

NYLENE®
 Monofilament Nylon
 NON – ABSORBABLE Suture

EN

CE Mark	CE 0297, Classification IIb
Colour Coding	Suture pack - Green, Thread – Dark Blue
Needle Image / Length	1/2 = 1/2 Circle needle 3/8 = 3/8 Circle needle
	Length (eg. 35mm) = Stretched length of the needle in mm
● Round Bodied Taper	● A-Cute® (RB Cutting Tip)
▼ Reverse Cutting	▼ Reverse Premium Cutting Point (PCP)
▼ Straight Cutting	↗ Blunt
▲ Conventional Cutting	▽ Special Cutting
▲ Finesline® Cutting	▽ Lancet-Spatula (side cutting)

CE 0297 CE-Mark and Identification Number of the Notified Body Product conforms to the Essential Requirements of the Medical Device Directive 93/42/EEC

CV300 Unique Stainless Steel Material (high bending resistance, yet flexible when bent)


Met Refers to the thread diameter in 1/10mm
 The number above Met (eg. 2/0) explains the thread size in USP/EP

 Expiry Date (year, month)

LOT Refers to the batch number and allows full traceability


STERILE Sterile

STERILE R Method of sterilisation R = gamma irradiation


 Do not reuse


 Caution


REF Reference number


 Do not use if package is damaged


EC REP Authorised EU Representative


 Date of manufacture


 Manufacturer's name and address

 Recyclable materials


 Do not resterilise

 Fragile, handle with care

 Consult Instructions For Use

 Keep away from sunlight

 Keep dry

 Store below 25°C

Description - Nylene® suture is a monofilament of polyamide nylon 6. The suture is untreated and supplied as either clear (undyed) or dark blue (coloured with FD & C Blue # 2). The material is non-absorbable.


Intended Use - Nylene® sutures are indicated for use in general soft tissue approximation.
 To be used in procedures requiring a non-absorbable suture.


Actions - As with other synthetic sutures, Nylene® may cause minimal tissue reaction.


Indications - Nylene® suture should only be used in surgical procedures requiring a non-absorbable suture or ligature.

Contraindications - Due to the gradual loss of tensile strength which may occur *in vivo* over prolonged period, the use of Nylene® monofilament suture is not recommend where permanent retention of the tensile strength is required.

Nylene® sutures are not indicated for use in the heart, the central circulatory system and central nervous system.

 **Warnings** - Nylene® sutures are supplied sterile and are single use only devices. Nylene® sutures should not be resterilised under any circumstance. **Sterility is not guaranteed if the suture package is damaged or opened.**

 Nylene® sutures are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving non-absorbable sutures before employing Nylene®.

 All decision and responsibility regarding the selection, use of the suture and interpretation contained in this instruction for use, remains that of the user.

Instructions for Use - Knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the end user.

For easy handling and opening of the suture pack, please refer to Fig. 1. As with all sutures, care should be exercised during handling and use to avoid compromising the suture. In particular, precaution should be taken when using surgical instruments such as needle holders to grasp the suture. Instruments should be in good working condition with no sharp edges to avoid crushing or severing the suture. In all instances, the suture should only be held at the free end.

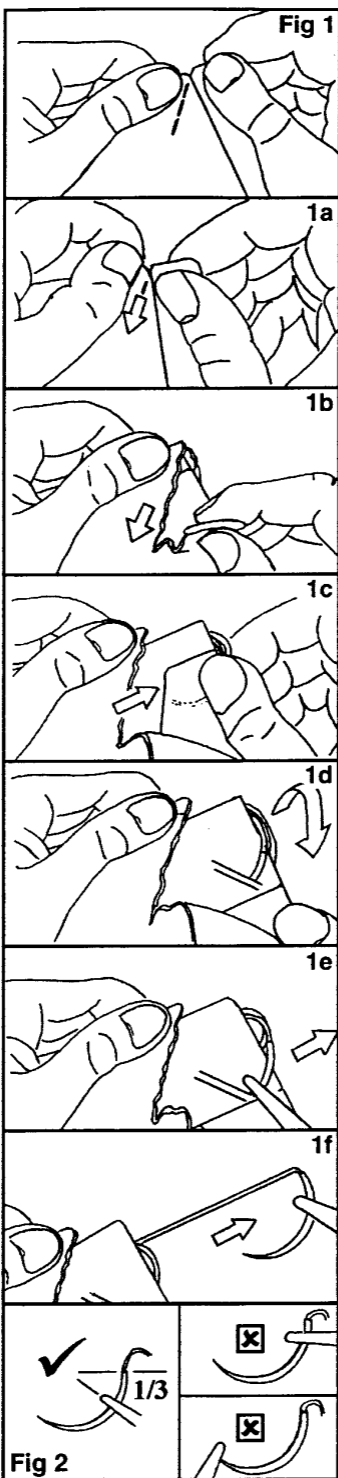
To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Nylene® sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 6/0 to 2 (Metric 0.7. to 5). Other sizes may be available upon request.



Storage - Nylene® sutures should be stored at temperatures below 25 degrees Celsius, away from direct heat and moisture to ensure that packaging integrity is maintained.

® Registered trademark of Dynek Pty Ltd



Dynek Pty Ltd
 9 Circuit Drive, Hendon SA 5014, Australia
 Tel. +61 8 8268 2033 Fax +61 8 8347 0434
 Website: www.dynek.com
 Email: dynek@dynek.com

EC REP: Obelis s.a.

Bd. Général Wahis 53
 1030 Brussels, Belgium
 Tel: +(32) 2 732-59-54
 Fax: +(32) 2 732-60-03

CE 0297
 ISO 13485

REF: IFU-N/Rev7 Date Issued: 25/03/2022