



Safegut Chromic™

Absorbable, Chromic Catgut

DESCRIPTION

Safegut Chromic (Chromic Catgut) is an absorbable sterile surgical suture, composed of purified connective tissue (mostly collagen) derived from either the serosal layer of beef (bovine) or the submucosal fibrous layer of sheep (ovine) intestines. Chromic gut is treated with chromic salt solutions.

INDICATIONS

Safegut Chromic 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.

ACTIONS

When gut suture is placed in tissue, a moderate tissue inflammation occurs which is characteristic of foreign body response to a substance. This is followed by a loss of tensile strength and a loss of suture mass, as the proteolytic enzymatic digestive process dissolves the gut suture. This process continues until the suture is completely absorbed. Many variable factors may affect the rate of absorption. Some of the major factors which can affect tensile strength loss and absorption rates are:

1. Type of suture - Chromic gut generally absorbs less rapidly than plain gut.
2. Infection - Gut suture is absorbed more rapidly in infected tissue than in non-infected tissue.
3. Tissue sites - Gut suture will absorb more rapidly in tissue where increased levels of proteolytic enzymes are present, as in the secretions exhibited in the stomach, cervix and vagina.

CONTRAINDICATIONS

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

The use of this suture is contraindicated in patients with known sensitivities or allergies to collagen or chromium, as gut is a collagen based material and chromic gut is treated with chromic salt solutions.

WARNINGS

Users should be familiar with surgical procedures and techniques involving gut suture before using the suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing. As this is an absorbable material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of sites which may undergo expansion, stretching or distention or which may require additional support. As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, Safegut Chromic may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

Do not resterilize. Discard opened packages and unused sutures.

Certain patients may be hypersensitive to collagen or chromium and might exhibit an immunological reaction resulting in inflammation, tissue granulation or fibrosis, wound suppuration and bleeding, as well as sinus formation.

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 application of surgical instruments such as forceps or needle holders. Gut sutures require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

The surgeon should avoid unnecessary tension when running down knots, to reduce the occurrence of surface fraying and weakening of the strand.

Avoid prolonged exposure to elevated temperatures.

To avoid damaging 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. Discard used needles in waste bin.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, variable rates of absorption over time (depending on such factors as the type of suture used, the presence of infection and the tissue site), failure to provide adequate wound support in closure of sites where expansion, stretching or distension occur, etc., unless additional support is supplied through the use of non-absorbable suture material, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from cancer, obesity, diabetes, infection or other conditions which may delay wound healing, allergic response in patients with known sensitivities to collagen or chromium which may result in an immunological reaction resulting in inflammation, tissue granulation or fibrosis, wound suppuration and bleeding, as well as sinus formation, infection, moderate tissue inflammatory response characteristic of foreign body response, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs and transitory local irritation at the wound site.

STORAGE

Store this suture below 25⁰ C.

Keep away from moisture and direct heat.

Do not use if the date is expired.

SYMBOLS USED ON LABELLING

 = Do not reuse

 = Expiry date

 = Sterilized using irradiation

 = Batch Number

 = See instructions for use

 = Manufacturing date

IP = Indicative price

COMMERCIAL PACK

Each box contains 6 packs of Chromic Catgut suture.



Manufactured by

Incepta Pharmaceuticals Ltd.

Hospicare Division

Dhamrai, Dhaka, Bangladesh

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