

Description

CliniSorb Q is a synthetic absorbable sterile surgical suture composed of homopolymers of glycolide 100 %. CliniSorb Q sutures are only available undyed. CliniSorb Q sutures are a rapidly absorbed synthetic suture when compared to CliniSorb. CliniSorb Q meets all the requirements established by the U.S.P. for synthetic absorbable sutures.

Indications

CliniSorb Q is indicated for superficial soft tissue approximation where only short term wound support is required (7-10days). CliniSorb Q should not be used in ligation, ophthalmic, cardiovascular and neurological procedures.

Actions

CliniSorb Q sutures, when used as indicated, usually start to disintegrate within 7-10 days after insertion. As a result they can be removed by wiping with a gauze swab. Since they lose their tensile strength rapidly, there is in all probability no need to remove the stitches mechanically. CliniSorb Q elicits a minimal acute inflammatory reaction in tissues, which is followed by encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of CliniSorb Q suture occurs by means of hydrolysis where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Implantation studies in animals indicate that CliniSorb Q(2USP) retains approximately 50% of its tensile strength at 5 days post-implantation. 14 days after implantation all of the original tensile strength is lost. Absorption is essentially complete after 3 weeks.

Contra-Indication

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

Warning

Before employing CliniSorb 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. The use of CliniSorb Q may not be indicated in elderly, malnourished or debilitated patients or those where wound healing is delayed due to their condition. CliniSorb Q, being an absorbable suture, may need the additional support of non-absorbable sutures when closing sites prone to expansion, stretching or distension.

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 forceps or needle holders. 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

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

Storage

Recommended storage conditions: between 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 material

Adverse reactions associated with the use of this device include wound dehiscence, failure to provide sufficient wound support in closure of sites, where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing. Localised 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.

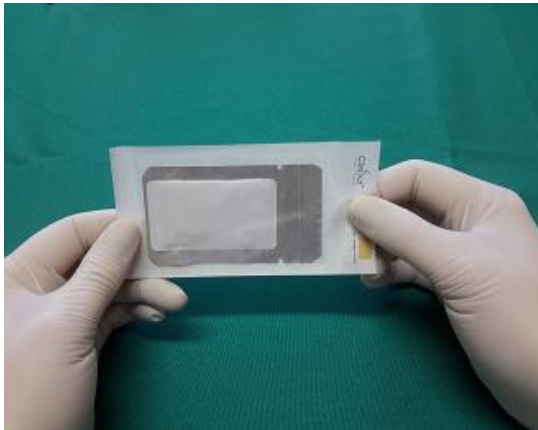


How supplied

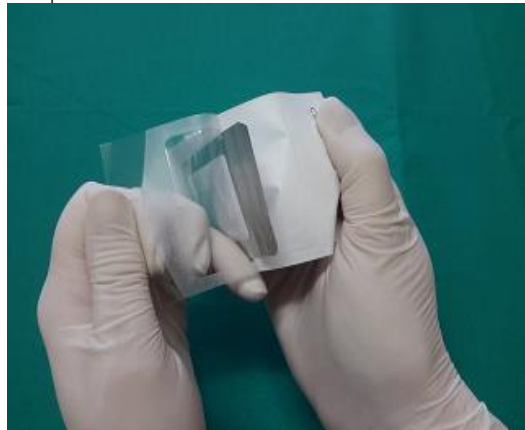
CliniSorb Q Synthetic Absorbable braided suture is available in sizes 6/0 through 2, undyed. The suture is supplied attached to various needle types in boxes of one dozen.

INSTRUCTIONS FOR OPENING OF CLINISORB Q SUTURE

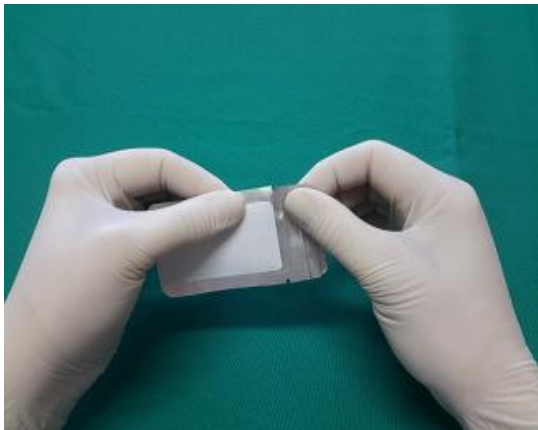
1. Hold suture facing you with opening on right side.



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



CliniSorb Q Sutures

