ar	خيوط جراحية حريرية
cs	HEDVÁBNÝ ŠICÍ MATERIÁL
da	SILKESUTUR
de	NAHTMATERIAL AUS SEIDE
el	ΜΕΤΑΞΩΤΟ ΡΑΜΜΑ
en	SILK SUTURE
es	SUTURA DE SEDA
fi	SILKKIOMMELAINE
fr	FIL DE SUTURE EN SOIE
hu	SELYEM VARRÓANYAG
it	SUTURA IN SETA
ko	견제 봉합사
nl	ZIJDEN HECHTDRAAD
no	SILKESUTUR
pl	NICI JEDWABNE
pt	FIO DE SUTURA DE SEDA
ru	ШЕЛКОВЫЙ ШОВНЫЙ МАТЕРИАЛ
sk	HODVÁBNA NIŤ
sv	SILKESUTUR
tr	İPEK SÜTÜR
zh-cn	蚕丝缝线
zh-tw	絲質縫合線

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CE 0086

Instructions for use

SILK SUTURE

SURGICAL NONABSORBABLE, USP/PH. EUR.

DESCRIPTION

Silk suture may be marketed as MERSILK™ Suture or PERMA-HAND™ Silk Suture in some markets. 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 for braided material is processed to remove the natural waxes and gums. Braided silk is coated with wax or silicone and is available undyed and dyed black with Hematine HCK (Colour Index Number 75290). For virgin silk, the sericin gum is not removed and holds the twisted filaments together. Virgin silk is available dyed blue with methylene blue (Colour Index Number 52015) or dyed black with Hematine HCK (Colour Index Number 75290).
Silk suture is available in a range of gauge sizes and lengths, attached to needles of various types and sizes as described in the HOW SUPPLIED section.
Silk sutures comply with the requirements of the United States Pharmacopoeia (USP) for Nonabsorbable Sutures and the European Pharmacopoeia (Ph. Eur.) for Sterile Braided Silk Suture. The European Pharmacopoeia recognizes units of measure Metric and Ph. Eur. as equivalent, which is reflected on the labeling.

INDICATIONS

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

APPLICATION

Sutures should be selected and implanted depending on patient's condition, surgical experience, surgical technique and wound size.

PERFORMANCE/ACTIONS

Silk suture elicits an initial, minimal inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissues. While silk is not absorbed, progressive degradation of the proteinaceous silk fiber *in vivo* may result in a 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 all of the suture's 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 nonabsorbable sutures before employing silk suture for wound closure, because of the risk of wound dehiscence which may vary with the site of application and with 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. Like all foreign bodies, this product may potentiate infection.

Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in "Sharps" container.

Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.

PRECAUTIONS

To avoid damaging needle points and swage 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. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. 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 blood-borne pathogens.

When handling this or any other suture, care should be taken to avoid damage. Avoid crushing or crimping damage due to the 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 as indicated by surgical circumstances and the experience of the surgeon.

ADVERSE REACTIONS

Adverse effects with the use of silk sutures include wound dehiscence, gradual loss of all tensile strength over time, allergic response in patients who 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.

STERILITY

Silk sutures are sterilized by irradiation. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

STORAGE

No special storage conditions required. Do not use after expiry date.

HOW SUPPLIED

Please note that not all sizes are available in all markets. Please contact your local sales representative for size availability.

PERMA-HAND™ Sutures are available in USP sizes 9-0 through 5 (metric sizes 0.3-7.0) in a variety of lengths with and without permanently attached needles and on LIGAPAK™ Dispensing Reels. SUTUPAK™ Pre-Cut Sterile Sutures are also available.

PERMA-HAND™ Sutures are also available in USP sizes 4-0 through 1 (metric sizes 1.5-4.0) attached to CONTROL RELEASE™ (CR) Removable Needles which enable the needles to be pulled off instead of being cut off.

PERMA-HAND™ Sutures are available in one, two or three dozen units per box.

SYMBOLS USED ON LABELING


Do not reuse


Use by – year and month

Sterilized using Irradiation

CE-mark and Identification number of Notified Body.
The product meets the essential requirements of
Medical Device Directive 93/42/EEC

Batch number


Caution

Catalogue number


Manufacturer


Number of units

Authorized Representative in the European community