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MONOFILAMENT POLYAMIDE (NYLON) NON ABSORBABLE SURGICAL SUTURE

GDT NYLON

INSTRUCTIONS FOR USE

DESCRIPTION

GDT Nylon 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. Available in light blue color.
Available in a broad range of sutures sizes, attached to hardened 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.

INDICATIONS

Polyamide (Nylon) suture is suitable for closing skin subcuticular layers. Its high degree of elasticity contributes to its great strength in the fine sizes, enabling the plastic surgeons, the micro surgeons & the dentists to tie secure knots.

SELECTION

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

PERFORMANCE

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

ADVERSE REACTIONS

Adverse reactions associated with the use of GDT Nylon include transitory local irritation at the wound site or transitory inflammatory foreign body

response. Like all foreign bodies, GDT Nylon 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 the 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 sutures 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 devise 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 or illness of the patient.

f. Do not use for invasive procedures related to the 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 Monofilament 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.

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 lose 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

Suture is supplied gamma-sterilized. The sterility of undamaged, unopened packs is guaranteed. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.

STORAGE

Recommended storage condition 5°C-25°C, away from moisture and direct heat. Do not use after the expiry date.

DISPOSAL

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

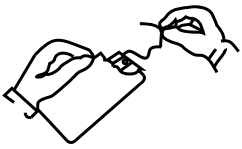
INSTRUCTIONS FOR USE

A. Technique for opening the over wrap

1. The scrub nurse should hold the sterile pack in their 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-needled 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.



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

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.

PACKAGING

3/0 USP (metric EP 2.0)	**Ref: NY30**
4/0 USP (metric EP 1.5)	**Ref: NY40**
5/0 USP (metric EP 1.0)	**Ref: NY50**

SYMBOLS

	Consult instructions for use		Do not resterilize
	Caution, consult accompanying documents		Do not re-use/ for single use only
	Temperature limit		Manufacturer
	Keep away from sunlight	REF	Catalog number
	Keep dry	LOT	Batch code
STERILE R	Sterilised using irradiation		Use by
	Do not use if package is damage		Date of Manufacture

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material.
The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.