

CliniLene Sutures

Description

CliniLene polypropylene suture (clear or pigmented) is a non-absorbable sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The suture is pigmented blue to enhance visibility.

CliniLene sutures meet requirements established by the European Pharmacopoeia for non-absorbable surgical sutures.

Indications

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

Actions

CliniLene sutures exhibits a minimal acute inflammatory reaction in tissue which is followed by a gradual encapsulation of the suture by fibrous connective tissue. CliniLene sutures are not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. As a monofilament, CliniLene sutures, resists involvement in infection and has been successfully employed in contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion. The lack of adherence to tissues has facilitated the use of CliniLene suture as a pull-out suture.

Contraindications

None known

Warning

Users should be familiar with surgical procedure and techniques involving non-absorbable sutures before employing CliniLene sutures for wound closure, as risk of wound dehiscence may vary with the site of application and suture material used.

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact or any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice must be followed for the management of infected or contaminated wounds.

Precautions

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to the application of surgical instruments, such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, square ties of single suture strands. The use of additional throws is particularly appropriate when knotting polypropylene sutures.

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

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

Storage

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

Adverse Reactions

Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection minimal acute inflammatory reaction and transitory local irritation at 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 transmission of bloodborne pathogens.

How supplied

CliniLene sutures are available in sizes 6/0 through 2. The suture is supplied attached to various needle types in boxes of one dozen.

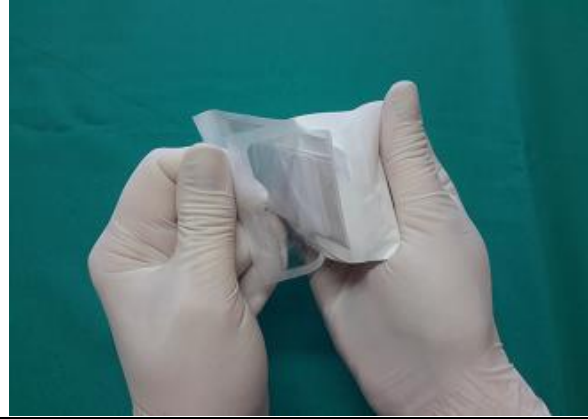


INSTRUCTIONS FOR OPENING OF CLINILENE SUTURE

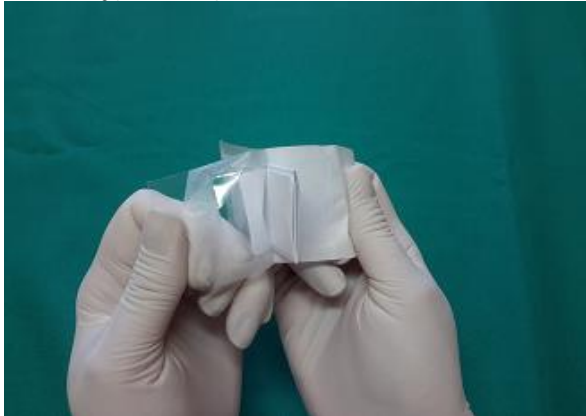
1. Hold suture facing you with opening on right side.



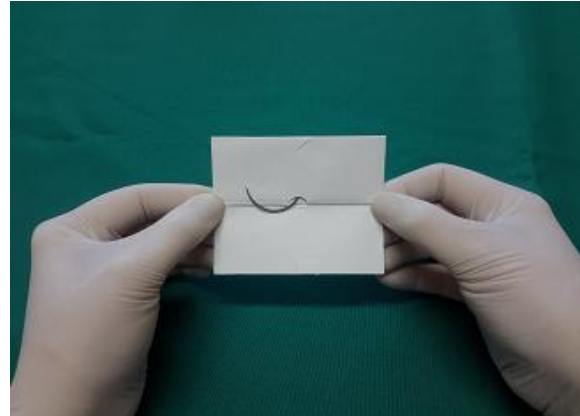
2. Open outer pouch by pulling it apart until inner pouch is exposed and remove.



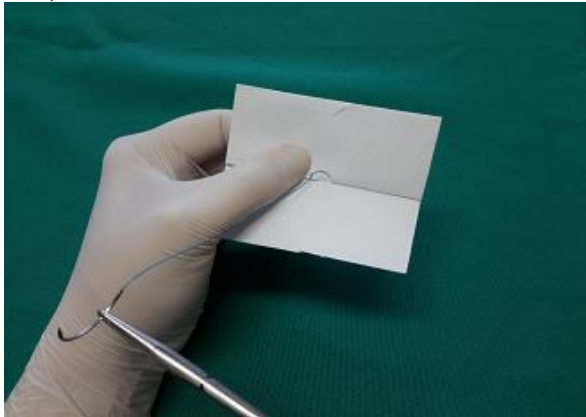
3. Remove inner pouch and open by pulling it apart until inner winding pouch is exposed.



4. Remove inner winding pouch to expose suture.

















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



The suture is now ready for use



Description of Symbols

 Do not reuse	 Date of Manufacture
 Temperature limit	 Sterilized using ethylene oxide
 See instruction for use	 Use-by date
 Keep dry	 Consult instruction for use
 Humidity limitation	 Manufacturer
 Batch Code	 Do not resterilize
 Keep away from sunlight/Keep away from heat	
 Authorized representative in the European Community	