

RESOLON™

Instructions for use, please read carefully!

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

Polyamide 6 – 6/6 suture material

sterile, nonabsorbable

DESCRIPTION

RESOLON™ is a monofilament, non-absorbable, surgical suture material made from polyamide 6 – 6/6, extruded from a copolymer of polyamide 6 and polyamide 6/6. RESOLON™ is available dyed blue ((Phthalocyaninato{2})copper). RESOLON™ satisfies the requirements of the European Pharmacopoeia and United States Pharmacopoeia for sterile non-absorbable suture material.

INDICATIONS

RESOLON™ is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neurological procedures.

ACTION

RESOLON™ sutures elicit a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. As with any polyamide sutures, though non absorbable, gradual loss of tensile strength can occur over a long time in vivo due to gradual hydrolysis of the polyamide.

CONTRAINDICATIONS

As RESOLON™ eventually loses some of its tensile strength, it is not suitable for indications in which lasting stability of the suture material is required.

WARNINGS

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

As with all foreign bodies, prolonged contact between RESOLON™ and saline solutions can lead to the formation of calculi (urinary and biliary tracts).

RESOLON™ is used where indicated in accordance with standard surgical suturing and knotting techniques and the experience of the user.

Do not re-sterilise. Open, unused or damaged packs should be discarded.

PRECAUTIONS

As with all suture material, care must 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 surgical gloves, as this can damage the thread.

In order to not damage the needle, always grasp it $\frac{1}{3}$ – $\frac{1}{2}$ of the distance from the reinforced end to the point. Do not bend the needle, as this leads to a 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 effects associated with the use of this device include wound dehiscence, calculi formation (urinary and biliary tracts) when prolonged contact with salt solutions occurs, minimal acute inflammatory tissue reaction typical of a moderate inflammatory response to a foreign body, and transitory local irritation.



















HOW SUPPLIED

RESOLON™ sutures are available in USP 11 – 0 to 2 (metric 0.1 to 5). The sutures are supplied sterile, in pre-cut lengths and ligating reels with a variety of needle options available. The boxes contain 1, 2 or 3 dozen sutures and may be packaged in cartons as single packs, multipacks or procedure packs.

STORAGE CONDITIONS

Store at not more than 25 °C protected from moisture and direct heat. Do not use after the expiry date!

DESCRIPTION OF THE SYMBOLS USED ON THE PACKAGE

	Reference Number
	Batch Number
	Use by year – month
	Consult instructions for use
	Do not reuse
	Do not re-sterilise
	Do not use if package is damaged
	Sterilised using ethylene oxide
	Upper limit of temperature
	Dyed, monofilament, non-absorbable
	Polyamide
	HIBC Code
	Removable needle
	Ligature pack
	Sterile individual suture on a small roll
	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
	Prescription only (only for the USA)

Manufacturing address


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