COVIDIEN™

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) though 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.

Do not use if package is opened or damaged.

Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage.

Bei geöffneter oder beschädigter Verpackung nicht verwenden.

Non utilizzare se la confezione è aperta o danneggiata.

No usar el dispositivo si la envoltura está abierta o dañada.

Não utilizar se a embalagem estiver aberta ou danificada.

Niet gebruiken als de verpakking beschadigd of geopend is.

Får ej användas om förpackningen är öppnad eller skadad.

Må ikke anvendes, hvis emballagen er åbnet eller beskadiget.

Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut.

Μη χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά.

Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone.

Ambalaj açılmış ya da zarar görmüşse kullanmayın.

Не используйте изделие, если упаковка вскрыта или повреждена.

Pokud je balení otevřené nebo poškozené, produkt nepoužívejte.

Tilos felhasználni, ha a csomagolás kinyílt vagy megsérült.

Nepoužívajte, ak je obal otvorený alebo poškodený.

Skal ikke brukes hvis emballasjen er åpnet eller skadet.

Ne uporabljajte, če je embalaža odprta ali poškodovana.

如果包装已打开或破损，请勿使用。

如果包裝已開啟或損毀，則請勿使用。

포장이 개봉되어 있거나 손상된 경우에는 사용하지 마십시오.

Не използвайте, ако опаковката е отворена или повредена.

A nu se utiliza în cazul în care ambalajul este deschis sau deteriorat.

Ärge kasutage, kui pakend on avatud või kahjustatud.

Nelietot, ja iepakojums ir atvērts vai bojāts.

Ne koristite ako je pakiranje otvoreno ili oštećeno.

Ne koristiti ako je pakovanje otvoreno ili oštećeno.

Nenaudokite, jei pakuotė atidaryta arba pažeista.

Syneture™

STERILE R STERILE EO Rx ONLY

Caution, consult accompanying documents

130°F 54°C Upper temperature limit

CE 0123

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