

Instructions for use

PETCRYL[®] 910
ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC)

COATED AND BRAIDED POLYGLACTIN 910

DESCRIPTION:

PETCRYL[®] 910 suture is a synthetic absorbable sterile surgical suture composed of a copolymer made from 90% Glycolide and 10% L - Lactide. The empirical formula of the copolymer is $(C_2H_2O_2)_m(C_3H_4O_2)_n$. Braided **PETCRYL[®] 910** sutures are coated with a mixture composed of equal parts of co polymer of Glycolide and Lactide (Polyglactin 370) and Calcium Stearate. Polyglactin 910 co-polymer and Polyglactin 370 co-polymer with Calcium Stearate have been found to be non antigenic, non pyrogenic and elicit only a slight tissue reaction during absorption.

PETCRYL[®] 910 sutures are dyed by adding D & C violet # 2 (Colour index number 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 requirements of the United States Pharmacopoeia for "Absorbable Surgical Suture" and the European Pharmacopoeia for "Sterile Synthetic Absorbable Braided Sutures"

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.

APPLICATION

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

PERFORMANCE

Petcryl[®] 910 suture elicits a minimal initial inflammatory reaction in tissues and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of **Petcryl[®] 910** sutures occurs by means of hydrolysis where the co-polymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass. The suture retains approximately 75% of the tensile strength after 2 weeks, 50% of tensile strength after 21 days & 25% after 28 days of implantation and the suture is essentially absorbed completely between 56 and 70 days.

CONTRAINDICATIONS

Petcryl® 910 suture, being absorbable, should not be used where extended approximation of tissues under stress is required.

WARNINGS/PRECAUTIONS/INTERACTIONS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing **Petcryl® 910** suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Surgeons should consider the in vivo performance (under PERFORMANCE section) when selecting 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, **Petcryl® 910** suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

As this is an absorbable suture material, 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.

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 orthopaedic 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. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration, normally associated with the absorption process. The suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.

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 surgical instruments such as forceps or needle holders. 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. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping the needles may cause them to lose strength and make less resistant to bending and breaking.

Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard the needles after use in container labeled as "SHARPS".

ADVERSE REACTIONS

Adverse reaction, associated with the use of the device include allergic response in certain patients, transient local irritation at the wound site, transient inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures.

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 is to store at temperature between 10°C and 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.

TECHNIQUE FOR OPENING THE TEAR OPEN PACK:

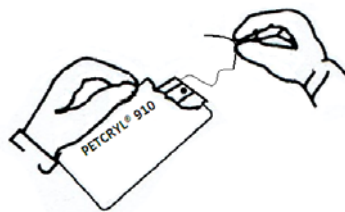
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



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.

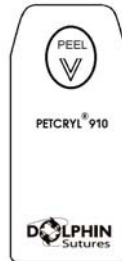


3. Tear the folder till the needle is visible. Then with the help of sterilized forceps, withdraw the needed suture. For non-needed suture, pull out the entire folder from the pack, with the sterilized forceps, open the folder and retrieve the suture.

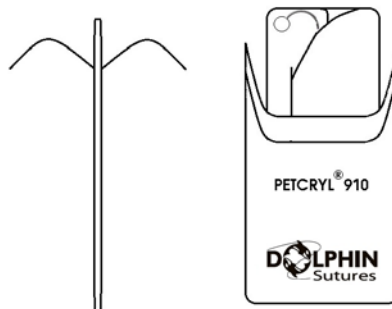


TECHNIQUE FOR OPENING THE PEEL OPEN PACK

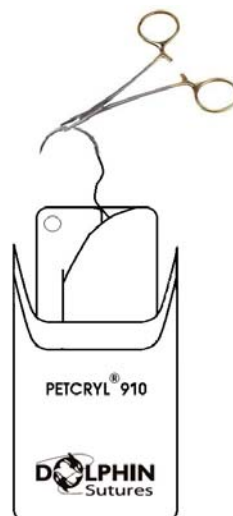
1. Hold the pack in an upright manner and see the peel logo.

















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 needled suture from the folder by grasping the needle, at one third and one half distance away from the swaged end.



SYMBOLS USED ON THE LABELS

	Do not re-use		Batch number
	Date of manufacture		CE logo
	Date of expiry		Registered
	Sterilized by Ethylene Oxide		EU REPRESENTATIVE
	Temperature limitation		Do not re-sterilize
	Do not use if package is damaged or opened		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture

MANUFACTURER:

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