

## 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 absorbing 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 over 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.

### WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing fast absorbing polyglycolic acid 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 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 any suture with salt solutions, such as those found in the urinary or biliary tracts, may

result in calculus formation. As an absorbable suture, fast absorbing polyglycolic acid suture may act transiently as a foreign body.

Acceptable surgical protocol should be followed for the management of contaminated or infected wounds.

Users should be familiar with surgical procedures and techniques involving fast absorbing sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. The use of supplemental nonabsorbable 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.

### PRECAUTIONS

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. 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 remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as necessary.

Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.

### 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 for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi 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 (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

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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