For recognized legal manufacturer, refer to product label.

ETHICON, Inc.
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151
USA
1-877-ETHICON
+1-513-337-6928

ETHICON, LLC
475 C Street
Los Frailes Industrial Park
Suite 401 Guaynabo, Puerto Rico 00969
USA
1-877-ETHICON
+1-513-337-6928

Ethicon LLC
Highway 183 Km 8.3
San Lorenzo 00754, Puerto Rico
USA
1-877-ETHICON
+1-513-337-6928

Johnson & Johnson INTERNATIONAL
c/o European Logistics Centre
Leonardo Da Vincilaan, 15
BE-1831 Diegem, Belgium
+1-513-337-6928

EC REP Johnson & Johnson Medical Ltd
Simpson Parkway
Kirkton Campus
Livingston
EH54 7AT
United Kingdom

SILK

ar خيط جراحي
cs ŠICÍ MATERIÁL
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Instructions for use

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SILK

STERILE NON-ABSORBABLE SURGICAL SUTURE, USP / Ph. Eur.

DESCRIPTION

Silk Suture may be marketed as PERMA-HAND™ Silk or Virgin Silk Suture, and is a sterile, non-absorbable 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.

Silk Suture is available undyed and dyed black with Hematine HCK (Color Index Number 75290) to enhance visibility in the surgical field. For virgin silk, the sericin gum is not removed and holds the twisted filaments together. Virgin silk is available dyed blue with methylene blue (Color Index Number 52015).

Silk Suture is available in a range of gauge sizes and lengths, non-needled or attached to needles of various types and sizes as described in the HOW SUPPLIED section.

Silk Suture complies with the requirements of the European Pharmacopoeia (Ph. Eur.) for Sterile Braided Silk Suture and United States Pharmacopeia (USP) for Non-Absorbable Surgical Suture.

The European Pharmacopoeia recognizes units of measure Metric and Ph. Eur. sizes 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 neurosurgical 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 non-absorbable sutures before employing silk suture for wound closure, as risk of wound dehiscence may vary with the site of application and with the suture material used.

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

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. Like all foreign bodies, this product may potentiate infection.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the standard surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.

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

ADVERSE REACTIONS

Adverse reactions with the use of silk sutures include wound dehiscence, gradual loss of tensile strength over time, allergic response in patients who are known to be sensitive to silk, calculi formation in urinary or biliary tracts when prolonged contact with salt solutions such as urine or bile occurs, minimal inflammatory tissue reaction, and transient local irritation at the wound site.

STERILITY

Silk Suture is 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.

Silk Suture is available as sterile strands in 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.

Silk Suture is also available as sterile strands attached to CONTROL RELEASE™ (CR) removable needles which enable the needles to be pulled off instead of being cut off.

Silk Suture is available in one, two or three dozen units per box.