POLY (GLYCOLIDE-CO-CAPROLACTONE) (PGCL) ANTI-MONILAL FILAMENTS WOUND 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 Pharmacopea (U.S.P.), except for diameter, which complies with the European Pharmacopa.

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.

WARNINGS
Do not resuture; reapplications 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 remain in place longer than 7 days may cause localized irritation and should be stripped 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 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-dozan boxes.

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 of injury. Wound infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, calcule formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transeptal local irritation. Do not use this product on patients with a potential for hypersensitivity or a history of allergies to chlorhexidine diacetate.

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

FOR VETERINARY USE ONLY

SYMBOL DEFINITIONS
LOT
Expiration Date
Do Not Reuse
Do Not Re Sterilize
See Instructions For Use
STERILE EO
Manufacturer

CP Medical Inc.
1775 Corporate Drive, Suite 150
Norcross, GA 30093 USA

Effective Date 01/04/2019