



KRUUSE PGA synthetic absorbable suture

Description

KRUUSE PGA suture is a synthetic, absorbable, multifilament, sterile surgical suture composed of polyglycolic acid. The empirical formula of the polymer is $(C_2H_2O_2)_n$. KRUUSE PGA suture is available dyed violet with D&C Violet No. 2 (Colour index number 60725).

KRUUSE PGA suture is available as braided strands in a range of gauge sizes and in a variety of lengths, with and without attached stainless steel needles of varying types and sizes. Braided sutures are uniformly coated with polycaprolactone and calcium stearate.

KRUUSE PGA suture complies with the requirements of the European Pharmacopoeia for "Sutures, Sterile Synthetic Absorbable Braided" and the requirements of United States Pharmacopoeia for "Absorbable Surgical Suture".

Indications

KRUUSE PGA Suture is intended for use in general soft tissue approximation and/or ligation.

Application

KRUUSE PGA 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 PGA 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 glycolic 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%
21 days	40%

Complete mass absorption in approximately 60-90 days.

Contraindications

This suture, being absorbable should not be used where extended approximation of tissues under stress is required. KRUUSE PGA suture is not intended for use in cardiovascular tissue, neurosurgery or ophthalmic surgery.

Warnings/precautions/interactions

- Do not use if package is opened or damaged
- Discard opened leftover unused sutures
- Do not use after expiration date
- Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing KRUUSE PGA 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, it 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, care should be taken to avoid damage. Avoid crushing or crimping damage due to the 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. 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



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indicated by surgical circumstances and the experience 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 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 wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching or distension occur, failure to provide adequate wound support in senior, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localised irritation when skin sutures are left in place for more than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site.

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 PGA 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
Casette: 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