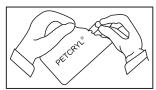
# TECHNIQUE FOR OPENING THE TEAR OPEN PACK

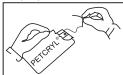
The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



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 needled suture with sterilized forceps.



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

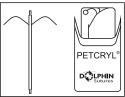


# TECHNIQUE FOR OPENING THE PEEL OPEN PACK

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

STWIBOLS USED ON THE LABELS	
2	Do not reuse
~~/	Date of manufacture
$\square$	Date of expiry
STERILE EO	Sterilized by ethylene oxide
99.0	Temperature limitation
	Do not use if package is damaged or opened
*	Avoid direct sunlight
LOT	Batch number
<b>C</b> €	CE logo
®	Registered
EC REP	EU REPRESENTATIVE
STERNIZE	Do not resterilize
(li	Consult instructions for use
<del>*</del>	Avoid Moisture
	Absorbable Suture Coated & Braided (Dyed/ Undyed)

## **FUTURA SURGICARE PVT LTD**

INSTRUCTION FOR USE

# PETCRYL<sup>®</sup>

Synthetic absorbable surgical suture U.S.P

Coated & Braided Polyglycolic acid.

(Dyed/ Undyed)



Futura Surgicare Pvt Ltd, 86/C2, 3<sup>rd</sup> Main, Yeshwanthpur Industrial Suburb,2nd Stage, Bangalore – 560022, India

Mfg Lic No: KTK/28/273/1995

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Doc no.: IFU/PGA Issue date: 1.6.2011 Rev no.: 05 Rev date: 29.09.2017

#### Description:

Petcryl<sup>®</sup> suture is a synthetic absorbable sterile surgical suture composed of homo polymer of glycolide (100%). Petcryl® is dyed violet with CI solvent violet 13 (=CI #60725) and coated with unique combination of polycaprolactone and calcium stearate. PETCRYL® 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® complies with the requirements of the United States Pharmacopoeia monograph for "Absorbable surgical suture"

Entire detail of the product range is contained in the catalogue. Petcryl® complies with the requirements of the United States Pharmacopoeia for synthetic absorbable surgical suture.

#### Indication:

Petcryl® sutures are indicated for use in general, soft tissue including use in ophthalmic. But not for use in cardio vascular & neurological tissues. If there is any localized inflammation, itching or any sort of allergy of a particular patient then the usage of this product should be stopped and medical advice should be taken immediately.

# Applications:

Suture should be selected and implanted depending on the patient's condition, surgical experience, surgical technique and wound size.

#### Mode of action:

Petcryl® 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 75% of the tensile strength after 2 weeks, 50% of tensile strength after 21 days & 25% after 28 days when implanted in rat and the suture is essentially absorbed within 60 – 70 days.

#### Performance:

Petcryl® elicits a minimal initial inflammatory reaction in tissues. Progressive loss of tensile strength occurs as the suture gets absorbed by means of hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized in the body. Absorption begins with loss of tensile strength followed by loss of mass. All of the original tensile strength is lost between four and five weeks post implantation. Absorption of Petcryl® suture is essentially completed between 60 – 90 days.

# Contra - indications:

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

# Warnings/ Precautions/ Interaction:

Donot resterilize. Discard open 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 it may act transiently as a foreign body.

User should be familiar with surgical procedure and techniques involving synthetic absorbable sutures before employing Petcryl® for wound closure as a risk of wound dehiscence may vary with the site of application and the suture material used.

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

The use of this suture may be inappropriate in patients suffering from conditions which may delay wound healing.

As this is an absorbable suture material, the surgeon in the closure of sites undergoing expansion, stretching or distension, which may require additional support, should consider the use of supplemental non – absorbable sutures.

Under some circumstances, notably orthopedic procedure, immobilization by external support may be employed at the discretion of the surgeon Petcryl® sutures require the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstances and the experiences of the surgeon.

Care should be taken to avoid damage while handling surgical needles. Grasp the needle in an area of one third (1/3) to one half (1/2) of the distance from the attachment end to 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 loose 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 "SHARP"

#### Adverse reactions:

Adverse reactions associated with the use of this device include allergic response in certain patients, transient local irritation at the wound site, transient inflammatory foreign body response, and erythema and indurations during the absorption process of sub cuticular sutures.

#### Sterility:

Petcryl® 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  $10-35\,^{\circ}\text{C}$ , 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.