FAST ABSORBING POLYGLYCOLIC ACID (PGA)
SYNTHETIC ABSORBABLE SUTURES, U.S.P.

DESCRIPTION

Fast absorbing polyglycolic acid (PGA) suture is a synthetic, braided absorbable sterile surgical suture composed of a 100% polymer made from polyglycolic acid. The characteristic of rapid loss of strength is achieved by use of a polymer material with a lower molecular weight than polyglycolic acid suture. Coated fast absorbing polyglycolic acid sutures are obtained by coating the braided suture material with a mixture composed of equal parts of polymer and calcium stearate.

Although this suture is a synthetic absorbable suture, its performance characteristics are intended to model the performance of collagen (surgical gut) suture established by the United States Pharmacopoeia (USP) and European Pharmacopoeia (EP) requirements for synthetic absorbable sutures, with the exception of knot tensile strength. Knot tensile strength meets the USP and EP for collagen sutures.

INDICATIONS

Fast absorbing polyglycolic acid synthetic absorbable suture is indicated only for use in superficial soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required.

ACTIONS

Fast absorbing polyglycolic acid suture, when used in closure of skin and mucous membranes, typically begins to fall-off 7-10 days post-operative and can be wiped off subsequently with sterile gauze. Natural mechanical abrasion of the sutures while in situ may also accelerate this absorption rate. Rapid loss of tensile strength may preclude the need for stitch removal.

Fast absorbing polyglycolic acid elicits a minimal to moderate initial inflammatory reaction in tissue. Polyglycolic acid polymer with calcium stearate have been found to be nonantigenic, nonpyrogenic and elicit only a mild tissue reaction during absorption.

Progressive loss of tensile strength and eventual absorption of fast absorbing polyglycolic acid occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass.

Fast absorbable polyglycolic acid suture, which is treated with coating to enhance handling characteristics, requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Subcutaneous tissue implantation studies of fast absorbing polyglycolic acid sutures in rats show that 7 days post-implantation approximately 54% of the original tensile strength remains. All of the original tensile strength is lost by approximately 10-14 days post-implantation. Intramuscular implantation studies in rats show that the absorption of these sutures occurs thereafter and is essentially complete by 42 days.

CONTRAINDICATIONS

Fast absorbing polyglycolic acid suture is contraindicated for use in ligation, ophthalmic, cardiovascular or neurological procedures.

Because of the loss of tensile strength that may occur with prolonged periods in vivo, fast absorbing polyglycolic acid (PGA) surgical sutures should not be used where permanent retention of tensile strength is required. Due to the rapid loss of tensile strength, this suture should not be used where extended approximation of tissues under stress is required or where wound support beyond 7 days 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.

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 distention occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place longer than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calcification formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site.

HOW SUPPLIED

Fast absorbing polyglycolic acid sutures are available sterile in various USP sizes. Fast absorbing polyglycolic acid sutures are supplied in a wide range of lengths affixed to a diverse assortment of needle types.

DISPENSING (ractrack cartridge only):

For best results, pull the suture from the ractrack 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

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

SYMBOL DEFINITIONS

LOT
Expiry Date
Do Not Reuse
Do Not Resterilize
See Instructions For Use
Sterile By Ethylene Oxide
Keep away from sunlight and heat
Do not use if package is damaged
Keep dry
Manufacturer

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

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