

INSTRUCTIONS FOR USE

Polyglactin 910 Suture

Absorbable - Multifilament - Synthetic - Sterile

Description:

POLYGLACTIN 910 suture is synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. POLYGLACTIN 910 sutures are available dyed and undyed (natural). POLYGLACTIN 910 suture fulfills all of the requirements of the EP and USP for the sterile synthetic braided absorbable sutures. POLYGLACTIN 910 sutures are coated with poly (glycolide-co-L-lactide) and calcium stearate.

Indications:

POLYGLACTIN 910 sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

Actions:

POLYGLACTIN 910 suture elicits a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. The implantation studies in rats indicate that POLYGLACTIN 910 suture retains approximately 75% of the original tensile strength at two weeks post implantation. Absorption is essentially complete about 56-70 days.

Contraindications:

Due to the rapid loss of tensile strength, POLYGLACTIN 910 should not be used where extended approximation of tissue is required.

Warnings:

POLYGLACTIN 910 suture should not be re-sterilized. Contents in packing have been sterilized. Do not use if package is opened or damaged. Discard opened packages and unused sutures. POLYGLACTIN 910 should be stored at room temperature. Away from moisture and direct heat. Users have to be familiar with surgical procedure including absorbable sutures. Particular factors of each patient should be taken into consideration when healing process in vivo. Handling infected or contaminated wounds. Proper surgical practices should be followed. The use of this suture might be improper in the elderly, patient that are under

nourished, weak patients, and patients under certain conditions that could delay the healing of the wound. Do not use after expiry date.

Precautions:

When working with POLYGLACTIN 910 suture materials, great care must be taken to ensure that the use of surgical instruments, such as forceps and needle holders, does not cause the material to be damaged by being pinched or kinked. The user of POLYGLACTIN 910 sutures should be familiar with surgical suture technique of flat and square ties with additional throws as warranted by the surgical circumstances and the experiences of the surgeon.

Reactions:

Slight inflammatory tissue reactions may occur initially in the environment of the suture material. Prolonged contact of any suture with salt solutions, such as those in the urinary or biliary tracts, may cause calculus formation.

Adverse Reactions:

Reported adverse reactions include tissue reaction, localized irritation and wound separation.

How supplied:

POLYGLACTIN 910 sutures are available from USP sizes: USP2 to 8-0. They are available violet coloured and are supplied sterile, in a variety of lengths, non-needled or affixed to various needle types in one, two or three dozens per box.

Storage Conditions:

It is recommended that POLYGLACTIN 910 sutures are stored below 25°C kept away from direct heat and moisture. Carefully observe the expiry date.

Manufacturer:

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Explanation of the Symbols on Packaging:

	Do not re-use
	Gamma irradiation
	Ethylene Oxide irradiation
	Consult instructions for use
	Do not use if package is damaged
	Expiration Date
	Manufactured Date
	Catalogue Number
	Batch number
	Keep away from sunlight
	Keep dry
	Temperature Limitation
	Fragile: Handle with care
	CE Mark and identification number of Notified Body. Product conforms to the essential requirements of the medical device directive 93/42/EEC

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