



KRUUSE Silk natural non-absorbable suture

Description

KRUUSE Silk suture is a natural, non-absorbable, multifilament, sterile 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 braided material is processed to remove the natural waxes and gums.

Braided silk is coated with silicone and is available dyed black with Sulphol Black or Logwood Black. Black CI 53185 Sulphol Black 1 (EP Vol III), Logwood Black (CI 75290).

Natural Tinctorial Wood Extract obtained from Haematoxylon Campechianum. Conforms to US Code of Federal Regulations 21 CFR 73.1410.

KRUUSE Silk suture is available in a range of gauge sizes and in a variety of lengths, with and without stainless steel needles of varying types and sizes.

KRUUSE Silk suture complies with the requirements of the European Pharmacopoeia for Sterile Non-absorbable Silk Suture and the United States Pharmacopoeia for Non-absorbable Sutures.

Indications

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

Application

KRUUSE Silk suture should be selected and implanted depending on patient condition, surgical experience, surgical technique, and wound size. Applicable for all patients meeting the intended use, including pregnant and juvenile patients.

Performance

KRUUSE Silk suture elicits an initial inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissues. Since silk is not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of all 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 tensile strength which may occur over prolonged periods in vivo, silk sutures should not be used where permanent retention of tensile strength is required. It is not indicated for the central circulatory system and central nervous system.

Warnings/precautions/interactions

- Do not use if package is opened or damaged. Discard opened unused sutures
- Do not use after expiration date
- Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing KRUUSE Silk sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used
- Acceptable surgical practice should be followed for the management of infected or contaminated wounds

- As with any exogenous material, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation
- Adequate knot security requires the standard surgical technique of flat and square ties, with additional throws as indicated by surgical circumstances and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilament sutures
- When handling this or any other suture, care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders
- 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 a "Sharps" container
- Dispose of material in accordance with all the state, local, and hospital regulations. Responsibility for proper waste disposal is with the owner of the waste
- Do not re-use: Infection hazard for patients and/or users and impairment of products functionality due to re-use. Risk of injury, illness, or death due to contamination and/or impaired functionality of the product
- Do not re-sterilise: Infection hazard for patients and/or users and impairment of products functionality due to use of re-sterilised suture. Risk of injury, illness, or death due to contamination and/or impaired functionality of the product

Adverse reactions

Adverse effects associated with the use of this device include allergic response in patients that are known to be sensitive to silk, initial inflammatory tissue reaction, and transient local irritation at the wound site. Like all foreign bodies, silk may enhance an existing infection.

Sterility

KRUUSE Silk suture is sterilised by ethylene oxide gas. Do not re-sterilise.

Storage

Recommended storage conditions: Store at temperature between 1 °C to 25 °C, away from moisture corrosion and direct heat.

Shelf life

Peel pack: 5 years
Cassette: 3 years

For veterinary use only



Temperature limit



Sterilized using ethylene oxide



Der Grüne Punkt



Keep away from sunlight



Keep dry



Do not reuse



Do not use if package is damaged