



Ti-Cron™

Coated Braided Polyester

PT00120741



(92)PT00120741

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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Ti-Cron™ braided polyester sutures are nonabsorbable, sterile, surgical sutures composed of Polyethylene Terephthalate. They are prepared from fibers of high molecular weight, long chain, linear polyesters having recurrent aromatic rings as an integral component. Ti-Cron™ braided sutures are available coated uniformly with silicone to increase surface lubricity, thereby enhancing handling characteristics, ease of passage through tissue, and knot run-down properties. Ti-Cron™ sutures are inert and elicit only minimal local tissue reaction. Ti-Cron™ sutures are available dyed with D&C Blue No. 6 colorant or undyed (white).

Ti-Cron™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for nonabsorbable surgical sutures.

INDICATIONS

Ti-Cron™ polyester sutures are indicated for use in general soft tissue approximation and/or ligation.

ACTIONS

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

CONTRAINDICATIONS

None known.

WARNINGS

1. As with any foreign body, prolonged contact of any suture with salt solutions may result in calculus formation.
2. Reuse, reprocessing and/or resterilization of this device may create the risk of contamination, patient infection, permanent impairment or life threatening injury. Do not reuse, reprocess or resterilize this device. Sterile unless packaging has been opened or damaged. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.
3. Users should be familiar with surgical procedures and techniques involving sutures before employing Ti-Cron™ polyester nonabsorbable sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.
4. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

PRECAUTIONS

1. 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.
2. Adequate knot security requires the acceptable 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. Dispose of used instruments in accordance with the end-user's medical and biological waste disposal requirements.

ADVERSE REACTIONS

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

HOW SUPPLIED

Ti-Cron™ polyester sutures are available undyed (white) or dyed with D&C Blue No. 6 and braided, coated, in sizes 5 (7 Metric) through 7-0 (0.5 Metric). The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needled or affixed to various needle types using both permanent and removable needle attachment techniques. The sutures are available in box quantities of one, two and three dozen. Ti-Cron™ polyester 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.