

**C-PTFE™
POLYTETRAFLUOROETHYLENE (PTFE)
NONABSORBABLE MONOFILAMENT
SUTURES, U.S.P.**

DESCRIPTION

The C-PTFE™ Suture is a nonabsorbable, monofilament suture manufactured from 100% polytetrafluoroethylene (PTFE). The C-PTFE™ Suture exhibits excellent biocompatibility, high knot pull and tensile strength, and absence of blood and tissue fluid penetration into the suture.

C-PTFE™ suture has shown good results with regard to patient allergic reactions during recovery. The suture manufactured undyed without additives.

INDICATIONS

C-PTFE™ nonabsorbable monofilament surgical suture is indicated for use in general soft tissue approximation and/or ligation, including dental, and general surgical procedures.

C-PTFE™ suture is provided sterile as a single use device.

ACTIONS

C-PTFE™ is chemically inert which supports sterilization of the suture. The C-PTFE™ Suture is nonabsorbable. The surface structure of the C-PTFE™ also inhibits the merging of the skin and tissues. No significant loss of tensile strength occurs over time

CONTRAINDICATIONS

C-PTFE™ suture is contraindicated for use in microsurgery, peripheral neural tissues, cardiovascular, ophthalmic and neurological surgery.

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

The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions, which may delay wound healing.

WARNINGS

The C-PTFE™ Suture is supplied STERILE. 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, which will result in adverse patient reaction.

The C-PTFE™ suture is classified and manufactured as a single use medical device. Reuse of this suture may cause severe complications which may result in infection, serious illness and even patient death.

Users should be familiar with surgical procedures and techniques (including appropriate use of surgical tools) involving nonabsorbable sutures before employing C-PTFE™ suture for wound closure, as a risk of wound dehiscence may vary with the site of application and the suture material used.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.

Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in a "sharps" container.

Store in a cool dry environment.

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.

Acceptable surgical practice must be followed, especially with respect to drainage and closure of infected or contaminated wounds.

PRECAUTIONS

Care should be taken to avoid damage when handling this, or any surgical suture. Avoid crushing or crimping application of surgical instruments such as forceps and needle holders to the suture strand except when grasping the free end of the suture during instrument tie.

Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstances and the experience of the surgeon.

Skin sutures, which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, wound infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation.

HOW SUPPLIED

C-PTFE™ sutures are available in various USP sizes. C-PTFE™ sutures are supplied in a wide range of lengths affixed to a diverse assortment of needle types.

DISPENSING (racetrack cartridge only):

For best results, pull the suture from the racetrack cartridge using a slow, steady pull. If binding occurs, the suture can be removed from the card by removing the press-fit label and opening the plastic hinges.


CAUTION (Rx Only)


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

SYMBOL DEFINITIONS

 Lot Number

 Expiration Date


 Do Not Reuse

 Do Not Resterilize

 See Instructions For Use

 Sterilized By Ethylene Oxide


 Keep away from sunlight and heat

 Do not use if package is damaged

 Keep dry

 Manufacturer

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