INSTRUCTIONS FOR USE

SYNTHECON NYLON

NON–ABSORBABLE POLYAMIDE SUTURE

DESCRIPTION:
SYNTHECON NYLON is a non-absorbable, sterile monofilament surgical suture composed of the long-chain aliphatic polymers. SYNTHECON NYLON is available in black, blue and clear color to enhance visibility in tissue. SYNTHECON NYLON fulfills all the requirements of the European Pharmacopoeia and of the United States Pharmacopoeia for non-absorbable surgical suture.

INDICATIONS:
SYNTHECON NYLON suture is indicated for use in surgical operations for general soft tissue approximation and/or ligation.

ACTIONS:
SYNTHECON NYLON is a synthetic non-absorbable monofilament suture that produces minimal acute inflammatory tissue response followed by encapsulation by fibrous connective tissue. The material is not metabolized by the body; however, slow hydrolytic degradation may occur in vivo and can lead to a gradual decrease in tensile strength during prolonged implantation.

CONTRAINDICATIONS:
Although nylon is classified as non-absorbable, it undergoes slow hydrolytic degradation in vivo that may result in a gradual reduction of tensile strength over time. Therefore, nylon sutures should not be used in applications where long-term maintenance of high tensile strength is required.

WARNING:
Users should be familiar with surgical procedures and techniques involving non-absorbable suture before employing nylon 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 Nylon 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 effects associated with the use of this device include wound dehiscence, gradual loss of tensile strength over the time, calculus formation in urinary and biliary tracts when prolonged contact with salt solution such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transitory local irritation at the wound site.
Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood borne pathogens.

STERILITY:
SYNTHECON NYLON sutures are sterilized by ethylene oxide and gamma radiation. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused pouches.

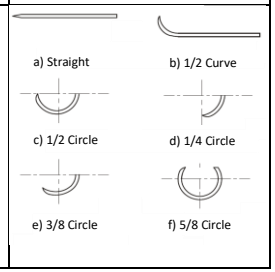
STORAGE:
Recommended storage condition below 25 ºC, away from moisture and direct heat. The shelf life of SYNTHECON NYLON is five years. Do not use after expiry date.

SUPPLY
SYNTHECON NYLON 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	
2-0	3		
3-0	2	STRAIGHT CUTTING	
4-0	1.5		
5-0	1	SPATULA	
6-0	0.7		
7-0	0.5	COLT	
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
	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

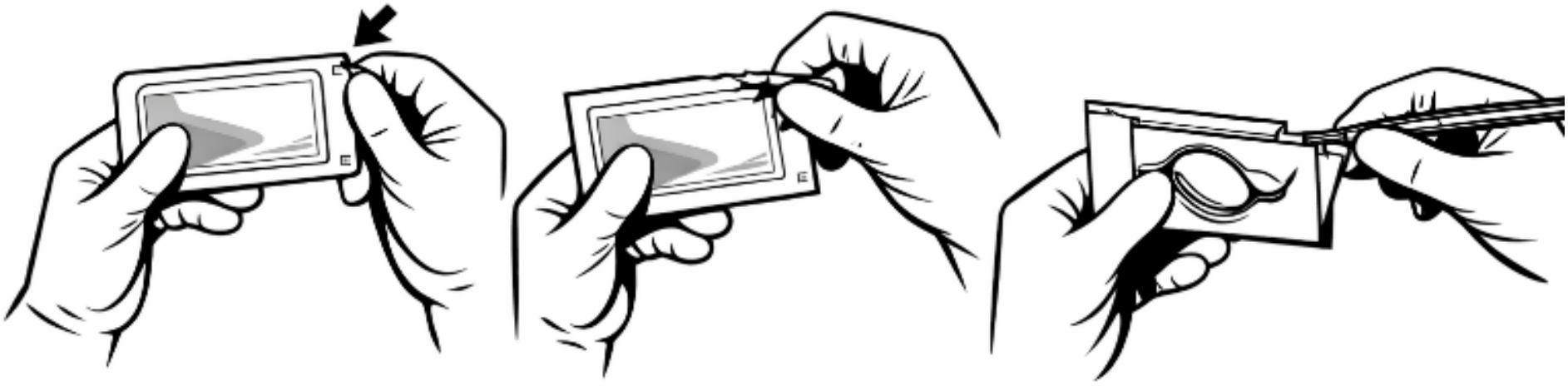
MANUFACTURED BY:

Synthecon

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

Synthecon

TECHNIQUE FOR OPENING THE TEAR OPEN PACK



1. Hold Pack at Notch
2. Tear at Notch
3. Remove Suture