KRUUSE PD-X Plus synthetic antibacterial absorbable suture

Description

KRUUSE PD-X Plus is a synthetic, absorbable, monofilament, sterile, surgical suture composed of polydioxanone. The suture contains chlorhexidine diacetate, a broad-spectrum antibacterial agent, at no more than 60µg/m. The suture is available dyed violet with D&C Violet No. 2 (Colour index number 60725).

KRUUSE PD-X Plus suture is available in a range of gauge sizes and lengths, attached to stainless steel needles of varying types and sizes.

KRUUSE PD-X Plus antibacterial suture complies with the requirements of the European Pharmacopoeia for "Sutures, Sterile Synthetic Absorbable Monofilament".

Indications

KRUUSE PD-X Plus suture is intended for use in general soft tissue approximation, including use in paediatric cardiovascular tissue where growth is expected to occur and in ophthalmic surgery. This suture is particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

Application

KRUUSE PD-X Plus suture should be selected and implanted depending on patient condition, surgical experience, surgical technique, and wound size. All patients meeting the intended use, including pregnant and juveniles, all patients at any age.

Performance

KRUUSE PD-X Plus suture elicits a minimal initial inflammatory reaction in tissues and is eventually replaced with an in-growth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of sutures occurs by means of hydrolysis, where the polymer degrades to the monomeric acid 2-hydroxyethoyacetic acid which is subsequently absorbed and eliminated by the body.

Absorption begins as loss of tensile strength followed by a loss of mass. Implantation studies in rats show the following profile:

Days of implantation	Approximate % of original strength remaining
14 days	75%
28 days	65%
42 days	50%

Absorption is minimal until about the 90th post implantation day and is complete in approximately 180-220 days.

Contraindications

This suture, being absorbable, should not be used where prolonged (beyond 6 weeks) approximation of tissues under stress is required and is not to be used in conjunction with prosthetic devices, for example, heart valves or synthetic grafts.

KRUUSE PD-X Plus suture is not indicated in juvenile cardio tissue, ophthalmic tissue, adult cardiovascular tissue, microsurgery, and neural tissue.
KRUUSE PD-X Plus suture should not be used in patients with known allergic reactions to chlorhexidine diacetate.

Warnings/precautions/interactions

- Do not use if package is opened or damaged
- Discard opened leftover unused sutures
- Do not use after expiration date
- The safety and effectiveness of KRUUSE PD-X Plus suture have not been established in contact with the central nervous system, in adult cardiac tissue, or in large vessels
- Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing KRUUSE PD-X Plus suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Surgeons should consider the in vivo performance (See Performance section) when selecting a suture
- As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Being an absorbable suture, KRUUSE PD-X Plus suture may act transiently as a foreign body
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds
- As this is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distension, or which may require additional support
- Skin sutures that must remain in place longer than 7 days may cause localised irritation and should be snipped off or removed as indicated
- Under some circumstances, notably orthopaedic procedures, immobilisation of joints by external support may be employed at the discretion of the surgeon
- Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur
- Subcuticular sutures should be placed as deeply as possible to minimise the erythema and induration normally associated with the absorption process
- This suture may be inappropriate in senior, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing
- When handling this or any other suture material, 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)

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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. Broken needles may result in extended or additional surgeries or residual foreign bodies

- Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experiences of the surgeon. The use of additional throws may be particularly appropriate when knotting any monofilament suture
- Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. 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 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 sutures. Risk of injury, illness, or death due to contamination and/or impaired functionality of the product
- Conjunctival, cuticular and vaginal epithelium sutures that remain in place longer than 10 days may cause localised irritation and should be snipped off or removed

Adverse reactions

Adverse effects associated with this device include wound dehiscence, failure to provide adequate wound support in sites where expansion, stretching, or distention occur, failure to provide adequate wound support in patients with conditions which may delay wound healing, localised irritations, when skin sutures are left in place for more than 7 days, calculi formation when prolonged contact with salt solutions such as urine and bile occur, enhanced bacterial infectivity, minimal acute inflammatory reaction and pain, edema and erythema at the wound site. Hardening of tissues may not always be avoided during absorption of subcuticular sutures and existing infections may also occasionally be enhanced.

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.

Sterility

KRUUSE PD-X Plus suture is sterilised by ethylene oxide gas. Do not re-sterilise.

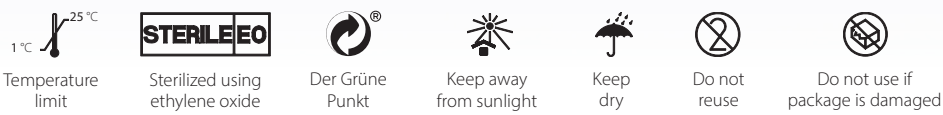
Storage

Recommended storage conditions: Store at a 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

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