INSTRUCTIONS FOR USE

Polyester Suture

Non-absorbable - Braided - Sterile

Description:

Polyester suture is a sterile non-absorbable, braided, surgical suture composed of Poly (ethylene terephthalate). Polyester suture is prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component.

Polyester sutures are braided for optimal handling properties, and for good visibility in the surgical field, are dyed green coated with Silicon which grants extraordinary smoothness, softness and non-thrombogenic features to the suture. Polyester Sutures are available from USP sizes: USP4-6/0.

Polyester suture meets all the requirements of the EP and USP for Non-absorbable surgical suture.

Indications:

Polyester suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Actions:

Polyester suture elicits a minimal acute inflammatory reaction in tissue, followed by a gradual encapsulation of the suture by fibrous connective tissue. Implantation studies in animals show no meaningful decline in polyester suture strength over time. Both polyester fiber suture material and the coating materials are pharmacologically inactive.

Contraindications:

None Known.

Warnings:

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing polyester suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Do not reserilize. Discard opened packages and unused sutures. As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

Precautions:

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.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

To avoid damaging needle points and swags areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

Adverse Reactions:

Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction 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 bloodborne pathogens.

How supplied:

Polyester Sutures are available as sterile braided strands from USP4-6/0, in a variety of lengths, without needled or affixed to various needle types in one, two or three dozen per box.

Storage Conditions:

It is recommended that Polyester Sutures are stored below 23°C kept away from direct heat and moisture.

Carefully observe the expiry date.

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

Manufacturer:

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