

## INSTRUCTIONS FOR USE

# SYNTHECON PLAIN & CHROMIC CATGUT

### ABSORBABLE PLAIN & CHROMIC CATGUT SUTURES

#### DESCRIPTION:

PLAIN and CHROMIC CATGUT sutures are sterile, absorbable sutures manufactured from the intestinal serosa of animals sourced exclusively from BSE negligible-risk countries. The sutures are supplied as a spun fiber that has been centerless ground and polished to provide smooth handling characteristics.

PLAIN CATGUT sutures are untreated and are intended to provide short-term wound support before being absorbed by the body through enzymatic degradation while CHROMIC CATGUT sutures are treated with a chromic salt solution (0.15–0.30%) to prolong tensile strength and delay absorption. PLAIN and CHROMIC CATGUT sutures are supplied in a solution of 90% Isopropanol (C<sub>3</sub>H<sub>8</sub>O), 9% Water and 1% Triethanolamine (i.e. isopropanol and demineralized water). PLAIN and CHROMIC CATGUT fulfill all the requirements of the European Pharmacopoeia and of the United States Pharmacopoeia.

#### INDICATIONS:

PLAIN and CHROMIC CATGUT absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, where temporary wound support is required. Due to the rapid loss of tensile strength associated with absorbable sutures of natural origin, these sutures are not intended for use in cardiovascular or neurological tissues where prolonged wound support may be required.

#### ACTIONS:

PLAIN and CHROMIC CATGUT absorbable sutures provide temporary wound support and elicit a minimal acute inflammatory tissue reaction, followed by encapsulation by fibrous connective tissue. The sutures are gradually absorbed through enzymatic degradation in the body, resulting in a progressive loss of tensile strength and eventual absorption of the suture material. As the sutures are absorbable, they do not require removal.

#### TENSILE STRENGTH RETENTION:

- PLAIN CATGUT retains approximately 40% of its tensile strength at 7 days post-implantation and 5% at 14 days with complete absorption within 70 days.

- CHROMIC CATGUT retains approximately 55% of its tensile strength at 7 days post-implantation, 25% at 14 days, and 5% at 21 days, with absorption generally complete within 90 days.

#### CONTRAINDICATIONS:

These sutures, being rapidly absorbed, should not be used where extended approximation of tissue is required.

#### WARNINGS:

Before employing PLAIN and CHROMIC CATGUT absorbable sutures, users should be familiar with surgical techniques for absorbable sutures and proper wound closure procedures. Risk of wound dehiscence may occur depending on the surgical site. Extra caution is advised in elderly, malnourished, debilitated, or patients with delayed wound healing. Absorbable sutures may require additional support with non-absorbable sutures in areas subject to expansion, stretching, or distension. Do not re-sterilize or reuse. Reuse may compromise suture integrity and increase the risk of infection or transmission of blood-borne pathogens. Discard opened packages and unused sutures. Prolonged contact with salt-containing solutions (e.g., urine or bile) may result in calculus formation. Absorbable sutures may act transiently as a foreign body; follow accepted surgical practice for contaminated or infected wounds.

#### PRECAUTIONS:

Skin sutures left in place longer than one week may cause localized irritation; remove or snip as appropriate. Delayed absorption may occur in tissues with poor blood supply. Avoid crushing, crimping, or excessive handling of sutures with instruments. Ensure knot security using flat, square ties with additional throws as needed. Handle needles carefully: grasp 1/3 to 1/2 distance from the swaged end; do not reshape needles, as this may weaken them. Exercise caution to avoid needle sticks; discard used needles in approved “sharps” containers. Sutures are sterilized with gamma irradiation; do not use if the package is opened or damaged. Discard unused sutures from opened packages.

#### ADVERSE REACTIONS:

Adverse effects associated with the use of this device include wound dehiscence or inadequate wound support, particularly in areas subject to expansion, stretching, or distension, or in elderly, malnourished, debilitated, or patients with delayed wound healing. Localized irritation may occur if skin closures remain in place for longer than one week. Broken needles may lead to additional surgical procedures or residual foreign bodies.

#### STERILITY:

PLAIN and CHROMIC CATGUT sutures are sterilized by Gamma Irradiation. 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 PLAIN and CHROMIC CATGUT is five years. Do not use after expiry date.

#### SUPPLY:

CATGUT 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.

#### 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 Gamma Irradiation
	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:

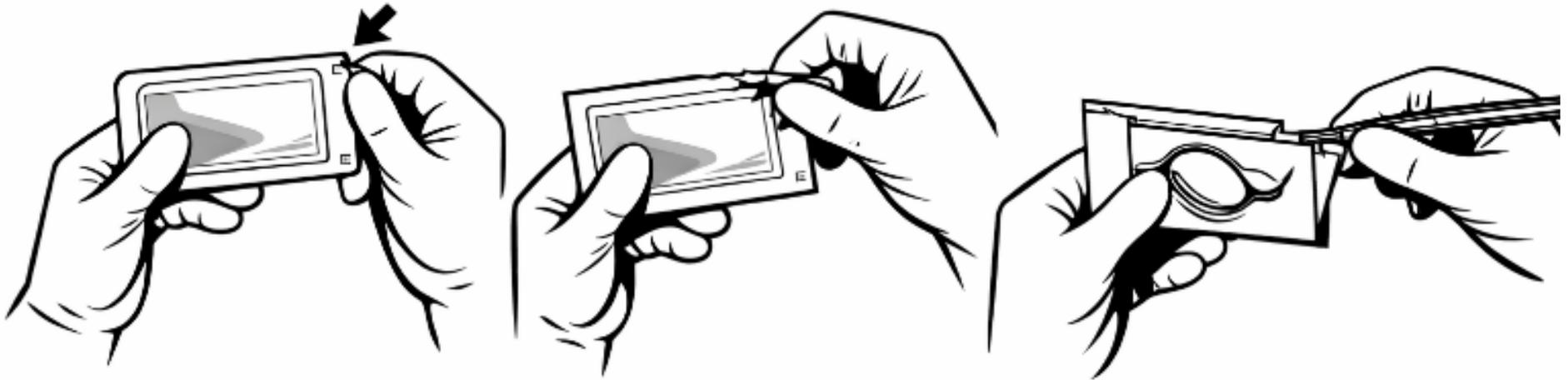


 Synthecon

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**

