

INSTRUCTIONS FOR USE

SYNTHECON SYNLENE

NON-ABSORBABLE POLYPROPYLENE SUTURE

DESCRIPTION:

SYNLENE Polypropylene is a sterile, non-absorbable, monofilament surgical suture composed of a strand of synthetic linear polyolefin. Polypropylene suture is pigmented blue for enhanced visibility in the surgical field. SYNLENE Polypropylene sutures comply with the requirements of the European Pharmacopoeia and the United States Pharmacopoeia.

INDICATIONS:

SYNLENE Polypropylene sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures where a non-absorbable suture with high tensile strength is required.

ACTIONS:

SYNLENE Polypropylene surgical sutures elicit a minimal acute inflammatory reaction in tissue, followed by gradual encapsulation of the suture by fibrous connective tissue. SYNLENE Polypropylene suture is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. As a monofilament, SYNLENE Polypropylene suture, U.S.P. resists involvement in infection and has been successfully employed in contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion. The lack of adherence to tissues has facilitated the use of SYNLENE Polypropylene suture as a pull-out suture.

CONTRAINDICATIONS:

This suture should not be used in patients with known hypersensitivity or allergy to polypropylene. As a non-absorbable suture material, polypropylene should not be used where the surgeon determines that permanent foreign material may be undesirable or where long-term retention of the suture could increase the risk of infection or interfere with healing. The selection of suture material should be based on the patient's clinical condition, the type of tissue being repaired, and the duration of wound support required, as determined by the surgeon.

WARNING:

Users should be familiar with accepted surgical procedures and techniques involving non-absorbable sutures before using polypropylene sutures for wound closure, as the risk of wound dehiscence may vary depending on the site of application, the tissue involved, and the suture material used. As with any foreign body, prolonged contact of polypropylene sutures with salt

solutions, such as those present in the urinary or biliary tracts, may result in calculus formation. Appropriate surgical practices should be followed when managing infected or contaminated wounds. This product is supplied sterile for single use only; do not re-sterilize, as re-sterilization may alter the physical characteristics and performance of the suture. Do not use the product if the sterile package is opened, damaged, or if the expiration date has been exceeded.

PRECAUTIONS:

In handling this or any other surgical suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, square ties of single suture strands. The use of additional throws is particularly appropriate when knotting SYNLENE sutures. To avoid damaging needle points and swaging area, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in a "sharps" container. Avoid storing product at elevated temperatures.

ADVERSE REACTIONS:

Adverse reactions associated with the use of SYNLENE Polypropylene surgical sutures may include wound dehiscence, infection, minimal acute inflammatory tissue reaction, and transient local irritation at the wound site. Prolonged contact of the suture with salt-containing solutions, such as those present in urine or bile, may result in calculus formation in the urinary or biliary tracts. As with any implanted foreign material, local tissue reactions may occur depending on the patient's condition and the nature of the tissue involved.

STERILITY:

SYNLENE Polypropylene sutures are sterilized by ethylene oxide. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.

STORAGE:

Recommended storage condition below 25 °C, away from moisture and direct heat. The shelf life of SYNLENE Polypropylene is five years. Do not use after expiry date.

SUPPLY:

SYNLENE detailed specification of suture length, needle profile, needle curvature read the primary label on the suture pack.

DEVICE READINESS:

Ready to use as found inside the container.

MANUFACTURING CONDITIONS:

Manufactured under an ISO 13485 Quality Management System to ensure these medical devices are safe, effective, and ready for clinical use with minimal risk and maximum patient benefit.

PRODUCT SPECIFICATIONS:

USP Sizes (mm)	Metric size (Gauge No.) Max.	Needle Profile	Needle curvature
2	5	TAPER POINT	
1	4	TAPER BLUNT	
0	3.5	REVERSE CUTTING	a) Straight
2-0	3	STRAIGHT CUTTING	b) 1/2 Curve
3-0	2	SPATULA	c) 1/2 Circle
4-0	1.5	COLT	d) 1/4 Circle
5-0	1		e) 3/8 Circle
6-0	0.7		f) 5/8 Circle
7-0	0.5		
8-0	0.4		
9-0	0.3		
10-0	0.2		

DISPOSAL

To be disposed as per user's country disposal regulations and hospital/clinic protocol.

EXPLANATION OF SYMBOLS:

Symbol	Explanation
	Manufacturer
	Manufactured date
	Use until
STERILE EO	Sterilization by Ethylene oxide
	Do not re- use
	Do not re-sterilize
LOT	Batch
	Keep from Sunlight
	Keep dry
	Warning
	Temperature limitation
	Don't use when packing damaged

MANUFACTURED BY:

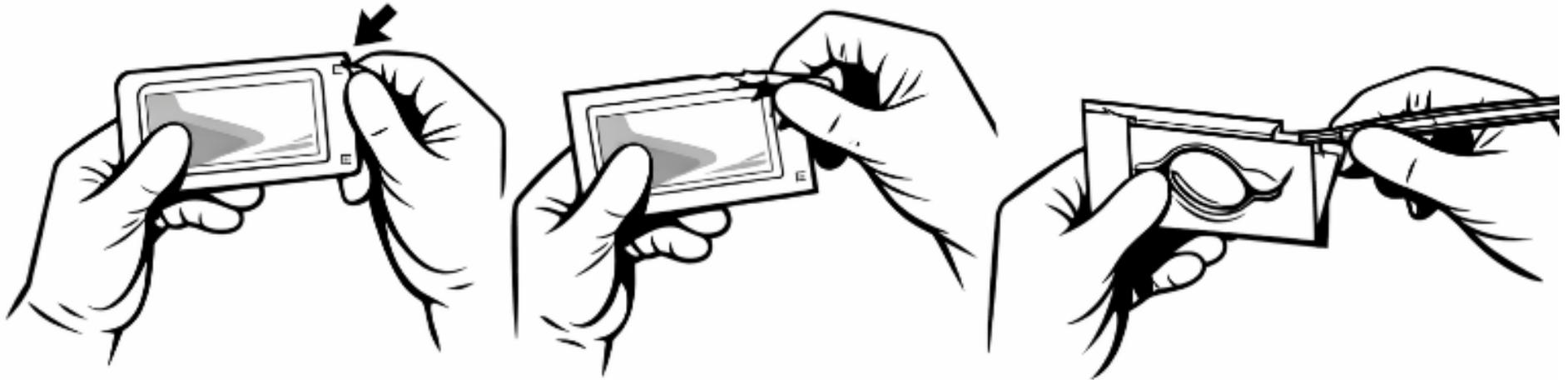


Synthecon

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TECHNIQUE FOR OPENING THE TEAR OPEN PACK



1. Hold Pack at Notch

2. Tear at Notch

3. Remove Suture

