TI Medical Private Limited

Khasra No. 1051/1&2, Twin Industrial Estate, Selaqui,
Dehradun 248197, Uttarakhand, INDIA.

LOTUS™
A Brand of **TI MEDICAL**

INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/04, Issue No.: 02, Rev. No.: 03, Rev. Dt.: 10/05/2026)

LOTUS™
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STERILE ABSORBABLE SURGICAL SUTURES

FAST ABSORBABLE BRAIDED COATED POLYGLACTIN 910 SUTURE

Fast Absorbable Braided Coated Polyglactin 910 Suture with needle (Undyed)

Fast Absorbable Braided Coated Polyglactin 910 Suture without needle (Undyed)

BRAND NAME: - SOLUS SWIFT 910®

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:

Fast Absorbable Braided Coated Polyglactin 910 Suture is a single-use, synthetic, absorbable, sterile, surgical suture, composed of the Polyglactin 910, made from co-polymer 90% Glycolide and 10% Lactide. This suture is coated with a mixture, composed of equal parts of the co-polymer Polyglactin 370 (Glycolide 30% and Lactide 70%), and Calcium Stearate. The characteristic of rapid loss of strength is achieved by use of a polymer material with a lower molecular weight than Braided & Coated polyglactin 910 sutures. These sutures are undyed. 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 aluminum 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". This suture is intended to be used only in a sterile clinical environment.

INTENDED PURPOSE:

Fast Absorbable Braided Coated Polyglactin 910 suture is intended for use in soft tissue approximation where only short-term wound support is required and where the rapid absorption of the suture would be beneficial.

INDICATIONS FOR USE:

Fast Absorbable Braided Coated Polyglactin 910 sutures are indicated for use in soft tissue approximation of skin, oral mucosa, pediatric surgery, episiotomies, circumcision.

INTENDED PATIENT POPULATION:

This device is intended for the closure of wounds or surgical incisions on the skin or any other body tissues in patients of varying age groups in line with the intended use, indication, and contraindication.

INTENDED USERS:

Fast Absorbable Braided Coated Polyglactin 910 sutures are used by general surgeons, obstetricians/gynecologists, urologists, pediatricians, and other qualified and trained medical professionals.

CLINICAL BENEFITS:

- Reduced tissue reaction
- Excellent handling and knot security
- Reduced scar formation
- Reduced patient discomfort
- Facilitates wound Healing

PERFORMANCE CHARACTERISTICS:

- Flexible and easy to handle
- Good knot security
- High tensile strength
- Predictable absorption rate
- Minimal tissue reaction

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:

Fast Absorbable Braided Coated Polyglactin 910 sutures due to the rapid loss of tensile strength, this suture should not be used where an extended approximation of tissues under stress is required or when wound support beyond 7 days is required.

LIMITATIONS:

Fast Absorbable Braided Coated Polyglactin 910 sutures are not intended for use in ligation, ophthalmic, cardiovascular, or neurological procedures.

OVERALL QUALITATIVE AND QUANTITATIVE INFORMATION:

Raw Material		Quantity/ Concentration	Formulation
Suture Material	Poly (glycolide-co-l-lactide)/ (Glacomer 91)	≥ 95.0 %	[$(C_2H_2O_2)$ x-($C_3H_4O_2$)y]n (where x:y = 9:1)
Coating Material	Glacomer 37	≤ 5 %	$C_6H_{10}O_2$)n
	Calcium stearate		$C_{36}H_{70}CaO_4$

WARNINGS:

- Do not use this device if package is found open/damaged.
- Discard open packages and unused sutures.
- The device should be disposed of as per the user country 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.
- Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing suture 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. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions that may delay wound healing.
- As with any foreign body, prolonged contact of any suture 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. 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 which may require additional support.

PRECAUTIONS:

- Care should be taken to avoid damage during Skin sutures that remain in place for more than 7 days may cause localized irritation and should be snipped off or removed as indicated.
- Consideration should be taken in the use of absorbable suture in tissue with poor blood supply as suture extrusion and delayed absorption may occur. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration, normally associated with the absorption process.
- When handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
- As with any suture material, adequate knot security requires the accepted surgical techniques of flat and square ties, with additional throws as warranted by surgical circumstances and the experience of the surgeon.
- 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 butt or 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 unused needles in "Sharps" containers.
- Avoid excessive tension when tying the sutures, as it may lead to tissue ischemia or damage. Use the appropriate tension for the specific surgical procedure and the patient's condition.
- Consider the patient's medical history, allergies, and individual factors that may affect the choice and use of sutures.

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

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STERILITY:

Do not re-sterilize as the Fast Braided Coated Polyglactin 910 sutures 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 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

EU REP **OBELIS S.A**
Bd. Général Wahis, 53
1030 Brussels, Belgium

TI Medical Private Limited
Khasra No. 1051/1&2, Twin Industrial Estate,
Selaqui, Dehradun 248197, Uttarakhand, INDIA.
Customer Care Number (24x7): +91 135 2698661
Email: info@timedical.murugappa.com
Website: www.timedical.com

Mfg. Lic. No.: MFG/MD/2024/000202

MANUFACTURER NAME:	TI Medical Private Limited		USE COLOR:
PRODUCT:	IFU for Polyglactin 910 (Fast) 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/04
OTHER REMARK:			REVISION NO.: 03