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PLAIN AND CHROMIC GUT
ABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION
Plain and Chromic Gut suture are absorbable sterile sutures composed of purified connective tissue (mostly collagen) derived from the serosal layer of beef (bovine) intestines. The sutures are available in Plain and Chromic Gut and packaged in 90% isopropanol, 0.5% sodium benzoate, 0.5% diethylethanolamine, and water q.s. ad 100%. These sutures meet requirements established by the United States Pharmacopoeia (USP) and European Pharmacopoeia (EP) for Absorbable Collagen Suture, except for diameter.

INDICATIONS
Plain and Chromic Gut Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neural tissues.

ACTIONS
When Plain and Chromic Gut suture are placed in tissue; a moderate tissue inflammation occurs characteristics of foreign body response to a substance. This is followed by a loss of tensile strength and 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 is expected to absorb 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.

Testing conducted in-vivo in an animal model indicates that absorption is usually complete within 70 days for plain gut and within 90 days for chromic gut.

CONTRAINDICATIONS
The use of this suture is contraindicated in patients with known

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sensitivities or allergies to any of its components. These sutures, being absorbable, should not be used where extended approximation of tissue is required. Certain patients may be hypersensitive to collagen or chromium and might display an immunological reaction resulting in inflammation, fibrosis, wound suppuration and bleeding as well as sinus formation.

The use of this suture is contraindicated in patients with known sensitivities or allergies to plain or gut sutures.

Because of the gradual loss of tensile strength that may occur over prolonged periods in vivo, plain or gut surgical sutures should not be used where permanent retention of tensile strength is required.

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.

WARNINGS
Users should be familiar with surgical procedures and techniques involving gut suture before using Plain and Chromic gut suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. In cases where closure of site may undergo expansion, stretching, or distention, the use of supplemental nonabsorbable sutures should be considered.

Do not use if package is open or damaged or if the expiration date has been exceeded. Discard open, unused suture.

Do not resterilize; resterilization may alter the physical properties of the suture and which will result in adverse patient reaction.

User should exercise caution when handling surgical needle to avoid inadvertent needle sticks. Discard used needles in a "sharps" container.

Store in a cool dry environment.

As with any foreign body, prolonged contact of this or any other sutures with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, plain or gut suture may act transiently as a foreign body.

Accepted surgical practices must be followed with the respect to the management of contaminated or infected wounds. Also use of

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these sutures is not appropriate in elderly, debilitated, malnourished, or patients with conditions which may delay wound healing.

PRECAUTIONS
In handling this or any other surgical suture, 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.

Adequate knot security requires the accepted surgical technique of flat, square ties with additional throws as warranted by surgical circumstances 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. Adequate knot security requires flat, square ties with additional throws as warranted by surgical circumstances and the experience of the surgeon.

ADVERSE REACTIONS
Adverse effects associated with the use of this device include: wound dehiscence, increased rates of absorption over time (depending on the type of suture used, the presence of infection and the tissue site), failure to provide adequate wound support in closure of the abdomen, chest joints, and other sites where failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from cancer, anemia, 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, enhanced bacterial infectivity, 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 pain, edema and erythema at the wound site.

Discuss the potential for allergic reaction in patients that are known to be sensitive to plain or gut suture.

HOW SUPPLIED
Plain and Chromic gut sutures are available sterile in various USP sizes. Plain and Chromic gut sutures are supplied in a wide range of lengths affixed to a diverse assortment of needle types.

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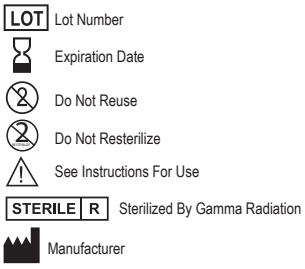
CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

SYMBOL DEFINITIONS



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