C687-135/QOS

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. The suture complies with United States Pharmacopoeia (U.S.P) and European Pharmacopoeia (E.P).

Suture diameter in mm	U.S.P Size	E.P SIZE (Metric)
0.900 – 1.000	7	9
0.800 – 0.899	6	8
0.700 – 0.799	5	7
0.600 – 0.699	3 & 4	6
0.500 – 0.599	2	5
0.400 – 0.499	1	4
0.350 – 0.399	0	3.5
0.300 – 0.339	2-0	3
0.200 – 0.249	3-0	2
0.150 – 0.199	4-0	1.5
0.100 – 0.149	5-0	1
0.070 – 0.099	6-0	0.7

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 loose 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
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 or sterilized gloved hand.

3. Then with the help of sterilized gloved hand or sterilized forceps pull the needle which is visible. For non-needled suture, pull out the entire paper folder from the pack, 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.

SYMBOLS USED ON THE LABELS

	Do not re-use	LOT	Batch number
	Date of manufacture	CE 2460	CE Mark with Notified Body Number
	Date of expiry		Registered
STERILE EO	Sterilized by Ethylene Oxide	EC REP	EU REPRESENTATIVE
	Temperature limitation	STERILE	Do not re-sterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture

Futura Surgicare Pvt Ltd
96/C2, 3rd Main, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore, Karnataka, India, Pin – 560 022
E-mail: sales@dolphinsutures.com
Web Site: www.dolphinsutures.com

EC REP
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

CE 2460

Doc No: IFU/BBS Issue date: 1.8.2011 Rev 11
Rev date: 21.10.2020