VISORB QUICK PRODUCT INSERT

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. 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. Fast absorbing polyglycolic acid sutures are available dyed (D&C Violet No. 2) or undyed.

Although this suture is a synthetic absorbable suture, its performance characteristics are intended to model the performance of collagen (surgical gut) suture.

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. Fast absorbing polyglycolic acid suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.

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 minimally to moderately acute 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.

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.

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.

CONTRAINDICATIONS

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. 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 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 practice should be followed for the management of contaminated or infected wounds.

As this is an absorbable suture material, 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.

cpmedical
803 NE 25th Avenue
Portland, OR 97232 USA
phone 503 232-1555
fax 503 230-9993
www.cpmedical.com

VISORB QUICK PRODUCT INSERT

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 Lot Number

Expiration Date

Do Not Reuse

Do Not Resterilize

See Instructions For Use

STERILE EO Sterilized By Ethylene Oxide

Manufacturer

CP Medical, Inc.
803 NE 25th Ave.
Portland, OR 97232 U.S.A.

CE 0470

EC REP

MDSS GmbH SCHIFFGRABEN 41
30175 HANNOVER, GERMANY

PUB014-03