

## **FUTURA SURGICARE PVT LTD**

### **INSTRUCTION FOR USE**

Brand name: **DURACRYL**

Material: Monofilament Polydioxanone.

Synthetic absorbable surgical suture (Dyed)

#### Description:

DURACRYL is a sterile synthetic absorbable monofilament suture made from the polyester, poly (p-dioxanone). The empirical formula of the polymer is  $(C_4H_6O_3)_n$ . Polydioxanone polymer has been found to be non-antigenic, non pyrogenic and elicits only a slight tissue reaction during absorption. Polydioxanone sutures are dyed by adding D & C violet no 2. (Colour index number 60725) during polymerization. Duracryl 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.

#### Indications

Polydioxanone monofilament synthetic absorbable sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. Polydioxanone suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

#### Action:

Two important characteristic describe the in-vivo performance of the absorbable sutures: first the tensile strength retention, second the absorption rate (loss of mass)

#### Application:

Duracryl sutures should be selected and implanted depending on the patient condition, surgical experience, suturing technique and wound size.

#### Performance:

Duracryl sutures elicit minimal initial inflammatory reaction in tissues and are eventually replaced with an ingrowth of fibrous connective tissues. Progressive loss of tensile strength and eventual absorption of Duracryl sutures occurs by means of hydrolysis where the polymer degrades to monomeric acid to 2 hydroxyethoxyacetic acid which subsequently absorbed and eliminated by the body. Absorption begins as a loss of tensile strength followed by loss

of mass. Implantation studies in rat show that the suture retains 70 % of the initial strength within 14 days of implant, 50% after 28 days of implant and 25% after 42 days of implant and the suture is essentially absorbed within 180 – 210 days.

#### Contraindications

These sutures, being absorbable, are not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required and are not to be used in conjunction with prosthetic devices, i.e., heart valves or synthetic grafts.

#### Warnings/ Precautions/ Interaction:

The safety and effectiveness of Polydioxanone sutures have not been established in neural tissue, adult cardiovascular tissue or for use in microsurgery. Under certain circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon. Do not resterilize. Polydioxanone suture knots must be properly placed to be secure. As with other synthetic sutures, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the operator. As with any suture, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needle holders and forceps, to the strand except when grasping the free end of the suture during an instrument tie. Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated. Subcuticular sutures should be placed as deeply as possible in order to minimize the erythema and induration normally associated with absorption. Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

#### Adverse reactions:

Adverse effects associated with the use of the device includes transient local irritation at the wound site, transient inflammatory foreign body response, erythema and indurations during the absorption process of the sub cuticular tissues. Like all foreign bodies Polydioxanone may potentiate an existing infection.

#### Sterility:

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

#### Storage

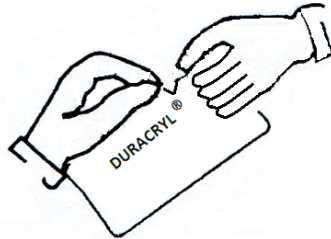
Recommended storage condition 10 – 35 °C, away from moisture and direct heat. Do not use after expiry date.

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:

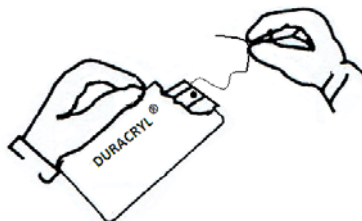
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



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.

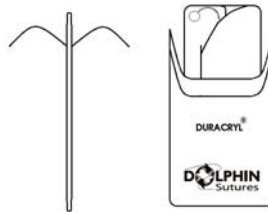


Technique for opening the peel open pouches containing **DURACRYL** :

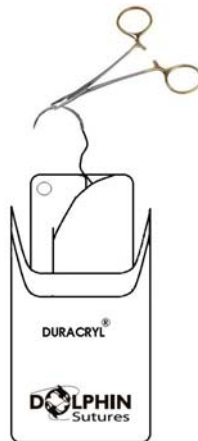
1. Hold the pack in an upright manner and see the peel logo.









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

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