



Surgipro™ and Surgipro™ II Monofilament Polypropylene

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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Surgipro™ and Surgipro™ II monofilament sutures (clear or pigmented) are inert, nonabsorbable, sterile sutures composed of an isotactic crystalline stereoisomer of polypropylene (a synthetic linear polyolefin) and polyethylene. The suture is pigmented blue to enhance visibility.

Surgipro™ and Surgipro™ II polypropylene sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for nonabsorbable surgical sutures, except for size 7-0 and 8-0, which DIFFER FROM USP AND EP MAXIMUM DIAMETER REQUIREMENTS BY UP TO 0.007 mm.

INDICATIONS

Surgipro™ and Surgipro™ II polypropylene sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neural tissue.

ACTIONS

Surgipro™ and Surgipro™ II polypropylene sutures elicit a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Surgipro™ and Surgipro™ II polypropylene sutures are not absorbed, nor is any significant change in strength retention known to occur in vivo.

CONTRAINDICATIONS

None known.

WARNINGS

As with any foreign body, prolonged contact of any suture with salt solutions may result in calculus formation.

Do not resterilize. Sterile unless packaging has been opened or damaged. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing Surgipro™ and Surgipro™ II polypropylene 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 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, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

ADVERSE REACTIONS

Adverse effects, which may be associated with the use of this product, include: wound dehiscence, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

HOW SUPPLIED

Surgipro™ and Surgipro™ II polypropylene sutures are available either undyed (clear) or dyed with Copper Phthalocyanine Blue. Surgipro™ sutures are available in sizes 10-0 (0.2 Metric), 6-0 (0.7 Metric), and 2-0 (3 Metric) through 2 (5 Metric). Surgipro™ II sutures are available in sizes 8-0 (0.4 Metric) through 3-0 (2 Metric).

The sutures are supplied sterile, affixed to various types of needles, using both permanent and removable needle attachment techniques. The sutures are available in box quantities of one, two and three dozen.

Surgipro™ and Surgipro™ II polypropylene sutures are also available with PTFE (polytetrafluorethylene) Pledgets for use as a pad between the suture area and the tissue surface to increase the load bearing area. Surgipro™ polypropylene sutures are available in presentations containing Bead and Collar components to anchor the ends of the suture for subcuticular closure or for use as tendon sutures.

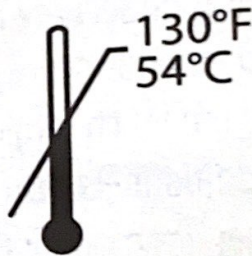
Syneture™

STERILE EO

**Rx
ONLY**




Caution, consult
accompanying
documents



Upper temperature
limit

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