














DYFLEX® - POLYFLEX® - TEFLEX® EN
 Braided Siliconised Polyester
 NON-ABSORBABLE Sutures

CE Mark	C € 0297 , Classification IIb
Colour Coding	Dyflex® Pack - Orange, Thread - Green Polyflex® Pack - Orange, Thread - Black Teflex® Pack - Orange, Thread - White
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)

C **€ 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 – Dyflex®, Polyflex® and Teflex® sutures are braided multifilaments of polyester (polyethylene terephthalate). All sutures are supplied siliconised. Dyflex® suture is green (coloured with D & C Green # 6), Polyflex® is black (coloured with Renol Black) and Teflex® is white (undyed).

Intended Use - Dyflex®, Polyflex® and Teflex® 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, Dyflex®, Polyflex® and Teflex® may cause minimal tissue reaction.

Indications - Dyflex®, Polyflex® and Teflex® sutures should only be used in surgical procedures requiring a non-absorbable suture or ligature.

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

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

Dyflex®, Polyflex® and Teflex® suture are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving non absorbable sutures before employing Dyflex®, Polyflex® and Teflex®.

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.

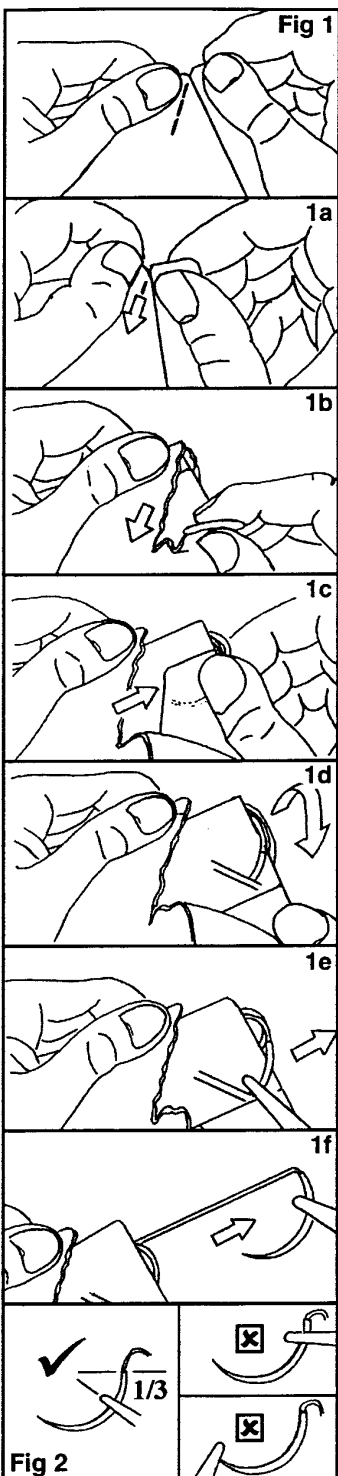
To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2.

Supplied - Dyflex®, Polyflex® and Teflex® sutures are supplied in various sizes and lengths, with or without preattached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 6/0 to 5 (Metric 0.7. to 7). Other sizes may be available upon request.

Storage - Dyflex®, Polyflex® and Teflex® 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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