

INSTRUCTIONS FOR USE

Silk Suture

Non-absorbable -Braided - Sterile

Description:

Silk suture is a nonabsorbable sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species *Bombyx mori* (B. mori) of the family Bombycidae. Silk sutures are processed to remove the natural waxes and gums. Silk suture is dyed black and coated with a special wax mixture. Silk suture is also available in its natural color. The virgin silk suture is available in which the sericin gum is not removed and serves to hold the filaments together. Silk suture meets requirements established by the United States Pharmacopoeia (U.S.P.) for non-absorbable surgical suture.

Indications:

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

Actions

Silk Suture elicits an acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. While Silk suture is not absorbed, progressive degradation of the proteinaceous silk fibre 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 suture 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 silk suture for wound closure, as risk of wound dehiscence may vary with the sites of application and the suture material used. 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.

Do not re-sterilize/reuse. Discard opened packages and unused sutures.

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 warranted by surgical circumstance and the experience of the surgeon.

To avoid damaging needle points and swaged 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. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

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. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

How supplied:

Silk Sutures are available as sterile braided strands from USP8-8/0, in a variety of lengths, without needled or affixed to various needle types in one, two or three dozens per box.

Storage Conditions:

It is recommended that Silk Sutures are stored below 25°C kept away from direct heat and moisture. Carefully observe the expiry date.

Manufacturer:

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Explanation of the Symbols on Packaging:

	Do not re-use
	Gamma irradiation Ethylene Oxide irradiation
	Consult instructions for use
	Do not use if package is damaged
	Expiration Date
	Manufactured Date
	Catalogue Number
	Batch number
	Keep away from sunlight
	Keep dry
	Temperature Limitation
	Fragile: Handle with care
	CE Mark and identification number of Notified Body. Product conforms to the essential requirements of the medical device directive 93/42/EEC

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