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INSTRUCTIONS FOR USE

MONOFAST-PGCL
Synthetic monofilament absorbable surgical suture made from Polyglycolic acid-co-polycaprolactone

Description
MONOFAST surgical suture is a synthetic absorbable monofilament sterile surgical suture composed from a copolymer of polyglycolic acid-co-polycaprolactone. The empirical molecular formula of the polymer is $(C_2H_2O_2)_m(C_6H_{10}O_2)_n$. MONOFAST suture is available undyed or dyed (violet) in a wide range of diameter - length combinations attached to high quality stainless steel needles of different sizes and types. All those different combinations are described in detail in the product's catalogue.
MONOFAST monofilament absorbable sutures comply fully with the requirements of the European Pharmacopoeia for sterile synthetic absorbable sutures and with the essential requirements of the directive 93/42/EEC.

Indications
MONOFAST monofilament synthetic absorbable suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular tissues and tissues of central nervous system and also in microsurgery and ophthalmic surgery.

Application
The selection of MONOFAST synthetic monofilament absorbable surgical sutures depends on patient condition, size of tissue and wound and surgical technique and experience.

Performance
The implantation of the MONOFAST monofilament synthetic absorbable surgical suture elicits a minimal inflammatory reaction, which is followed by the development of fibrous connective tissue in place. Progressive loss of tensile strength and eventual absorption of the suture occurs by means of hydrolysis, where the polymer degrades to adipic acid, which is subsequently absorbed and metabolized by the tissues. Absorption begins as a loss of tensile strength without appreciable loss of mass. The retention of the MONOFAST suture is 68-78% of the original tensile strength after the 1st week and approximately 30% after the end of the 2nd week. The absorption of the suture is essentially completed after a period of 90 -110 days. Its original tensile strength is essentially lost 28 days after its implantation.

Contraindications
This suture, being absorbable, should not be used where extended approximation of tissue is required.

Warnings / Precautions / Interactions
MONOFAST surgical sutures should be used only from professionals who are familiar with surgical procedures and techniques involving absorbable sutures and wound closure techniques, as the risk of wound dehiscence may vary with the site of application and the suture material used. When selecting a suture its in vivo performance should be taken into consideration. The use of MONOFAST sutures may be inappropriate in elderly, malnourished and debilitated patients or patients suffering from other conditions that may delay wound healing. Furthermore, the degradation rate may vary following the tissue type (i.e. oral cavity).
As with any foreign body, prolonged contact with salt solutions, such as those found in urinary or billiard tracts, may result in calculus formation. As with any other absorbable surgical suture MONOFAST suture may have the temporary act of a foreign body. Acceptable surgical practice should be followed with respect to

drainage and closure of contaminated or inflected wounds. The use of supplemental non absorbable sutures may be appropriate in certain circumstances at the discretion of the surgeon (i.e. sites which may undergo expansion, stretching, or distension or cases that may require an additional support).
Topical skin sutures which must remain in place longer than 7 – 10 days may cause localized irritation and the external portion should be cut and snipped off or removed, as indicated.
Adequate knot security is achieved with the standard surgical technique of flat and square ties, with additional throws depending on the surgical circumstances and the experience of the surgeon.
In handling this or any other 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. Special care should be taken in handling surgical needles. The needleholder should grasp the needle in an area which should not exceed the 1/3 to 1/2 of the total length of the needle from the suture attachment point. Grasping the needle from its penetration point could impair seriously its penetration performance or even cause a needle fracture. An attempt to reshape a bended needle could cause loss of its strength and its resistance to breaking. Used needles should be discarded in special waste containers.

Adverse Reactions
The use of MONOFAST suture in some patients may cause temporary local irritation or temporary inflammatory response to foreign body or even erythema and induration, in cases of subcuticular applications. An additional adverse effect associated with the use of this device can be suture extrusion. Like every other foreign body MONOFAST suture may potentiate an existing infection.

Sterilization
MONOFAST surgical sutures are sterilized with Ethylenoxide gas. 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 resterilized.

Storage
Store below 25°C, away from direct heat and moisture. Do not use the suture after its expiration date.

Symbols used on 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.