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INSTRUCTIONS FOR USE

PROFIMED

Undyed monofilament non absorbable sterile PTFE surgical suture

Description

PROFIMED is a sterile non absorbable monofilament surgical suture made from polytetrafluoroethylene (PTFE) polymer. The molecular formula of the polymer is $(C_2F_4)_n$.

The suture is available undyed 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.

PROFIMED 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

PROFIMED surgical sutures are used for soft tissue approximation and/or ligation, even in cardiovascular and dental procedures, but are not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

Application

PROFIMED 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.

Performance

Implantation of the suture elicits a minimal inflammatory reaction followed by gradual encapsulation by fibrous connective tissue.

Contra indications

There are no known contra indications

Warnings / Precautions / Interactions

The safety and effectiveness of PROFIMED suture in ophthalmic, microsurgical, and peripheral neural applications has not been established.

PROFIMED sutures should be used only from members of experienced surgical teams. PROFIMED surgical sutures should be used only from professionals who are familiar with surgical procedures and techniques involving non absorbable sutures and wound closure techniques, as the risk of wound dehiscence may vary with the site of application and the suture material used. 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.

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

PROFIMED surgical sutures are sterilized with Ethylenoxide gas. 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*



: *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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