

PremiCron®

Description

PremiCron® is a sterile non-absorbable synthetic suture composed of polyester yarns made of polyethylene terephthalate (PET) braided and coated with silicone. The polyester suture PremiCron® is available either white (undyed) or dyed green (D&C Green No. 6) from sizes USP5 to USP6/0. PremiCron® can be offered with pledgets. The pledgets are made from 100% polytetrafluoroethylene (PTFE). PremiCron® fulfils all the requirements of the European and the United States Pharmacopia for sterile, synthetic nonabsorbable sutures.

Indications

PremiCron® nonabsorbable surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular and vascular, ophthalmic and neurological procedures.

Mode of action

PremiCron® causes a minimal, initial inflammatory reaction in tissues, followed by a gradual encapsulation of the suture material by fibrous connective tissue without meaningful decline in suture strength.

Contraindications

None known.

Warning note

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

PremiCron® polyethylene terephthalate sutures are available in USP 5 to 6/0 (metric 7 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. PremiCron® is also available attached to pledgets made from 100% polytetrafluoroethylene (PTFE) measuring 1/8" x 1/8" x 1/16" (3.0 mm x 3.0 mm x 1.5 mm), 1/4" x 1/8" x 1/16" (6.0 mm x 3.0 mm x 1.5 mm). The boxes contain 1, 2 or 3 dozens of sutures.

Sterility

PremiCron® sutures without pledgets are gamma or ethylene oxide sterilized. PremiCron® sutures with pledgets are sterilized by ethylene oxide gas.

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

Distributed by:

Tissue Seal, LLC

4401 Varsity Drive, Suite D
Ann Arbor, MI 48108 – U.S.A.

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