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INSTRUCTIONS FOR USE

NEOSORB (PGLA)

Synthetic absorbable braided multifilament surgical suture polyglactin 910 coated with Poly (glycolide-co-lactide) (30/70) and calcium stearate

Description
NEOSORB (PGLA) (polyglactin 910) suture is a braided synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. NEOSORB (PGLA) suture is provided coated with Poly(glycolide-co-lactide) (30/70) and calcium stearate. The substances contained in the coating and suture are noncollagenous and nonantigenic.
The suture is available undyed or dyed (violet) in a wide range of diameter - length combinations attached to high-quality stainless-steel needles of different sizes and types. All those different combinations are described in detail in the product's catalogue.
NEOSORB (PGLA) 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
NEOSORB (PGLA) synthetic absorbable surgical suture 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 procedures.

Application
The selection of NEOSORB (PGLA) synthetic multifilament absorbable surgical sutures depends on patient condition, size of tissue and wound and surgical technique and experience.

Performance
NEOSORB (PGLA) 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 NEOSORB (PGLA) synthetic absorbable surgical suture occurs by means of hydrolysis, where the polymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. NEOSORB (PGLA) retains approximately 50% of the average E.P. tensile strength requirement at the end of the 3rd post implantation week. The absorption of the suture is essentially complete between 56-70 days.

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

Warnings / Precautions / Interactions
NEOSORB (PGLA) 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. Adequate knot security is achieved with the standard surgical technique of flat and square ties, with additional throws depending on the surgical circumstances and the experience of the surgeon. 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.
Special care should be taken in handling surgical needles. The needle holder should grasp the needle in an area which should not exceed the 1/3 to 1/2 of the total length of the needle from the suture attachment point. Grasping the needle from its penetration point could impair seriously its penetration performance or even cause a needle fracture. An attempt to reshape a bended needle could cause loss of its strength and its resistance to breaking. Used needles should be discarded in special waste containers.
When selecting a suture, its in vivo performance should be taken into consideration. The use of NEOSORB (PGLA) 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) or concomitant therapy (i.e. radiotherapy).
As with any other absorbable surgical suture NEOSORB (PGLA) may have the temporary act of a foreign body. Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or inflected wounds.
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 NEOSORB (PGLA) suture in some patients may cause temporary local irritation or temporary inflammatory response to foreign body or even erythema and induration in cases of subcuticular applications. Like every other foreign body, NEOSORB suture may potentiate an existing infection.

Sterilization
NEOSORB (PGLA) 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.*
0°C 25°C	: Store below 25 °C, away from direct heat and moisture