Sofsilk™
Coated Braided Silk

1300379

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 fibrin. This protein is derived from the domesticated silkworm species Bombyx mori of the family bombyciidae. The silk fibers are treated to remove the naturally-occurring sericin gum and bleached 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.

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, calculus 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 5-0 (7 Metric) through 8-0 (0.4 Metric). The sutures are supplied sterile, in pre-cut lengths and latching reels, non-needle or affixed to needles using both permanent and removable needle attachment techniques. The suture are available in quantities of one, two and three dozen.

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.
Do not use if package is opened or damaged.
Ne pas utiliser en cas d’ouverture ou d’endommagement de l’emballage.
Gei geöffnete oder beschädigte Verpackung nicht verwenden.
Non utilizzare se la confezione è aperta o danneggiata.
No user 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.
For ej använda om förpackningen är öppnad eller skadad.
Må ikke anvendes, hvis emballagen er åbnet eller beskadiget.
Если упаковка вскрыта, не использовать.
Εάν ανοιχτή η χαρτοφυλάκιο, δεν χρησιμοποιείται.
Мяг не используется, если упаковка открыта или повреждена.
Pokud je balení otevřené nebo poškozené, produkt nepouživejte.
Тіло фіксувати, а якщо словник або шовки. Не використовуйте, якщо упаковка відкрита або пошкоджена.
Пакуво не користуйте, якщо упаковка відкрита або пошкоджена.
Ne užívajte, pokud je obal otevřený nebo poškozený.
Se dargarvi dobbeltværing og ikke brug denne.
Не использовать, если упаковка вскрыта или повреждена.
A nincs, hogy a csomag zárt és nem sérült.
Ако куточка е потаена или повредена, не използвайте.
Ne koristite ako je pakiranje otvoreno ili oštećeno.
Ne koristite ako je pakiranje otevreno ili oštećeno.
Nenauziskite, je pakunje odprto ali poškodljivo.

Syneture™

STERILE R STERILE EO RX ONLY

Caution, consult accompanying documents

Upper temperature limit 130°F (54°C)

© 2011 Covidien.
Covidien Ic, 15 Hampshire Street, Mansfield, MA 02048 USA.
CECIP Covidien Ireland Limited,
DA Business & Technology Park, Tallaght.
www.covidien.com
10/14 - 4