

INSTRUCTIONS FOR USE

SYNTHECON SILK

NON–ABSORBABLE SILK SUTURE

DESCRIPTION:

Synthecon SILK is a sterile, non-absorbable, braided surgical suture designed for general soft tissue approximation and ligation. The braided construction provides excellent handling, knot security, and pliability. For improved visibility in the surgical field, the sutures are available in black. Synthecon SILK sutures comply with the requirements of the European Pharmacopoeia and the United States Pharmacopoeia.

INDICATIONS:

Synthecon SILK sutures are indicated for general soft tissue approximation and/or ligation, including applications in cardiovascular procedures where a non-absorbable suture with high tensile strength is required.

ACTIONS:

Synthecon SILK surgical sutures elicit a minimal acute inflammatory reaction at the tissue site, followed by gradual encapsulation of the suture by fibrous connective tissue. As a non-absorbable suture, SILK is not degraded by enzymatic or hydrolytic activity in vivo and maintains its tensile strength over time. The suture material is pharmacologically inert and is not known to produce systemic effects.

CONTRAINDICATIONS:

Synthecon SILK sutures should not be used in patients with a known hypersensitivity or allergic reaction to silk or any component of the suture, including any coatings applied to the suture material.

WARNING:

Users should be familiar with surgical procedures and techniques involving non-absorbable suture before employing silk sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds. Do not re-sterilize; re-sterilization may alter the physical characteristics of this suture. Do not use if package is open or 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 SILK 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 this device may include wound dehiscence, calculi formation in the urinary and biliary tracts when prolonged contact with salt-containing solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transient local irritation at the wound site. Broken needles may result in extended or additional surgical procedures or the presence of residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood-borne pathogens.

STERILITY:

Synthecon SILK 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 Synthecon SILK is five years. Do not use after expiry date.

SUPPLY:

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

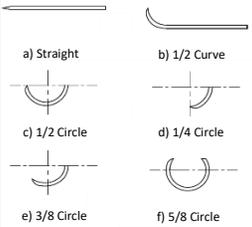
DEVICE READINESS:

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
4 & 3	6	TAPER POINT	
2	5	TAPER BLUNT	
1	4	REVERSE CUTTING	
0	3.5	STRAIGHT CUTTING	
2-0	3	SPATULA	
3-0	2	COLT	
4-0	1.5		
5-0	1		
6-0	0.7		
7-0	0.5		
8-0	0.4		

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
	Sterilization by Ethylene oxide
	Do not re- use
	Do not re-sterilize
	Batch
	Keep from Sunlight
	Keep dry
	Warning
	Temperature limitation
	Don't use when packing damaged

MANUFACTURED BY:

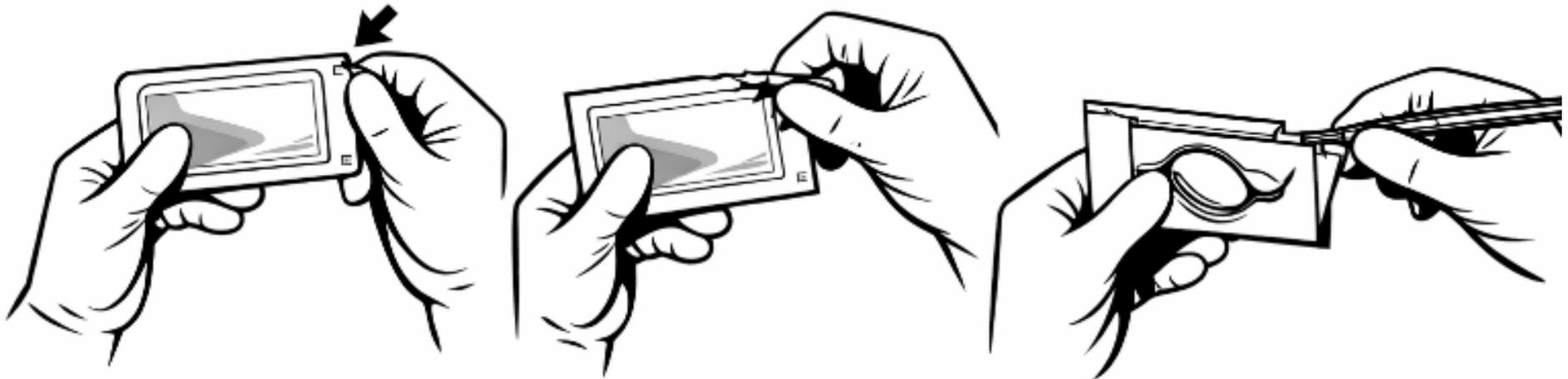


 Synthecon

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TECHNIQUE FOR OPENING THE TEAR OPEN PACK



1. Hold Pack at Notch

2. Tear at Notch

3. Remove Suture

