

# INSTRUCTION FOR USE-NON ABSORBABLE STAINLESS STEEL SURGICAL SUTURE

## STAINLESS STEEL STERILE NON-ABSORBABLE of STAINLESS STEEL SURGICAL SUTURE U.S.P

### DESCRIPTION

Stainless steel sutures are composed of 316LVM stainless steel conforming to ASTM F138 Grade 2 "Stainless steel bar and wire for surgical implants". 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 "Non absorbable surgical suture" for non-absorbable surgical sutures

### INTENDED USE

STAINLESS STEEL SUTURE is indicated for use in sternal closure and also for certain orthopaedic procedures (Cerclage or tendon repair).

### SELECTION CRITERIA

The suture should be selected and implanted depending on patient's condition, surgical experience, surgical technique, and wound size. Normally the skin sutures are removed within 30 days depending on wound condition. The decision of physician is final in removing the skin sutures.

### 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 overall use. It is used for permanent fixtures in sternum and orthopedic

effective as a pull out suture as it lacks the adherence to tissues. It is

### ADVERSE REACTIONS

Adverse reactions associated with the use of Stainless Steel Suture include transitory local irritation at the wound site or transitory inflammatory foreign body response. Like all foreign bodies Stainless Steel may potentate an existing infection.

### CONTRAINDICATIONS

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

- a. Surgeons should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing of Stainless Steel Suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.
- b. For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury or illness.
- c. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- d. Contamination of the device may lead to injury or illness of the patient.

### PRECAUTIONS

- a. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- b. In handling this suture material, 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.
- c. Avoid crushing or crimping damage due to surgical instruments such as forceps or needle holders.
- d. 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.
- e. The use of addition throws is particularly appropriate when knotting Mono filament of Stainless Steel Suture.
- f. Care should be taken to avoid damage while handling surgical needle, 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 sharp point.
- g. Grasping in the sharp point area could impair the penetration performance and cause fracture of the needle.
- h. Grasping at the butt or attachment end could cause bending or breakage.
- i. Reshaping the needles may cause them to loose strength and make less resistant to bending and breaking.
- j. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury.
- k. Discard the used needles appropriately.

### STERILITY

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

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## STORAGE

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

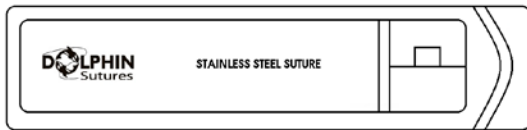
## DISPOSAL

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

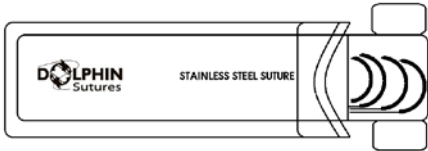
## INSTRUCTION FOR USE

### A. TECHNIQUE FOR OPENING THE OVER WRAP:

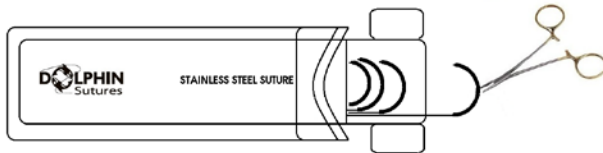
1. Hold the pack in a horizontal manner.



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.



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## SYMBOLS USED ON THE LABELS

	Do not reuse	<b>LOT</b>	Batch number
	Date of manufacture	<b>CE</b> <b>2460</b>	CE Mark with Notified Body Number
	Date of expiry	<b>(R)</b>	Registered
<b>STERILE EO</b>	Sterilized by ethylene oxide	<b>EC REP</b>	EU REPRESENTATIVE
	Temperature limitation		Do not resterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture