Braided Treated Silk	
NON – ABSORBABLE Suture	
CE Mark C € 0297, Classification IIb Colour Coding Suture pack - Light Blue, Thread - Black Needle Image / Length 11/2 = 1/2 Circle needle 3/8 = 3/8 Circle needle Length (eg. 35mm) = Stretched length of the needle in mm ● Round Bodied Taper P A-Cute® (RB Cutting Tip)	
<ul> <li>Reverse C</li> <li>Straight Ci</li> <li>Convention</li> <li>Fineline® C</li> </ul>	Initial         Image: Reverse Premium Cutting Point (PCP)           utting         Image: Blunt           nal Cutting         Image: Special Cutting
C € 0297	CE-Mark and Identification Number of the Notified Body Product conforms to the Essential Requirements of the
CV300	Medical Device Directive 93/42/EEC 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 R	Sterile Method of sterilisation R = gamma irradiation
8	Do not reuse
$\Delta$	Caution
REF	Reference number
	Do not use if package is damaged Authorised EU Representative
M	Date of manufacture
ES .	Manufacturer's name and address Recyclable materials
	Do not resterilise
I	Fragile, handle with care
	Consult Instructions For Use
* K	keep away from sunlight
J <sup>25*</sup>	Keep dry
A Store below 25°C	
Description - Dysilk <sup>®</sup> suture is a braided multifilament of silk filaments.	

Description - Dysik® suture is a braided multifilament of silk filaments. Dysik® suture is supplied as either black (coloured with Logwood Extract or white (undyed). Dysik® suture is supplied wax treated. Dysik® suture is non-absorbable.

Intended Use - Dysilk® sutures are indicated for use in general soft tissue approximation.

To be used in procedures requiring a non-absorbable suture.

Actions - Dysilk® may cause minimal tissue reaction.

Indications - Dysilk<sup>®</sup> sutures should only be used in surgical procedures requiring a <u>non-absorbable</u> suture or ligature.

Contraindications - The use of Dysilk<sup>®</sup> sutures is contraindicated in patients with known sensitivities or allergies to silk.

Due to the gradual loss of tensile strength which may occur *in vivo* over prolonged period, the use of Dysilk<sup>®</sup> sutures is not recommend where permanent retention of the tensile strength is required.

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

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

 $\triangle$ Dysilk<sup>®</sup> sutures are for use by appropriately trained personnel only. Users should be familiar with surgical techniques involving non-absorbable sutures before employing Dysilk<sup>®</sup>.

 $\triangle$  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.

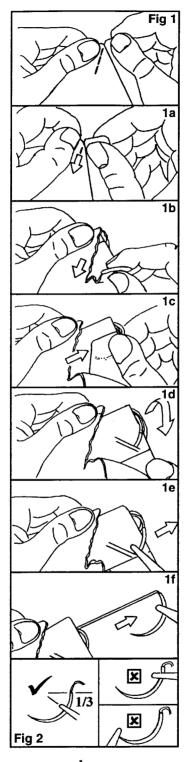
To prevent needle detachment the needle should be held away from the shank, approximately one third of the way down. The operator should not grasp the needle by the point as this could damage it. Please refer to Fig. 2. Supplied - Dysilk® (black or white/undyed) sutures are supplied in various sizes and lengths, with or without pre-attached stainless steel needles of varying length, curvature and cutting profile. Standard sizes range from USP 7/0 to 5 (Metric 0.5. to 7). Other sizes may be available upon request.

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

<sup>®</sup> Registered trademark of Dynek Pty Ltd

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