



CliniGut Plain & Chromic Sutures

Description

CliniGut is an absorbable natural sterile surgical suture manufactured from uniform, twisted strands of collagen. The origin of the latter is purified bovine intestine. CliniGut Chromic in addition has been treated with chromium salt solutions to retard its absorption rate. Both types are packaged in hydrating fluid. CliniGut Plain sutures and CliniGut Chromic sutures meet all the requirements established by the B.P., the U.S.P. and the E.P.

Indications

CliniGut suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues. CliniGut sutures are intended for use where an absorbable suture or ligature is indicated for short term wound support. Surgical indications include the following:

Urological, Gastro-intestinal, Oral, Skin

Subcutaneous and Obstetrical Gynaecological

CliniGut Chromic catgut sutures are indicated where longer wound support is necessary. Apart from the indications above, chromic catgut sutures are used in procedures involving the liver and orthopaedics.

Actions

CliniGut elicits an inflammatory reaction in tissues and is digested by enzymes contained in body tissues. Several factors may influence the absorption rate of CliniGut (normal absorption is between 7-10 days)

- the type of tissue in which the gut is inserted. Serous and mucous membranes absorb gut faster than muscle
- if the gut is exposed to the digestive enzymes of the gastro-intestinal tract absorption is faster
- absorption is also faster in the presence of infection
- the physical condition of the patient can also affect the rate of absorption

Contra-indications

CliniGut sutures, being absorbable, should not be used where extended approximation of tissue is required.

Warning

Users should be familiar with surgical procedures and techniques before employing CliniGut sutures for wound closure, as a risk of wound dehiscence may vary with the site of application and the suture material used. Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or infected wounds.

The use of this suture may be inappropriate in patients suffering from conditions that may delay wound healing. As this is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of sites under going expansion, stretching or distension, or which require additional support.

Precautions

Under some circumstances immobilization by external support may be employed at the discretion of the surgeon. In handling this or any other suture material care should be taken to avoid damage. Avoid crushing or crimping damage due to the application of surgical instruments, such as forceps or needle holders. 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

CliniGut sutures are sterilized by gamma radiation. 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

Adverse reactions associated with the use of this device include wound dehiscence, failure to provide wound support at sites where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients, or in patients suffering from cancer, anaemia, obesity, diabetes, infected or other conditions which may delay wound healing, enhance bacterial infectivity and pain and oedema at the 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 blood-borne pathogens.

How supplied

CliniGut Plain and CliniGut Chromic Sutures are available in sizes 6/0 through 2. The suture is supplied in non-needled standard lengths (ligatures) or attached to various needle types in boxes of one dozen.



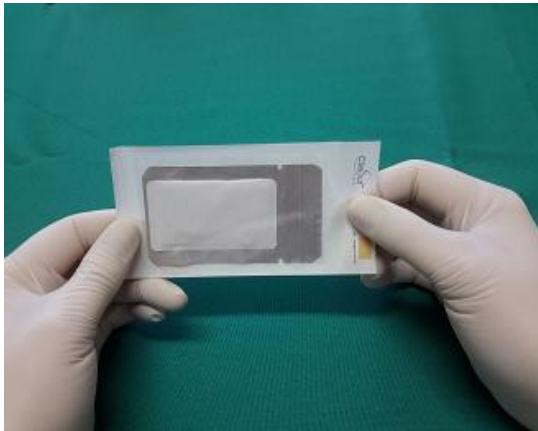
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Date: 30 Sept. 2016
Revision: 5

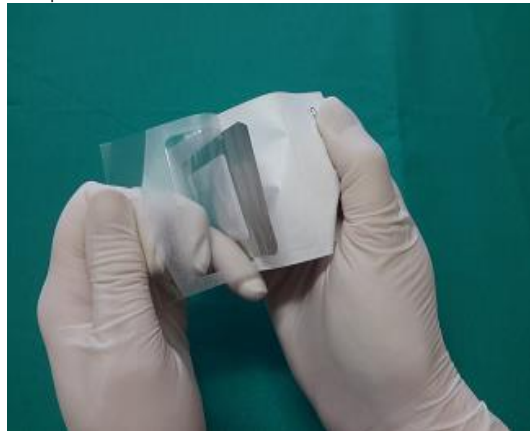
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INSTRUCTIONS FOR OPENING OF CLINIGUT SUTURE

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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