

INSTRUCTIONS FOR USE

ARNIGUT

CATGUT CHROMIC / CATGUT PLAIN ABSORBABLE SURGICAL SUTURE U.S.P.

DESCRIPTION:

Catgut suture is absorbable, sterile, surgical suture, composed of purified connective tissue (collagen) derived from the sub mucosal layer of sheep or goat intestine.

Catgut Chromic is the suture material, which has been tanned by treatment with Chromium salts in the trivalent form and with oxidized Pyrogallol. (Colour Index No.: 76515) to prolong its resistance to absorption and to colour the material dark brown.

Catgut Plain is the suture material, which is neither treated with any chemical nor colored with any dye.

Catgut suture is available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes.

Catgut suture complies with requirements, established in the United States Pharmacopeia, under the monograph, "Absorbable Surgical suture".

INTENDED USE:

Catgut sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures.

APPLICATION:

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.

MECHANISM OF ACTION:

When catgut chromic is implanted, a moderate tissue inflammation occurs which is characteristic of a foreign body response. Loss of tensile strength and loss of mass follows as the proteolytic enzymatic digestive process resorbs the surgical catgut. Due to the inherent variability of a natural material, figures for the strength loss and absorption following implantation are only for guidance.

Effective strength is lost by 21-25 days in case of Catgut Chromic and by 14 days in case of Catgut Plain. Absorption is essentially complete by 90 to 100 days both with Chromic and Plain catgut. In humans, various factors may affect the tensile strength and rate of absorption. Two of the major factors are:

Infection: Catgut Chromic is absorbed more rapidly in infected tissue than in non-infected tissue.

Tissue sites: Catgut Chromic is absorbed more rapidly absorbed in tissues where increased levels of proteolytic enzymes are present as in the secretions from the stomach, cervix and vagina.

CONTRAINDICATIONS:

Being absorbable, Catgut sutures should not be used where extended approximation of tissues under stress is required.

Catgut Chromic is contraindicated for use in cardiovascular and neurological tissues. Catgut Chromic is contraindicated in patients with known sensitivities or allergies to collagen or Chromium since Catgut Chromic is a collagen-based material which has been treated with Chromic salt solution.

WARNING/PRECAUTIONS/INTERACTIONS:

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Catgut sutures for wound closure as risk of wound dehiscence may vary with the site of application and the suture material used.

Surgeons should consider the in-vivo performance (under Mechanism of Action section) of catgut, when selecting a suture. This suture may be inappropriate in elderly, malnourished, diabetic patients or in patients suffering from conditions which may delay wound healing.

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

Acceptable surgical practice should be followed for the management of contaminated or infected wounds. As this is an absorbable suture material, the use of supplemental non absorbable sutures should be considered by the surgeon for the management of contaminated wounds and in the closure of sites undergoing expansion, stretching or distention which may require additional support.

Some patients may be hyper-sensitive to collagen or Chromium and may exhibit immunological reaction. Under some circumstances, notably orthopedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

Consideration should be taken in the use of absorbable suture in tissue with poor blood supply as suture extrusion and delayed absorption may occur. Adequate knot security requires the standard surgical techniques of flat and square ties with additional throws as indicated by surgical and the experience of the surgeon.

When 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. Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one third (1/3) to one half (1/2) of the distance from the attachment end to the point.

Grasping in the point area, could impair the penetration performance and cause fracture of the needle. Grasping at the attachment end could cause bending or breakage. 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 stick injury. Discard unused needles in "Sharps" containers.

ADVERSE REACTIONS:

Adverse effects associated with the use of Catgut sutures include allergic response in certain patients, transient local irritation at the wound site, followed by moderate transient inflammatory foreign body response. Like all foreign bodies, Catgut may enhance an existing infection.

STERILITY:

Catgut sutures are sterilized by Ethylene Oxide. Do not re-sterilize. Catgut sutures are packed with sterilizing fluid, the constituents of which are Iso Propanol, water, Sodium Benzoate and Ethylene Oxide in the concentration of 0.5% w/v. Do not use if package is found opened or damaged. Discard the opened or unused sutures.

SUPPLY:

Catgut Chromic and Plain sutures are available in U.S.P. sizes, 3 to 4-0. The suture is supplied sterile in pre-cut lengths, non-needled or attached with various needle type, shape and length.

STORAGE:

Recommended storage conditions:
Below 30° C, away from moisture and direct sunlight. Do not use after expiry.

DISPOSAL:

To be disposed as per user's country disposal regulations and Hospital/Clinic protocol.

Manufactured by:

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EXPLANATION OF SYMBOLS	
Symbol	Explanation
	Manufacturer
	Date of Manufacture
	Use-By Date
	Sterilization by Ethylene Oxide
	Do not re- use
	Do not re-sterilize
	Batch number
	Keep away from Sunlight
	Keep dry
	Warning
	Temperature Limit
	Do not use if package is damaged
	Read Instructions for use