

CliniMono Q Sutures

Description

CliniMono Q is a synthetic absorbable sterile surgical suture composed of poly (glycolide-co-caprolactone) monofilament (PGCL). CliniMono Q sutures are only available undyed. CliniMono Q sutures are rapidly absorbed synthetic suture when compared to CliniSolv. CliniMono Q meets all the requirements established by the B.P., U.S.P. and the E.P.

Indications

CliniMono Q is indicated for superficial soft tissue approximation and/or ligation, but not for the use in cardiovascular and neurological surgery or ophthalmic procedures.

Actions

CliniMono Q elicits a minimal acute inflammatory reaction in tissues, which is followed by encapsulation of the suture by fibrous connective tissue. Tensile strength is progressively lost at a more rapid rate than with conventional monofilament. CliniMono Q(2USP) retains approximately 68-78% of its original strength at 7 days post-implantation. Absorption is complete within 90 days.

Contra-Indications

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

Warning

Before employing CliniMono Q sutures, users should be familiar with surgical procedures and techniques relating to synthetic absorbable sutures and wound closure. Depending on the site of application, there is a risk of wound dehiscence. This risk is variable. In elderly, malnourished or debilitated patients or in those where wound healing is delayed due to their condition, the use of CliniMono Q may not be indicated. CliniMono Q, being an absorbable suture, may need the additional support of non-absorbable sutures when closing sites prone to expansion, stretching or distortion.

Precautions

Localized irritation may result if skin sutures remain in place for longer than one week and in these cases snipping off/removal is advised. In tissues with poor blood supply, it must be borne in mind that delayed absorption may occur when employing absorbable sutures. During handling, crushing or crimping damage must be avoided when using instruments such as needle holders or forceps. Adequate knot security requires the accepted practice of flat, square ties with additional throws as warranted by the surgical circumstances and the experience of the surgeon. To avoid damage to 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 exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" container.

Sterility

CliniMono Q sutures are sterilized by ethylene oxide gas. Do not use if package is opened or damaged. Discard opened unused sutures.

Storage

Recommended storage condition: 15°C to 30°C, away from direct heat. Do not use after expiry date.

Adverse Reactions

Potential Adverse effects

- Infection
- Dehiscence with need for retreatment
- Acute inflammation

These reactions may occur in patients who are hypersensitive to the materials

Adverse reactions associated with the use of this device include wound dehiscence, failure to provide sufficient wound support in closure of sites where expansion, distension or stretching occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing. Localized irritation may occur when skin closures are left in place for more than 1 week. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in transmission of blood-borne pathogens.

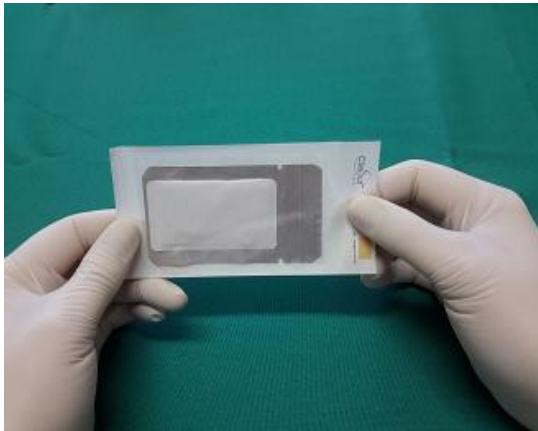
How supplied

CliniMono Q synthetic absorbable monofilament suture is available in sizes 6/0 through 2, undyed. The suture is supplied attached to various needle types in boxes of one dozen.

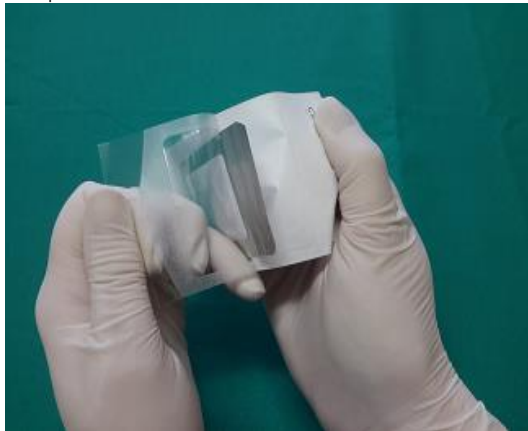


INSTRUCTIONS FOR OPENING OF CLINIMONO Q SUTURE

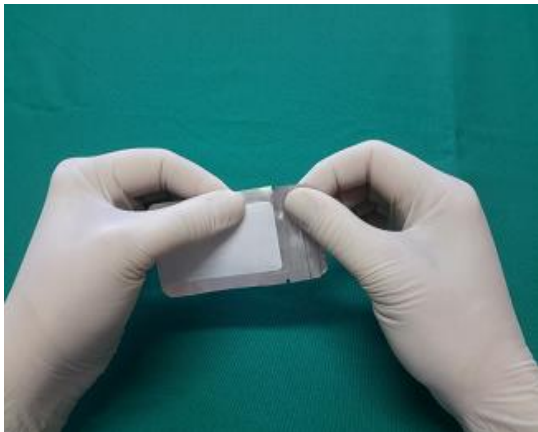
1. Hold suture facing you with opening on right side.



2. Open outer pouch by pulling it apart until inner pouch is exposed and remove.



3. Open foil pouch at tearing notch.



4. Tear open so that inner winding pouch can be removed.



5. Remove inner winding pouch to expose suture.



6. Secure needle in needle holder and pull out of winding pouch.



The suture is now ready for use



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