

INSTRUCTIONS FOR USE

SYNCRON POLYESTER

NON–ABSORBABLE POLYESTER SUTURE

DESCRIPTION:

SYNCRON Polyester is a sterile, non-absorbable, multifilament surgical suture composed of poly(ethylene terephthalate), a high-molecular-weight, long-chain linear polyester containing recurrent aromatic rings. The suture consists of braided polyester fibers coated with poly(butylene adipate) or poly(oxy-1,4-butanediolyxo (1,6-dioxo-1,6-hexanediyl)), a non-absorbable, relatively non-reactive lubricant that improves tissue passage and handling characteristics.

The braided construction provides optimal handling properties. For enhanced visibility in the surgical field, the sutures are available dyed green or undyed (white). SYNCRON Polyester sutures comply with the requirements of the European Pharmacopoeia and the United States Pharmacopoeia.

INDICATIONS:

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

ACTIONS:

SYNCRON Polyester sutures elicit a minimal acute inflammatory reaction in tissue, followed by gradual encapsulation of the suture by fibrous connective tissue. Polyester sutures are non-absorbable and are not degraded by enzymatic activity in vivo. No significant loss of tensile strength is known to occur in vivo. Both the polyester fiber suture material and the polybutylate coating are pharmacologically inactive.

CONTRAINDICATIONS:

This suture should not be used in patients with known hypersensitivity or allergic reactions to polyester or to any of the suture components, including the coating material.

WARNING:

Users should be familiar with surgical procedures and techniques involving non-absorbable suture before employing polyester 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 polyester 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:

SYNCRON 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 SYNCRON Polyester is five years. Do not use after expiry date.

SUPPLY:

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

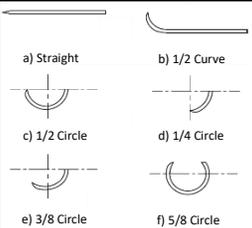
DEVICE READINESS:

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
5	7	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		

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:

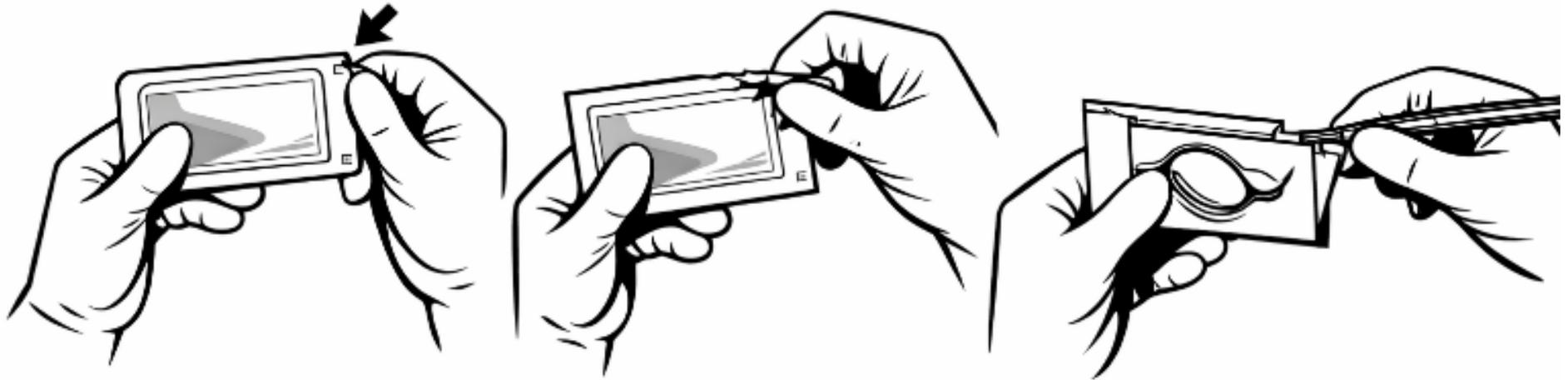


 Synthecon

1 POWER STREET, ISANDO, JOHANNESBURG
1600, GAUTENG, SOUTH AFRICA



TECHNIQUE FOR OPENING THE TEAR OPEN PACK



1. Hold Pack at Notch

2. Tear at Notch

3. Remove Suture

