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## INSTRUCTIONS FOR USE

### SILK

#### Black braided - wax treated non absorbable sterile surgical suture

#### Description – Physical properties

Silk is a sterile non absorbable surgical suture made from braided fibers of natural silk derived from Bombyx Mori L. The fibers are dyed black. The number of fibers used in the braiding process depends on the required suture diameter. Silk sutures are coated with a thin layer of wax.

The suture is available in a wide variety of length - diameter combinations, with or without needle of various sizes and types, manufactured from high quality medical grade stainless steel. All these different types are described in detail in the company's product catalogue.

Silk sterile surgical sutures are manufactured according to the requirements of the European Pharmacopoeia for sterile braided silk sutures and with the essential requirements of the directive 93/42/EEC.

#### Indications

Braided non absorbable Silk suture is indicated for use in general soft tissue approximation and/or ligation but not for use in cardiovascular tissues and tissues of the central nervous system.

#### Application

Silk sterile surgical suture selection depends on the condition of the patient, the size of the tissue and wound and the experience of the surgeon.

#### Performance

The implantation of the Silk suture in tissues results to an initial inflammatory reaction, followed by gradual encapsulation of the suture by connective tissues. Silk sutures are not absorbed, but the protein fibers are progressively degraded with gradual loss of their tensile strength.

#### Contra indications

Silk sutures should not be used where permanent tensile strength is required. Their use is also contraindicated in patients with known sensitivity or allergy to silk fibers.

#### Warnings / Precautions / Interactions

Silk sutures should be used only from members of experienced surgical teams. Users must be familiar with suture handling and knotting techniques. Knot security requires standard surgical technique of flat and square ties according to the experience of the surgeon and the nature of the operation. Unnecessary knot tension and suture handling with surgical instruments such as needle holders or forceps can damage the surface and weaken the suture and therefore must be avoided. Dehiscence of the suture upon removal may occur in case of improper use.

Special care should be taken in handling of surgical needles. The needle should be grasped with the needle holder in an area 1/3 to 1/2 of the distance from the attachment end to the point. Grasping the needle from the opposite end area can damage the point or even cause a needle fracture. Deformed needles should not be forced

to their original shape as this can cause loss of strength or even needle fracture. Used needles should be safely discarded in special containers.

#### Adverse reactions

The use of the suture in some patients can cause allergic response or temporary local irritation which is followed from temporary inflammatory reaction. As every foreign body it can enhance an existing infection.

#### Sterilization

Silk surgical sutures are sterilized with gamma irradiation. It is intended to be used only once and it should be discarded if its package is damaged or opened. Unused open sutures must be discarded. Sutures should not be re-sterilized.

#### Storage

Store below 25 °C, away from direct heat and moisture. Never use after expiration date.

#### Symbols used in labeling



: Date of production



: Do not reuse



: Sterile unless the package is damaged or opened.  
Method of sterilization : Irradiation



: See instructions for use



: Use until Year & Month



: Product Number



: Batch Number



: CE-mark and identification number of notified body.  
Product conforms to the essential requirements of the  
Medical Device Directive 93/42/EEC.



: Store below 25 °C, away from direct heat and moisture