



KRUUSE Promilene synthetic non-absorbable suture

Description

KRUUSE Promilene suture is a synthetic, non-absorbable, monofilament, sterile suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The molecular formula is $(C_3H_6)_n$. KRUUSE Promilene suture is available dyed blue with phthalocyanine blue (Color Index Number 74160) and pink (fluorescence).

KRUUSE Promilene suture is available in a range of gauge sizes and in a variety of lengths, with stainless steel needles of varying types and sizes.

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

Indications

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

Application

KRUUSE Promilene 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 Promilene suture elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. Due to its relative biological inertness it is recommended for use where the least possible suture reaction is desired. As a monofilament it has been successfully employed in surgical wounds which subsequently become infected or contaminated where it can minimise later sinus formation and suture extrusion. Because of its lack of adherence to tissue, KRUUSE Promilene suture is effective as a pull-out suture.

Contraindications

None known.

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 Promilene 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 reactions associated with the use of this device include minimal initial inflammatory tissue reaction and transient local irritation at the wound site.

Like all foreign bodies, polypropylene suture may potentiate an existing infection.

Sterility

KRUUSE Promilene 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

5 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