



**Monofilament Polyvinylidene Fluoride (PVDF)  
NON-ABSORBABLE Suture**


CE Mark	 <b>0297</b> , Classification III
Colour Coding	Suture pack - Rust, Thread - Yellow
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

 Store below 25°C


**Description** - Radene® suture is a monofilament of polyvinylidene fluoride. The suture is untreated and supplied as a yellow colour using an FDA approved colouring agent. The material is non-absorbable.


**Intended Use** - Radene® 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, Radene® may cause minimal tissue reaction.

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

**Contraindications** - None

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

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

 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.

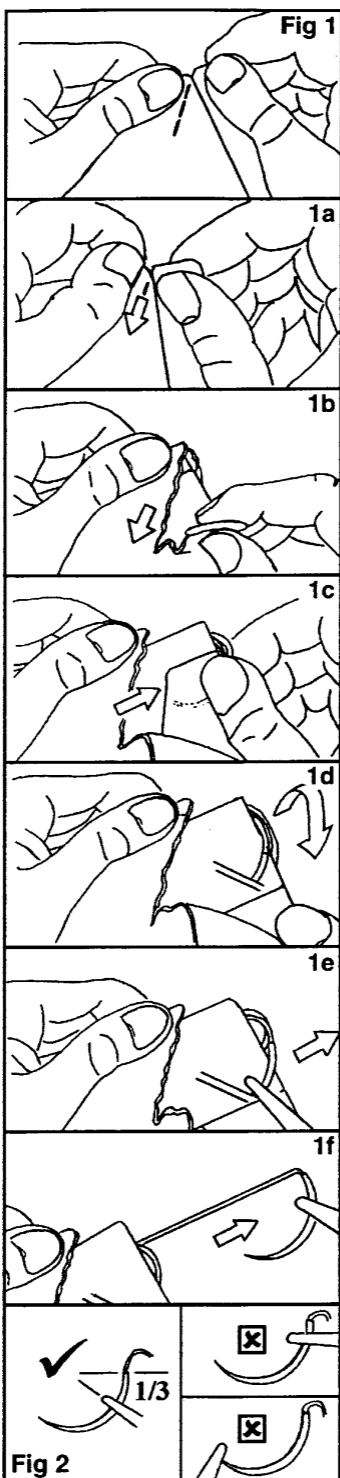
**Supplied** - Radene® sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 11/0 to 5

(Metric 0.1 to 7). Other sizes may be available upon request. All Radene® sutures are sterilised by gamma irradiation.



**Storage** - Radene® 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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