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

DESCRIPTION
Plain and Chromic Surgical Gut suture are absorbable sterile surgical sutures 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. The sutures are available in Plain and Chromic Surgical Gut and packaged dry or in 89% 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 Surgical Suture, except for diameter.

INDICATIONS
Plain and Chromic Gut Surgical 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 surgical 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 - surgical gut is absorbed more rapidly in infected tissue than in non-infected tissue.
3. Tissue sites - surgical 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.

CONTRAINDICATION
The use of this suture is contraindicated in patients with known sensitivities or allergies to any of its components. These sutures, being absorbable, should not be used where extended approximation of tissue is required.

WARNINGS
Do Not resterilize. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

Prolonged contact of this or any other sutures with salt solutions such as urine and bile occurs, and pain, redness, edema and erythema at the wound site. 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 responses, calculus 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.

HOW SUPPLIED
Plain and Chromic surgical gut sutures are available in (USP) sizes 9-0 through 4 (metric sizes 0.4 - 8). The sutures are absorbable, sterile Plain and Chromic. The sutures are supplied in various lengths or on ligating reels, both non-needle or affixed to various needle types: in one-, two-, and three dozen boxes.

LOT
Lot number

Expiration Date

Do Not Reuse / Resterilize

See Instructions for use.

STERILE R
Sterilized by Gamma radiation

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