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PROLENE™

ar	خيط جراحي	fr	SUTURE	ru	ШОВНЫЙ МАТЕРИАЛ
cz	ŠICÍ VLÁKNO	hu	VARRÓFONAL	sk	CHIRURGICKÁ NIŤ
da	SUTUR	it	SUTURA	sv	SUTUR
de	NAHTMATERIAL	ko	봉합사	tr	SÜTÜR
el	ΡΑΜΜΑ	nl	HECHTMATERIAAL	zh-cn	缝线
en	SUTURE	no	SUTUR	zh-tw	縫合線
es	SUTURA	pl	NICI CHIRURGICZNE		
fi	OMMELAINE	pt	FIO DE SUTURA		

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Instructions for use

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PROLENE™
(MONOFILAMENT POLYPROPYLENE)
STERILE SYNTHETIC NON-ABSORBABLE
SUTURE

DESCRIPTION

PROLENE™ Suture is a monofilament, synthetic, non-absorbable, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The molecular formula is $(C_3H_6)_n$. PROLENE™ is available undyed (clear) and dyed blue with phthalocyanine blue, Color Index Number 74160. PROLENE™ is available in a range of gauge sizes and lengths attached to stainless steel needles of various types and sizes. The material is also available in presentations containing the following:

1. HEMO-SEAL™ Needle Suture combination in which the diameter of the suture and the needle wire have been more closely aligned to reduce the degree of needle-hole bleeding.
2. A range of components in a variety of materials to anchor the ends of the suture for subcuticular closure or for use as tendon sutures.
3. Tubing to allow use as a retention suture.
4. PROLENE™ with PTFE (polytetrafluoroethylene) pledgets for use as a pad between the suture and the tissue surface to increase the load-bearing area.

Full details of the product range are contained in the catalog. PROLENE™ complies with the requirements of the European Pharmacopoeia for Sterile Non-Absorbable Strands and the requirements of the United States Pharmacopeia for Non-Absorbable Surgical Suture except for a slight oversize in gauge size Metric 0.5 (7/0).

INDICATIONS

PROLENE™ Sutures are for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurosurgical procedures.

APPLICATION

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique, and wound size.

PERFORMANCE

PROLENE™ Suture elicits a minimal initial inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. PROLENE™ Suture is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. Due to its relative biological inertness, it is recommended for use where the least possible suture reaction is desired. As a monofilament, it has been successfully employed in surgical wounds which subsequently become infected or contaminated where it can minimize later sinus formation and suture extrusion. Because of its lack of adherence to tissue, PROLENE™ is effective as a pull-out suture.

CONTRAINDICATIONS

None known.

WARNINGS / PRECAUTIONS / INTERACTIONS

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

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.

Care should be taken to avoid damaging the surface of the material with surgical instruments as this could lead to fracture of the material in use. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the surgeon. The use of additional throws is particularly appropriate when knotting polypropylene sutures.

Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one third (1/3) to one half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. 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-stick injury. Discard used needles in 'Sharps' containers.

Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.

ADVERSE REACTIONS

Adverse reactions associated with the use of this device include minimal initial inflammatory tissue reaction and transient local irritation at the wound site. Like all foreign bodies, PROLENE™ may potentiate an existing infection.

STERILITY

PROLENE™ Sutures are sterilized by ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

STORAGE

No special storage conditions required. Do not use after expiry date.

SYMBOLS USED ON LABELING


Do not reuse


Number of units


Use by – year and month

Sterilized using Ethylene Oxide

CE-mark and Identification Number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42/EEC

Batch number


Caution: See instructions for use


Manufacturer

Catalogue Number