

# TI Medical Private Limited

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



A Brand of TI MEDICAL

## INSTRUCTIONS FOR USE

(Doc. No.: TI/IFU/08, Issue No.: 02, Rev. No.: 03, Rev. Dt.: 10/05/2026)



### STERILE NON-ABSORBABLE SURGICAL SUTURES BRAIDED COATED SILK SUTURE

**Braided coated Silk suture with needle (Black)**  
**Braided coated Silk suture without needle (Black)**  
**BRAND NAME: - SILKUS®**

| USP Sizes – Suture with Needle                           | Metric Size (Gauge No.) | Needle Profile                                                                                                          |
|----------------------------------------------------------|-------------------------|-------------------------------------------------------------------------------------------------------------------------|
| 9-0                                                      | 0.3                     | Lancet Microprint, Conventional cutting, Reverse cutting, round-bodied, Taper point, Micro point spatulated, Taper cut. |
| 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: 1/4 circle, 1/2 circle, and 3/8 circle |                         |                                                                                                                         |
| USP Sizes–Suture without Needle                          | Metric Size (Gauge No.) | Needle Profile                                                                                                          |
| 5-0                                                      | 1                       | Not Applicable                                                                                                          |
| 4-0                                                      | 1.5                     |                                                                                                                         |
| 3-0                                                      | 2                       |                                                                                                                         |
| 2-0                                                      | 3                       |                                                                                                                         |
| 0                                                        | 3.5                     |                                                                                                                         |
| 1                                                        | 4                       |                                                                                                                         |
| 2                                                        | 5                       |                                                                                                                         |
| 3&4                                                      | 6                       |                                                                                                                         |

**DEVICE DESCRIPTION:**  
This is a non-absorbable, sterile, surgical suture, composed of an organic protein, called fibroin. This protein is derived from the domesticated species Bombyx mori of the family Bombycidae. This is coated with silicone which helps in passage through the

tissue without irritation, limits absorption, and increases ductility. This is available in black (Hematin HCK dye) and available in a range of gauge sizes, lengths, and non-needled and attached to stainless steel needles of varying types and sizes. The finished sutures are packed in a medical-grade paper and polyfilm 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). Then such multiple mono cartons are packed in the master carton. These sutures comply with the requirements of the United States Pharmacopoeia for "Non-Absorbable Surgical Suture". This suture is intended to be used only in a sterile clinical environment like the operating room.

**INTENDED PURPOSE:**  
Braided coated silk suture is intended for use in general soft tissue approximation and/or ligation.

**INDICATIONS FOR USE:**  
This is indicated for repairing or joining the soft tissues of wounds or incisions through approximation and for ligation of tubal structures, during gynecological, gastrointestinal tract surgery, ophthalmic surgery, and orthopedic procedures.

**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 intended use, indication and contraindication.

**INTENDED USERS:**  
Used by trained & experienced orthopedics, gynecologists, endoscopic surgeons, registered nurses & other medical personnel only.

**CLINICAL BENEFITS:**

- Better wound healing
- Reduced patient discomfort & pain
- Higher patient satisfaction with no visible scars
- Minimum tissue reaction

**PERFORMANCE CHARACTERISTICS:**

- Excellent tensile strength
- Excellent handling
- Good knot security

**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.

**LIMITATIONS:**  
There is no evidence of limitations.

| Raw Material              | Composition (Wt.%) | Formulation |
|---------------------------|--------------------|-------------|
| Silk fibroin              | 95-98              | –           |
| Hematin HCK Dye           | <1.0               | –           |
| Nu-Sil MED-2174 Elastomer | 2.0- 4-0           | –           |

**WARNINGS:**

- Do not use tampered or improperly labelled packages.
- Do not use the damaged suture, that happened during the process of transportation and/or storage.
- Do not open the pack in a non-sterile environment.
- Do not use the suture beyond the specified expiry date.
- Due to the gradual loss of tensile strength which may occur over a prolonged period in vivo silk suture should not be used where permanent retention of tensile strength is required.
- 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 prick injuries, and any infectious diseases.

**PRECAUTIONS:**

- Ensure the package is intact before opening.
- Read the labelling instructions thoroughly on the package before opening it.
- Read and follow the instructions before the procedure.
- Sutures should be handled only by trained and experienced medical professionals.
- Only trained and experienced surgeons must perform the approximation and/or ligation procedure.
- 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 holders.
- Avoid off-label use and misuse of the suture.
- Allergy tests must be recommended for patients of unknown sensitivities.
- Silk fibroin
- Closely monitor and manage the wound and suture sites to avoid infection and inflammation, post-surgery.
- Suture should be removed appropriately, after the wound is healed, to prevent any complications.
- 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.
- Early removal of suture post-surgery (dental, oral, or other topical areas) may lead to bleeding, infection, and/or wound dehiscence.

**RESIDUAL RISKS/ UNDESIRABLE SIDE EFFECTS:**

- Use of silk sutures on patients who have an unknown clinical history of allergy to fibroin / silk 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, and 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 Ethylene Oxide. Do not re-sterilize the suture.

**APPLICATION:**  
Braided-coated silk 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.



2. Grasp transparent poly film with the thumb and index finger of the left hand, gripping the pack between knuckles thus exposing it to a 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 the 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 icon                     | Manufacturer                                                        |
| EU REP                                | Authorized Representative in the European Community/ European Union |
| Date of Manufacture icon              | Date of Manufacture                                                 |
| STERILE EO                            | Sterilized using Ethylene Oxide                                     |
| Do not re-use icon                    | Do not re-use                                                       |
| Do not re-sterilize icon              | Do not re-sterilize                                                 |
| LOT                                   | Batch code                                                          |
| Use-by Date icon                      | Use-by Date                                                         |
| REF                                   | Catalogue Number                                                    |
| Caution icon                          | Caution                                                             |
| Do not use if package is damaged icon | Do not use if package is damaged and consult instructions for use   |
| Keep away from Sunlight icon          | Keep away from Sunlight                                             |
| UDI                                   | Unique Device Identifier                                            |
| Upper limit of temperature icon       | Upper limit of temperature                                          |

|                           |                                                                                        |
|---------------------------|----------------------------------------------------------------------------------------|
| STERILE EO                | Single Sterile Barrier System used in combination with Sterilized using ethylene oxide |
| Protective packaging icon | Single Sterile Barrier System with protective packaging outside                        |
| MD                        | Medical device                                                                         |
| Consult instructions icon | Consult instructions for use or consult electronic instructions for use                |
| Importer icon             | Importer                                                                               |
| Distributor icon          | Distributor                                                                            |
| Keep dry icon             | Keep dry                                                                               |

CE 2975

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

MANUFACTURER NAME: TI Medical Private Limited

PRODUCT: IFU for Silk Suture

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/08

OTHER REMARK: REVISION NO.: 03

USE COLOR:

PANTONE RED

PANTONE BLACK