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INSTRUCTIONS FOR USE

NEOSORB RAPID (RPGLA)

Synthetic absorbable undyed braided multifilament surgical suture polyglactin 910 coated with a co-polymer polyglactin 370 and calcium stearate

Description

NEOSORB RAPID (polyglactin 910) suture is a braided synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. The empirical molecular formula of the copolymer is $(C_7H_{12}O_2)_m(C_5H_8O_2)_n$. The characteristic rapid loss of strength occurs due to the lower molecular weight than the normal NEOSORB PGLA. The suture is available undyed.

NEOSORB RAPID 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 RAPID Synthetic Absorbable Surgical Suture is indicated only for use in soft tissue approximation of the skin and mucosa, plastic surgery, where only short-term wound support is required. It is not indicated for use in ligation, ophthalmic, cardiovascular, or neurological procedures.

Application

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

Performance

NEOSORB RAPID 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 RAPID Synthetic Absorbable Sutures occurs by means of hydrolysis, where the polymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. NEOSORB RAPID retains approximately 50% of the original tensile strength at 5 days post implantation. All of the original tensile strength is lost by approximately 10 to 14 days. Absorption is essentially complete by 42 days.

Contraindications

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

Warnings / Precautions / Interactions

NEOSORB RAPID 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 may vary with the site of application and the suture material used. When selecting a suture its in vivo performance should be taken into consideration. The use of NEOSORB RAPID sutures may be inappropriate in elderly, malnourished and debilitated patients or patients suffering from other conditions that may delay wound healing.

As with any other absorbable surgical suture NEOSORB RAPID may have the temporary act of a foreign body. Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or infected 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.

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.

Adverse Reactions

The use of NEOSORB RAPID 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 RAPID suture may potentiate an existing infection.

Sterilization










NEOSORB RAPID 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 unless the package is damaged or opened.
Method of sterilization : Ethylene Oxide
-  : See instructions for use
-  : Use until Year & Month
-  : Product Number
-  : Batch Number
-  0653 : CE-mark and identification number of notified body.
Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.
-  : Store below 25 °C, away from direct heat and moisture