TI Medical Private Limited

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LOTUS™
A Brand of **TI MEDICAL**

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/07, Issue No.: 02, Rev. No.: 03, Rev. Dt.: 10/05/2026)

LOTUS™
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STERILE ABSORBABLE SURGICAL SUTURES

MONOFILAMENT POLY (GLYCOLIDE CO-CAPROLACTONE) SUTURE

Monofilament Poly (Glycolide Co-Caprolactone) Suture with needle (Violet)

Monofilament Poly (Glycolide Co-Caprolactone) Suture without needle (Violet)

Monofilament Poly (Glycolide Co-Caprolactone) Suture with needle (Undyed)

Monofilament Poly (Glycolide Co-Caprolactone) Suture without needle (Undyed)

BRAND NAME: - MONOLUS®

USP Sizes	Metric Size (Gauge No.)	Needle Profile
6-0	0.7	Taper Point (Round Body), Taper Cutting, Reverse Cutting, Cutting, Blunt, Spatulated, Trocar Point, Diamond Point
5-0	1	
4-0	1.5	
3-0	2	
2-0	3	
1-0	3.5	
1	4	
2	5	
Needle Curvature: 1/2 Circle, 1/4 Circle, 3/8 Circle, 5/8 Circle Straight & J type		

DEVICE DESCRIPTION:

This is a single-use, sterile, monofilament synthetic absorbable suture, composed of a co-polymer, made from Glycolide and caprolactone. The Copolymer Poly (Glycolide Co-Caprolactone) has been found to be non-antigenic, and non-pyrogenic and elicits only a slight tissue reaction during absorption. This suture is available in undyed and violet colour. The violet colour suture is dyed by adding D & C Violet # 2, during polymerization. These sutures are available in a range of gauge sizes and lengths, non needled or attached to stainless steel needles of varying types and sizes. The finished sutures are packed in aluminium foil pouch and this primary package is sterilized by using ETO. These pouches are supplied in 12, 24, or 36 units per mono carton along with Instruction for Use (IFU). It complies with the requirements of the United States Pharmacopoeia for Absorbable Surgical suture, Synthetic", except for diameter. This suture is ntended to use only in a sterile clinical environment.

INTENDED PURPOSE:

Monofilament Poly (Glycolide Co-Caprolactone) Suture device is intended for use in general soft tissue approximation and / or ligation.

INDICATIONS FOR USE:

This device is indicated for use in general soft tissue surgeries/ intradermal layers/ subcuticular repair and ligation where prolonged support is not necessary. They can be used in gynaecological, obstetrical procedures, gastroenterology, urology, and Plastic surgery.

INTENDED PATIENT POPULATION:

This device is 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:

This device is used by general surgeons, gynaecologists / obstetricians, urologists, gastroenterologists, plastic surgeons, and other qualified and trained medical professionals.

CLINICAL BENEFITS:

- Facilitates Wound Healing
- Reduced Tissue Reaction
- Reduced scar formation
- Higher level of patient satisfaction
- Reduced patient discomfort

PERFORMANCE CHARACTERISTICS:

- Flexible and easy to handle
- Good Initial tensile strength
- Predictable absorption
- Smooth passage through tissue

TYPE OF USE:

This device is for single use only. Reuse of the device can lead to dangerous biological contamination causing severe consequences to the patient.

CONTRAINDICATIONS:

- These sutures, being absorbable, should not be used where an extended approximation of tissues under stress is required.
- Undyed suture must not be used for abdominal or fascial tissue closure.

LIMITATIONS:

This suture is not for use in cardiovascular and neurologic tissues and for usage in ophthalmic and microsurgery.

OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION:

Raw Material		Quantity/ Concentration	Formulation
Monofilament Poly(Glycolide Co-Caprolactone) Suture (Violet)			
Suture Material	Poly (Glycolide Co-Caprolactone)	≥ 99.9 %	$[(C_2H_2O_2)x - C_6H_{10}O_2)y]n$ (where x:y = 75:25)
	D&C VIOLET NO. 2	≤ 0.1 %	$C_{21}H_{15}NO_3$
Monofilament Poly(Glycolide Co-Caprolactone) Suture (Undyed)			
Suture Material	Poly (Glycolide Co-Caprolactone)	100 %	$[(C_2H_2O_2)x - C_6H_{10}O_2)y]n$ (where x:y = 75:25)

WARNINGS:

- Do not use this device if package is found open/ damaged.
- Discard open packages and unused sutures.
- Do not reprocess or re-sterilize as it may compromise the structural integrity of the device and / or lead to device failure, which, in turn, may result in patient injury or illness and may also create a risk of contamination of the device and/or cause patient infection or cross-infection.
- The device should be disposed of in accordance with the user's country's disposal regulations and Hospital / Clinic protocol. If not disposed of properly it may lead to environmental pollution, needle pricks, and infectious diseases.
- Do not make the sutures wet or moist during handling, prior to being implanted in tissue.
- Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing these sutures for wound closure as the risk of wound dehiscence may vary with the site of application and the suture material used.
- Surgeons should consider the in-vivo performance when selecting a suture for use in patients. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.
- As with any foreign body, Prolonged contact of this Suture with a salt solution such as those found in urinary and biliary tracts may result in calculus formation.
- As this is an absorbable suture material, the use of supplemental non absorbable sutures should be considered by the surgeon in the closure of sites undergoing expansion, stretching or distention or which may require additional support.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

PRECAUTIONS:

- Skin sutures, which remain in place for more than 7 days may cause localized irritation and should be snipped off or removed as indicated.
- Sub-cuticular sutures should be placed as deeply as possible to minimize the erythema and induration, normally associated with the absorption process.
- Consideration should be taken in the use of absorbable sutures in tissue with poor blood supply as suture extrusion and delayed absorption may occur.
- When handling this or any other suture material, care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
- Suture knots must be properly placed to be secure. Adequate knot security requires the standard surgical techniques of flat and square ties with additional throws as warranted by surgical circumstances and the experience of the surgeon. Use of additional throws may be particularly appropriate when knotting any monofilament suture.
- Avoid prolonged exposure to elevated temperatures.
- Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one third (1/3) to one half (1/2) of the distance from the attachment end to the point. Grasping the needle in the point area could impair the penetration performance and cause fracture of the needle. Grasping the needle at the attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.
- Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in "Sharps" containers.
- Consider the patient's medical history, allergies, and individual factors that may affect the choice and use of sutures.

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RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:

- The suture may act transiently as a foreign body and may cause transient local irritation or Inflammation and discomfort at the wound site.

STERILITY:

Do not re-sterilize as the Monofilament Poly (Glycolide Co-Caprolactone) Suture are sterilized by using Ethylene Oxide.

APPLICATION:

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 pack in your hand. Grasp the upper foil flap in your right hand and lower foil flap in your left hand. Roll thumbs outward separating the flaps and exposing sterile card.

2. Project the sterile card on the sterile table only after peeling apart the peelable foil completely.
3. Hold the card in the gloved left hand securely without bending it as shown in the figure.

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 Poliglecaprone 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/07
OTHER REMARK:			REVISION NO.: 03