

Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood borne pathogens.











STERILITY


Gut suture (plain and chromic) is sterilized by gamma radiation. Do not resterilize. Do not use if package is opened or damaged. Discard opened unused sutures. Do not use after expiration date.

HOW SUPPLIED

Gut suture (plain and chromic) is available sterile, in various lengths, in USP diameter sizes, 7-0 through 4 (metric sizes 0.5 through 6). USP sizes 6-0 through 4 are packaged in a wetting solution. USP size 7-0 is packaged dry. Gut suture is available in pre-cut lengths either non-needled or affixed to various needle types.

SYMBOLS USED FOR LABELING

-  Product Code
-  Caution—Refer to Accompanying Documents
-  Do Not Reuse
-  Use by
-  Sterilized using irradiation
-  Do Not Resterilize
-  Lot Code
-  Date of Manufacture
-  Manufacturer
-  Do not use if package is damaged

 **CAUTION:** Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

GUT SUTURE

Absorbable Surgical Suture, USP
(Plain and Chromic)

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GUT SUTURE

Absorbable Surgical Suture, USP
(Plain and Chromic)

DESCRIPTION

Gut suture (plain and chromic) 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 processed to provide greater resistance to absorption. Gut suture (plain and chromic) is packaged either dry or in a wetting solution containing approximately 89.5% Reagent Grade Isopropyl Alcohol, 1.0% Diethylethanolamine, 0.25% Sodium Benzoate (USP Grade) and 9.25% Sterile Water. Gut suture (plain and chromic) meets all requirements established by the United States Pharmacopeia (USP) for absorbable surgical suture.

INDICATIONS

Gut 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 procedures.

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. 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 - plain gut generally absorbs more rapidly than chromic gut.
2. Infection - gut is absorbed more rapidly in infected tissue than in non-infected tissue.
3. Tissue sites - gut 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

Do not resterilize. Discard open, unused sutures and associated surgical needles.

Users should be familiar with surgical procedures and techniques involving gut suture before employing gut suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the *in vivo* performance (under ACTIONS section) when selecting a suture for use in patients. 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 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 calculi formation. As an absorbable suture, gut may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

As this is an absorbable material, the use of supplemental nonabsorbable 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.

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

Care should be taken to avoid damage when handling. Avoid crushing or crimping the suture material with surgical instruments such as needle holders and forceps.

Infections, erythema, foreign body reactions, transient inflammatory reactions and in rare instances wound dehiscence are typical or foreseeable risks associated with any suture

and hence are also potential complications associated with gut suture.

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

Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

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. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device may include: wound dehiscence; variable rates of absorption over time (depending on the type of suture used, the presence of infection and 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 nonabsorbable suture material; failure to provide adequate wound support in elderly, malnourished, or debilitated patients or in patients suffering from 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.