

INSTRUCTIONS FOR USE- STERILE NON-ABSORBABLE BLACK BRAIDED SILK SURGICAL SUTURE

SUTURA®

STERILE NON-ABSORBABLE SURGICAL SUTURE U.S.P BLACK BRAIDED SILK

DESCRIPTION

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, usfda approval number §73.1410. Silk sutures are available in range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types, sizes and shapes. The needles are attached permanently to the suture. Entire details of the product range are available in the catalogue.

Sutura® complies with the requirements established by the United States Pharmacopoeia (U.S.P) for “Non-absorbable surgical suture” for “Sterile Braided Silk Strand”.

INTENDED USE

Sutura® 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 CRITERIA

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

PERFORMANCE

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 suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.
- b. 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.
- c. 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.
- d. 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.
- e. Contamination of the device may lead to injury and 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 Silk suture.
- 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

INSTRUCTIONS FOR USE- STERILE NON-ABSORBABLE BLACK BRAIDED SILK SURGICAL SUTURE

Sutura® sutures are sterilized by ethylene oxide. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened unused sutures.

STORAGE

Recommended storage condition is to store at temperature between 10°C-35°C, away from moisture and direct heat. Do not use after expiry date.

DISPOSAL

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

INSTRUCTION FOR USE

A. TECHNIQUE FOR OPENING THE TEAR OPEN PACK:

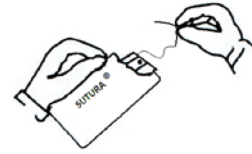
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



2. 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. Tear the folder till the needle is visible. Then with the help of sterilized forceps, withdraw the needled suture. For non-needled suture, pull out the entire folder from the pack, with the sterilized forceps, open the folder and retrieve the suture.

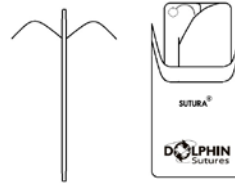


B. TECHNIQUE FOR OPENING THE PEEL OPEN PACK

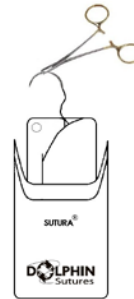
1. Hold the pack in an upright manner and see the peel logo.



2. Hold the protruded portions of the aluminum foils and peel open till the needle fixed on the paper folder is visible.



3. With the help of sterilized forceps pull out the needled suture from the folder by grasping the needle, at one third and one half distance away from the swaged end.



Futura Surgicare Pvt Ltd

86/C2, 3rd Main, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore, Karnataka, India, Pin – 560 022

E-mail: sales@dolphinsutures.com

Web Site: www.dolphinsutures.com



Obelis s.a

Bd. Général Wahis 53

1030 Brussels, BELGIUM

Tel: + (32) 2. 732.59.54

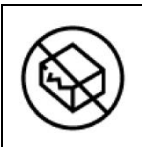
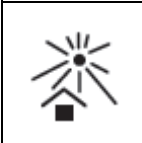

Fax: +(32) 2.732.60.03

E-Mail : mail@obelis.net

SYMBOLS USED ON THE LABELS

	Do not re-use		Batch number
	Date of manufacture		CE logo
	Date of expiry		Registered
	Sterilized by Ethylene Oxide		EU REPRESENTATIVE
	Temperature limitation		Do not re-sterilize

INSTRUCTIONS FOR USE- STERILE NON-ABSORBABLE BLACK BRAIDED SILK SURGICAL SUTURE

	Do not use if package is damaged or opened		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture