PPOLYDIOXANONE (PDO)

DESCRIPTION

SURCANONE monofilament synthetic absorbable suture is prepared from the polyester, poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4 H_6 O_3)_x$.

SURCANONEhas been found to be non-antigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

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

INDICATIONS

SURCANONE suture is indicated for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and also in ophthalmic surgery. SURCANONE suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue.

These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

ACTIONS

Two important characteristics describe the in vivo performance of absorbable sutures: tensile strength retention and the absorption rate (loss of mass). SURCANONEsynthetic absorbable suture has been formulated to minimize the variability of these characteristics and to provide wound support through an extended healing period. The result of implantation studies of Polydioxanone monofilament suture in animals indicate that approximately 70% of its original strength remains four weeks after implantation, and at six weeks, approximately 50% of the original strength is retained. Data obtained from implantation studies in rats show that the absorption of these sutures is minimal until about the 90th post-implantation day. Absorption of Polydioxanone absorbable synthetic suture is essentially complete between 180 and 210 days.

CONTRAINDICATIONS

These sutures, being absorbable, are not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required and are not to be used in conjunction with prosthetic devices, i.e., heart valves or synthetic grafts. Polydioxanone suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue.

WARNINGS

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

The safety and effectiveness of Polydioxanone sutures have not been established in neural tissues, adult cardiovascular tissue or for use in microsurgery. Under certain circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

PRECAUTIONS

SURCANONEsuture knots must be properly placed to be secure. As with other synthetic sutures, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstances and the experience of the operator.

As with any suture, care should be taken to avoid damage when handling.

Avoid the crushing or crimping application of surgical instruments, such as needle holders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.

Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated.

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

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

ADVERSEREACTIONS

Due to prolonged suture absorption, some irritation and bleeding has been observed in the conjuctiva and mild irritation has been observed in the vaginal mucosa.

HOW SUPPLIED

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

SURCANONEsutures 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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