



## PP Suture

Title

Instructions for Use (IFU)

Code

PAN-TF-02-09-PP

Issue / Revision No.

01/02

Revision Date

17.05.2025

Page 1 of 5

Synthetic, Sterile, Non-Absorbable, Monofilament, Colored(Blue), Non-Coated, With or Without Needles, Single Use

### DESCRIPTION:

P.G. PROLENE suture is synthetic non-absorbable sterile surgical suture, composed of isotactic crystalline stereoisomer of Polypropylene, a synthetic linear polyolefin. It is Monofilament dyed([phtalocyaninato(2-)] copper FDA approved

P.G. PROLENE suture has high in vivo tensile strength and has the further advantages of being remarkably smooth & easy to handle resulting in minimal tissue trauma.

P.G. PROLENE sutures are available in range of gauge sizes and lengths, attached to stainless steel needles of varying types, sizes and shapes. The needles are attached permanently to the suture. Entire detail of the product range is contained in the catalogue. The suture complies with United States Pharmacopoeia (U.S.P) and European Pharmacopoeia (E.P).

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. PROLENE suture** is indicated for use in general soft tissue approximation and ligation, including use in, plastic procedures. **P.G. PROLENE suture** is not indicated for ophthalmic, cardio vascular and neurological procedures.

### CONTRAINDICATIONS:

un known

### Application & Selection Criteria

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

### Instruction For Use:

1. Hold the pack in an upright manner.

PAN-TF-02-09-PP



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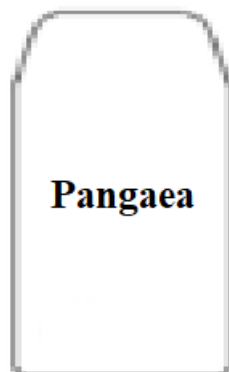
Issue / Revision No.

01/02

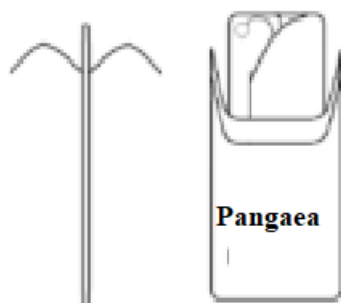
Revision Date

17.05.2025

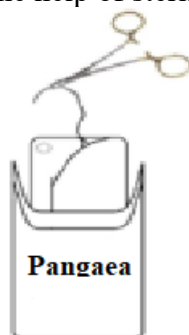
Page 2 of 5



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.



### Performance :

P.G. PROLENE suture elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. P.G. PROLENE suture is not absorbed nor is it subjected to degradation or weakening by the action of tissue enzymes. Due to its relative biological inertness it is recommended for use where the least possible suture reaction is desired. As a mono – filament it has been

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Issue / Revision No.

01/02

Revision Date

17.05.2025

Page 3 of 5

successfully employed in surgical wound which subsequently become infected or contaminated where it can minimize later sinus formation and suture extrusion. Its lack of adherence to tissue P.G. PROLENE is effective as a pull-out suture.

### WARNINGS:

- Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing P.G. PROLENE suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.
- 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. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- 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

### 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. PROLENE 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. The use of addition throws may be appropriate when knotting Mono filament Polypropylene sutures.

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.

### ADVERSE REACTIONS

PAN-TF-02-09-PP

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

### **Discard**

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

### **INTEDED PATIENT POPULATION:**

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

### **TARGET USER:**

.Surgeon, Nurses.

### **STERILITY:**

P.G. PROLENE 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

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