



KRUUSE Sacryl Rapid synthetic absorbable suture

Description

KRUUSE Sacryl Rapid suture is a synthetic, absorbable, multifilament, sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. The empirical formula of the copolymer is $(C_2H_2O_2)_m(C_3H_4O_2)_n$.

The characteristic rapid loss of strength is achieved by use of a polymer material with a lower molecular weight than regular KRUUSE Sacryl (Polyglactin 910) suture. KRUUSE Sacryl Rapid suture is available undyed.

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

KRUUSE Sacryl Rapid suture is uniformly coated with polyglycolide-co-lactide (30/70) and calcium stearate.

KRUUSE Sacryl Rapid 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 diameter).

| 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 Rapid suture is intended for use in general soft tissue approximation where only short term wound support is required, including ophthalmic (e.g., conjunctiva) and oral surgical procedures.

Application

KRUUSE Sacryl Rapid 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 Sacryl Rapid 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 Rapid 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 |
|----------------------|--|
| 7 days | 55% |
| 14 days | 20% |
| 21 days | 5% |

Complete mass absorption in approximately 42-56 days.

Contraindications

Due to the rapid loss of tensile strength, KRUUSE Sacryl Rapid suture should not be used where extended approximation of tissues under stress is required or where wound support or ligation beyond 7 days is required. The safety and effectiveness of the Sacryl Rapid sutures have not been established in contact with the eyeball.

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 Rapid 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 Rapid 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
- 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



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- 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
- 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 Rapid 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

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