KRUUSE Sacryl Plus synthetic antibacterial absorbable suture

Description

KRUUSE Sacryl Plus (Polyglactin 910) suture is a synthetic absorbable, sterile, surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. KRUUSE Sacryl Plus suture is coated with a mixture composed of a copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate. The suture contains chlorhexidine diacetate, a broad-spectrum antibacterial agent, at no more than 60µg/m. The copolymers in this product have been found to be non-antigenic, non-pyrogenic and elicit only a mild tissue reaction during absorption. The suture is available dyed (D&C Violet No. 2).

KRUUSE Sacryl Plus 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" (except for an occasional slight oversize in some gauges).

Maximum suture oversize in diameter (mm) from USP	
USP suture size designation	Maximum oversize (mm)
6-0	0.021
5-0	0.036
4-0	0.031
3-0	0.036
2-0	0.011
0	0.056
1	0.046
2	0.031

Indications

KRUUSE Sacryl Plus suture is intended for use in general soft tissue approximation and/or ligation.

Application

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique, and wound size. All patients meeting the intended use purpose, including pregnant and juveniles, all patients at any age.

Performance

KRUUSE Sacryl Plus suture elicits a minimal initial inflammatory reaction in tissues and in-growth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of KRUUSE Sacryl Plus suture occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids which are 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%
28 days	20%

Complete mass absorption in approximately 56-70 days.

Contraindications

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

KRUUSE Sacryl 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
- Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing KRUUSE Sacryl 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 Sacryl 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 which 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

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- 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) 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 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 Sacryl 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

1 °C 25 °C Temperature limit

STERILE EO 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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