

SURGICAL SUTURE

1. PRODUCT DESCRIPTION:

Suture is a non-absorbable, sterile, Silk sutures are entwined thread from silk worm larva. Silk sutures are coated and braided non-absorbable sutures. Silk sutures are specially treated with silicone to give strength and smoothen the surface which provides easy passage through tissues.

Nylon is a synthetic, nonabsorbable, monofilament made of a chemically inert polyamide thermoplastic.

Sutures are available in range of gauge sizes and lengths, non-needed or attached to stainless steel needles of varying types, sizes and shapes. The suture complies with United States Pharmacopoeia (U.S.P) and European Pharmacopoeia (E.P)

2. INTENDED USE:

Suture is indicated for use in general soft tissue approximation and/or ligation including cardiovascular surgery, neurosurgery and ophthalmic procedures including microsurgery.

3. PRODUCT SPECIFICATIONS:

Product Size	Diameter (mm)
1 (Metric 4)	0.400-0.499
2 (Metric 5)	0.500-0.599
3 (Metric 6)	0.600-0.699
1-0 (Metric 3.5)	0.350-0.399
2-0 (Metric 3)	0.300-0.399
3-0 (Metric 2)	0.200-0.299
4-0 (Metric 1.5)	0.150-0.199

(a)Type of Surgical Suture: Pearsilk / Silkfil

Product Size	Diameter (mm)
20 (USP 1)	0.500-0.599
30 (USP 2/0)	0.400-0.499
40 (USP 3/0)	0.300-0.399
60 (USP 3)	0.200-0.299
80 (USP 4/0)	0.150-0.199
100 (USP 5/0)	0.100-0.120

(b)Type of Surgical Suture: Barblin / Linefil

4. WARNING:

- Surgeons should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Silk suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.
- In surgery of the urinary or biliary tract, care should be taken to avoid prolonged contact of this or any other suture with salt solution, to prevent calculus formation

- For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury or illness
- Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another
- Contamination of the device may lead to injury and illness of the patient.

5. PRECAUTIONS:

- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- In handling this suture material, care should be taken to avoid damaging the surface of the material with surgical instruments as this could lead to fracture of the material in use.
- Avoid crushing or crimping damage due to surgical instruments such as forceps or needle holders.
- Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon.
- The use of addition throws is particularly appropriate when knotting Silk suture.
- When handling this or any other suture, 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.
- Care should be taken to avoid damage while 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 fracture of the needle.
- Grasping at the butt or attachment end could cause bending or breakage.
- Reshaping the needles may cause them to lose strength and make less resistant to bending and breaking.
- Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard the needles after use.

6. SIDE EFFECT & CONTRAINDICATIONS:

The use of this suture is contraindicated in patients with known sensitivities or allergies to Silk and silicone. Due to gradual loss of tensile strength which may occur over prolonged periods in vivo, silk sutures should not be used where permanent retention of tensile strength is required.

7. MAIN PERFORMANCE INDICES:

Appearance: Smooth. Sterility: The Product is sterilized by EO.

8. INDICATIONS:

Suture is indicated for use in general soft tissue approximation and/or ligation in all surgical procedures excluding use in cardiovascular, ophthalmic and neurological procedures.

9. DIRECTION FOR USE:

A. TECHNIQUE FOR OPENING THE OVER WRAP

1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.
2. Then with the help of sterilized gloved hand or sterilized forceps pull the paper folder till the needle is visible. For non-needed suture, pull out the entire paper folder from the pack, open the folder and retrieve the suture.
3. Again with the help of sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.

Note: For non-needed suture, pull out the entire folder from the pack, with the sterilized forceps, open the folder and retrieve the suture

B. TECHNIQUE FOR OPENING THE PEEL OPEN POUCHES CONTAINING PETCRYL:

1. Hold the pack in an upright manner and see the peel logo.
2. Hold the protruded portions of the aluminum foils and peel open to see the needle fixed on the paper folder.
3. With the help of sterilized forceps pull the needle to remove the suture from the folder.













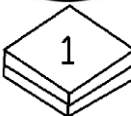
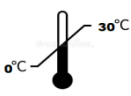

10. STORAGE:

Recommended storage condition 10°C-35°C, away from moisture and direct heat. Do not use after expiry date.

11. DISPOSAL:

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted hospital medical practice, and applicable local European and international disposal regulation.

Explanation of symbols as per MDD 93/42/EEC, ISO 15223-1:2021:

Sr. No.	Symbol	Meaning
1.		Symbol for “Reference number”
2.		Symbol for “Batch code”
3.		Symbol for “Date of manufacture”
4.		Symbol for “Use Before”
5.		Symbol for “Do not reuse”
6.		Symbol for “Manufacturer”
7.		Symbol for “Caution”
8.		Symbol for “Do Not use if package is damaged”
9.		Symbol for “Keep away from sunlight”
10.		Symbol for “Keep Dry”
11.		Symbol for Consult Instruction for Use
12.		Symbol for Do not Re-sterilize
13.		Symbol for Quantity
14.		Store at 0-30 °C
15.		Non Pyrogenic

Warranty / Liability:

Although this product has been manufactured under carefully controlled quality conditions, Seguro Life Science has no control over the conditions under which this product is used. Seguro Life Science therefore disclaims all warranties both express and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Seguro Life Science shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Seguro Life Science to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular term held to be invalid.

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