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INSTRUCTIONS FOR USE

MONOSORB-PDO (Polydioxanone)
Synthetic monofilament absorbable surgical suture made from poly (p-dioxanone)

Description
MONOSORB Surgical Suture is a sterile synthetic absorbable monofilament suture composed from polyester poly (p-dioxanone). The empirical molecular formula of this polymer is $(C_4H_6O_3)_n$. MONOSORB suture is available 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.
Poly (p-dioxanone) 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
MONOSORB synthetic absorbable surgical sutures are used for general soft tissue approximation and/or ligation. But they are not for use in cardiovascular tissues and tissues of the central nervous system.

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

Performance
The implantation of the MONOSORB 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 carbon dioxide and water which are subsequently absorbed and metabolized by the tissues. Absorption begins as a loss of tensile strength without appreciable loss of mass. The retention of MONOSORB absorbable surgical suture is 65-70% of the original tensile strength after 4 weeks and 50-60% after 6 weeks. The absorption of the suture is essentially completed after a period of 180 - 220 days.

Contraindications
The MONOSORB synthetic absorbable surgical sutures, being absorbable, should not be used where extended, or permanent approximation of tissue under stress is required, or desirable.

Warnings / Precautions / Interactions
The safety and effectiveness of MONOSORB sutures for use in the cardiac tissue, the large vessels and the central nervous system is not yet well established.

MONOSORB 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 MONOSORB 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 MONOSORB 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 needle holder 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 MONOSORB suture in some patients may cause temporary local irritation or temporary inflammatory response to foreign body or even erythema and induration in cases of sub-cuticular applications. Like every other foreign body MONOSORB suture may potentiate an existing infection.

Sterilization
MONOSORB surgical sutures are sterilized with Ethylenoxide Gas. The sterilization method is mentioned on each single package. MONOSORB sutures are intended to be used only once and they should be discarded if their package is damaged or opened. Unused open sutures must be discarded. MONOSORB surgical sutures should not be re-sterilized.

Storage
It is recommended that the sutures are stored below 25°C, away from direct heat and moisture. Sutures should not be used after their expiration date.

Symbols used on Labeling

 : *Date of production*

 : *Do not reuse*

STERILE EO : *Sterile unless the package is damaged or opened.*
Method of sterilization : Ethylene Oxide

 : *See instructions for use*

 : *Use until Year & Month*

REF : *Product Number*

LOT : *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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