

POLYPROPYLENE NONABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION

Polypropylene is a monofilament, nonabsorbable, sterile surgical suture composed of a strand of polypropylene, a synthetic linear Polyolefin. Polypropylene sutures are undyed or dyed blue (Phthalocyaninato [2-] Copper).

Polypropylene sutures meet all the requirements established by the United States Pharmacopeia (U.S.P.) for nonabsorbable surgical sutures.

INDICATIONS

Polypropylene is indicated for use in general soft tissue approximation/ligation.

ACTIONS

Polypropylene sutures elicit a minimal inflammation reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Polypropylene 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

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing polypropylene 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 if the expiration date has been exceeded.

Discard open unused suture. Do not resterilize; resterilization may alter the physical properties of this suture, which will result in an adverse patient reaction.

Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in a "sharps" container.

Store in a cool dry environment.

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.

Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or infected 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. The use of additional throws may be particularly appropriate when tying monofilaments.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include: wound dehiscence, calculus formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infected wounds, minimal acute inflammatory tissue reaction, and transitory local irritation.

Discuss the potential for allergic reaction in patients that are known to be sensitive to polypropylene suture.

HOW SUPPLIED

Polypropylene sutures are available in various USP sizes. Polypropylene sutures are supplied in a wide range of lengths affixed to a diverse assortment of needle types.

DISPENSING (racetrack cartridge only):

For best results, pull the suture from the racetrack cartridge using a slow, steady pull. If binding occurs, the suture can be removed from the card by removing the press-fit label and opening the plastic hinges.

CAUTION

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


SYMBOL DEFINITIONS

LOT Lot Number

 Expiration Date


 Do Not Reuse

 Do Not Resterilize

 See Instructions For Use

STERILE EO Sterilized By Ethylene Oxide

 Keep away from sunlight and heat

 Do not use if package is damaged

 Keep dry

 Manufacturer

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