SYMBOL DEFINITIONS

LOT Lot Number


Expiration Date


Do Not Reuse


Do Not Resterilize


See Instructions For Use

STERILE EO Sterilized By Ethylene Oxide


Keep away from sunlight and heat


Do not use if package is damaged


Keep dry


Manufacturer


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PUB204 R07
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POLY(GLYCOLIDE-CO-CAPROLACTONE) PGCL WITH CHLORHEXIDINE DIACETATE
MONOFILAMENT SYNTHETIC ABSORBABLE SUTURE

DESCRIPTION
PGCL synthetic, absorbable, monofilament surgical suture is composed of poly(glycolide-co-caprolactone). PGCL Sutures are available dyed (D&C violet #2) or undyed (natural). This antibacterial suture contains ≤ 60 µg/m of a common antimicrobial agent, chlorhexidine diacetate. PGCL suture meets all requirements established by the United States Pharmacopeia (U.S.P.), except for diameter, which complies with the European Pharmacopeia.

INDICATIONS
PGCL sutures are indicated for use in animals in soft tissue approximation, and/or ligation, but not for use in cardiovascular or neurological surgery, microsurgery, or ophthalmic surgery.

ACTIONS
PGCL sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of PGCL sutures occurs by means of hydrolysis.

Absorption begins as a loss of tensile strength followed by a loss of mass. Implantation studies in animals indicate that PGCL suture retains approximately 40% to 60% of its original tensile strength at 7 days post implantation and approximately 10% to 30% of its original tensile strength at 14 days post implantation. Absorption of PGCL suture is essentially complete between 91 and 120 days.

This suture is coated with chlorhexidine diacetate, an antimicrobial agent which is intended to reduce or inhibit the colonization of *Staphylococcus aureus* and *Staphylococcus epidermidis*, and methicillin-resistant *S. aureus* (MRSA) and *S. epidermidis* (MRSE) that may be present at the surgical site.

CONTRAINDICATIONS
PGCL monofilament is contraindicated for use in cardiovascular or neurological surgery, microsurgery, or ophthalmic surgery.

Because of the loss of tensile strength that may occur over prolonged periods in vivo, PGCL monofilament surgical sutures should not be used where permanent retention of tensile strength is required.

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

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing PGCL suture for wound closure, as a risk of wound dehiscence may vary with the site of application and the suture material used.

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.

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 should be followed with respect to drainage and closure of contaminated or infected wounds.

The use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of sites which may undergo expansion, stretching, or distention, or which may require additional support as this is an absorbable suture material.

PRECAUTIONS

PGCL suture knots must be properly placed to be secure. In handling this or any other surgical suture, care should be taken to avoid damage from handling. Avoid crushing or crimping damage during the use of surgical instruments such as forceps or needle holders.

Skin sutures, which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with absorption.

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.

A reduction in the colonization of or microbial growth on this device has not been shown to directly correlate with a reduction of infections in patients; acceptable surgical practice should be followed with respect to aseptic technique and the drainage and closure of infected wounds.

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. Do not use this product on patients with a potential for hypersensitivity or a history of allergies to chlorhexidine diacetate.

Discuss the potential for allergic reaction in patients that are known to be sensitive to PGCL monofilament suture or Chlorhexidine Diacetate.

HOW SUPPLIED

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

CAUTION

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

FOR VETERINARY USE ONLY