**Softcat® plain / Softcat® Chrom**

**Description**
The suture materials Softcat® plain and Softcat® chrom are sterile, absorbable suture materials produced from the collagen of the gut wall of cattle (serosa) or sheep (submucosa). The catgut suture materials are available as “plain” or “chrom”. The suture material is treated with glycerol-containing solution before packing. The suture material retains its original flexibility and softness on removal from the pack. The suture materials described here fulfill all the requirements of the European Pharmacopoeia for sterile catgut (Chorda resoribilis sterilis).

**Indications**
Softcat® plain and Softcat® chrom are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissues.

**Mode of action**
When Softcat® plain and Softcat® chrom sutures are employed host tissue reacts with a mild inflammation reaction, which is typical for an endogenous reaction to a foreign body. The foreign body reaction is accompanied by a loss of strength and mass of the material as a result of the action of proteolytic enzymes (e.g. collagenase) and the degradation of the collagen suture material until it has been completely absorbed.

The speed of absorption is affected by many factors.

Some of the most important factors affecting the rate of absorption and reduction in strength are:
- The “plain” variety is generally absorbed more rapidly than the “chrom” variety.
- There is more rapid absorption in regions containing more proteolytic enzymes.

**Contraindications**
The use of Softcat® plain and Softcat® chrom suture materials is contra-indicated in the region of infected wounds, since absorption is more rapid here.

The use of this suture is also contra-indicated in patients with known sensitivities or allergies to collagen or chromium, as gut is collagen based material. Furthermore, Softcat® plain and Softcat® chrom sutures are contra-indicated for indications where the suture requires support over long periods (e.g. cardiovascular or neural tissues).

**Warning note**
The user should be familiar with surgical suturing techniques, before employing Softcat® plain or chrom suture materials for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the “in vivo” performance, when selecting a suture material. The use of an absorbable suture material may be inappropriate in patients with any conditions which, in the opinion of the surgeon may cause or contribute to delayed wound healing (elderly, malnourished or debilitated patients, or in case of cancer, anemia, obesity, diabetes, infection etc.).

As this is an absorbable suture, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the abdomen, chest, joints or other sites subject to expansion or requiring additional support.

As an absorbable suture, Softcat® may act transiently as a foreign body. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Certain patients may be hypersensitive to collagen or chromium and might exhibit an immunological reaction resulting in inflammation, tissue granulation or fibrosis, wound suppuration and bleeding, as well as sinus formation.
As with all other suture materials, long contact with salt solutions such as urine and bile, can lead to lithiasis.
Do not resterilize. Open, unused or damaged packs should be discarded. The Softcat® suture material should be stored at room temperature. Do not expose to extreme temperatures for a prolonged period of time.

**Note/precautionary measures**
Great care must be taken when working with Softcat® plain and Softcat® chrom in order to avoid damage as a result of crushing or snapping, due to the use of surgical instruments such as tweezers and needle holders. As with any suture material, 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.
Under some circumstances, notably orthopedic procedures, immobilization of joints by external support may be employed at the discretion 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.
To avoid damaging needles points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should be careful when handling surgical needles to avoid inadvertent needle sticks. Discard needles in “sharps” containers.

**Adverse reactions**
Adverse effect associated with this device include wound dehiscence, variable rates of absorption over time (depending on the type of suture used, the presence of infection, the tissue site, etc.) failure to provide adequate wound support in sites where expansion, stretching or distention occur, failure to provide adequate wound support in patients, with 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, infection, transitory local irritations in the wound site, calculi formation when prolonged contact with salt solutions occur, minimal acute inflammatory reaction characteristic as foreign body response.
Broken needles may result in extended or additional surgeries or residual foreign bodies.
Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

**How supplied**
Softcat® plain sutures are available in USP 4 to 6/0 (metric 8 to 1) and Softcat® chrom sutures are available in USP 3 to 5/0 (metric 7 to 1.5). The sutures are supplied sterile, in precut lengths and ligating reels, non-needled or attached to needles, with permanent or removable (take-off) needle attachment techniques. The boxes contain 1, 2 or 3 dozens of sutures.
Caution
Federal (USA) law restricts this device to sale or use by or on the order of a physician.

Symbols used on labeling
- Do not reuse
- Use by: Year + Month
- Sterile unless package is opened or damaged. Method of Sterilization - Gamma Radiation
- Batch number
- See instructions for use

REF Cat. No.

CUSTOMER SERVICE
For further information regarding Softcat® Sutures please contact Aesculap, Inc. Customer Service at 1-800-282-9000.

Distributed by:

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