

## **FUTURA SURGICARE PVT LTD**

### **INSTRUCTION FOR USE**

Brand name: **LINEX**

Material: Monofilament Polyamide (Nylon)

Non absorbable surgical suture U.S.P

#### Description:

Linex<sup>®</sup> suture is an extremely strong very pliable surgical monofilament suture composed of long chain aliphatic polymers nylon 6 and nylon 6.6. It has high in vivo tensile strength, does not support bacterial growth & has the further advantages of being remarkably smooth & easy to handle. Nylon sutures are available in black and blue coloured and are available in range of gauge sizes and lengths, non needled or attached to stainless steel needles of varying types, sizes and shapes. The needles are attached permanently to the suture. Entire detail of the product range is contained in the catalogue. Linex<sup>®</sup> complies with the requirements of the United States Pharmacopoeia for non absorbable surgical suture.

#### Indications:

Linex<sup>®</sup> is suitable for closing skin sub cuticular layers. Its high degree of elasticity contributes to its great strength in the fine sizes, enabling the plastic surgeons, the micro surgeons & the ophthalmologists to tie secure knots.

#### Actions:

Linex<sup>®</sup> elicit a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the sutures by fibrous connective tissues. While nylon is not absorbed progressive hydrolysis of the nylon in vivo may result in gradual loss over time of tensile strength.

#### Applications:

Suture should be selected and implanted depending on the patient's condition, surgical experience, surgical technique and wound size.

#### Performance:

Linex<sup>®</sup> suture elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. Linex<sup>®</sup> 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. As a monofilament it has been successfully employed in surgical wounds which subsequently become infected or contaminated where it can minimize later sinus formation and suture extrusion.

Its lack of adherence to tissue Linex<sup>®</sup> is effective as a pull out suture.

#### Contra – indications:

Due to gradual loss of tensile strength which may occur due to prolonged periods in vivo, nylon sutures should not be used where permanent retention of tensile strength is required.

#### Warnings/ Precaution/ Interaction:

User should be familiar with surgical procedure and techniques involving non – absorbable sutures before employing Linex<sup>®</sup> 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.

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 addition throws is particularly appropriate when knotting Mono filament polyamide sutures.

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 loose 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:

Adverse reactions associated with the use of this device include: minimal initial inflammatory tissue reaction and transient local irritation at the wound site. Like all foreign bodies Linex<sup>®</sup> may potentate an existing infection.

#### Sterility:

Linex<sup>®</sup> sutures are sterilized by ethylene oxide. Do not re – sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.

#### Storage

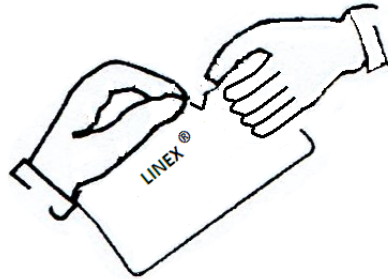
Recommended storage condition 10 – 35 °C, away from moisture and direct heat. Do not use after expiry date.

#### 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:

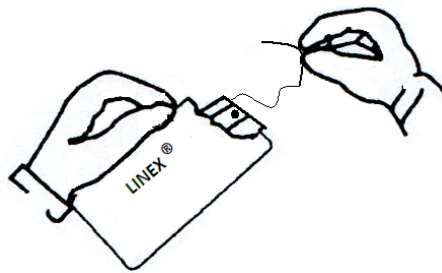
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



2. Then with the help of sterilized gloved hand or sterilized forceps pull the paper folder till the needle is visible. For non-needed suture, pull out the entire paper folder from the pack, open the folder and retrieve the suture.

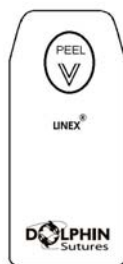


3. Again with the help of sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.

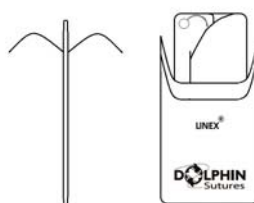


Technique for opening the peel open pouches containing LINEX.

1. Hold the pack in an upright manner and see the peel logo.



2. Hold the protruded portions of the aluminum foils and peel open to see the needle fixed on the paper folder.









3. With the help of 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

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