# TI Medical Private Limited

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LOTUS™
A Brand of **TI MEDICAL**

## INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/06, Issue No.: 02, Rev. No.: 03, Rev. Dt.: 10/05/2026)

LOTUS™
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**STERILE ABSORBABLE SURGICAL SUTURES**

**MONOFILAMENT POLY(P-DIOXANONE) SUTURE**

**Monofilament Poly(p-dioxanone) Suture with needle (Violet)**

**Monofilament Poly(p-dioxanone) Suture without needle (Violet)**

**BRAND NAME: - MASS®**

| USP Sizes | Metric Size (Gauge No.) | Needle Profile |
|---|---|---|
| 7-0 | 0.5 | Taper Point (Round Body), Taper Cut, Reverse Cutting, Cutting, Blunt, Spatulated, Trocar Point, Diamond Point |
| 6-0 | 0.7 | |
| 5-0 | 1 | |
| 4-0 | 1.5 | |
| 3-0 | 2 | |
| 2-0 | 3 | |
| 1-0 | 3.5 | |
| 1 | 4 | |
| 2 | 5 | |
| **Needle Curvatur**: 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, made from Poly(p-dioxanone). It has been found to be non-antigenic, and non-pyrogenic and elicits only a slight tissue reaction during absorption. These sutures are dyed by adding D & C Violet # 2 during polymerization. They 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). This suture complies with the requirements, established in the United States Pharmacopeia, under the monograph, "Absorbable Surgical Suture, Synthetic," except for diameter. This suture is intended to be used only in a sterile clinical environment.

**INTENDED PURPOSE:**

Monofilament Poly(p-dioxanone) Suture is intended for use in general soft tissue approximation and/or ligation.

**INDICATIONS FOR USE:**

These sutures are indicated for use in general soft tissue approximation, including use in abdominal wall closure, intestinal anastomosis, bronchial anastomosis, ligament & tendon repair (Orthopaedic), gynaecologic, plastic, digestive, colonic surgeries, and ligation. They are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

**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, orthopaedic surgeons, gastrointestinal surgeons, gynaecologists, plastic surgeons, and other qualified & trained medical professionals.

**CLINICAL BENEFITS:**

- Reduces the risk of wound dehiscence.
- Lowers the risk of complications.
- Low incidence of anastomotic problems
- Lesser spread and better quality of the revised scar.

**PERFORMANCE CHARACTERISTICS:**

- Flexible and easy to handle
- High tensile strength
- Long duration of absorbability
- Low reactivity and maintains integrity in the face of infection.

**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:**

This suture, being absorbable should not be used where prolonged (beyond six weeks) approximation of tissues under stress is required or in conjunction with prosthetic devices, for example, heart valves or synthetic grafts.

**LIMITATIONS:**

The safety and effectiveness of this suture have not been established in cardiovascular tissue, microsurgery, and neural tissue.

**OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION:**

| Raw Material | Quantity/ Concentration | Formulation |
|---|---|---|
| Monofilament Poly(p-dioxanone) Suture (Violet) | | |
| Poly(p-dioxanone) | ≥ 99.9 % | $C_4H_6O_3)n$ |
| D&C VIOLET NO. 2 | ≤ 0.1 % | $C_{21}H_{15}NO_3$ |

**WARNINGS:**

- Do not use this device if package is found open/damaged.
- Discard open packages and unused sutures.
- 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 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.
- Do not make the sutures wet or moist during handling, prior to being implanted in tissue.
- Under certain circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon.
- Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing sutures for wound closure, as 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.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

**PRECAUTIONS:**

- Care should be taken to avoid damage during handling. Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders to the strand except when grasping the free end of the suture during an instrument tie.
- The Polydioxanone suture knots must be properly placed to be secure. As with other synthetic sutures, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstances and the experience of the operator.
- Acceptable surgical practice must be followed for the management of infected or contaminated wounds.
- Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be 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.
- 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 in the point area could impair the penetration performance and cause a fracture of the needle. Grasping at the attachment end could cause bending or breakage. Reshaping needles may cause them to lose length and be less resistant to bending and breaking.
- Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard unused needles in "Sharps" containers.
- Consider the patient's medical history, allergies, and individual factors that may affect the choice and use of sutures.

**RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:**

Bacterial pathogens colonizing the suture surface may lead to surgical site infection.

**STERILITY:**

Do not re-sterilize as the Monofilament Poly (p-dioxanone) sutures are sterilized by using Ethylene Oxide.

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**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 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 your 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 Poly(p-dioxanone) Suture | | PANTONE RED<br>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/06 |
| OTHER REMARK: | | | REVISION NO.: 03 |