



Instruction for use

EN

Absorbable Surgical Suture With / Without Needle

PGCL(MONOFAST) Suture

DEVICE NAME

Absorbable Surgical Suture With / Without Needle PGCL(MONOFAST) Suture

INTENDED PURPOSE

The device is intended for general soft tissue suturing and/or ligation, but not for *ophthalmic surgery*; cardiovascular and neurological tissues.

INDICATIONS:

The device is used for surgeries that need soft tissue suturing and/or ligation, where wound support (up to 2 weeks) is required.

CONTRAINDICATIONS:

The sutures should not be used :

- A. Where extended approximation of tissues under stress is required;
- B. In *ophthalmic*; cardiovascular and neurological tissues;
- C. When there is an allergy to the suture material.

PATIENT POPULATIONS:

The target patient is the patient who needs general soft tissue suturing and/or ligation but not for use in *ophthalmic surgery*, cardiovascular, and neurological procedures.

Patient age includes Children, Adolescents and Adults.

INTENDED USERS:

The product should be used only by medical professional trained in surgical suture procedures.

USER GROUP REQUIREMENTS:

The term "user group" describes the personnel responsible who have been assigned by the operating organization to perform a particular task on a product. Duties of the operating organization The operating organization must ensure the following:

- A. Every user group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience).
- B. Every user group has been trained to perform the task.
- C. Every user group has read and understood the relevant chapters in this document.

PRODUCT DESCRIPTION



PGCL(MONOFAST) suture is a sterile synthetic absorbable monofilament suture prepared from a copolymer of glycolide and ϵ -caprolactone. The empirical molecular formula of the polymer is $(C_2H_2O_2)_m(C_6H_{10}O_2)_n$

PGCL(MONOFAST) has been found to be non-antigenic, non-pyrogenic and elicits only a slight tissue reaction during absorption.

PGCL(MONOFAST) sutures are dyed by adding D&C violet No.2 (Colour Index Number 60725) during polymerisation. Sutures are also available in the undyed form.

PGCL(MONOFAST) sutures with needle are attached to a needle made of X30Cr13 stainless steel with good corrosion resistance and biocompatibility.

PGCL(MONOFAST) suture is sterilized by Ethylene oxide. The product complies with the requirements of the European Pharmacopoeia for sterile absorbable sutures.

MECHANISM OF ACTION

PGCL(MONOFAST) suture elicits a minimal initial inflammatory reaction in tissues and is eventually replaced with an in-growth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of PGCL(MONOFAST) sutures occurs by means of hydrolysis, where the polymer degrades to adipic acid which is subsequently absorbed and metabolised in the body.

PGCL (MONOFAST) has a high initial tensile strength. 60%-70% of the original tensile strength is retained up to 7 days after surgery. After two weeks, the tensile strength of PGCL (MONOFAST) is 30- 40%, it can be completely absorbed within 84-110 days. And the absorption of different tissues are slightly different.

CLINICAL BENEFIT

A. The evaluation device can be used for general soft tissue suturing to promote wound healing.

B. The evaluation device can be absorbed by the human body, reducing complications such as pain caused by secondary suture removal.

MODELS & SPECIFICATIONS

PGCL(MONOFAST) sutures are available in sizes 0.7~5 (USP 6-0 ~ 2#), attached to a needle or without needle

Thread Size	Thread Length(cm)	Needle Type	Needle Length	Arc Size	Colour
0.7; 1; 1.5; 2; 3; 3.5; 4; 5 (USP 6-0~2#)	20;30;45;60;70 ;75;90;100;120 ;150;200;250; 300;350	Round needle or “○” Triangle needle or “△” Taper cut or “▽”	6; 8; 10; 11; 12; 13; 15; 16; 17; 18; 19; 20; 22; 24; 25; 26、 28; 30; 31; 35; 36; 37; 38; 39; 40; 44; 45; 48; 50; 53; 55; 60; 65; 70; 75; 80; 85; 90; 95; 100	1/2 circle 3/8 circle 1/4 circle 5/8 circle Straight needle	D & C violet No. 2 Undyed

NEEDLE TYPE



Needle Type	Arc Sizes
Round needle or “○”	1/2 circle 3/8 circle 1/4 circle 5/8 circle Straight needle
Triangle needle or “△” “▽”	1/2 circle 3/8 circle 1/4 circle 5/8 circle Straight needle

SUTURE MODEL

EP size	USP size	Diameter (mm)
0.7	6-0	0.095–0.149
1	5-0	0.15–0.199
1.5	4-0	0.20–0.249
2	3-0	0.30–0.349
3	2-0	0.35–0.399
3.5	0	0.40–0.499
4	1	0.500-0.599
5	2	0.571-0.610

THE MATCHING PRINCIPLE OF SUTURE NEEDLE AND NEEDLE HOLDERS

1. Round needle (○) : Use a needle holder without teeth or with fine serrated teeth (such as Castroviejo) to avoid damaging the needle body.
2. Triangular needle (△/▽) : A strong locking force needle holder (such as Webster) is required to prevent the cutting needle from sliding.
3. Short arc (1/4 circle, 3/8 circle) : It is advisable to use a short jaw needle holder (Mathieu).
4. Long arc (5/8 circle) : A bent or long-handled needle holder (such as Graefe) is required.
5. For Thick thread ($\geq 2-0$) : The standard needle holder (Mayo-Hegar) provides sufficient clamping area.
6. For sutures without needle, the appropriate needle model should be selected in accordance with the Annex Product catalogue.

