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STERILE NON-ABSORBABLE SURGICAL SUTURE

GDT SILK SUTURE

INSTRUCTIONS FOR USE

DESCRIPTION

GDT Silk suture 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. Silk Sutures are processed to remove the natural waxes and gums. Braided Silk is coated with silicone and is available dyed in black with Logwood Black extract. Available in a broad range of sutures sizes and lengths, attached to hardened stainless steel needles of varying types and sizes.
The needles are attached permanently to the suture. Entire detail of the product range is contained in the catalogue.

INDICATIONS

The 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.

SELECTION

Sutures should be selected and implanted depending on the patient's condition, surgical experience, surgical technique and wound size.

PERFORMANCE

GDT Silk suture elicits an initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. While Silk Sutures are not absorbed, progressive degradation of the proteinaceous Silk fiber in vivo may result in gradual loss of the entire tensile strength over time.

ADVERSE REACTIONS

Adverse reactions associated with the use of this device include: allergic response in patients known to be sensitive to Silk, initial inflammatory tissue reaction and transient local irritation at the wound site. Like all foreign bodies Silk suture may potentiate an existing infection.

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.

WARNINGS

a. Surgeons should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Silk sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

b. 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 devise failure which, in turn, may result in patient injury and illness.

c. 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.

d. Contamination of the device may lead to injury or illness of the patient.

PRECAUTIONS

a) Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

b) 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.

c) Avoid crushing or crimping damage due to surgical instruments such as forceps or needle holders.

d) 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.

e) The use of addition throws is particularly appropriate when knotting Monofilament polyamide sutures.

f) Care should be taken to avoid damage while handling surgical needles. Grasp the needle in an area of one-third (1/3) to one-half (1/2) of the distance from the attachment end to the sharp point.

g) Grasping in the sharp point area could impair the penetration performance and cause fracture of the needle.

h) Grasping at the butt or attachment end could cause bending or breakage.

i) Reshaping the needles may cause them to lose strength and make less resistant to bending and breaking.

j) Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury.

k) Discard the used needles appropriately.

l) Do not expose the pack to chemical disinfectants containing oxidizing agents like Hydrogen Peroxide or other similar chemicals which may affect the product quality.

STERILITY

Suture is supplied gamma-sterilized. The sterility of undamaged, unopened packs is guaranteed. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.

STORAGE

Recommended storage condition 5°C-25°C, away from moisture and direct heat. Do not use after the expiry date.

DISPOSAL

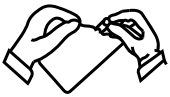
Discard used sutures and needles contaminated with blood in the container meant for "infectious waste". Unused expired pouches should be incinerated.

INSTRUCTIONS FOR USE

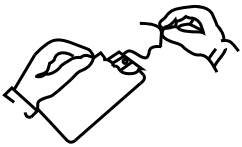
A. Technique for opening the over wrap

1. The scrub nurse should hold the sterile pack in their left hand with the color-coded top facing her. The notch will be located at the top right.

2. Holding the pack with the left hand, tear the foil with the right hand thumb, and fore finger at the notch position. Pull out the folder containing the needled suture with sterilized forceps.



3. Again with the help of a sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.



B. Technique for opening the peel open pouches containing sutures.

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.

PACKAGING

3/0 USP (metric EP 2.0)	**Ref: SK30**
4/0 USP (metric EP 1.5)	**Ref: SK40**
5/0 USP (metric EP 1.0)	**Ref: SK50**

SYMBOLS

	Consult instructions for use		Do not resterilize
	Caution, consult accompanying documents		Do not re-use/ for single use only
	Temperature limit		Manufacturer
	Keep away from sunlight	REF	Catalogue number
	Keep dry	LOT	Batch code
STERILE R	Sterilised using irradiation		Use by
	Do not use if package is damage		Date of Manufacture

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material.
The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.