POLYPROPYLENE PRODUCT INSERT

POLYPROPYLENE
NONABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION
Polypropylene is a monofilament, nonabsorbable, sterile surgical suture composed of a strand of polypropylene, a synthetic linear Polyolefin. Polypropylene sutures are clear or dyed blue (Phthalocyanino [2] Copper).

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

INDICATIONS
Polypropylene is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

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

CONTRAINDICATIONS
The use of this suture is contraindicated on patients with known sensivities or allergies to its components.

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 Polypropylene 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. 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, 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
Polypropylene suture is available in (USP) sizes 10-0 through 5 (metric size 0.2-7). Polypropylene sutures are clear or dyed blue (Copper Phthalocyanine Blue {2-}). The sutures are supplied sterile in precut lengths or ligating reels; both non-needle and affixed to various needle types including removable needles; in one, two, or three dozen boxes.

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

SYMBOL DEFINITIONS
Lot Number
Sterilized By Ethylene Oxide
See Instructions For Use
Do Not Reuse
Do Not Resterilize
Stainless Steel Needle
Expiration Date
Manufactured

MDSS GmbH SCHIFFGRABEN 41
30175 HANNOVER, GERMANY

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