

General Instructions for opening and handling of Lotus packages are mentioned below:

**(I) Recommended technique for opening and handling Peelable Aluminum foil Pack**



a) Hold pack in your hand. Grasp the upper foil flap in your right hand and lower foil flap in your left hand. Roll thumbs outward separating the flaps and exposing sterile card.



**(II) Recommended technique for opening and handling Primary foil Paper / Tyvek Pack**



b) Project the sterile card on the sterile table only after peeling apart the peelable foil completely. For paper / tyvek packing follow step (II)  
c) Hold the card in the gloved left hand securely without bending it as shown in the figure.



d) Arm the needle with an appropriate needle holder using the no-touch technique.  
e) Remove the needled suture with a smooth and moderate pull in a direction parallel to the card. If resistance is observed while removing, then relax the suture and pull again. Please do not pull against the swaged end of the suture.

b) Grasp transparent poly film with thumb and index-finger of left hand, gripping pack between knuckles.



c) Roll thumbs outward separating the flaps and exposing sterile primary foil paper/Tyvek. Keep constant pressure between knuckles for best control.



d) Remove the needled suture with a smooth and moderate pull in a direction parallel to the card. If resistance is observed while removing, then relax the suture and pull again. Please do not pull against the swaged end of the suture.

a) Hold the foil in left hand, grasp foil flap between thumb and index-finger of right hand, thus exposing poly film.

**INSTRUCTIONS FOR USE**

MONOFILAMENT POLYAMIDE  
Brand Name-Nylus®

**DESCRIPTION:**

Nylus® suture meets requirements established by the United States Pharmacopoeia (U.S.P.) non-absorbable surgical suture  
Nylus® - Polyamide suture is a non-absorbable, sterile, surgical suture, composed of long chain-aliphatic polymers, Nylon 6 and Nylon 6.6. Monofilament Polyamide suture meets all the requirements, established by the United States Pharmacopoeia for Non-absorbable Surgical Suture. It is only available as dyed.

**PERFORMANCE:**

Nylus® - black & blue suture elicits a minimal initial inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While polyamide is not absorbed, progressive hydrolysis of the polyamide in vivo may result in gradual loss over time of tensile strength because of its lack of adherence to tissue.

**INDICATIONS:**

Nylus® - suture is indicated for use in general soft tissue approximation and/or ligation.

**APPLICATION:**

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.

**CONTRAINDICATIONS:**

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, NYLUS black suture should not be used where permanent retention of tensile strength is required.

**WARNINGS/ PRECAUTIONS/INTERACTIONS:**

Users should be familiar with surgical procedures and techniques involving non absorbable sutures before employing NYLUS® black suture for wound closure, as 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. 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 may be particularly appropriate when knotting monofilament sutures. Acceptable surgical practices should be followed for the management of infected or contaminated wounds. When handling this or any other suture care should be taken to avoid damage to the suture material. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one-third (1/3) to one half (1/2) of the distance from the attachment end lathe point. Grasping in 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 needles may cause them to loose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needles stick injury. Discard used needles in "Sharps" container.

**ADVERSE REACTIONS:**

Adverse effects associated with this device include allergic minimal initial inflammatory tissue reaction and transient local irritation at the wound site. Like all foreign bodies NYLUS® black/ blue may enhance an existing infection.

**SUPPLY:**

Polyamide suture is available in U.S.P. sizes and EP Metric sizes. The suture is supplied sterile in pre-cut length and attached to various needle type, shape and length. 12 unit, 24 unit & 36 unit packs are packed in a printed box. As per requirement such boxes are packed in a master carton.

USP Sizes (mm)	Metric size (Gauge No.)	Needle Profile	Needle curvature
10.0	0.2	Taper point (round body), Taper cut, Cutting, Reverse cutting, Blunt, Spatulated, Trocar point, Diamond point	1/2 circle
9.0	0.3		
8.0	0.4		
7.0	0.5		
6.0	0.7		
5.0	1	3/8 circle	5/8 circle
4.0	1.5		
3.0	2		
2.0	3		
1.0	3.5		
1	4	circle	circle
2	5		
3&4	6		
5	7	straight	straight

**STERILITY:**  
NYLUS® suture are sterilized by Ethylene Oxide Gas. Do not re-sterilize. Do not use, if package is opened or damaged. Discard opened unused sutures as well as damaged primary packs.

**STORAGE:**  
Recommended storage conditions: Store below 26°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 for "infectiouswaste". Unused expired pouches should be incinerated.

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**INSTRUCTIONS FOR USE**

MONOFILAMENT POLYAMIDE

NYLUS®



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**SYMBOLS USED ON LABELLING**

- CE Logo with Notified Body Number
- Do not re-use
- keep away from sunlight
- Manufactured by
- Lot Number
- Date of Manufacture(MM/YYYY)
- Use by (MM/YYYY)
- Sterilized using Ethylene Oxide
- Caution, consult accompanying documents
- Authorized Representative in the European Community
- Temperature Limitation (store below 26°C)
- Do not re-sterilize
- Do not use if package is damaged
- Consult instructions for use
- Keep Dry