

INSTRUCTIONS FOR USE

SYNTHABS PGA, SYNCRYL PGLA & SYNCRYL RAPIDE

ABSORBABLE PGA AND PGLA SUTURES

DESCRIPTION:

SYNTHABS PGA is a sterile, synthetic, absorbable, braided surgical suture composed of polyglycolic acid (PGA), a homopolymer of glycolide. SYNCRYL PGLA and SYNCRYL RAPIDE are sterile, synthetic, absorbable, braided Polyglactin 910 surgical sutures composed of a copolymer of 90% glycolide and 10% L-lactide. The sutures are coated with a mixture of polyglactin 370 and calcium stearate to enhance handling characteristics and facilitate smooth passage through tissue. PGA and PGLA sutures are available dyed (violet) and undyed. SYNTHABS PGA, SYNCRYL PGLA and SYNCRYL RAPIDE fulfill all the requirements of the European Pharmacopoeia and of the United States Pharmacopoeia.

INDICATIONS:

SYNTHABS PGA, SYNCRYL PGLA and SYNCRYL RAPIDE absorbable sutures are indicated for general soft tissue approximation and/or ligation, including ophthalmic procedures, where temporary wound support is required. These sutures are not intended for use in cardiovascular or neurological tissues, where prolonged tensile strength may be necessary.

ACTIONS:

SYNTHABS PGA, SYNCRYL PGLA and SYNCRYL RAPIDE 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 hydrolysis, breaking down into biocompatible byproducts that are metabolized by the body. Sutures may not require mechanical removal.

TENSILE STRENGTH RETENTION:

- SYNTHABS PGA retains approximately 90% of its tensile strength at 7 days post-implantation and 75% at 14 days, and 45% at 21 days, with complete absorption within 60–90 days.
- SYNCRYL PGLA retains approximately 90% of its tensile strength at 7 days post-implantation, 75% at 14 days, and 45% at 21 days, with absorption generally complete within 54–70 days.
- SYNCRYL RAPIDE retains approximately 50% of its tensile strength at 7 days post-implantation and 20% at 14 days, and 5% at 21 days, with complete absorption within 40–60 days.

CONTRAINDICATIONS:

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

WARNINGS:

Before employing SYNTHABS PGA, SYNCRYL PGLA and SYNCRYL RAPIDE 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 ethylene oxide; 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:

SYNTHABS PGA, SYNCRYL PGLA and SYNCRYL RAPIDE 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 SYNTHABS PGA, SYNCRYL PGLA and SYNCRYL RAPIDE is five years. Do not use after expiry date.

SUPPLY:

SYNTHABS PGA, SYNCRYL PGLA and SYNCRYL RAPIDE 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 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:

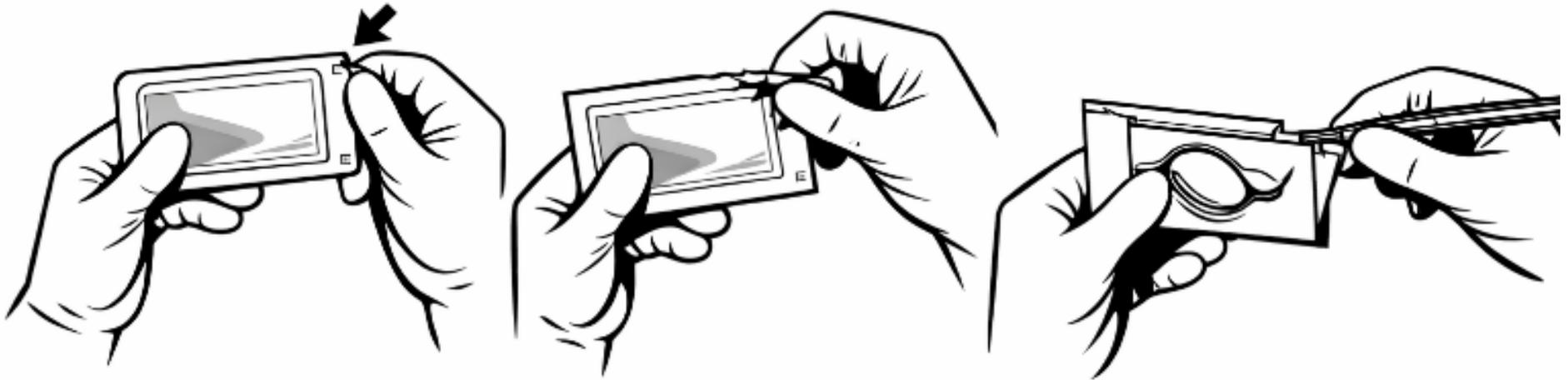


 Synthecon

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TECHNIQUE FOR OPENING THE TEAR OPEN PACK



1. Hold Pack at Notch

2. Tear at Notch

3. Remove Suture

