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POLY (GLYCOLIDE-CO-CAPROLACTONE) (PGCL 25) ANTIBACTERIAL MONOFILAMENT ABSORBABLE SUTURE WITH CHLORHEXIDINE DIACETATE

DESCRIPTION
PGCL synthetic, absorbable, monofilament surgical suture is composed of poly(glycolide-co-caprolactone). PGCL Sutures are available dyed (FD&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
This absorbable suture should not be used where extended approximation of tissue is required. The use of this suture may be inappropriate in elderly, malnourished, and debilitated patients, or in patients suffering from conditions that may delay wound healing. Not for use in cardiovascular or neurological surgery, microsurgery, or ophthalmic surgery. For use in animals only, not for use in humans.

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WARNINGS
Do not resterilize; resterilization may alter the physical properties of this suture. Do not use if package is open or damaged or if the expiration date has been exceeded. Discard open, unused 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.

PRECAUTIONS
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.

Consideration should be taken in the use of absorbable sutures in tissue with poor blood supply as suture extrusion and delayed absorption may occur. In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders.

PGCL suture knots must be properly placed to be secure. 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 tying monofilaments.

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. As an absorbable suture, PGCL suture may act transiently as a foreign body.

Acceptable surgical procedure must be followed with respect to drainage and closure of contaminated or infected wounds. Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing PGCL sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

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.

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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.

HOW SUPPLIED
PGCL synthetic absorbable monofilament sutures are available in U.S.P. sizes 6-0 through 2 (metric sizes 0.7-5). They are available dyed or undyed. The sutures are supplied sterile, in pre-cut lengths, non-needled or affixed to various needle types: in one- or three-dozen boxes.

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

FOR VETERINARY USE ONLY

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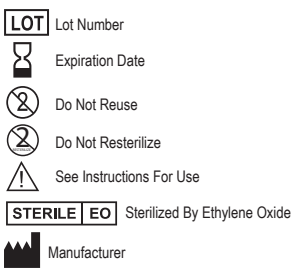
SYMBOL DEFINITIONS



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