

INSTRUCTION FOR USE-ABSORBABLE MONOFILAMENT POLYDIOXANONE SURGICAL SUTURE

DURACRYL®

STERILE ABSORBABLE SURGICAL SUTURE

DESCRIPTION

DURACRYL® is a sterile synthetic absorbable monofilament suture composed of 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 No. 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.

SELECTION CRITERIA

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

PERFORMANCE

DURACRYL® suture leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. DURACRYL® gradually loses tensile strength and is finally absorbed by hydrolytic process. During hydrolysis, the co-polymer degrades monomeric acid to 2 hydroxyethoxyacetic acid which subsequently absorbed and eliminated by the body. Absorption begins

as a loss of tensile strength followed by a loss of mass. Absorption pattern for suture when tested on rats:-
Approx 78.45 % of tensile strength at 14 days,
Approx 69.7 % tensile strength after 28 days and
Approx 57.95 % tensile strength after 43 days.
Approx 40.55 % tensile strength after 57 days.

ADVERSE REACTIONS

Adverse reaction, associated with the use of the device include transitory local irritation at the wound site, transitory inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures. Like all foreign bodies, DURACRYL® suture may enhance an existing infection.

CONTRAINDICATIONS

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

WARNINGS

- a. Surgeons should be familiar with surgical procedures and techniques involving absorbable sutures before employing DURACRYL® 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. This suture may be inappropriate in patients suffering from conditions which may delay wound healing e.g., patient that are elder, malnourished or depilated. As this is an absorbable suture, the use of supplemental non-absorbable suture should be considered by the surgeon in the close of the

abdomen, chest, joints or other sites subjects to expansion or requiring additional support.

- d. 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 and illness.
- e. 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.
- f. Contamination of the device may lead to injury, illness of the patient.

PRECAUTIONS

- a. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- b. Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated.
- c. 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.
- d. Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.
- e. When handling this or any other suture, 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.
- f. Care should be taken to avoid damage while handling surgical needles. Grasp the needle in an area, one third (1/3) to one half (1/2) of the distance from the attachment end to the point.

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- g. Grasping in the point area could impair the penetration performance and cause fracture of the needle.
- 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. Discard the needles after use.

STERILITY

DURACRYL® 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

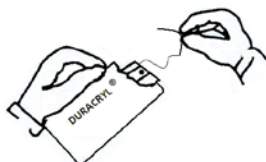
1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.



2. Then with the help of sterilized gloved hand or sterilized forceps pull the paper folder till the needle is visible. For non-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.

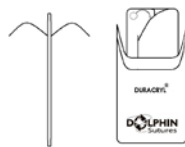


B. Technique for opening the peel open pouches containing DURACRYL

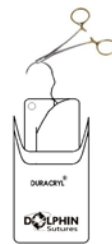
1. Hold the pack in an upright manner and see the peel logo.



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.



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SYMBOLS USED ON THE LABELS

	Do not reuse	LOT	Batch number
	Date of manufacture		CE Mark with Notified Body
	Date of expiry		Registered
STERILE EO	Sterilized by ethylene oxide	EC REP	EU REPRESENTATIVE
	Temperature limitation		Do not resterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture