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INSTRUCTIONS FOR USE

POLYESTER

Braided - wax treated non absorbable sterile surgical suture

Description

Polyester is a sterile non absorbable surgical suture composed of Poly (Ethylene terephthalate). Polyester sutures are coated with a thin layer of wax. They are available white or dyed with D&C Green No.6. The dyestuff meets all FDA requirements.

The suture is available in a wide variety of length - diameter combinations, with needle of various sizes and types, manufactured from high quality medical grade stainless steel. All these different types are described in detail in the company's product catalogue.

Polyester sterile surgical sutures are manufactured according to the requirements of the European Pharmacopoeia for sterile non absorbable sutures and with the essential requirements of the directive 93/42/EEC.

Indications

Polyester sterile surgical sutures are used for soft tissue approximation and ligation, even in ophthalmic, cardiovascular and neurological procedures.

Application

Polyester sterile surgical suture selection depends on the condition of the patient, the size of the tissue and wound and the experience of the surgeon. Polyester suture is intended to be used in adult and pediatric populations, regardless of gender.

Performance

The implantation of the Polyester suture in tissues results to an initial inflammatory reaction, followed by gradual encapsulation of the suture by connective tissues. Polyester sutures are not absorbed, nor is any significant change in tensile strength known to occur in vivo.

Contra indications

There are no known contra indications.

Warnings / Precautions / Interactions

Polyester sutures should be used only from members of experienced surgical teams. Users must be familiar with suture handling and knotting techniques. Knot security requires standard surgical technique of flat and square ties according to the experience of the surgeon and the nature of the operation. Unnecessary knot tension and suture handling with surgical instruments such as needle holders or forceps can damage the surface and weaken the suture and therefore must be avoided. Dehiscence of the suture upon removal may occur in case of improper use.

Special care should be taken in handling of surgical needles. The needle should be grasped with the needle holder in an area 1/3 to 1/2 of the distance from the attachment end to the point. Grasping the needle from the opposite end area can

damage the point or even cause a needle fracture. Deformed needles should not be forced to their original shape as this can cause loss of strength or even needle fracture. Used needles should be safely discarded in special containers.

Adverse reactions

The use of the suture in some patients can cause allergic response or temporary local irritation which is followed from temporary inflammatory reaction. As every foreign body, it can enhance an existing infection.








Sterilization

Polyester surgical sutures are sterilized with gamma irradiation. It is intended to be used only once and it should be discarded if its package is damaged or opened. Unused open sutures must be discarded. Sutures should not be resterilized.

Storage

Store below 25°C, away from direct heat and moisture. Never use after expiration date.

Symbols used in labeling

	: Date of production
	: Do not reuse
	: Sterile unless the package is damaged or opened. Method of sterilization : Irradiation
	: See instructions for use
	: Use until Year & Month
<i>REF</i>	: Product Number
	: Batch Number
 0653	: 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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