

VALKYRIE® LOOPED STERNOTOMY SUTURE



DIRECTIONS FOR USING STERNOTOMY SUTURE MATERIALS

The information given in this package leaflet is updated regularly. Please read instructions carefully prior to use.

DESCRIPTION

A Sternotomy Suture is a monofilament non-absorbable implantable surgical suture made of high-grade surgical stainless steel AISI 316LVM.

Sternotomy Sutures are available in different lengths and diameters and include single high-grade stainless-steel needles of different types of points, lengths, and curves to accommodate surgical need and surgeon preference. Sternotomy sutures comply with the requirements of U.S. pharmacopoeia in terms of sterile, surgical suture materials.

INDICATION

Sternotomy Sutures are intended for - sternal closure, abdominal wound closure, hernia repair, and orthopedic procedures including cerclage and tendon repair.

APPLICATION

The needle and thread combination to be used is selected according to the condition of wound, patient, area of application, surgical technique being applied, and corresponding with the experience of the surgeon.

ACTION

Sternotomy sutures are of high-grade stainless steel that can trigger a minimal acute inflamed reaction in the tissues. Absorption does not occur.

CONTRAINDICATIONS

Sternotomy Sutures are contraindicated in patients with known sensitivities or allergies to steel and/or its principal metallic components, chromium and nickel.

WARNINGS/PRECAUTIONS

Since the risk of wound dehiscence is dependent on the area of the body and suture material being inserted, the user should be familiar with surgical methods and techniques by which means sutures are used for sealing wounds. In the event of drainage, or closure of infected or contaminated wounds, generally acknowledged surgical techniques must be followed.

In general, when using Sternotomy Sutures, you should ensure that the suture material is not damaged or squashed by surgical instruments such as forceps, needle-holders or tweezers, since this could result in negative changes in the tensile strength of the suture material and in its safety.

Acceptable surgical practice should be followed for management of infected or contaminated wounds. The image produced by MR Imaging Equipment could be distorted in patients with stainless steel sutures. There is minimal risk of suture movement during procedures using MR Imaging Equipment.

When using Sternotomy sutures, you should ensure that you grip the middle of the needle and do not damage either the point or armed end of the needle with surgical instruments like tweezers or needle holders, since this can cause the needle to bend or break.

When separating the needle from suture wire suitable forceps should be used and the separation must occur at a distance of at least 4-5 cm from the end of the needle shaft. In general, surgical needles should be handled with meticulous care when in use in order to avoid needle-prick injuries to patient and user. Suitable containers must be used for the disposal of needles.

Re-use could lead to a negative functional, immunological, toxicological or hygienic impact.

MRI INFORMATION

A patient with this device can be scanned safely, immediately after placement, at static magnetic flux densities up to 3.0 T. Like any implanted metal object, the Sternotomy Suture Material has the potential to undergo slight heating during the MRI examination. Patients with sternal wires should be advised to notify the technologist if any discomfort develops during the procedure.

SIDE-EFFECTS

The following side-effects can occur with the insertion of Sternotomy suture materials made of high-grade stainless steel: transient local irritation, inflammatory reactions to the foreign body; formation of suture fistulas or granulomas.

STERILITY

Sternotomy Sutures are sterilized using ethylene oxide. Do not use sutures from packaging that is already open or damaged. Sterility is guaranteed until the use-by date as long as the packaging is closed. Do not resterilize.














DISPOSAL

In order to avoid a possible transfer or cross-contamination by the products, they are to be used and disposed of with special care, especially if coming into contact with infectious tissue.

HOW SUPPLIED

Sternotomy Sutures are available in U.S.P sizes 7-0 through 7 (metric 0.5-9). The suture is supplied sterile in pre-cut length affixed to various needle types.

Explanation of the symbols used on the packaging.

-  REF Reference number
-  LOT Batch number
-  Use by year - month
-  Consult instructions for use
-  Do not reuse
-  Do not resterilize
-  Do not use if package is damaged
-  STERILE EO Sterilized using ethylene oxide
-  Undyed / monofilament / nonabsorbable
-  STEEL Steel wire
-  Manufacturer
-  Caution
-  MR conditional

Rx Only CAUTION: Federal (USA) Law restricts This device to sale and use by, of on the order of, a physician.



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