INSTRUCTION FOR USE-NON ABSORBABLE COATED & BRAIDED POLYESTER SURGICAL SUTURE

PROCARE ®

STERILE NON-ABSORBABLE POLYESTER SURGICAL SUTURE U.S.P

DESCRIPTION

Procare® suture is made of fine filaments of polyethylene terephthalate fiber braided to produce suture that remains soft & pliable, coated with silicone. Procare® sutures are dyed with D&C Green No. 5, usfda approval number §74.1205. The suture is also available in undyed form.

Procare® 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. The suture complies with United States Pharmacopoeia (U.S.P) and European Pharmacopoeia (E.P).

Suture diameter in mm	U.S.P Size	E.P SIZE (Metric)
0.900 – 1.000	7	9
0.800 – 0.899	6	8
0.700 – 0.799	5	7
0.600 – 0.699	3 & 4	6
0.500 – 0.599	2	5
0.400 – 0.499	1	4
0.350 – 0.399	0	3.5
0.300 – 0.339	2-0	3
0.200 – 0.249	3-0	2
0.150 – 0.199	4-0	1.5
0.100 – 0.149	5-0	1
0.070 – 0.099	6-0	0.7

INTENDED USE

Procare® sutures are intended for use in orthopaedic, general and ophthalmic surgery.

SELECTION CRITERIA

The suture should be selected and implanted depending on patient's condition, surgical experience, surgical technique, and wound size. Normally the skin sutures are removed within 30 days depending on wound condition. The decision of doctor is final in removing the skin sutures.

PERFORMANCE

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.

ADVERSE REACTIONS

Adverse reactions associated with the use of Procare® Suture include transitory local irritation at the wound site or transitory inflammatory foreign body response. Like all foreign bodies Procare® may potentate an existing infection.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to polyester and silicone.

WARNINGS

a. Surgeons should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing polyester suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

b. In surgery of the urinary or biliary tract, care should be taken to avoid prolonged contact of this or any other suture with salt solution, to prevent calculus formation.

c. For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury or illness.

d. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

e. Contamination of the device may lead to injury or illness.

f. Do no use for invasive procedures related to central nervous system and central circulatory system.

PRECAUTIONS

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

b. In handling this suture material, 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.

c. Avoid crushing or crimping damage due to surgical instruments such as forceps or needle holders.

d. 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.

e. The use of addition throws is particularly appropriate when knotting Procare® sutures.

f. Care should be taken to avoid damage while handling surgical needle, 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 sharp point.

g. Grasping in the sharp point area could impair the penetration performance and cause fracture of the needle.

INSTRUCTION FOR USE-NON ABSORBABLE COATED & BRAIDED POLYESTER SURGICAL SUTURE

h. Grasping at the butt or attachment end could cause bending or breakage.
i. Reshaping the needles may cause them to loose strength and make less resistant to bending and breaking.
j. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury.
k. Discard the used needles appropriately.

ADVERSE REACTIONS

Adverse reactions associated with the use of Procare® sutures include transitory local irritation at the wound site or transitory inflammatory foreign body response. Like all foreign bodies Procare® sutures may potentate an existing infection.

STERILITY

Procare® 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°C-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.

INSTRUCTIONS FOR USE

A. 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.

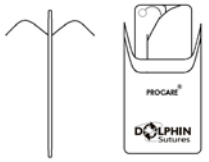
2. Then with the help of sterilized gloved hand or sterilized forceps pull the paper folder till the needle is visible. For non-needled suture, pull out the entire paper folder from the pack, open the folder and retrieve the suture.

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.

B. TECHNIQUE FOR OPENING THE PEEL OPEN POUCHES.

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.

Futura Surgicare Pvt Ltd
86/C2, 3rd Main, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore, Karnataka, India, Pin – 560 022
Mfg Lic No: KTK/28/273/1995
E-mail: sales@dolphinsutures.com
Web Site: www.dolphinsutures.com

EC REP
Obelis s.a
Bd. Général Wahis 53
1030 Brussels, BELGIUM
Tel: + (32) 2. 732.59.54
Fax: +(32) 2.732.60.03
E-Mail : mail@obelis.net

INSTRUCTION FOR USE-NON ABSORBABLE COATED & BRAIDED POLYESTER SURGICAL SUTURE

CE
2460

SYMBOLS USED ON THE LABELS

	Do not reuse		Batch number
	Date of manufacture		CE Mark with Notified Body Number
	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