

Trelon® Instructions for use

Description

Trelon® is a sterile, braided and coated non-absorbable surgical suture material produced from polyamide 6/6. Trelon® sutures are coated with silicone. Trelon® is available in black, coloured with Logwood extract (C.I. Natural Black 1) to make it more readily recognizable and also undyed (clear). Trelon® fulfils all the requirements of the European Pharm. and the United States Pharm. current edition for sterile, non- absorbable sutures.

Indications

Trelon® sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Mode of action

Suture materials are used primarily for adaptation of the wound edges to render possible an undisturbed wound healing. When Trelon® suture materials are employed, a minimal inflammatory tissue reaction will occur followed by a gradual encapsulation of the suture material by fibrous connective tissue. Like all polyamide materials, over a long period of time Trelon® in vivo is subject to a gradual loss of total suture strength through the action of body enzymes.

Contra-indications

On account of the gradual loss of strength, which can occur in vivo over a longer period, the use of Trelon® is contraindicated when a permanent retention of suture strength is of importance.

Warning note

The user should be familiar with surgical suturing techniques, before employing Trelon® 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 Trelon® 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.

Note/precautionary measures

Great care must be taken when working with Trelon® 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. 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. To avoid damaging needle 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 the use of this device include: wound dehiscence, calculi formation when prolonged contact with salt solution occurs, enhanced bacterial infectivity, infection, minimal acute inflammatory reaction and transitory local irritation. 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

Trelon® polyamide sutures are available in USP 2 to 7/0 (metric 5 to 0.5). 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. Methode of Sterilization - Gamma radiation



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 Trelon® Suture please contact Tissue Seal, LLC's Customer Service at 1-877-754-6458 or customerservice@tissue seal.com

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01-01/20