

FUTURA SURGICARE PVT LTD**INSTRUCTION FOR USE****Brand name: PETCRYL® MONO**

Material: Monofilament Poliglecaprone 25.

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

Description:

PETCRYL® MONO suture is a monofilament synthetic absorbable surgical suture prepared from a copolymer of glycolide and epsilon-caprolactone. Poliglecaprone 25 copolymer has been found to be non antigenic, non pyrogenic and elicits only a slight tissue reaction during absorption. PETCRYL® MONO sutures are available in range of gauge sizes and lengths, 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® MONO complies with the requirements of the United States Pharmacopoeia monograph for “Absorbable surgical suture”

Indications

PETCRYL® MONO sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Applications:

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

Mode of action

Petcryl® Mono 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 – 60 % of the tensile strength at 7 days, 20 – 30 % of tensile strength at 14 days when implanted in rat and the suture is essentially absorbed within 91 – 119 days.

Contraindications

PETCRYL® MONO suture, being absorbable, should not be used where extended approximation of tissue under stress is required, such as in fascia.

Warnings/ Preacutions/ Interaction:

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing PETCRYL[®] MONO 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 for use in patients. 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. 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[®] MONO 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.

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. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with absorption. 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 tissue 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[®] MONO suture knots must be properly placed to be secure. Adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

Avoid prolonged exposure to elevated temperature. 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” containers.

Adverse reactions:

Adverse effects associated with the use of synthetic absorbable sutures 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[®] MONO 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:

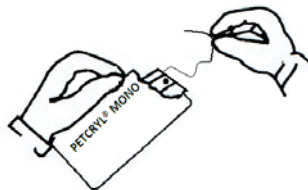
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



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.

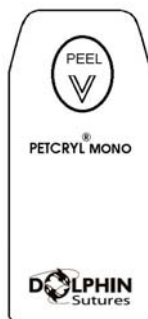


3. Again with the help of sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.

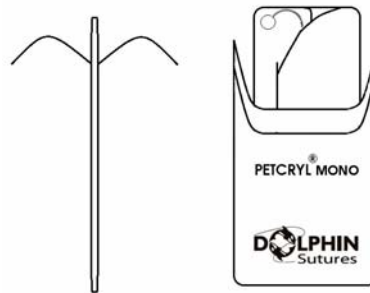


Technique for opening the peel open pouches containing **Petcryl[®] MONO** :

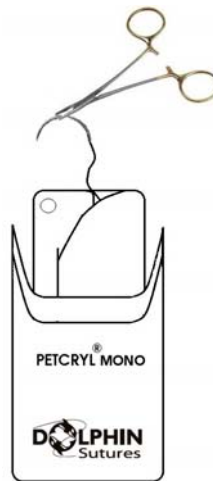
1. Hold the pack in an upright manner and see the peel logo.



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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