

POLYPROPYLENE

DESCRIPTION

SURLENE is a monofilament, nonabsorbable, sterile surgical suture composed of a strand of polypropylene, a synthetic linear Polyolefin. SURLENE sutures are dyed blue (Pthalocyanite [2] Copper).

SURLENE fulfills all the requirements of the European Pharmacopoeia and of the United States Pharmacopoeia.

INDICATIONS

SURLENE suture is indicated for use in general soft tissue approximation and/or ligation.

ACTIONS

SURLENE surgical suture elicits a minimal inflammation reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. SURLENE suture is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

CONTRAINDICATIONS

The use of this suture is contraindicated on patients with known sensitivities or allergies to its components.

WARNINGS

Do not use if package is open or damaged or if 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 this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing Polypropylene for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

PRECAUTIONS

In handling this or any other surgical 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, squared ties with additional throws as warranted by surgical circumstance and experience of the surgeon.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, gradual loss of tensile strength over the time, allergic response in patients that are known to be sensitive to silk, calculus formation in urinary and biliary tracts when prolonged contact with salt solution such as urine and bile occur, infected wounds, acute inflammatory tissue, and transitory local irritation.

HOW SUPPLIED

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

SURLENE 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.
2803	
	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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