

NYLON PRODUCT INSERT

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 white (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 and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

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

Due to the gradual 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.

WARNINGS

Do not use if package is open or damaged or if the expiration date has been exceeded. Do not resterilize; reesterilization may alter the physical characteristics 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 suture before employing Nylon suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

PRECAUTIONS

Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

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 techniques 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.

HOW SUPPLIED

Nylon nonabsorbable is a monofilament and is clear, dyed black (logwood extract), or blue (FD&C Blue No.20.) It is available in USP sizes 12-0 through 5 (metric sizes 0.1-7). The suture is supplied sterile in precut lengths attached to various needle types in one- to three-dozen boxes, or non-needled on ligating reels.

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

 Manufacturer





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