PGA RESORBA™

Instructions for use, please read carefully!

The information given in this package leaflet is updated regularly.
Please read instructions carefully prior to use.

POLYGLYCOLIC ACID suture material

sterile, absorbable, synthetic

DESCRIPTION

PGA RESORBA™ is a synthetic sterile absorbable surgical suture material that consists of a polymer of glycolic acid. The braided thread is coated with resolactone (a mixture of calcium stearate and polycaprolactone) to reduce friction. PGA RESORBA™ is available dyed violet (D&C Violet No.2) and undyed (white). PGA RESORBA™ satisfies the requirements of the European Pharmacopoeia and United States Pharmacopeia for sterile synthetic absorbable sutures.

INDICATIONS

PGA RESORBA™ is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not in cardiovascular surgery or neural tissue.

ACTION

PGA RESORBA™ causes a slight inflammatory tissue reaction initially and is then slowly and progressively encapsulated by connective tissue. The gradual loss of tensile strength and the absorption of PGA RESORBA™ suture material are due to hydrolytic breakdown to glycolic acid, which is then absorbed and metabolized in the body. Absorption leads initially to a loss of tensile strength and then to a reduction in mass. Implantation studies demonstrated the loss of tensile strength as shown below. Absorption is fully complete in approximately 90 days.

Time of Measurement	Remaining tensile strength (% of original tensile strength)
7 days	90 %
14 days	80 %
21 days	50 %

CONTRAINDICATIONS

PGA RESORBA™ is absorbable, it should not be used for wound coaptations where extended approximation of tissue under stress is required.

WARNINGS

The risk of wound dehiscence varies with location of the wound and the suture material used, therefore the user should be familiar with the surgical techniques in which PGA RESORBA™ is to be used.

As with all suture materials, prolonged contact between PGA RESORBA™ and saline solutions can lead to the formation of calculi (urinary and biliary tracts).

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

As PGA RESORBA™ is an absorbable suture material, the surgeon should if necessary also use non-absorbable suture material for sutures that are under tension, are stretched, or need additional support. Under certain circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

PGA RESORBA™ may be inappropriate in elderly, malnourished or debilitated patients, or in patients with delayed wound healing.

Do not resterilise. Open, unused or damaged packs should be discarded.

PRECAUTIONS

PGA RESORBA™ is used where indicated in accordance with standard surgical suturing and knot-tying techniques and the experience of the user Skin sutures that must remain in situ for more than seven days can cause local irritation. The external part of the suture should therefore be cut off if necessary.

Caution is required when absorbable suture materials are used in poorly perfused tissue, as rejection of the thread and delayed absorption may occur. As with all suture material, care should be taken to ensure that the thread is not damaged during handling. In particular, it must not be kinked or crushed by surgical instruments such as needle holders. When tightening the suture always pull on the thread between the needle and the puncture channel. Do not pull the thread too firmly or over sharp objects. When stretching the thread avoid friction with the surgical glove, as this can damage the thread.

In order not to damage the needle, always grasp it $^1/_3$ – $^1/_2$ of the distance from the reinforced end to the point. Do not bend the needle, as this leads to loss of stability. Because of the risk of infection, the user should take particular care not to incur stab wounds when using surgical needles.

Used needles must be disposed of correctly (in order to avoid possible risks of infection).

For single use only. Risk of contamination if reused.

ADVERSE REACTIONS

Adverse events associated with this device include wound dehiscence, failure to provide adequate wound support in sites where expansion, stretching or distention occur. Failure to provide adequate wound support in patients with conditions which may delay wound healing. Localized irritation when skin sutures are left in place for more than 7 days. Calculi formation when prolonged contact with salt solutions occur. Minimal acute inflammatory reaction and local irritation at the wound site.

Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

PGA RESORBA™ sutures are available in USP 10 – 0 to 5 (metric 0.2 to 7).The sutures are supplied sterile, in pre-cut lengths and ligating reels, with a variety of needle options available. The boxes contain 1 or 2 dozen sutures and may be packaged in cartons as single packs, multipacks or procedure packs.

STORAGE CONDITIONS

Store at temperatures not exceeding 25 °C and protect from moisture and direct heat. Do not use after the expiry date!

DESCRIPTION OF THE SYMBOLS USED ON THE PACKAGE

REF	Reference Number
LOT	Batch Number
	Use by year – month
	Consult instructions for use
	Do not reuse
	Do not re-sterilise
	Do not use if package is damaged
STERILE R	Sterilised using ethylene oxide
25°C	Upper limit of temperature
	Undyed, braided, coated, absorbable
	Dyed, braided, coated, absorbable
PGA	Polyglycolic acid
	HIBC Code
A	Removable needle
	Ligature pack Sterile individual suture on a small roll
CE 0197	CE marking and identification number of the notified body. Product conforms to the essential requirements of the Council Directive 93/42/EEC
	Content in pieces
Rx only	Prescription only (only for the USA)

Manufacturing address

RESORBA®
REPAIR AND REGENERATE

an Advanced Medical Solutions Group plc company

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