

Silkin™

Non-absorbable Natural Multifilament, Silk (Black)

DESCRIPTION

Silkin (Silk) is a non-absorbable sterile surgical suture, composed of an organic protein, fibroin. This protein is derived from the domesticated species *Bombyx mori* (b. More) of the family Bombycidae. Silkin sutures are processed to remove the natural waxes and gums. Silkin suture is dyed black and coated with a special wax mixture.

INDICATIONS

Silkin suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

ACTIONS

Silkin suture elicits an acute inflammatory reaction in tissue, which is followed by a 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 all of the suture's tensile strength over time.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to silk.

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, silk should not be used where permanent retention of tensile strength is required.

WARNINGS

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

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

PRECAUTIONS

In handling this or any other suture material, 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.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Discard used needles in waste bin.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, gradual loss of all tensile strength over time, allergic response in patients that are known to be sensitive to silk, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, acute inflammatory tissue reaction and transitory local irritation at the wound site.


STORAGE

Store this suture below 25° C.

Keep away from moisture and direct heat.

Do not use if the date is expired.


SYMBOLS USED ON LABELLING

 = Do not reuse

 = Expiry date

 = Sterilized by Ethylene Oxide

 = Batch Number

 = See instructions for use

 = Manufacturing date

IP = Indicative price

COMMERCIAL PACK

Each box contains 12 packs of Silk (Black) suture.

Manufactured by



Incepta Hygiene & Hospicare Ltd

Dhamrai, Dhaka, Bangladesh

V.N.01