

POLYGLACTIN 910

DESCRIPTION

SUTCRYL is a sterile synthetic absorbable monofilament surgical suture is a copolymer made of 90% glycolide and 10%L-lactide. SUTCRYL is colored violet with the dyestuff D&C Violet N^o2. SUTCRYL fulfills all the requirements of the European Pharmacopoeia and of the United States Pharmacopoeia.

INDICATIONS

SUTCRYL suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

ACTIONS

SUTCRYL suture elicits a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of SUTCRYL occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass. Absorption studies indicate that PGLA retains approximately 75% of its original strength two weeks post implantation. At three weeks, approximately 50% of the original strength is retained.

All of the original tensile strength is lost approximately five to six weeks post implantation, and complete absorption of SUTCRYL is essentially complete between 56 and 70 days.

CONTRAINDICATIONS

This suture, being absorbable, should not be used where extended approximation of tissue is required. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.

Not for use in cardiovascular and neurological surgery.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing SUTCRYL suture for wound closure, as a risk of wound dehiscence may vary with the site of application and the suture material used. Do not use if package is open or damaged or the expiration date has been exceeded. Discard open, unused suture.

Do not resterilize; resterilization may alter the physical properties of this suture. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in a "sharps" container.

Avoid storing product at elevated temperatures.

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. As an absorbable suture, SUTCRYL suture may act transiently as a foreign body.

Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

PRECAUTIONS

Skin sutures, which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstances and the experience of the surgeon.

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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 elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory response reaction, localized irritation when skin sutures are left in place for greater 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.

HOW SUPPLIED

SUTCRYL sutures are available sterile, dyed and attached to stainless steel needles of varying types and sizes in one dozen boxes, or non-needled.

SUTCRYL sutures are available in various lengths in sizes: 6/0 to 2 (0.7 to 5.0 metric).

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

SYMBOLS USED ON LABELING

CE symbol and identification number of the notified body.



Lot number (batch)



"Use by" expiration date (year-month)



Date of manufacture (year-month)



Do not use if package is damaged



Single use



consult instruction for use on



Do not resterilize



Manufacturer



Product code



Store below 25 °C



Keep away from sunlight



protect from humidity



Double sterile barrier system



Medical Device



Package is sterile when not damaged or opened. EO sterilization method -Ethylene oxide.

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