

Sofsilk™

Coated Braided Silk

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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Sofsilk™ braided silk sutures are nonabsorbable, sterile, non-mutagenic surgical sutures composed of natural proteinaceous silk fibers called fibroin. This protein is derived from the domesticated silkworm species *Bombyx mori* of the family *bombycidae*. The silk fibers are treated to remove the naturally-occurring sericin gum and braided to produce Sofsilk™ surgical silk sutures. The braided sutures are available coated uniformly with either silicone or a special wax mixture to reduce capillarity and to increase surface lubricity which enhances handling characteristics, ease of passage through tissue, and knot run-down properties. Sofsilk™ sutures are available white or colored black with Logwood extract.

Sofsilk™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for nonabsorbable surgical sutures, except for size 8-0, which DIFFERS FROM USP MAXIMUM DIAMETER REQUIREMENTS BY UP TO 0.005 mm.

INDICATIONS

Sofsilk™ sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery, and neurological surgery.

ACTIONS

Sofsilk™ sutures elicit a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While Sofsilk™ sutures are not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result 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.

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

WARNINGS

As with any foreign body, prolonged contact of any suture with salt solutions may result in calculus formation.

Do not resterilize. Sterile unless packaging has been opened or damaged. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

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

Acceptable surgical practice must be followed with respect to drainage and closure of contaminated or infected 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.

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

ADVERSE REACTIONS

Adverse effects, which may be associated with the use of this product, include: wound dehiscence, gradual loss of tensile strength over time, allergic response in patients with known sensitivities to silk, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

HOW SUPPLIED

Sofsilk™ sutures are available white or colored black with Logwood extract and uniformly coated with silicone or a special wax mixture, in sizes 5 (7 Metric) through 8-0 (0.4 Metric).

The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needled or affixed to needles using both permanent and removable needle attachment techniques. The suture are available in quantities of one, two and three dozen.

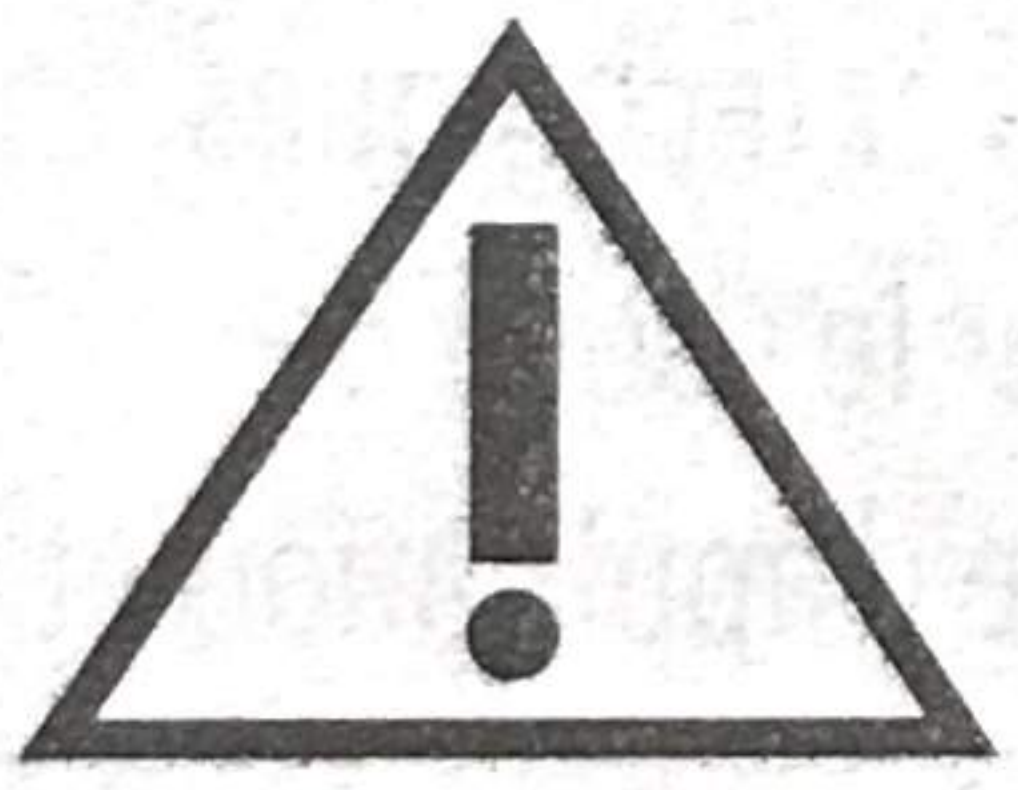


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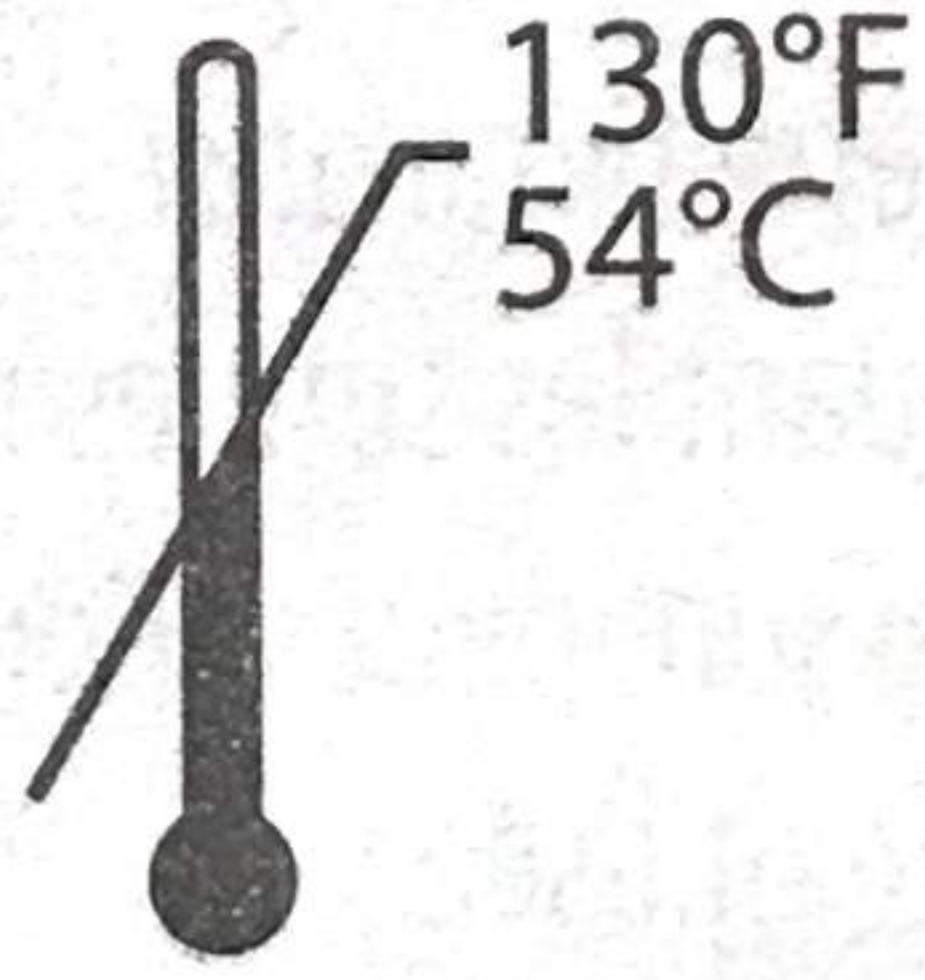
STERILE R

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**Rx
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