STEEL PRODUCT INSERT

SURGICAL STAINLESS STEEL
NONABSORBABLE SURGICAL SUTURES, 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 opened or damaged or the expiration date has been exceeded. Discard open, unused suture. Do not reuse or resterilize. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in a “sharps” container. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.

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

HOW SUPPLIED
Stainless steel sutures are available in sizes 5 (metric sizes 7.0), 6 and 7, in pre-cut lengths with a permanently attached needle and typically supplied in a 48-count suture box.

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

SYMBOL DEFINITIONS

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.

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.

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