

INSTRUCTION FOR USE-ABSORBABLE POLYGLACTIN-910 SURGICAL SUTURE

PETCRYL[®] 910

STERILE ABSORBABLE POLYGLACTIN 910 SURGICAL SUTURE U.S.P

DESCRIPTION

PETCRYL[®] 910 suture is a braided coated synthetic sterile Polyglactin 910 surgical suture. It is composed of a copolymer made from 90% Glycolide and 10% L - Lactide.

PETCRYL[®] 910 sutures are coated with a mixture containing equal parts of copolymer of glycolide and Lactide (Polyglactin 370) and Calcium Stearate.

Polyglactin 910 co-polymer and Polyglactin 370 with Calcium Stearate exhibit non-antigenic, non-pyrogenic and elicit only a slight tissue reaction during absorption.

PETCRYL[®] 910 sutures are dyed by adding D & C Violet No. 2 (Colour Index No. 60725) during polymerization.

PETCRYL[®] 910 sutures are also available in undyed form.

PETCRYL[®] 910 sutures are available in range of gauge sizes and lengths, non needled or attached to stainless steel needles of varying types, sizes and shapes. The needles are attached permanently to the suture. Entire details of the product range are available in the catalogue.

PETCRYL[®] 910 complies with the "Absorbable Surgical Suture" requirements as per the United States Pharmacopoeia (U.S.P).

INDICATIONS

Petcryl[®] 910 suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, peripheral nerve anastomosis and microsurgery for vessels less than 2 mm diameter. The safety and effectiveness of PETCRYL[®] 910 sutures in cardiovascular tissue have not been established.

SELECTION CRITERIA

PETCRYL[®] 910 sutures should be selected and implanted depending on the patient's condition, surgical experience, surgical technique and wound size.

PERFORMANCE

PETCRYL[®] 910 suture leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. PETCRYL[®] 910 gradually loses tensile strength and is finally absorbed by hydrolytic process. During hydrolysis, the co-polymer degrades to glycolic and lactic acids which are then absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass. Absorption pattern for suture when tested on rats:-

Approx 94.1 % of the tensile strength at 7 days,

Approx 74.9 % of tensile strength at 14 days,

Approx 49.1 % tensile strength after 21 days and

Approx 26.7 % tensile strength after 28 days.

ADVERSE REACTIONS

Adverse reaction, associated with the use of the device include transitory local irritation at the wound site, transitory inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures. Like all foreign bodies, PETCRYL[®] 910 suture may enhance an existing infection.

CONTRAINDICATIONS

Petcryl[®] 910 suture, being absorbable, should not be used where extended approximation of tissues under stress is required. The use of this suture is contraindicated in patients with known sensitivities or allergies to Polyglactin, polyglycolide co lactide, calcium stearate.

WARNINGS

- a. Surgeons should be familiar with surgical procedures and techniques involving absorbable sutures before employing PETCRYL[®] 910 suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.
- b. In surgery of the urinary or biliary tract, care should be taken to avoid prolonged contact of this or any other suture with salt solution, to prevent calculus formation.

- c. This suture may be inappropriate in patients suffering from conditions which may delay wound healing e.g., patient that are elder, malnourished or depilated. As this is an absorbable suture, the use of supplemental non-absorbable suture should be considered by the surgeon in the close of the abdomen, chest, joints or other sites subjects to expansion or requiring additional support.
- d. 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.
- e. 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.
- f. Contamination of the device may lead to injury, or illness.

PRECAUTIONS

- a. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- b. Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.
- c. Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.
- d. Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.
- e. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration, normally associated with the absorption process.
- f. When handling this or any other suture, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of

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surgical instruments such as forceps or needle holders.

- g. Care should be taken to avoid damage while handling surgical needles. Grasp the needle in an area, one third (1/3) to one half (1/2) of the distance from the attachment end to the point.
- h. Grasping in the point area could impair the penetration performance and cause fracture of the needle.
- i. Grasping at the butt or attachment end could cause bending or breakage.
- j. Reshaping the needles may cause them to loose strength and make less resistant to bending and breaking.
- k. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard the needles after use.

STERILITY

PETCRYL® 910 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 10°C-35°C, away from moisture and direct heat. Do not use after expiry date.

DISPOSAL

Discard used sutures and needles contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

INSTRUCTIONS FOR USE

A. TECHNIQUE FOR OPENING THE TEAR OPEN PACK

1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



2. Holding the pack with the left hand, tear the foil with the right hand thumb and fore finger at the notch position. Pull out the folder containing the needed suture with sterilized forceps.



3. Tear the folder till the needle is visible. Then with the help of sterilized forceps, withdraw the needed suture. For non-needed suture, pull out the entire folder from the pack, with the sterilized forceps, open the folder and retrieve the suture.

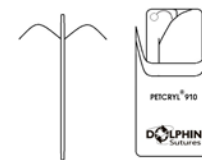


B. TECHNIQUE FOR OPENING THE PEEL OPEN PACK

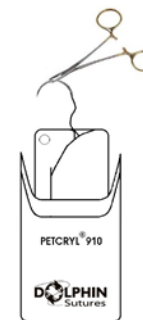
1. Hold the pack in an upright manner and see the peel logo.



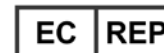
2. Hold the protruded portions of the aluminum foils and peel open till the needle fixed on the paper folder is visible.



3. With the help of sterilized forceps pull out the needed suture from the folder by grasping the needle, at one third and one half distance away from the swaged end.



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







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SYMBOLS USED ON THE LABELS

	Do not reuse	LOT	Batch number
	Date of manufacture		CE Mark with Notified Body

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	Date of expiry		Registered
	Sterilized by ethylene oxide		EU REPRESENTATIVE
	Temperature limitation		Do not resterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture