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POLYBLEND NONABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION

Polyblend is a braided, nonabsorbable, sterile, surgical suture composed of polyethylene terephthalate braid. It is prepared from fibers of high molecular weight, long-chain, linear polyester.

The braided polyblend suture is available undyed (white) or white with a blue tracer (D&C Blue No. 6) or a black tracer (Logwood extract). Polyblend sutures meet all requirements established by the United States Pharmacopeia (U.S.P.) for nonabsorbable surgical sutures.

INDICATIONS

Polyblend sutures are indicated for use in general soft tissue approximation and/or ligation, including use in orthopedic surgeries.

ACTIONS

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

CONTRAINDICATIONS

Polyblend surgical sutures are contraindicated for use in cardiovascular, ophthalmic and neurological surgeries.

WARNINGS

Do not use if package is open or damaged or the expiration date has been exceeded. Discard open, unused suture. Do not resterilize; resterilization 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

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involving nonabsorbable sutures before employing Polyblend sutures 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

Handle with care to avoid damaging the suture material. 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, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

ADVERSE REACTION

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.

HOW SUPPLIED

Polyblend 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.

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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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