

ADVERSE REACTION:

Adverse reactions associated with the use of the device include allergic response in certain patients, transient local irritation at the wound site, followed by moderate transient inflammatory foreign body response. Like all foreign body catgut may enhance an existing reaction.

STERILITY:

Catgut sutures are sterilized by ethylene oxide. Do not re-sterilize. Do not use if the pack is opened or damaged. Discard unused sutures.

STORAGE:

Recommended storage condition 10–35 °C, away from moisture and direct heat. Do not use after expiry date

DISPOSAL:

Discard used sutures and needles contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

TECHNIQUE FOR OPENING THE PACK:

- 1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



- 2. Then with the help of sterilized gloved hand or sterilized forceps pull the paper folder till the needle is visible. For non-needed suture, pull out the entire folder from the pack, open the folder and retrieve the suture.



- 3. Again with the help of sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.



SYMBOL USED ON LABEL:

	Do not reuse		Batch number
	Date of manufacture		Do not resterilize
	Date of expiry		Consult instructions for use
	Sterilized by ethylene oxide		Avoid Moisture
	Temperature limitation		Avoid direct sunlight
	Do not use if package is damaged		manufactured by

MANUFACTURER:

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INSTRUCTION FOR USE

FUTURA SURGICARE PVT LTD

Catgut surgical suture USP
(Except for overage in diameter)

DESCRIPTION

Catgut suture is a sterile absorbable suture composed of purified connective tissue (collagen) derived from the submucosal layer of sheep (Ovine) and goat intestine. Catgut sutures are available in a range of gauge sizes and length, non needled or attached to stainless steel needles of varying types, sizes and shapes. The needles are attached permanently to the suture and also available without needles. Catgut sutures complies with the requirements of the United States Pharmacopoeia monograph for “Absorbable surgical suture - collagen” except for slight overage in diameter. The surgical suture is packed in a sterilizing fluid which contains isopropanol, purified water and ethylene oxide. Catgut plain is devoid of chromium salts and pyrogallol whereas catgut chromic has been tanned by a treatment with chromium salt in the trivalent form and with oxidized pyrogallol to prolong its resistance to absorption and to colour the material dark brown.

Maximum suture oversize in diameter (mm) from USP.

USP suture size designation	Maximum oversize (mm)
2	0.050
1	0.050
0	0.050
2-0	0.050
3-0	0.050
4-0	0.070
5-0	0.050

INDICATION:

Catgut sutures are used for general soft tissue approximation and/or ligation.

MODE OF ACTION:

Catgut suture elicits a minimal tissue reaction and in growth of fibrous connective tissue. Absorption of bio absorbable suture occurs by enzymatic action: beginning with loss of tensile strength with loss of mass.

APPLICATION:

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

PERFORMANCE:

When the catgut suture is implanted, a moderate tissue inflammation occurs which is a characteristic of a foreign body response. Loss of tensile strength and loss of suture mass follows as the proteolytic enzymatic digestive process resorbs the surgical catgut. Due to inherent variability of a natural material, figures for the strength loss and absorption following implantation are for guidelines only. Catgut sutures are absorbed more rapidly in infected tissues than in non infected tissues.

TISSUE SITES:

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

CONTRA INDICATIONS:

These sutures, being absorbable, should not be used where extended approximation of tissues under stress is required. Catgut sutures is contraindicated for use in cardiovascular, neurological tissues, pediatric and dental usages. Catgut plain suture is contraindicated in patients with known sensitivity or allergies to collagen. Catgut chromic suture is contraindicated in patients with known sensitivity or allergies to collagen, pyrogallol and chromium. The product should not be used in the infected tissue and where prolonged tissue approximation is required.

Warnings/ precautions/ interaction:

Users should be familiar with handling and knotting techniques involving catgut sutures before using this material for wound closure, since the risk of wound dehiscence may vary with the site of application and the type of suture used. Surgeons should consider the invivo performance of the catgut when selecting this suture. This suture may be inappropriate in elderly, malnourished patients or in patients suffering from conditions which may delay wound healing. As an absorbable suture, it acts transiently as a foreign body. As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in urinary or biliary tracts may result in calculus formation. Acceptable surgical practice should be followed for the management of contaminated or infected wound. As with all absorbable suture material, the use of supplemental non absorbable sutures should be followed for the management of contaminated or infected wounds.

As with the absorbable suture materials, the use of supplemental non – absorbable sutures should be considered by the surgeons in the closure of sites which may undergo expansion, stretching or distension or which may require additional support. Some patients may be hypersensitive to collagen or chromium and may develop immune reaction. Under some circumstances, notably orthopedic procedures, immobilizations of the joints by external support may be employed at the discretion of the surgeons. Consideration should be taken in the use of absorbable sutures in tissue with poor blood supply as suture extrusion and delayed absorption may occur.

In handling catgut suture care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instrument such as forceps or needle holders. Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. Avoid unnecessary tension while when running down the knots, to reduce the occurrence or surface fraying and weakening of the strand. Care should be taken when opening the pack as it contains sterilizing fluid. Care should be taken to avoid damage while handling the needles. Grasp the needle in an area one third to one half 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 the butt or the attachment of the needle may cause needle bending or breakage. Reshaping the needles may cause them to loose the strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard the used needles in sharp containers.