

DYLOC® EN
Monofilament Polyether
NON-ABSORBABLE Suture

CE Mark	0297 , Classification IIb
Colour Coding	Suture pack - Teal, Thread - Light 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
	Fineline® Cutting
	Lancet-Spatula (side cutting)

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)

Refers to the batch number and allows full traceability

Sterile

Method of sterilisation R = gamma irradiation

Do not reuse

Caution

Reference number

Do not use if package is damaged

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 - Dyloc® suture is a monofilament of a thermoplastic polyether-ester elastomer (polybutylene terephthalate). The suture is untreated and supplied as light blue using an FDA approved colouring agent. The material is non-absorbable.

Intended Use - Dyloc® 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, Dyloc® may cause minimal tissue reaction.

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

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

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

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

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.

As Dyloc® suture has elastic properties, care should be taken when using it as a subcuticular stitch. Dyloc® suture should not be pulled tightly or over stretched as it may recoil when being removed.

To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not

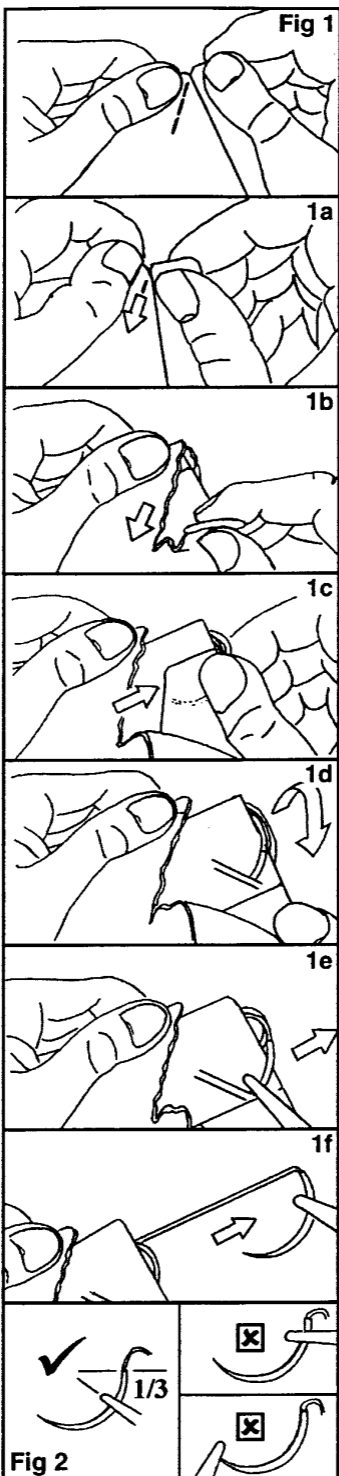
grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Dyloc® sutures are supplied in various sizes and lengths with 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 - Dyloc® sutures should be stored at temperatures below 25 degrees Celsius, away from direct heat and moisture to ensure that packaging integrity is maintained.



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