INSTRUCTION FOR USE-NON ABSORBABLE MONOFILAMENT POLYAMIDE (NYLON) SURGICAL SUTURE

LINEX®
Material: Monofilament Polyamide (Nylon)
Non Absorbable Surgical Suture U.S.P

DESCRIPTION

Linex® suture is a non-absorbable, sterile, surgical monofilament suture composed of long chain aliphatic polymers nylon 6.

It has high in-vivo tensile strength, does not support bacterial growth. Linex® sutures are dyed with Logwood extract, USFDA approval number §73.1410.

Available in abroad range of sutures sizes and lengths, is either non-needled or attached to standard stainless steel needles of varying types and sizes.

The needles are attached permanently to the suture. Entire detail of the product range is contained in the catalogue. The suture complies with United States Pharmacopoeia (U.S.P) and European Pharmacopoeia (E.P).

Suture diameter in mm	U.S.P Size	E.P SIZE (Metric)
0.900 – 1.000	7	9
0.800 – 0.899	6	8
0.700 – 0.799	5	7
0.600 – 0.699	3 & 4	6
0.500 – 0.599	2	5
0.400 – 0.499	1	4
0.350 – 0.399	0	3.5
0.300 – 0.339	2-0	3
0.200 – 0.249	3-0	2
0.150 – 0.199	4-0	1.5
0.100 – 0.149	5-0	1
0.070 – 0.099	6-0	0.7

INTENDED USE

Polyamide (Nylon) suture 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.

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

Linex® suture elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. Linex® 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® is effective as a pull out suture.

ADVERSE REACTIONS

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

CONTRAINDICATIONS

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. The product is not recommended to be used in central nervous system and circulatory system. The use of this suture is contraindicated in patients with known sensitivities or allergies to nylon.

WARNINGS

a. Surgeons should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Polyamide suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

b. In surgery of the urinary or biliary tract, care should be taken to avoid prolonged contact of this or any other suture with salt solution, to prevent calculus formation.

c. 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 and illness.

d. 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.

e. Contamination of the device may lead to injury, illness of the patient.

f. Do no use for invasive procedures related to central nervous system and central circulatory system.

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 polyamide sutures.

f. 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 sharp point.

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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

Linex® 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°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.

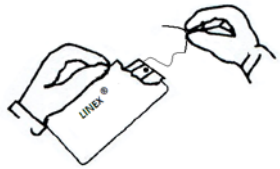
INSTRUCTION FOR USE

A. TECHNIQUE FOR OPENING THE TEAR OPEN POUCH

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. Holding the pack with the left hand, tear the foil with the right hand thumb and fore finger at the notch position. Pull out the folder containing the needled suture with sterilized forceps or sterilized gloved hand.

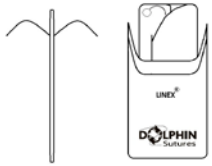
3. Then with the help of sterilized gloved hand or sterilized forceps pull the needle which is visible. For non-needled suture, pull out the entire paper folder from the pack, open the folder and retrieve the suture.



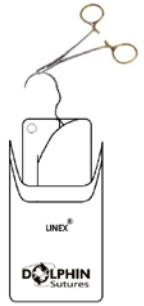
B. Technique for opening the peel open pouches containing LINEX.

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.



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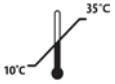
SYMBOLS USED ON THE LABELS

	Do not reuse		Batch number
	Date of manufacture		CE Mark with Notified Body Number
	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