



PGA Suture

Title

Instructions for Use (IFU)

Code

PGA-09-PAN-TF-01

Issue / Revision No.

01/02

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Revision Date

20.05.2025

P.G. CRYL is: Synthetic, Sterile, Absorbable, Braided, Colored, Coated, With or Without Needles, Single Use.

DESCRIPTION

P.G. CRYL suture is synthetic absorbable sterile surgical suture. It is composed of homo polymer prepared and synthesized from 99% Polyglycolic Acid. These sutures are braided, violet dyed (1-hydroxy-4-[(4-methyl-phenyl) amino]-9,10-anthracenedione) coated with polycaprolactone and calcium stearate.

P.G. CRYL suture is non-antigenic, non-pyrogenic and elicits only a mild tissue reaction during the absorption process, and is completely absorbed in 60-90 days. The In vitro retention of strength is in two weeks %73- 62

The use of supplemental non absorbable sutures should be considered by the surgeon in the closure of the “ sites

.which may undergo expansion, stretching or distention, or which may require additional support

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

P.G. CRYL suture complies with the requirements of the United States pharmacopoeia U.S.P. and European pharmacopoeia Ph. Eur. and European Medical Device Directive 93/42/EEC

Suture diameter in mm	U.S.P Size	E.P SIZE (Metric)
0.500 – 0.599	2	5
0.400 – 0.499	1	4
0.350 – 0.399	0	3.5
0.300 – 0.339	2-0	3
0.200 – 0.249	3-0	2
0.150 – 0.199	4-0	1.5
0.100 – 0.149	5-0	1
0.070 – 0.099	6-0	0.7

INDICATIONS:

P.G. CRYL suture is indicated for use in general soft tissue approximation and ligation, including the use in .ophthalmic procedures. P.G. CRYL is not for use in cardiovascular or neurological tissues

CONTRAINDICATIONS:

P.G. CRYL suture, being absorbable, should not be used where extended approximation of tissue is required

Application & Selection Criteria

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique, and wound size

Instruction For Use:

1. Hold the pack in an upright manner.



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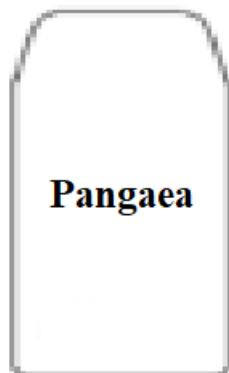
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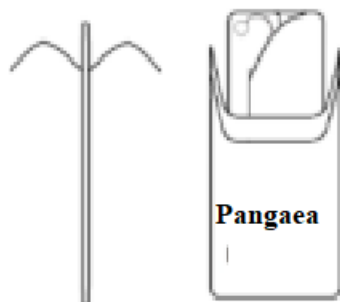
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2. Hold the protruded portions of the aluminium foils and peel open to see the needle fixed on the paper slat.



3. With the help of sterilized forceps pull the needle to remove the suture from the slat.



WARNINGS:

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing P.G. CRYL suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used

Users should consider the in vivo performance when selecting a suture. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which ..may delay wound healing



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As an absorbable suture, P.G. CRYL suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds

.Discard opened packages and unused sutures. Do not re-use

Do not re-sterilize.

Don't use after expiry date.

PRECAUTIONS:

-In handling this or any other 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

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

- In handling this suture material, care should be taken to avoid damaging the surface of the material with surgical instruments as this could lead to fracture of the material in use.

- Avoid crushing or crimping damage due to surgical instruments such as forceps or needle holders.

- Grasping at the butt or attachment end could cause bending or breakage.

- Reshaping the needles may cause them to loosen strength and make less resistant to bending and breaking.

- Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury.

P.G. CRYL sutures, which are treated to enhance handling characteristics, require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be .snipped off or removed as indicated

Under some circumstances, notably orthopedic procedures, immobilization of joints by external support may .be employed at the discretion of the surgeon

Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture .extrusion and delayed absorption may occur

To avoid damaging needle points and swage areas, 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 opened packages and unused sutures.

-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, in turn, may result in patient injury or illness.

-Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

ADVERSE REACTIONS

Adverse reactions associated with the use of P.G. CRYL include transitory local irritation at the wound site or transitory inflammatory foreign body response. Like all foreign bodies P.G. CRYL may potentate an existing infection

Discard

Discard used sutures and needles contaminated with blood in the container meant infectious waste.



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INTENDED PATIENT POPULATION:

Intended patient population: All Ages & Genders is not indicated for cardiovascular and neurological procedures)

TARGET USER:

Surgeon, Nurses.

STERILITY:

P.G. CRYL sutures are sterilized by ethylene oxide. Sterility is preserved only when opened under sterile conditions

.Do not re – sterilize





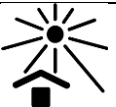
.Do not use if package is opened or damaged. Discard opened unused sutures

Storage

.Stores in ambient temperature is not exceeding 30°C

Store in dry, cool place with well ventilation All boxes put on metal racks

SYMBOLS USED ON THE PRODUCT:

Symbol	Meaning
	Date of manufacture
	Date of expiry
	lot Number
	Avoid Moisture
	Avoid direct sunlight



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Do not use if pack is opened or damaged



Do Not Reuse



Ethylene Oxide Sterilized Product



Do not re-sterilize



Temperature limitation



Consult instructions for use



Manufacturer

Manufacturer: Pangaea For Medical industries

Public Free Zone Ismailia - Egypt