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Theragenics

SILK NONABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION

Silk 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 surgical suture is braided and available undyed or dyed black (logwood extract). Braided sutures are coated with silicone (unless otherwise noted). Silk surgical suture meet all requirements established by the United States Pharmacopeia (U.S.P.) for nonabsorbable surgical sutures.

INDICATIONS

Silk surgical sutures are indicated for use in general soft tissue approximation/ligation.

ACTIONS

Silk surgical sutures elicit a minimal inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. While silk surgical suture is not absorbed, progressive degradation of the proteinaceous silk fiber in vivo results in gradual loss 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.

Because of the gradual loss of tensile strength that may occur over prolonged periods in vivo, silk surgical sutures should not be used where permanent retention of tensile strength is required.

The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions, which may delay wound healing.

WARNINGS

Do not use if package is open or damaged or if the expiration date has been exceeded. Discard open, unused suture.

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Do not resterilize; resterilization may alter the physical properties of the suture, which will result in adverse patient reaction.

User should exercise caution when handling surgical needle to avoid inadvertent needle sticks. Discard used needles in a "sharps" container.

Store in a cool dry environment.

As with any foreign body, prolonged contact of this or any other sutures with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, silk suture may act transiently as a foreign body.

Users should be familiar with surgical procedures and techniques involving silk suture before using silk suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical protocol should be followed for the management of contaminated or infected wounds.

PRECAUTIONS

In handling this or any other surgical suture, 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.

Adequate knot security requires the accepted surgical technique of flat, square ties with additional throws as warranted by surgical circumstances and the experience of the surgeon.

Skin sutures, which remain in place longer than 7 days, may cause localized irritation and should be snipped off or removed.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation, suture extrusion, calculi formation in urinary and biliary tracts when

prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site.

Discuss the potential for allergic reaction in patients that are known to be sensitive to silk.

HOW SUPPLIED

Silk sutures are available in various USP sizes. Silk is supplied in a wide range of lengths affixed to a diverse assortment of needle types.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

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SYMBOL DEFINITIONS

-  Lot Number
-  Expiration Date
-  Do Not Reuse
-  Do Not Resterilize
-  See Instructions For Use
-  Sterilized By Ethylene Oxide
-  Keep away from sunlight and heat
-  Do not use if package is damaged
-  Keep dry
-  Manufacturer

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