

Theragenics

NYLON NONABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION

Nylon is a nonabsorbable, sterile surgical suture composed of the long-chain aliphatic polymers Nylon 6 or Nylon 6,6. Monofilament Nylon sutures may be either dyed black (Logwood Extract), dyed blue (D&C Blue No.2) or clear (undyed). Braided Nylon sutures have a silicone coating.

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

INDICATIONS

Nylon surgical sutures are indicated for use in general soft tissue approximation/ligation.

ACTIONS

Nylon surgical sutures elicit a minimal inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. While Nylon surgical suture is not absorbed, progressive hydrolysis of the nylon in vivo may result in gradual loss of the suture's tensile strength over time.

CONTRAINDICATIONS

Because of the loss of tensile strength that may occur over prolonged periods in vivo, Nylon surgical sutures should not be used where permanent retention of tensile strength is required.

The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions, which may delay wound healing.

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

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing Nylon 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.

Suture may lose strength when subjected to axial torsional force.

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, gradual loss of tensile strength over time, calculi formation in urinary and biliary tracts when prolonged contact with salt solution 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 Nylon suture.

HOW SUPPLIED

Nylon sutures are available in various USP sizes. Nylon 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.

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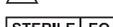
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SYMBOL DEFINITIONS

-  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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