

INSTRUCTION FOR USE-NON ABSORBABLE MONOFILAMENT POLYPROPYLENE SURGICAL SUTURE

Duracare® STERILE NON-ABSORBABLE MONOFILAMENT POLYPROPYLENE SURGICAL SUTURE U.S.P

DESCRIPTION

Duracare® suture is a monofilament synthetic non – absorbable, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The molecular formula is (C₃H₆)_n.

Duracare® is dyed with [Phthalocyaninato(2-)] copper, usfda approval number [§74.3045](#).

Duracare® 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 detail of the product range is contained 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

Duracare® suture is suitable for use in general soft tissue approximation and/or ligation. Excluding use in

cardiovascular, ophthalmic and neurological procedures.

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

Duracare® suture elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. Duracare® 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. As a mono – filament it has been successfully employed in surgical wound which subsequently become infected or contaminated where it can minimize later sinus formation and suture extrusion. Its lack of adherence to tissue Duracare® is effective as a pull out suture.

CONTRAINDICATIONS

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

WARNINGS

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

- 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.
- 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.
- Contamination of the device may lead to injury, illness of the patient.

PRECAUTIONS

- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- 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.
- 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 addition throws is particularly appropriate when knotting Mono filament polypropylene sutures.
- 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 sharp point.
- Grasping in the sharp 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.

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- i. Reshaping the needles may cause them to lose 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 Duracare® include transitory local irritation at the wound site or transitory inflammatory foreign body response. Like all foreign bodies Duracare® may potentiate an existing infection.

STERILITY

Duracare® 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.

INSTRUCTION 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-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.

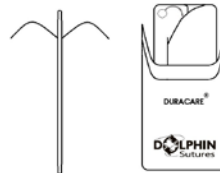


B. TECHNIQUE FOR OPENING THE PEEL OPEN POUCHES.

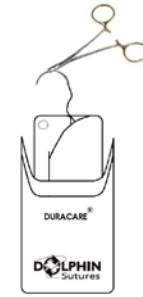
1. Hold the pack in an upright manner and see the peel logo.



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.



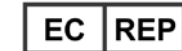
Futura Surgicare Pvt Ltd

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



Obelis s.a

Bd. Général Wahis 53

1030 Brussels, BELGIUM

Tel: + (32) 2. 732.59.54









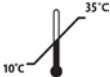





Fax: +(32) 2.732.60.03

E-Mail : mail@obelis.net



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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