WARNING ON INCOMPATIBLE COMBINATIONS

For Castroviejo needle holder, it should not be recommended for triangular needles



(Δ/∇), since the jaws are prone to wear.

For Webster locking pin holder, it is necessary to avoid clamping absorbable monofilament thread, as the locking pressure may cause indentation and breakage of the thread body.

CONTACT DURATION

Long-term: The use of the suture may take more than 30 days.

TECHNICAL SPECIFICATION

Structure	Monofilament
Suture Type	Absorbable
Composition	glycolide and ϵ -caprolactone
Coating	uncoated
Color of material	violet or undyed
Sizes	0.7~5 (USP 6-0 ~ 2#)
Needles	X30Cr13 stainless steel
Tensile strength	Comply with EP11
Needle and thread connection strength	Comply with EP11
Needle hardness	$\geq 490\text{HV}0.2$
Surface roughness of	$\leq 0.8\mu\text{m}$
Sterilization level	SAL= 10^{-6}
Sterilization method	Ethylene Oxide
Packaging information	The product is in the form of 1 piece /package, sterile product packaging material is Aluminium foil bag(medical seal bag). The secondary packaging is in the form of 1 sterile packaging, and the secondary packaging material is dialysis paper bag(medical paper bag) The outer packaging is in the form of 12 piece/package, 50 boxes/carton.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include:

transient local irritation at the wound site, such as erythema and induration, Suture reaction etc.
suture extrusion; wound dehiscence; wound infection ;Scar formation; Suture site abscess; leave foreign bodies or require additional surgery; Non-sharp needle or needle thread separation and needle thread breakage may prolong the operation time;Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

WARNING

A.Do not re-sterilize! Repeated sterilization can reduce the tensile strength of the suture material



and lead to brittleness of the sterile packaging material, so that the sterility of the product can no longer be guaranteed.

B.For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, may result in patient injury or illness.

C.Do not reuse or cross-use! This may result in device failure and increase the risk of post-operative infection.

D.Do not use if packaging is damaged! The product may be contaminated and its sterility cannot be guaranteed, which may lead to patient infection.

E.Do not use expired products! This may affect the performance of the product and increase the risk of post-operative infection.

F.Do not use rusty needles! The use of rusty needles may lead to fever and infection.

G.Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

H.If people are known to be allergic to suture materials, do not use them.

I. Oral surgeons and periodontists should be cautious when prescribing commercial mouthwashes for patients relative to their selection of suture materials. When patients use chlorhexidine and listerine, it accelerates the degradation of PGCL sutures, thereby affecting the tensile strength of PGCL sutures

J.Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

CAUTION

© Users should be professionally trained and familiar with the surgical procedures and techniques associated with absorbable surgical sutures. Surgeons should consider the in vivo performance (under MECHANISM OF ACTION section) when selection a suture.

© As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, PGCL(MONOFAST) may act transiently as a foreign body.

© Be careful to avoid damage to the sutures during the procedure. Avoid holding or bending sutures with surgical instruments (e.g., forceps and needle holders).

© To avoid damage to the needle tip and the needle thread connection, the needle must be held between one-third and one-half of the way from the end of the needle to the needle tip.

© The product should be disposed of properly after use to avoid accidental needle stick injury or environmental pollution.

© Dispose in approved puncture-resistant sharps container according to facility protocol and all applicable state, regional, and/or local laws and regulations.

© Keep in mind that suture needles are sharp instruments. Take proper precautions in handling suture needles so as not to injure yourself or others before,during,or after use. Seek proper training and instruction on use before handing.

© Avoid excessive use! If the needle becomes dull or breaks, dispose and replace the product.

Residual Risk



- A. Packaging issues
- B. Sterilization issues
- C. Components fall off
- D. Component breakage

Magnetic Resonance Imaging (MRI) /Carcinogenic, Mutagenic, Toxic to Reproduction (CMR)/ Endocrine Disrupting (ED) Safety Information

PGCL Sutures are MR safe. No known CMR Category 1a/1b and ED substances are present at >0.1%. Category 1a/1b are defined as known or presumed human carcinogen (H340), mutagen (H350), or reproductive toxicant (H360), based on human evidence and animal studies.

STORAGE

The product should be stored in a clean, well-ventilated place protected from direct sunlight, moisture and corrosive gases at a temperature between -20°C and 55°C and a relative humidity not higher than 80%. Avoid damage and moisture during transportation.

PERIOD OF VALIDITY

The shelf life of this product is three years under specified storage conditions.

SYMBOLS USED ON THE PACKAGING

	Do not re-use		Keep away from rain
	Do not re-sterilize		Manufacturer
	Batch code		Medical device
	Date of manufacture		Operating instructions
	Do not use if package is damaged		Sterilized using ethylene oxide
	Fragile; handle with care		Use by date
	Humidity limitation		Country of manufacture
	Temperature limit		Importer
	Keep away from sunlight		
	Single sterile barrier system with protective packaging outside		
	Authorized representative in the European Community		
	CE mark and Identification Number of Notified Body		

EFFECTIVE DATE

This version of the Instruction for Use takes effect on October 14, 2025 approved by notified body. Version: A/4

List of language Requirement for labels and IFU

The language list corresponding to the PGCL Suture labelling for the sales area is as



follows: English; Polish; German; Portuguese; Spanish; Italian; Russian ; Dutch.

Summary of Safety and Clinical Performance(SSCP) link:

<https://ec.europa.eu/tools/eudamed/eudamed>.

Electronic manual link:

<https://www.hy-medical.com/enhonor/153.html>

Password: 123456HY



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