

Steel

Monofilament Stainless Steel

1300380



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Stainless monofilament steel sutures are composed of 316L stainless steel conforming to ASTM Standard F138 Grade 2 Stainless steel bar and wire for surgical implants.*

Steel sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for nonabsorbable surgical sutures.

INDICATIONS

Steel sutures are indicated for use in abdominal wound closure, intestinal anastomosis, hernia repair and sternal closure.

ACTIONS

Steel sutures elicit a minimal acute inflammatory reaction in tissue, and are not absorbed.

CONTRAINDICATIONS

The use of these sutures are contraindicated in patients with known sensitivities or allergies to steel and/or its principal metallic components, chromium and nickel. Additionally, the presence of steel may interfere with certain radiodiagnosics and its use is contraindicated where radiotransparency of suture material is required.

WARNINGS

Do not resterilize. Sterile unless packaging has been opened or damaged. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing steel sutures 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 contaminated or infected wounds.

PRECAUTIONS

Acceptable surgical practice should be followed to place steel sutures sufficiently distal to wound edges to reduce the incidence of the suture cutting through tissue, when the wound is placed under extreme stress. Additionally, care should be taken to cut the "ears" of steel surgical knots to allow for the bending of sharp ends away from surrounding tissue.

ADVERSE REACTIONS

Adverse effects, which may be associated with the use of this product, include: wound dehiscence, allergic response in patients with known sensitivities to steel or its principal components, calcium formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

HOW SUPPLIED

Steel sutures are available in monofilament strands in sizes 3-0 (2 Metric) through 7 (9 Metric). The sutures are supplied sterile in pre-cut lengths, non-needed or affixed to various types of needles using permanent needle attachment techniques. The sutures are available in box quantities of one and three dozen.



Do not use if package is opened or damaged.
 Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage.
 Bei geöffneteter oder beschädigter Verpackung nicht verwenden.
 Non utilizzare se la confezione è aperta o danneggiata.
 No usar el dispositivo si la envoltura está abierta o dañada.
 Não utilizar se a embalagem estiver aberta ou danificada.
 Niet gebruiken als de verpakking beschadigd of geopend is.
 För ej användas om förpackningen är öppnad eller skadad.
 Mä ikke anvendes, hvis emballagen er åbnet eller beskadiget.
 Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut.
 Μη χρησιμοποιείτε αν η συσκευασία έχει ανοίξει ή υποστεί ζημιά.
 Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone.
 Ambalaj açılmış ya da zarar görmişse kullanmayın.
 Не использовать изделие, если упаковка вскрыта или повреждена.
 Pokud je balení otevřené nebo poškozené, produkt nepoužívejte.
 Tilos felhasználni, ha a csomagolás kinyitlt vagy megsejtült.
 Ne uporabljajte, ak je obal otvorenj alebo poškodeny.
 Skal ikke brukes hvis emballagen er åpnet eller skadet.
 Ne uporabljajte, če je embalaža odprta ali poškodovana.
 如果包装已打开或破损，请勿使用。
 如果包装已開啟或損毀，則請勿使用。
 포장이 개봉되어 있거나 손상된 경우에는 사용하지 마십시오.
 Не използвайте, ако опаковката е отворена или повредена.
 A nu se utiliza în cazul în care ambalajul este deschis sau deteriorat.
 Änge kasutage, kui pakend on avatud või kahjustatud.
 Nelietot, ja iepakojums ir atvērts vai bojāts.
 Ne koristite ako je pakiranje otvoreno ili oštećeno.
 Ne koristiti ako je pakovanje otvoreno ili oštećeno.
 Nenaudokte, jei pakuoat atdaryta arba pažeista.

Syneture™



Caution, consult accompanying documents



Upper temperature limit



© 2011 Covidien.
 Covidien Inc, 15 Hampshire Street, Mansfield, MA 02048 USA.
 COVIDIEN Covidien Ireland Limited,
 IDA Business & Technology Park, Tullamore.
 www.covidien.com
 10/04 - 4