

Monosyn®

Description

Monosyn® is a sterile synthetic absorbable monofilament surgical suture produced from a copolymer of 72% glycolide, 14% ε-Caprolactone, 14% Trimethylenecarbonate. Monosyn® is coloured violet with the dyestuff D&C Violet N°2 but is also available undyed, in the natural beige colour. Monosyn® fulfils all the requirements of the European Pharmacopoeia and of the United States Pharmacopoeia for sterile, synthetic absorbable monofilament sutures, except for minor variations in suture diameter.

Indications

Monosyn® Synthetic Absorbable Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery.

Mode of action

When Monosyn® suture materials are employed, there is a mild inflammatory reaction, which is typical for an endogenous reaction to a foreign body. Monosyn® is metabolised to glycolic acid by hydrolysis without causing any enduring change in the region of the wound. Approximately 50% of the original knot pull tensile strength is available after 13 to 14 days. The mass degradation of Monosyn® is essentially completed after 60 to 90 days.

Contraindications

Monosyn® suture materials are contra-indicated for indications where prolonged support of the wound closure is required (e.g. cardiovascular or neurological surgery).

Warning note

The user should be familiar with surgical suturing techniques, before employing Monosyn® suture materials for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with all other suture materials, long contact with salt solutions such as urine and bile, can lead to lithiasis. Do not resterilize. Open, unused or damaged packs should be discarded. The Monosyn® suture material should be stored at room temperature. Do not expose to extreme temperatures for a prolonged period of time. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds. The use of an absorbable suture material may be inappropriate in patients with any conditions which, in the opinion of the surgeon may cause or contribute to delayed wound healing. As this is an absorbable suture, the use of supplemental nonabsorbable sutures should be considered by the surgeon in closure of the abdomen, chest, joints or other sites subject to expansion or requiring additional support.

Note/precautionary measures

Great care must be taken when working with Monosyn® in order to avoid damage as a result of crushing or snapping, due to the use of surgical instruments such as tweezers and needle holders.

The user should be familiar with surgical suturing techniques, before employing Monosyn® suture materials. As with any suture material, adequate knot security requires the accepted surgical technique of flat, square ties with additional throws as warranted by surgical circumstances and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Under some circumstances, notably orthopedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

To avoid damaging needles points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should be careful when handling surgical needles to avoid inadvertent needle sticks. Discard needles in "sharps" containers.

Adverse reactions

Adverse effect associated with this device include wound dehiscence, failure to provide adequate wound support in sites where expansion, stretching or distention occur, failure to provide adequate wound support in patients with conditions which may delay wound healing, localized irritations, when skin sutures are left in place for more than 7 days, calculi formation such as urine and bile, when prolonged contact with salt solutions occur, enhanced bacterial infectivity, minimal acute inflammatory reaction and pain, edema and erythema at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens

How supplied

Monosyn® sutures are available in USP 2 to 6/0 (metric 5 to 0,7). The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needled or attached to needles, with permanent or removable (take-off) needle attachment techniques. The boxes contain 1, 2 or 3 dozens of sutures.

Caution

Federal (USA) law restricts this device to sale or use by or on the order of a physician.

Symbols used on labeling



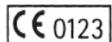
Do not reuse



Use by: Year + Month



Sterile unless package is opened or damaged. Method of Sterilization - Ethylene oxide



CE-mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.



Batch number



See instructions for use

REF

Cat. No.

CUSTOMER SERVICE

For further information regarding Monosyn® Suture please contact Tissue Seal, LLC's Customer Service at 1-877-754-6458 or customerservice@tissueseal.com

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