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

DESCRIPTION

Polyglycolic Acid (PGA) is a synthetic, absorbable, sterile surgical suture composed of braided Polyglycolic Acid and is available both dyed (D&C Violet No. 2) or undyed. The suture is coated with polycaprolactone and calcium stearate.

Polyglycolic Acid (PGA) meets all requirements established by the United States Pharmacopeia (U.S.P.) for synthetic absorbable surgical suture.

INDICATIONS

Polyglycolic Acid (PGA) is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological surgery.

ACTIONS

Polyglycolic Acid (PGA) elicits a minimal to moderate initial inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Loss of tensile strength and eventual absorption of Polyglycolic Acid (PGA) synthetic absorbable sutures occurs progressively. Absorption begins as a loss of tensile strength followed by a loss of mass. Implantation studies in animals indicate that Polyglycolic Acid (PGA) retains approximately 83% of its original tensile strength at 14 days post implantation, 52% of its original tensile strength at 21 days post implantation, and 20% of its original tensile strength at 28 days post implantation. Absorption of Polyglycolic Acid (PGA) absorbable synthetic suture is essentially complete between 60 and 90 days.

CONTRAINDICATIONS

Polyglycolic Acid (PGA) is contraindicated for use in cardiovascular and neurological surgery.

Because of the loss of tensile strength that may occur over prolonged periods in vivo, Polyglycolic acid (PGA) surgical sutures

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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 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 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

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.

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Skin sutures, which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed. 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, 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.

Discuss the potential for allergic reaction in patients that are known to be sensitive to Polyglycolic Acid (PGA) suture.

HOW SUPPLIED

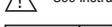
Polyglycolic Acid (PGA) sutures are available in various USP sizes. PGA sutures are supplied in a wide range of lengths affixed to a diverse assortment of needle types.

CAUTION

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

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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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