PGCL 25 "POLY(GLYCOLIDE-COCAPROLACTONE)"

DESCRIPTION

SURCAPRONE is a synthetic, absorbable, sterile surgical suture composed of poly(glycolide-cocaprolactone).

SURCAPRONEis colored violet with the dyestuff D&C Violet Nº2. SURCAPRONE fulfills all the requirements of the European Pharmacopoeia and of the United States Pharmacopoeia.

INDICATIONS

SURCAPRONE suture is indicated for use in soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery, microsurgery, or ophthalmic surgery.

ACTIONS

SURCAPRONE sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of PGCL sutures occurs by means of hydrolosis.

Absorption begins as a loss of tensile strength followed by a loss of mass. Implantation studies in animals indicate that PGCLsuture retains approximately 60% of it's original tensile strength at one week post implantation, approximately 30% of it's original tensile strength at two weeks post implantation, and 12% of it's original tensile strength at three weeks post implantation. Absorption of PGCLsuture is essentially complete between 90 and 120 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, and debilitated patients, or in patients suffering from conditions that may delay wound healing.

Not for use in cardiovascular or neurological surgery, microsurgery, or ophthalmic surgery.

WARNINGS

Do not resterilize; resterilization may alter the physical properties of this suture. Do not use if package is open or damaged or if the expiration date has been exceeded. Discard open, unused 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.

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. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with absorption.

Consideration should be taken in the use of absorbable sutures in tissue with poor blood supply as suture extrusion and delayed absorption may occur. In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders.

SURCAPRONE suture knots must be properly placed to be secure. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when tying monofilaments.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, PGCLsuture may act transiently as a foreign body.

Acceptable surgical procedure must be followed with respect to drainage and closure of contaminated or infected wounds.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing PGCL sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

ADVERSEREACTIONS

Adverse effects associated with the use of 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 elderly, malnourished, and debilitated patients or in patients suffering from conditions that may delay wound healing, infection, minimal acute inflammatory tissue 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 when prolonged contact with salt solution occurs, enhanced bacterial infectivity, and transitory local irritation.

HOW SUPPLIED

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

SURCAPRONEsutures 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.

SYMBOLSUSEDON LABELING

CE 2803	CE symbol and identification number of the notified body.
LOT	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
REF	Product code
	Store below 25 C
	Keep away from sunlight
	protect from humidity
	Double sterile barrier system
MD	Medical Device
STERILE EO	Package is sterile when not damaged or opened. EO sterilization method -Ethylene oxide.

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