

## **FUTURA SURGICARE PVT LTD**

### **INSTRUCTION FOR USE**

Brand name: **PROCARE**

Material: Coated & Braided Polyester.

Non absorbable surgical suture U.S.P

#### Description:

Procare<sup>®</sup> suture is made of fine filaments of polyethylene terephthalate fiber braided to produce suture that remains soft & pliable, coated with silicone. It is available in green colour colour index number D & C green number 6 C.I. 61565 and also in undyed form. Procare<sup>®</sup> 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. Procare<sup>®</sup> complies with the requirements of the United States Pharmacopoeia monograph for “Nonabsorbable surgical suture”

#### Indications:

Procare<sup>®</sup> sutures are an excellent choice for cardiovascular and ophthalmic surgery. 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.

#### Actions:

Procure sutures elicit a minimal acute inflammatory reaction in tissues, followed by a gradual encapsulation of the sutures by fibrous connective tissues. Implantation studies in animals have shown no meaningful decline in the tensile strength over a period of time. Polyester sutures are pharmacologically inactive.

#### Applications:

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

#### Performance:

Procare<sup>®</sup> suture elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. Procare<sup>®</sup> suture is not absorbed nor is it subjected to degradation or weakening by the action of tissue enzymes. Due to its relative biological inertness it is recommended for use where the least possible suture reaction is desired. Its lack of adherence to tissue Procare<sup>®</sup> is effective as a pull out suture.

#### Contra – indications:

None known.

#### Warnings/ Precautions/ Interaction:

User should be familiar with surgical procedure and techniques involving non – absorbable sutures before employing Procare<sup>®</sup> for wound closure as a risk of wound dehiscence may vary with the site of application and the suture material used.

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

Care should be taken to avoid damaging the surface of the material with surgical instruments as this could lead to fracture of the material in use. Avoid crushing or crimping damage due to surgical instruments such as forceps or needle holders.

Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. The use of additional throws is particularly appropriate when knotting coated polyester sutures.

Care should be taken to avoid damage when handling surgical needles. Grasping 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: minimal initial inflammatory tissue reaction and transient local irritation at the wound site. Like all foreign bodies Procure may potentiate an existing infection.

Sterility:

Procure® sutures are sterilized by ethylene oxide. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.

Storage

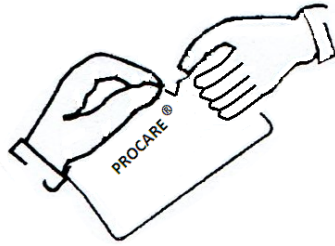
Recommended storage condition 10 – 35 °C, away from moisture and direct heat. Do not use after expiry date.

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:

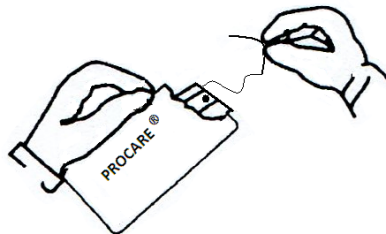
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



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.

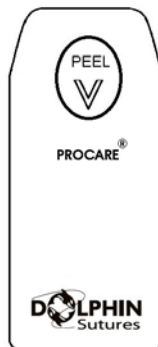


3. Again with the help of sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.

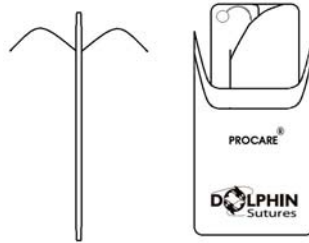


Technique for opening the peel open pouches.

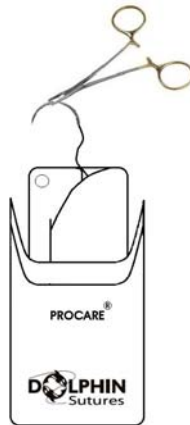
1. Hold the pack in an upright manner and see the peel logo.













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







- 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

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