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Instructions for use

SUPRAMID
Non absorbable sterile surgical suture

Description

SUPRAMID is a sterile non absorbable surgical suture available in two different structures depending on suture diameter:

- Supramid pseudo-monofilament consists of a core of polyamide 6.6 and a sheath of polyamide 6, ranging from USP 4/0 to 2.
- Supramid monofilament is made of polyamide 6 with a range from USP 7/0 to 5/0.

It is dyed black with Pigment Black 7.
The suture is available in a wide variety of length - diameter combinations, with or without 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.
SUPRAMID sterile surgical sutures are manufactured according to the requirements of the European Pharmacopoeia for sterile synthetic non absorbable sutures and with the essential requirements of the directive 93/42/EEC.

Indications

Non absorbable SUPRAMID suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular tissues and tissues of the central nervous system.

Application

SUPRAMID sterile surgical suture selection depends on the condition of the patient, the size of the tissue and wound, the surgical technique and the experience of the surgeon. SUPRAMID suture is not a permanent suture and should be removed in a period of 30 days following surgery.

Performance

SUPRAMID suture is not adherent to the tissues and it can be removed easily and painlessly. Therefore, it can be used as a pull-out suture.

Contraindications

There are no known contra indications

Warnings / Precautions / Interactions

SUPRAMID 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 and rupture of the suture upon removal may occur in case of improper use.

In case of infected wounds acceptable surgical practices should be followed.
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 initial skin irritation followed by a minimal inflammatory reaction at the wound site. As every foreign body it can enhance an existing infection.

Sterilization
SUPRAMID surgical sutures are sterilized with Ethylenoxide gas or gamma irradiation. The sterilization method is mentioned on each single package. 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 re-sterilized.

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 : Ethylene Oxide

 : *See instructions for use*

 : *Use until Year & Month*

REF : *Product Number*

: *Batch Number*

CE0653 : *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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