GLYCOLON™

Instructions for use, please read carefully!

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

PGA/PCL suture material

Synthetic absorbable suture USP Except For Diameter

DESCRIPTION

GLYCOLON™ is a sterile synthetic absorbable monofilament surgical suture produced from a copolymer of glycolic acid and ε-caprolactone. GLYCOLON™ is available dyed violet (D&C Violet No.2) and undyed (white). GLYCOLON™ fulfils the requirements of the European Pharmacopeia and the United States Pharmacopeia for synthetic absorbable monofilament sutures, except for minor variations in diameter.

GLYCOLON™ sutures are USP except for diameters in the following sizes:

Maximum Suture Oversize in Diameter (mm) from USP	
USP Suture Size Designation	**Maximum Oversize (mm)**
6/0	0.045
5/0	0.020
4/0	0.033
3/0	0.054
2/0	0.034
0	0.052
1	0.036

INDICATIONS

GLYCOLON™ is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

ACTION

GLYCOLON™ elicits a mild inflammatory tissue reaction, and an ingrowth of connective tissue cells occurs. The gradual loss of tensile strength and absorption of GLYCOLON™ occurs by the means of hydrolysis. On absorption, there is first a reduction in tensile strength followed by a loss of mass. Implantation studies showed that approximately 70% of the original tensile strength is available after seven days and approximately 40% after fourteen days. Absorption is fully complete in approximately 90 days.

CONTRAINDICATIONS

GLYCOLON™ is not indicated for use where extended approximation of the 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 GLYCOLON™ is to be used.

As with all suture materials, prolonged contact between GLYCOLON™ 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 GLYCOLON™ is an absorbable suture material, the surgeon should if necessary also use non-absorbable suture material for sites that are under tension, are stretched, or need additional support (e.g. closure of the abdomen, chest, joints or other sites subject to expansion or requiring additional support).

As with all absorbable sutures, GLYCOLON™ may be inappropriate in elderly, malnourished or debilitated patients, or in patients with delayed wound healing.

Physicians should consider the in-vivo performance (under ACTIONS section) when selecting a suture for use in patient.

Do not resterilise. Open, unused or damaged packs should be discarded. Do not expose to extreme temperatures for a prolonged period of time.

PRECAUTIONS

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.

Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.

Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

GLYCOLON™ is used where indicated in accordance with standard surgical suturing and knot-tying techniques and the experience of the user.

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 distension occur.

Failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients with conditions which may delay wound healing, infection, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction and pain, edema and erythema at the wound site, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in poorly perfused tissue.

Calculi formation (urinary and biliary tracts) when prolonged contact with salt solutions occur and transitory 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 blood borne pathogens.

HOW SUPPLIED

GLYCOLON™ sutures are available in USP 6 – 0 to 1 (metric 0.7 to 4).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 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 EO	Sterilised using ethylene oxide
25°C	Upper limit of temperature
	Undyed, monofilament, absorbable
	Dyed, monofilament, absorbable
PGA/PCL	Poly(glycolide-co-caprolactone)
	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

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