

USAGE INSTRUCTION

Material: **STAINLESS STEEL**

Non – absorbable surgical suture. U.S.P.

Description:

Stainless 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 European Pharmacopeia (EP) for non absorbable surgical sutures. Stainless steel sutures are the most inert among all suture materials and provide Maximum tensile strength. Steel sutures are available in range of gauge sizes and lengths, permanently attached to stainless steel needles of varying types, sizes and shapes. Entire details of the product range are available in the catalogue. Stainless steel sutures complies with the requirements of the United States Pharmacopoeia monograph for “Nonabsorbable surgical suture”

Indications:

Stainless steel sutures are indicated for use in abdominal wound closure, intestinal anastomosis, hernia repair, sternal closure and also for certain orthopedic procedures (cerclage or tendon repair).

Applications:

Stainless steel suture should be selected and implanted depending on the patient’s condition, surgical experience, surgical technique and wound size.

Performance:

Stainless steel suture has no elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. Stainless steel suture is not absorbed nor is it subjected to degradation or weakening by the action of tissue enzymes. Due to its relative biological inertness it is recommended for use where the least possible suture reaction is desired. It is effective as a pull out suture as it lacks the adherence to tissues.

Contra – indications:

The use of these sutures is 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 radio diagnostics and its use is contraindicated where radio transparency of suture material is required.

Warnings/ Precautions/ Interactions:

User should be familiar with surgical procedure and techniques involving non – absorbable sutures before employing STAINLESS STEEL SUTURE for wound closure as a risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

Precautions:

Care should be taken to avoid damaging the surface of the material with surgical instruments as this could lead to fracture of the material in use. Avoid crushing or crimping damage due to surgical instruments such as forceps or needle holders.

Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. The use of additional throws is particularly appropriate when knotting or twisting.

Care should be taken to avoid damage while handling surgical needles. Grasp the needle in an area of one third (1/3) to one half (1/2) of the distance from the attachment end to the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping the needles may cause them to lose strength and make less resistant to bending and breaking.

Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard the needles after use in container labeled as “SHARP”

Adverse reactions:

Stainless steel sutures elicit a minimal acute inflammatory reaction in tissue and are not absorbed.

Sterility:

STAINLESS STEEL SUTURE sutures are sterilized by ethylene oxide. Do not re – sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.

Storage

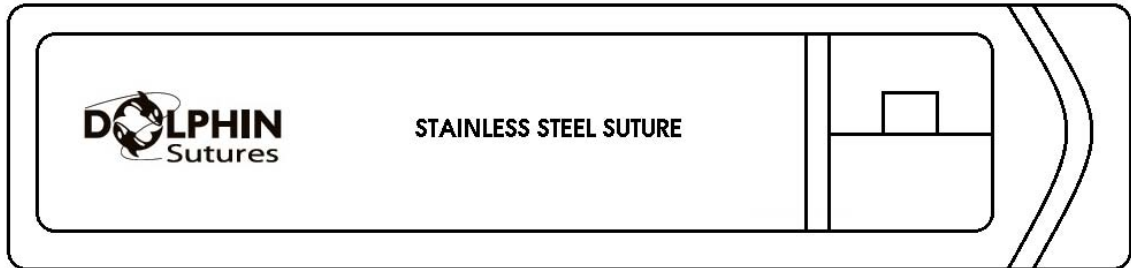
Recommended storage condition 10 – 35 °C, away from moisture and direct heat. Do not use after expiry date.

Disposal:

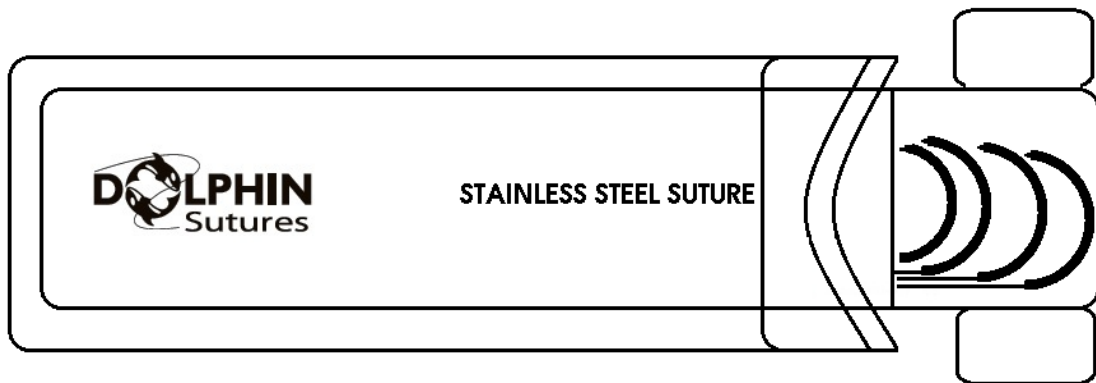
Discard used sutures and needles contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

Technique for opening the over wrap:

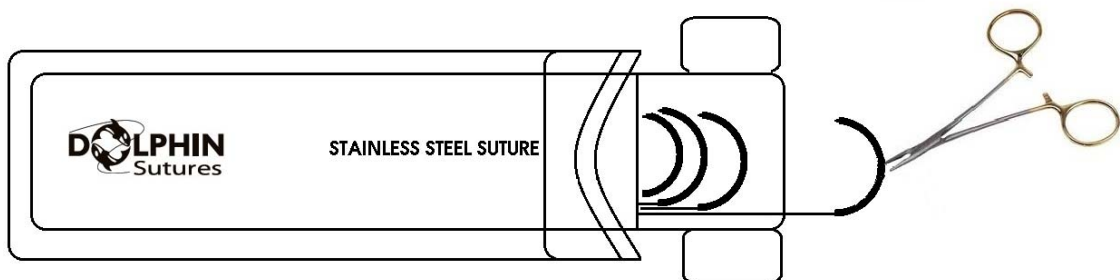
1. Hold the pack in a horizontal manner.

















2. Peel open the over wrap and unlock the folder.



3. With a sterilized forceps pull the needle to remove the suture from the folder.



Symbols used on the labels:

	Do not reuse		Batch number
	Date of manufacture		CE logo
	Date of expiry		Registered
	Sterilized by ethylene oxide		EU REPRESENTATIVE
	Temperature limitation		Do not resterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture

Manufacturer: Futura Surgicare Pvt Ltd, 86/C2, 3rd Main, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore – 560022, India. Mfg Lic No: KTK/28/273/1995

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