

VISORB® PRODUCT INSERT

POLYGLYCOLIC ACID (PGA) SYNTHETIC ABSORBABLE SUTURE, 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 (milk white). 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 acute 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

This suture, being absorbable, should not be used where extended approximation of tissue 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.

Not for use in cardiovascular and neurological surgery.

WARNINGS

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.

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. 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

Skin sutures, which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application 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.

Users should be familiar with surgical procedures and techniques involving absorbable suture before employing Polyglycolic Acid (PGA) synthetic absorbable suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

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.

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PRECAUTIONS

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

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 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, 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.

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.

HOW SUPPLIED

Coated Visorb Quick sutures are available sterile, dyed or undyed and attached to stainless steel needles of varying types and sizes in one to three-dozen boxes, or non-needled on ligating reels.

Visorb Quick sutures are available in various lengths in sizes: 6/0 to 1 (0.7 to 4.0 metric).

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



Manufacturer



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