

Monofilament Polyvinylidene Fluoride (PVDF) NON-ABSORBABLE Suture

CE Mark	CE 0297, Classification III
Colour Coding	Suture pack - Blue Bright, Thread - 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)
	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 - Vilene® suture is a monofilament of polyvinylidene fluoride. The suture is untreated and supplied as deep blue using an FDA approved colouring agent. The material is non-absorbable.


Intended Use - Vilene® sutures are indicated for use in general soft tissue approximation, requiring a nonabsorbable suture, including cardiovascular procedures.


Actions - Although physiologically inert, as with other synthetic sutures, Vilene® may cause minimal tissue reaction.

Indications - Vilene® is indicated for use in general soft tissue approximation, requiring a non-absorbable suture, including ophthalmologic and cardiovascular procedures.

Contraindications - None

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

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

 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.

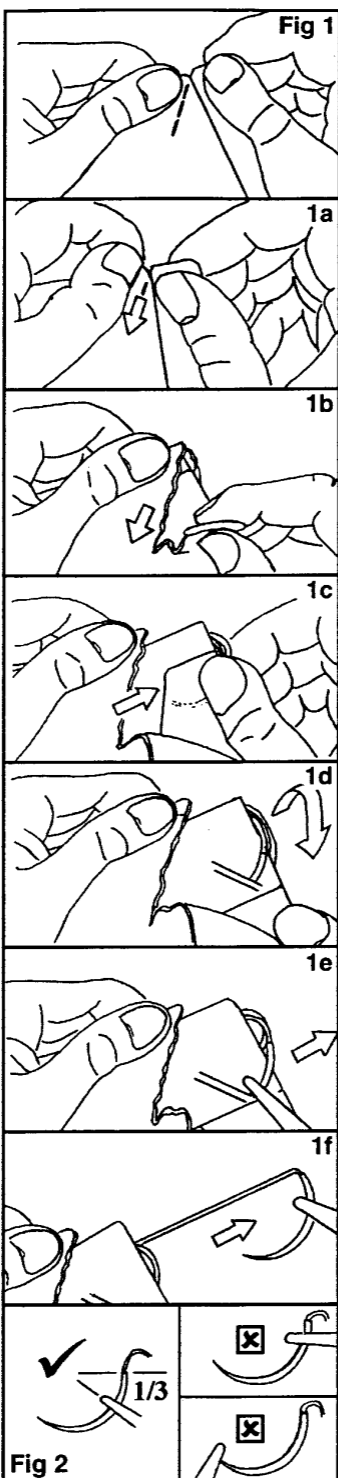
Supplied - Vilene® sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 11/0 to 5 (Metric 0.1

to 7). Other sizes may be available upon request. All Vilene® sutures are sterilised by gamma irradiation.



Storage - Vilene® 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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