

Theragenics
POLYESTER
NONABSORBABLE SURGICAL
SUTURES, U.S.P.

DESCRIPTION

Polyester is a braided, nonabsorbable, sterile, surgical suture composed of Poly (ethylene terephthalate). It is prepared from fibers of high molecular weight, long-chain, linear polyester having recurrent aromatic rings as an integral component.

The braided Polyester suture is silicone coated and available undyed (white) or dyed (green). Polyester sutures meet all requirements established by the United States Pharmacopeia (U.S.P.) for nonabsorbable surgical sutures.

INDICATIONS

Polyester sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

ACTIONS

Polyester sutures elicit a minimal inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Polyester suture is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

CONTRAINDICATIONS

None known.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing Polyester 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; reesterilization 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.

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 Polyester suture.

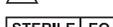
HOW SUPPLIED

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

CAUTION

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

SYMBOL DEFINITIONS

-  Lot Number
-  Expiration Date
-  Do Not Reuse
-  Do Not Resterilize
-  See Instructions For Use
-  Sterilized By Ethylene Oxide
-  Keep away from sunlight and heat
-  Do not use if package is damaged
-  Keep dry

 Manufacturer

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