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INSTRUCTIONS FOR USE

P.G.A.
Synthetic absorbable braided multifilament surgical suture polyglycolic acid coated with polycaprolactone + calcium stearate

Description
Polyglycolic Acid Suture is a braided synthetic absorbable sterile surgical suture composed of a homopolymer of glycolic acid. The Polyglycolic Acid Surgical Suture is provided coated with polycaprolactone + calcium stearate. The substances contained in the coating and suture are noncollagenous and nonantigenic. Polyglycolic Acid suture is available undyed or dyed (violet). The suture is available in a wide variety of length - diameter combinations, with or without needle of various sizes and types, manufactured from high quality medical grade stainless steel. All these different types are described in detail in the company's product catalogue.
Polyglycolic Acid Synthetic Absorbable Suture meets all requirements established by the European Pharmacopeia for sterile Synthetic Absorbable Braided Sutures and with the essential requirements of the directive 93/42/EEC.

Indications
Polyglycolic Acid Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular and neurological procedures.

Application
Polyglycolic Acid Synthetic Absorbable Surgical Suture selection depends on the condition of the patient, the size of the tissue and wound, the surgical technique and the experience of the surgeon.

Actions
Polyglycolic Acid Synthetic Absorbable Surgical Suture elicits a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Polyglycolic Acid Synthetic Absorbable Sutures occurs by means of hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Studies in animals indicate that the Polyglycolic Acid Synthetic Absorbable Suture PGA retains approximately 65% of the average E.P. tensile strength requirement at the end of the 2nd post implantation week, and more than 35% at the end of the 3rd week. The absorption of the 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.

Warnings/ Precautions/ Interactions

P.G.A. surgical sutures should be used only from professionals who are familiar with surgical procedures and techniques involving absorbable sutures and wound closure techniques, as the risk of wound dehiscence or wound rupture may vary with the site of application and the suture material used. Users must be familiar with suture handling and knotting techniques. Knot security requires standard surgical technique of flat and square ties according to the experience of the surgeon and the nature of the operation. Unnecessary knot tension and suture handling with surgical instruments such as needle holders or forceps can damage the surface and weaken the suture and therefore must be avoided.
In case of infected wounds acceptable surgical practices should be followed. Special care should be taken in handling of surgical needles. The needle should be grasped with the needle holder in an area 1/3 to 1/2 of the distance from the attachment end to the point. Grasping the needle from the opposite end area can damage the point or even cause a needle fracture. Deformed needles should not be forced to their original shape as this can cause loss of strength or even needle fracture. Used needles should be safely discarded in special containers.
When selecting a suture its in vivo performance should be taken into consideration. The use of P.G.A. sutures may be inappropriate in elderly, malnourished and debilitated patients or patients suffering from other conditions that may delay wound healing. Furthermore, the degradation rate may vary following the tissue type (i.e. oral cavity).
Topical skin sutures which must remain in place longer than 7 days may cause localized irritation and the external portion should be cut and snipped off, or removed as indicated.

Adverse reactions
The use of the suture in some patients can cause initial skin irritation followed by a minimal inflammatory reaction at the wound site. As every foreign body it can enhance an existing infection.

Sterilization
P.G.A. surgical sutures are sterilized with Ethylenoxide gas. The sterilization method is mentioned on each single package. It is intended to be used only once and it should be discarded if its package is damaged or opened. Unused open sutures must be discarded. Sutures should not be re- sterilized.

Storage
Store below 25°C, away from direct heat and moisture. Never use after expiration date.

Symbols used on labeling

 : *Date of production*

 : *Do not reuse*

STERILE EO : *Sterile unless the package is damaged or opened.*
Method of sterilization : Ethylene Oxide

 : *See instructions for use*

 : *Use until Year & Month*

REF : *Product Number*

LOT : *Batch Number*

CE0653 : *CE-mark and identification number of notified body.*
Product conforms to the essential requirements of the
Medical Device Directive 93/42/EEC.

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