

FUTURA SURGICARE PVT LTD

INSTRUCTION FOR USE

Brand name: **PETCRYL**

Material: coated & braided Polyglycolic acid.

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

Description:

Petcryl[®] 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”

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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:

Do not 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 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 “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

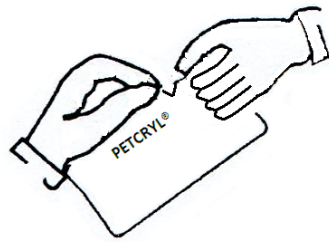
Recommended storage condition 10 – 35 °C, away from moisture and direct heat. Do not use after expiry date.

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:

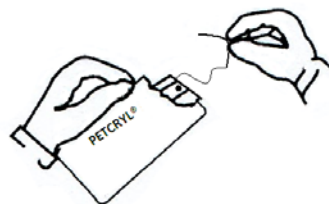
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



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.

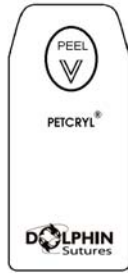


3. Again with the help of sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.

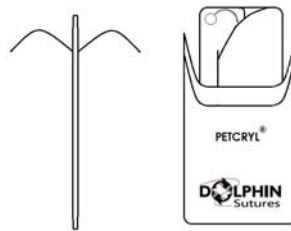


Technique for opening the peel open pouches containing **Petcryl**® :

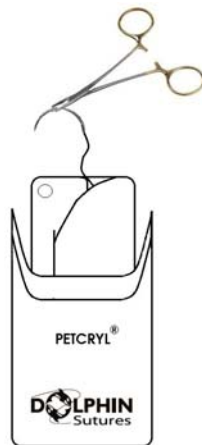
1. Hold the pack in an upright manner and see the peel logo.



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 resterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture

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

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