CE 2460

Instruction for use EN

Absorbable Surgical Suture With / Without Needle

RAPID PGA Suture

DEVICE NAME
Absorbable Surgical Suture With / Without Needle RAPID PGA Suture

INTENDED PURPOSE

The device is intended for general soft tissue suturing and/or ligation, but not intended for use in ophthalmic surgery, cardiovascular and neurological procedures.

INDICATIONS:

The device is used for surgeries that need soft tissue suturing and/or ligation, where only short-term wound support is required and where rapid absorption would be beneficial.

CONTRAINDICATIONS:
The device should not be used :

A. Where extended approximation of tissues under stress is required;
B. In ophthalmic surgery, 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 is not intended 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 procdures.

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

RAPID PGA suture is a braided synthetic absorbable suture composed of a copolymer made from Rapid Polyglycolic Acid. The empirical formula of the copolymer is $(C_2H_2O_2)_n$.

Braided RAPID PGA sutures are coated with a mixture composed of polycaprolactone and calcium stearate, which have been found to be non-antigenic, non-pyrogenic and elicits only a slight tissue reaction during absorption.

The suture is divided into dyed (Violet) and undyed. RAPID PGA sutures with needle are attached to a needle made of X30Cr13 stainless steel with good corrosion resistance and biocompatibility.

RAPID PGA suture is sterilized by Ethylene oxide.The product complies with the requirements of the European Pharmacopoeia for sterile absorbable sutures.

MECHANISM OF ACTION

RAPID PGA suture elicits a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption occurs by means of hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized by the body.

RAPID PGA has a high initial tensile strength. 50% of the original tensile strength is retained up to 7 days after surgery. The tensile strength is about 1%-6% after 14 days, it can be completely absorbed around 42 days postimplantation 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

RAPID PGA sutures are available in sizes EP 0.4~ EP 5（USP 8-0~2#), attached to a needle or without needle

Thread Size	Thread Length(cm)	Needle Type	Needle Length	Arc Size
0.4;0.5;0.7; 1;1.5;2;3;3.5;4;5 （USP 8-0~2#）	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;	1/2 circle 3/8 circle 1/4 circle 5/8 circle Straight needle

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)
0.4	8-0	0.040–0.049
0.5	7-0	0.050–0.069
0.7	6-0	0.070–0.099
1	5-0	0.10–0.149
1.5	4-0	0.15–0.199
2	3-0	0.20–0.249
3	2-0	0.30–0.349
3.5	0	0.35–0.399
4	1	0.40–0.499
5	2	0.500-0.599

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 braided suture, please choose to use a wide-jaw needle holder (Castroviejo) to distribute the pressure to avoid cutting the fibers.

6. For Thick thread (≥2-0) : The standard needle holder (Mayo-Hegar) provides sufficient clamping area.
   For Fine thread (≤6-0) : The ultra-fine needle holder at the tip (Graefe) prevents

slippage or deformation.

7. For sutures without needle, the appropriate needle model should be selected in accordance with the Annex Product catalogue.

WARNING ON INCOMPATIABLE COMBINATIONS

For Castroviejo needle holder, it should not be recommended for triangular needles (△/▽) , 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	Multifilament
Suture Type	Absorbable
Composition	Polyglyco acid
Coating	a mixture composed of equal parts of copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate
Color of material	undyed
Sizes	EP 0.4~ EP 5（USP 8-0~2#).
Needles	X30Cr13 stainless steel
Tensile strength	Comply with EP11
Needle and thread connection strength	Comply with EP11
Needle hardness	≥490HV0.2
Surface roughness of	≤0.8um
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, transient inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures. 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.
J. The RAPID PGA suture came into contact with electrosurgical/thermal instruments, and overheating caused the suture to become brittle and break.
K. Please store or transport the product according to the instructions and use it before the expiration date, otherwise the sterility of the product cannot be guaranteed and the patient may be infected.
I.The combination of RAPID PGA sutures with hydrolase-containing drugs may accelerate degradation (such as topical use of α -chymotrypsin).
L.Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

CAUTION

A. 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.
B. 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 RAPID PGA may
act transiently as a foreign body.
C. 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).
D. 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.
E. The product should be disposed of properly after use to avoid accidental needle stick injury or environmental pollution.
F. Dispose in approved puncture-resistant sharps container according to facility protocol and all

applicable state, regional, and/or local laws and regulations.
G. 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.
H. 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

RPGA 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
 Do not resterilize
 Batch code
 Date of manufacture
 Do not use if package is damaged
 Fragile; handle with care
 Humidity limitation
 Temperature limit
 Keep away from sunlight
 Single sterile barrier system with protective packaging outside
 Authorized representative in the European Community
CE 2460 CE mark and Identification Number of Notified Body

 Keep away from rain
 Manufacturer
 Medical device
 Operating instructions
 Sterilized using ethylene oxide
 Use by date
 Country of manufacture
 Importer

EFFECTIVE DATE

This version of the Instruction for Use takes effect on July 27,2025 approved by notified body.
Version: A/4

List of language Requirement for labels and IFU

The language list corresponding to the RPGA 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/154.ht
ml
Password: 123456HY

Huaiyin Medical Instruments Co.,Ltd.
Address 1：No.8 West Ming Yuan Road, 223003，Huaian,China
Address 2：No.2 Factory Building, No.106, Chaoyang West Road, Qingjiangpu District, 223003,Huai'an City, Jiangsu Province, China.
Tel：+86-517-83806499 Fax：+86-517-83806511 ZIP：223003
Email: hy-medical@hy-medical.com
Website：http://www.hy-medical.com/?LanguageAlias1=en

EC REP Wellkang Ltd, Enterprise Hub,
NW Business Complex, 1 Beraghmore Rd,
Derry, BT48 8SE, Northern Ireland
Tel 1: +44(20)32876300 Tel 2: +44(33)33031126 Fax: +44(20)7681187