**FUTURA SURGICARE PVT LTD**
INSTRUCTION FOR USE
Brand name: **PROGUT®**

Material: Catgut Chromic

Absorbable surgical suture U.S.P

Description:

Progut® surgical catgut suture is a sterile absorbable suture composed of purified connective tissue (collagen) derived from the submucosal layer of sheep (Ovine) and goat intestine. Progut® is a material which 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. Progut ® is 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. Entire details of the product range are available in the catalogue. Progut® complies with the requirements of the United States Pharmacopoeia monograph for "Absorbable surgical suture". The surgical suture is packed in a sterilizing fluid which contains isopropanol, purified water and ethylene oxide. Progut ® complies with the United States Pharmacopoeia for "Absorbable Surgical Suture".

Indications:

Progut ® is for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures.

Mode of action

Progut ® 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. The suture retains approx 50% of the tensile strength within 21 – 28 days when implanted in rat and the suture is essentially absorbed within 90 days.

Application:

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

Performance:

When Progut ® 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.

Infection:

Progut ® is absorbed more rapidly in infected tissues than in non infected tissues.

Tissue sites:

Progut ® is 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. Progut ® is contraindicated for use in cardiovascular and neurological tissues. Progut ® is contraindicated in patients with known sensitive or allergies to collagen or chromium since Progut ® is a collagen based which has been treated with chromic salt solutions. 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, Progut ® 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 bilary tracts may result in calculus formation. Acceptable surgical practice should be followed for the management of contaminated of 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.

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:

Progut ® sutures are sterilized by ethylene oxide. Don't re-sterilize! Do not use if the pack is opened or damaged! Discard unused sutures!

Storage

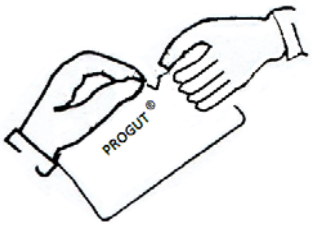
Recommended storage condition 10 – 35 °C, away from moisture and direct heat. Do not use after expiry date

Disposal:

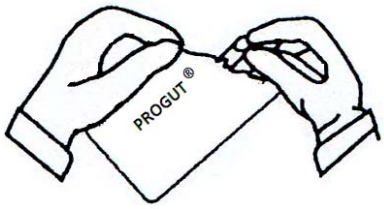
Discard used sutures and needles contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

Technique for opening the over wrap:

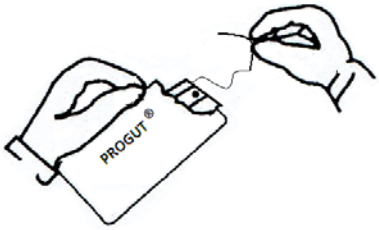
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.




2. Then with the help of sterilized gloved hand or sterilized forceps pull the paper folder till the needle is visible. For non-needled suture, pull out the entire paper 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 |  | Avoid Moisture |
|  | Date of expiry |  | Registered |
|  | Sterilized by ethylene oxide |  | Avoid direct sunlight |

| | | | |
|---|---|---|---|
|  | Temperature limitation |  | Do not resterilize |
|  | Do not use if package is damaged |  | Consult instructions for use |

Manufacturer: Futura Surgicare Pvt Ltd, 86/C2, 3rd Main, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore – 560022, India. Mfg Lic No: KTK/28/273/1995