismanagement of sutures at the surgical site by patients may lead to bleeding, infection, inflammation, wound dehiscence, and/or stitch abscess.

RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:

- Use of Monofilament Polyamide 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:

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

APPLICATION:

Monofilament polyamide 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 to 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 Polyamide 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/09
OTHER REMARK:			REVISION NO.: 03