Steelex Sternum Set / Steelex Suture
(Instructions for Use)

Description
The Steelex Sternum Set / Steelex Suture consist of a corrosion-resistant steel monofilament suture with a specially designed HRS needle for the sternum closure. The Steelex Sternum Set consists of a combination of 2 or 4 steel wire monofilaments and Steelex Sutures consists of a combination of 1, 5, or 6 wire monofilaments. Steelex Sternum Set / Steelex Suture are armed with a tapercut round bodied needle fixed or rotating. The wire for Steelex Sternum Set / Steelex Suture is made of stainless steel 316L (ASTM-F138) and the needle is made of stainless steel 302, 420 or 420F (ASTM-F899). The needle sizes for Steelex Sternum Set / Steelex Suture are available in the USP sizes 3, 4, 5, 6 and 7.

Indications
Steelex Sternum Set / Steelex Suture is indicated in abdominal surgery, for orthopaedic procedures (tendon operations and cerclages), hernia surgery and sternal closure. It is designed to remain in the patient.

Mode of Action
Steelex Sternum Set / Steelex Suture is used for temporary adaptation of wounds and is designed to remain inside the patient.

Application of Steelex Sternum Set/Steelex suture triggers a weak inflammatory reaction typically associated with the physiological reaction to a foreign body. With time, the suture material is encapsulated by a layer of fibrous connective tissue.

Contra-Indications
The use of Steelex Sternum Set / Steelex Suture is contraindicated in patients with allergy to the main components (manganese, nickel, chromium or molybdenum) of stainless steel.

Warnings
1. Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing the Steelex Sternum Set / Steelex Suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

2. As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions
1. In 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.

2. As with any suture material, adequate knot security requires the accepted, surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.
Application
Use should be based on surgical requirements.

The user must be acquainted with the surgical suture technique when using Steelex Sternum Set / Steelex Suture.

When working with Steelex Sternum Set / Steelex Sutures, special care should be taken to avoid crushing or bending by surgical instruments such as forceps or needle holders.

Adverse Reactions
Adverse effects associated with the use of this device include: wound dehiscence, allergic response in patients with known sensitivities to metals contained in 316L stainless steel, i.e., chromium, nickel, copper, cobalt, and iron, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, and pain, edema, and erythema at the wound site.

Notes and Details of Stability
Steelex Sternum Set / Steelex Sutures cannot be re-sterilized. Opened unused or damaged packages shall be discarded. Steelex Sternum Set / Steelex Suture material should be stored at room temperature. Avoid prolonged exposure to extreme temperatures.

How Supplied
The Steelex Sternum Set / Steelex Suture are available in sizes 3-4 through 7. The suture is supplied sterile in pre-cut lengths affixed to 1 of 2 needle types. The method of fixation between the suture and the needle is fixed or axial (rotating). The needles are supplied 2 or 4 dozen boxes.

CUSTOMER SERVICE
For further information regarding Steelex Sternum Set / Steelex Sutures please contact Aesculap, Inc. Customer Service at 1-800-282-9000.

Distributed by:

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