

## **FUTURA SURGICARE PVT LTD**

### **INSTRUCTION FOR USE**

Brand name: **PETCRYL<sup>®</sup> 910 FAST**

Material: Coated & braided Polyglactin – 910

Synthetic absorbable surgical suture U.S.P (Undyed)

#### Description:

Petcryl<sup>®</sup> 910 Fast suture is a synthetic absorbable surgical suture composed of a co polymer of 90% lactide and 10% co lactide. The empirical formula of the co polymer is  $(C_2H_2O_2)_m(C_3H_4O_2)_n$ . The characteristic loss of tensile strength is achieved by use of a polymer material with a lower molecular weight than conventional Petcryl<sup>®</sup> 910 sutures. Petcryl<sup>®</sup> 910 Fast Sutures are available in range of gauge sizes and lengths, attached to stainless steel needles of varying types, sizes and shapes. Entire details of the product range are available in the catalogue. Petcryl<sup>®</sup> 910 Fast complies with the requirements of the United States Pharmacopoeia monograph for “Absorbable surgical suture”.

#### Indications

Petcryl<sup>®</sup> 910 Fast suture is indicated for use in general soft tissue approximation and/or ligation where only short time tissue approximation is required. During to its short time absorption profile it is useful in skin closure, pediatric surgery, episiotomies, circumcision, closure of oral mucosa, ophthalmic procedures for conjunctiva surgeries.

#### Application:

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

#### Performance:

Petcryl<sup>®</sup> 910 FAST suture elicits a minimal tissue reaction and in growth of fibrous connective tissue. Absorption of bio absorbable suture occurs by hydrolysis: beginning with loss of tensile strength with loss of mass. The suture retains approx 50% of the tensile strength after 5 days and 0% after 10 -14 days when implanted in rat and the suture is essentially absorbed within 42 days.

#### Contraindications

Petcryl<sup>®</sup> 910 Fast suture, being absorbable, should not be used where extended approximation of tissue is required

### Warnings/ Precautions/ Interaction:

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Petcryl<sup>®</sup> 910 Fast suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) 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. 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. Do not resterilize. Discard opened packages and unused sutures. 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<sup>®</sup> 910 Fast suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

### Precautions

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. 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. Petcryl<sup>®</sup> 910 Fast 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. Avoid prolonged exposure to elevated temperatures. 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 used needles in "sharps" container.

### Adverse reactions:

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood borne pathogens.

Sterility: Petcryl® 910 Fast 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 – 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 over wrap:

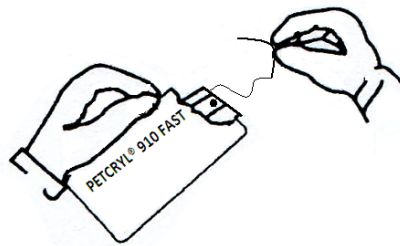
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



2. Then with the help of sterilized gloved hand or sterilized forceps pull the paper folder till the needle is visible. For non-needed suture, pull out the entire paper folder from the pack, open the folder and retrieve the suture.



3. Again with the help of sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.

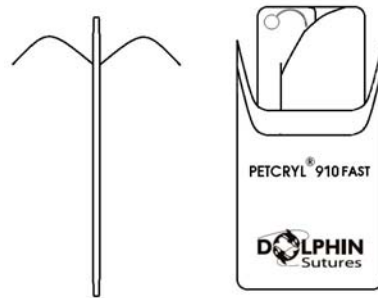


Technique for opening the peel open pouches containing **Petcryl® 910 FAST** :

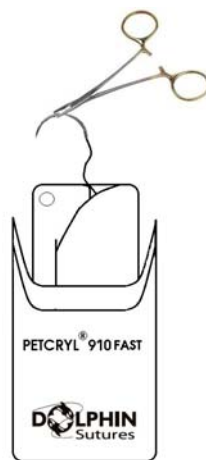
1. Hold the pack in an upright manner and see the peel logo.



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







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



Symbols used on the labels:

|  |                              |  |                     |
|--|------------------------------|--|---------------------|
|  | Do not reuse                 |  | 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 |  | Consult instructions for use |
|  | Avoid direct sunlight            |  | Avoid Moisture               |

Manufacturer: Futura Surgicare Pvt Ltd, 86/C2, 3<sup>rd</sup> Main, 2<sup>nd</sup> Stage, Yeshwanthpur Industrial Suburb, Bangalore – 560022, India. Mfg Lic No: KTK/28/273/1995

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