

## INSTRUCTIONS FOR USE

### *Nylon Suture*

Non-absorbable - Monofilament - Sterile

#### Description:

Nylon suture is a nonabsorbable, sterile surgical suture composed of the long-chain aliphatic polymer nylon 6 and nylon 6.6, resulting in a monofilament of a smooth and uniform surface which is prepared through synthetic chemical processes resulting in blue or black color threads. Nylon suture meets all the requirements of the EP and USP for Non-absorbable surgical suture.

#### Indications:

Nylon suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

#### Actions:

Nylon suture elicits a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. The Nylon Suture is not absorbed, neither any significant change occurs in the tension strength "in vivo" retention.

#### Contraindications:

The product is contraindicated in procedures where there is prolonged contact with saline solutions such as the ones found in the biliary and urinary tract. This may result in calculus formation.

#### Warnings:

The device will only be used under the surgeon's orientation through the applicable surgical techniques and it must only be manipulated by qualified personal. Do not re-sterilize/reuse. Discard opened packages and unused sutures. Avoid prolonged exposure to elevated temperature. User should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing. Must be careful so that it is done in an aseptic manner. Do not use the product beyond its expiration date. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

#### Precautions:

In handling this or any other suture material care should be taken to avoid damage from handling. Avoid crushing or crimping due to application of surgical instruments such as forces and needle holders.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

#### Adverse Reactions:

Adverse effects associated with the use of this device include wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transitory in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of the bloodborne pathogens.

#### How supplied:

Nylon Sutures are available as sterile monofilament strands from USP4-11/0, in a variety of lengths, non-needled or affixed to various needle types in one, two or three dozens per box.

#### Storage Conditions:

It is recommended that Nylon Sutures are stored below 25°C kept away from direct heat and moisture. Carefully observe the expiry date.

#### Manufacturer:

Shandong Haidike Medical Products Co., Ltd.  
Add: Tianfu Road, Dongcheng District, Shan County,  
274300 Heze City, Shandong Province, China

## Explanation of the Symbols on Packaging:

	Do not re-use
	Gamma irradiation
	Ethylene Oxide irradiation
	Consult instructions for use
	Do not use if package is damaged
	Expiration Date
	Manufactured Date
	Catalogue Number
	Batch number
	Keep away from sunlight
	Keep dry
	Temperature Limitation
	Fragile: Handle with care
	CE Mark and identification number of Notified Body. Product conforms to the essential requirements of the medical device directive 93/42/EEC

 CMC Medical Devices & Drugs S.L.  
Add: C/ Horacio Lengo No 18, CP 29006, Málaga, Spain  
Tel: +34 951 214 054  
Email: info@cmcmedicaldevicec.com

#### Importer:

GRAPH GROUP Vitalii Lutskov  
Add: Sikorskiego Av. 18/28, 02-758, Warsaw, Poland  
Tel: +48 884 099 660  
Email: info@graphgroup.pl  
Web: www.graphgroup.pl

SRN: PL-IM-000044202



Version No.: A/3