

## Instructions for use

### Silkam®

#### Description of the device

Silkam® is a suture material made from braided silk fibrils (polypeptide chains). Silkam® is available either undyed (white) or dyed black with hematein (Logwood black – 21 CFR 72.1410). Silkam® is coated with wax.

Silkam® fulfils all the requirements of the European Pharmacopoeia and United States Pharm., current edition, for sterile, non-absorbable sutures.

Silkam® sutures are available from size USP 8/0 (0.4 metric) to USP size 5 (7 metric). For a more detailed description of the product range see the respective product catalogue.

#### Indications for use

Silkam® is intended for use in soft tissue approximation in general surgery, skin closure, oral surgery, ophthalmic surgery and for ligation in general practices, when surgical procedures require the use of non-absorbable suture materials.

#### 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 its tensile strength.

#### Contraindications

On account of the gradual loss of tensile strength, which can occur *in vivo* over a longer period, Silkam® must not be used

where permanent retention of strength is required, especially in cardiovascular surgery (i.e. aortic valve replacement or coronary anastomosis). The use of this suture is contraindicated in patients with known sensitivities or allergies to its components (silk, hematein "Logwood black – 21 CFR 72.1410" or wax). Silkam® is contraindicated for use in neurological tissues.

#### Warnings

Silkam® must not be resterilised. Open and unused or damaged packs shall be discarded.

Do not reuse the product: Infection hazard for patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product.

#### Precautions

The user should be familiar with surgical suturing techniques, before employing suture materials. Silkam® should be used applying the standard surgical suturing and knotting (flat and square ties) techniques, taking into account the surgeon's experience with the surgical procedure. An inadequate tension could break the suture. Care should be taken that the knots are positioned properly and adequate knot security is given. Additional throws may be appropriate if required by the surgical circumstances.

Contaminated or infected wounds should be treated following the appropriate surgical practice.

When working with Silkam® great care must be taken to ensure that the use of surgical instruments, such as tweezers or needle holder, does not lead to crimping damage of the suture.

Care should be taken to avoid damaging the needle when using the suture material. Always grasp the needle in a section 1/3 to 1/2 of the distance from the fiber attachment end to the needle point, never at the end where the fiber is attached or the needle point.

Reshaping needles should be avoided as may result in a loss of their strength and resistance towards bending and breaking.

Care must be taken to avoid needle stick injuries when handling with surgical needles. Discard the needles after use in specially intended containers.

#### Side effects

As with all other suture materials long contact with salt solutions, such as urine and bile, can lead to litihiasis. After implantation a transient inflammation, temporary irritation at the wound site may occur occasionally. Existing infections may occasionally be enhanced by any foreign body. An occasional pain, haemorrhage, granulation and wound dehiscence or impaired aesthetic outcome may not be excluded.

#### Storage

Silkam® does not require special storage conditions.

#### Sterilisation

Silkam® is sterilised by gamma irradiation.

Date of information: 10/2020



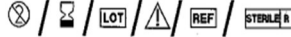
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DE Nicht wiederverwenden / Verwendbar bis / Chargennummer / Vorsicht /  
Bestellnummer / Durch Strahlung sterilisiert

GB Do not reuse / Use by date / Batch Code / Caution / Catalogue Number / Sterile