

POLYESTER

DESCRIPTION

SURLYEST 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 dyed (green).

SURLYEST fulfills all the requirements of the European Pharmacopoeia and of the United States Pharmacopoeia.

INDICATIONS

SURLYEST suture is indicated for use in general soft tissue approximation and/or ligation.

ACTIONS

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

CONTRAINDICATIONS

None known.

WARNINGS

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.

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 sutures before employing Polyester 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

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.

ADVERSEREACTIONS

Adverse effects associated with the use of this device include wound dehiscence, gradual loss of tensile strength over the time, allergic response in patients that are known to be sensitive to silk, calculus formation in urinary and biliary tracts when prolonged contact with salt solution such as urine and bile occur, infected wounds, acute inflammatory tissue, and transitory local irritation.

HOW SUPPLIED

SURLYEST sutures are available sterile, dyed and attached to stainless steel needles of varying types and sizes in one dozen boxes, or non-needled.

SURLYEST sutures are available in various lengths in sizes: 6/0 to 2 (0.7 to 5.0 metric).

CAUTION

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

SYMBOLS USED ON LABELING

-  **2803** CE symbol and identification number of the notified body.
-  Lot number (batch)
-  "Use by" expiration date (year-month)
-  Date of manufacture (year-month)
-  Do not use if package is damaged
-  Single use
-  consult instruction for use on
-  Do not resterilize
-  Manufacturer
-  Product code
-  Store below 25 C
-  Keep away from sunlight
-  protect from humidity
-  Package is sterile when not damaged or opened. EO sterilization method -Ethylene oxide.

 **SURGIMEDIC**
 104 - 106 A6 Industrial Zone
 10th of Ramadan-Egypt
 T: +20 (0) 12 2219 4006
 F: +20 (0) 2 2419 8050
 E: contact@surgimedic.com

 **OBELIS SA**
 Bd Général Wahis, 53
 B-1030 Brussels
 Belgium
 Tel: +3227325954
 Fax: +3227326003
 mail@obelis.net