INSTRUCTIONS FOR USE

Polypropylene Suture

Non-absorbable - Monofilament - Sterile

Description:

Polypropylene suture is a non-absorbable, sterile surgical suture composed of a strand of polypropylene, a synthetic linear polyolefin. Polypropylene suture is pigmented blue to enhance visibility and meet all the requirements of the EP and USP for Non-absorbable surgical suture. The diameter of the suture strand and the needle wire have been more closely aligned to reduce the degree of needle hole bleeding.

Indications:

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

Actions:

Polypropylene suture elicits an acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Polypropylene suture is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. As a monofilament, Polypropylene suture, U.S.P. resists involvement in infection and has been successfully employed in contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion. The lack of adherence to tissues has facilitated the use of Polypropylene suture as a pull-out suture.

Contraindications:

None known.

Warnings:

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

Do not resterilize. 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 must be followed for the management of infected or contaminated wounds.

Precautions:

In handling this 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. Adequate knot security requires the accepted surgical technique of flat, square ties of single suture strands. The use of additional throws is particularly appropriate when knotting polypropylene sutures.

To avoid damaging needle points and swage 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:

Polypropylene Sutures are available as sterile monofilament strands from USP2-7/0, in a variety of lengths, non-needled or affixed to various needle types in one, two or three dozens per box.

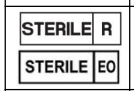
Storage Conditions:

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

Manufacturer:

Shandong Haidike Medical Products Co., Ltd.
Add: Tianfu Road, Dongcheng District, Shan County,
274300 Heze City, Shandong Province, China

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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Email: info@cmcmedicaldevicec.com

Importer:

GRAPH GROUP Vitalii Lutskov
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