TI Medical Private Limited

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LOTUS™
A Brand of **TI MEDICAL**

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/53, Issue No.: 02, Rev. No.: 03, Rev. Dt.: 10/05/2026)

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STERILE ABSORBABLE SURGICAL SUTURES

MONOFILAMENT POLY (P-DIOXANONE) BARBED SUTURE

Monofilament Poly (p-dioxanone) barbed suture with needle (Violet)

BRAND NAME: - BARB-E

USP Sizes	Metric Size (Gauge No.)	Needle Profile
4-0	1.5	Taper Point, Reverse Cutting, Taper Cut & Round Body
3-0	2	
2-0	3	
0	3.5	
1	4	
Needle curvature: 1/2 Circle, 3/8 Circle, 5/8 Circle, Straight & Ski		

DEVICE DESCRIPTION:

Monofilament Poly (p-dioxanone) Barbed suture is an absorbable, single use, EtO sterilized, synthetic surgical suture that is composed of a co-polymer made from Poly (p-dioxanone). It has barbs on its surface at an angle of 72° arranged in a spiral pattern and the barbs are arranged in a unidirectional or bidirectional manner. Barbs allow for tissue approximation without the need to tie surgical knots. It will be used in a sterile clinical environment like an operating room. These sutures are supplied in dyed form, attached to various needle types, shape, and length. They are packed in 12/24/36 units per box packing configuration.

INTENDED PURPOSE:

Monofilament Poly (p-dioxanone) Barbed Suture is intended for use in general soft tissue approximation.

INDICATIONS FOR USE:

These sutures are indicated for closure of soft tissues in geriatric surgeries, gynaecological surgeries, myomectomy, laparoscopic surgeries, variety of open surgical procedures, robot assisted surgical procedures, arthroplasty procedures, and vaginal stump closures.

INTENDED PATIENT POPULATION:

Monofilament Poly (p-dioxanone) Barbed Sutures are commonly used in patients above 18 years who require surgical wound closure.

INTENDED USERS:

This device is intended to be used by trained and qualified medical personnel with a vocational qualification certificate.

CLINICAL BENEFITS:

- Less time consumption for skin closure decreasing the rate of infection.
- Low complication rate
- Less bleeding

PERFORMANCE CHARACTERISTICS:

- Eliminate the need to tie knots.
- Secure, fast, and effective incision closure for patients
- Excellent high tensile strength
- Smooth tissue passage
- Excellent pliability
- Reliable bio absorbability

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:

- Monofilament Poly (p-dioxanone) Barbed Sutures are not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required (e.g., fascia).
- They are not to be used in conjunction with or for fixation of prosthetic devices (e.g., heart valves or synthetic grafts) that are non absorbable in nature.
- This device is not to be used in cardiovascular surgeries, neurological surgeries, micro-surgery and ophthalmic surgery.
- The use of these sutures is contraindicated in patients allergic to suture material, poor wound healing, infected wounds, fragile skin, and certain medical conditions such as diabetes mellitus.

LIMITATIONS:

- The usage of this suture is limited to being used in infants and pediatric patient population.
- The safety and effectiveness of this device has not been established for use in fascial closures (including abdominal wall, thoracic and extremity fascial closures) and gastrointestinal anastomoses.

OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION:

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

WARNINGS/ SAFETY INFORMATION:

- Read the instructions before use.
- Check the labelling instructions thoroughly on the package before opening it.
- Do not use this device if the package is found open/damaged.
- Do not store it in any inappropriate storage conditions.
- Usage of expired devices is strictly prohibited.
- Users should be familiar with surgical procedure and techniques involving absorbable sutures before employing this barbed suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.
- Physicians should consider in vivo performance when selecting a suture for use in patients. The use of this device 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 any device with salt solutions such as those found in the urinary or biliary tracts may result in calculus formation. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- Since this is an absorbable material, the use of supplemental non absorbable device should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching, or distention or distention or which may require additional support.
- Discard used needles in "sharps" containers and used/removed sutures in the container meant for "infectious waste". Unused expired pouches should be incinerated. If not disposed properly it may lead to environmental pollution, needle pricks, and infectious diseases.

PRECAUTIONS:

- Avoid off-label use or misuse of the suture.
- Avoid tying knots on the barbed suture as this will damage the barbs and potentially reduce the suture tensile strength and barb effectiveness.
- For the bidirectional forces to be created and for the device to function properly, both sides of these sutures must be engaged in the tissue. Additionally, when completing placement, an additional backstitch or bite of tissue lateral to the end of the incision is required to lock the device in place.
- Avoid contacting these sutures and associated needles with other materials (e.g. surgical gauze, drapes, etc.) in the surgical field to prevent ensnaring on the barbs. If the barbs catch, carefully pull the material in the opposite direction of the needle to disengage it from the barbs.
- Care should be taken to avoid damage when handling. Avoid crushing or crimping the suture material with surgical instruments, such as needle holders and forceps. Do not pull these sutures out of the package with the needles as this can cause the barbs to catch on to one another. Do not attempt to remove memory in the polymer by running fingers down the suture material as this can damage the barbs.
- Infections, erythema, foreign body reactions, transient inflammatory reactions and in rare instances wound dehiscence are typical or foreseeable risks associated with any suture and hence are also potential complications associated with these barbed sutures.
- When using this device subcutaneously, it should be placed as deeply as possible to minimize erythema and induration normally associated with absorption.
- Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.
- Skin sutures which remain in place for more than 7 days may cause localized irritation and should be snipped off or removed as indicated.
- To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. 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 sticks.

RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:

- Suture acts as a foreign body may cause infection and Inflammation/erythema.
- Use of suture on patients who are allergic to suture material may lead to allergic reaction / infection / inflammation / delay in wound healing/ post-surgery infection.

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STERILITY:

Monofilament Poly (p-dioxanone) Barbed Sutures are sterilized by Ethylene Oxide. Do not re-sterilize.

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.
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.

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 PDO Barbed 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/53
OTHER REMARK:			REVISION NO.: 03