

## **Silkam®**

### **Description**

Silkam® is a suture material made from braided or twisted silk fibrils. Silkam® is available either undyed (white) or dyed black with Logwood extract (C.I. Natural Black 1). Silkam® is coated with pure beeswax or refined paraffin wax. Silkam® fulfils all the requirements of the European Pharm. and United States Pharm. current edition for sterile, non-absorbable sutures.

### **Indications**

Silkam® sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

### **Mode of action**

Suture materials are used primarily for adaptation of the wound edges to render possible an undisturbed wound healing. Silkam® elicits an inflammation reaction in the tissue, after which it is gradually encapsulated by fibrous connective tissue. Although Silkam® is not absorbed, an in vivo biodegradation of the proteinaceous silk fibres can lead to long-term gradual loss of the total strength.

### **Contraindications**

On account of the gradual loss of strength, which can occur in vivo over a longer period, the use of Silkam® is not recommended when a permanent retention of strength is required.

### **Warning note**

The user should be familiar with surgical suturing techniques, before employing Silkam suture materials for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with all other suture materials, long contact with salt solutions such as urine and bile, can lead to lithiasis.

Do not resterilize. Open, unused or damaged packs should be discarded. The Silkam suture material should be stored at room temperature. Do not expose to extreme temperatures for a prolonged period of time.

Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Warning: this suture may cause allergic reactions to patients with known allergies to silk.

### **Note/precautionary measures**

Great care must be taken when working with Silkam® in order to avoid damage as a result of crushing or snapping, due to the use of surgical instruments such as tweezers and needle holders.

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

To avoid damaging needles 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. Users should be careful when handling surgical needles to avoid inadvertent needle sticks. Discard needles in "sharps" containers.

### Adverse reactions

Adverse effect associated with this device include wound dehiscence, gradual loss of all tensile strength over time, calculi formation when prolonged contact with salt solutions occur, enhanced bacterial infectivity, infection, minimal acute inflammatory reaction and transitory local irritation.

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 bloodborne pathogens.

### How supplied

Silkam sutures are available in USP 2 to 8/0 (metric 5 to 0,4). The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needled or attached to needles, with permanent or removable (take-off) needle attachment techniques. The boxes contain 1, 2 or 3 dozens of sutures.

### Caution

Federal (USA) law restricts this device to sale or use by or on the order of a physician.

### Symbols used on labeling



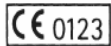
Do not reuse



Use by: Year + Month



ess package is opened or damaged. Method of Sterilization - Gamma



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



Batch number



See instructions for use

REF

Cat. No

### CUSTOMER SERVICE

For further information regarding Silkam® Suture please contact Tissue Seal, LLC's Customer Service at 1-877-754-6458 or [customerservice@tissue Seal.com](mailto:customerservice@tissue Seal.com)

Distributed by:

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**01-01/20**