

Theragenics

SURGICAL STAINLESS STEEL NONABSORBABLE SURGICAL SUTURE, U.S.P.

DESCRIPTION

Surgical stainless steel suture is a nonabsorbable, sterile surgical suture composed of 316L, or comparable, stainless steel. Stainless steel suture is available as a monofilament.

Stainless steel suture meets all requirements established by the United States Pharmacopoeia (U.S.P.) for nonabsorbable surgical sutures.

INDICATIONS

Surgical stainless steel suture is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopedic procedures including cerclage and tendon repair.

ACTIONS

Stainless steel suture elicits a minimal acute inflammatory reaction in tissue and is not absorbed.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to 316L, or comparable stainless steel, or constituent metals such as chromium and nickel.

WARNINGS

Do not use if package is open or damaged or if the expiration date has been exceeded. Discard open, unused suture.

Do not reuse or resterilize.

Users should be familiar with surgical procedures and techniques involving nonabsorbable, stainless steel sutures before employing stainless steel suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

This suture is nonabsorbable and may cause severe tissue damage when exposed to magnetic fields post operatively. Care needs to be taken when installing an S-ICD (subcutaneous implantable cardiovascular defibrillator) to avoid intermittent contact with sternotomy wire.

PRECAUTIONS

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.

Adequate knot security requires the accepted surgical technique of flat, squared ties with additional throws as warranted by surgical circumstance and experience of the surgeon. The use of additional throws may be particularly appropriate when tying monofilaments.

The six-sternal-wire closure may be successfully enhanced by the addition of one or two extra wires at the lower end of the sternotomy, depending on chest wall shape.

To avoid damaging needle 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.

Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, allergic response in patients with known sensitivities to 316L, or comparable stainless steel, or constituent metals such as chromium and nickel, infection, minimal acute inflammatory tissue reaction, pain, edema and local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies.

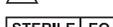
HOW SUPPLIED

Stainless steel sutures are available in various USP sizes. Stainless steel sutures are supplied in a wide range of lengths affixed to a diverse assortment of needle types.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

SYMBOL DEFINITIONS

-  Lot Number
-  Expiration Date
-  Do Not Reuse
-  Do Not Resterilize
-  See Instructions For Use
-  Sterilized By Ethylene Oxide
-  Keep away from sunlight and heat
-  Do not use if package is damaged
-  Keep dry
-  Manufacturer

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