# INSTRUCTION FOR USE-ABSORBABLE MONOFILAMENT POLYDIOXANONE SURGICAL BARBED SUTURE

**STERILE ABSORBABLE POLYDIOXANONE SURGICAL BARBED SUTURE**

**DESCRIPTION**

Polydioxanone barbed suture is a knotless wound closure device sterile synthetic absorbable monofilament suture made from the poly (p-dioxanone).

The empirical formula of the polymer is (C4H6O3) 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.

Polydioxanone barbed 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. With barbs on its surface at and an angle of 72 arranged in a spiral manner, the barbs are arranged in a unidirectional or bi directional manner. The unidirectional barbs have a terminal loop.

**INDICATIONS**

Polydioxanone monofilament, barbed and absorbable needled sutures (sterile) are indicated for use in Oncology, Geriatric, Gynaecology, Cosmetic surgery, Urology, Vaginal cuff closure after hysterectomy, Uro-gynaecology surgery myomectomy, Laparoscopy, Gastrointestinal, Laparoscopic.

**PERFORMANCE**

Polydioxanone barbed suture sutures elicit minimal initial inflammatory reaction in tissues and are eventually replaced with an in growth of fibrous connective tissues. Progressive loss of tensile strength and eventual absorption of Polydioxanone barbed suture 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. The suture retains approximately 85% of the initial tensile strength within 14 days of implant, 74% of tensile strength after 28 days, 59% after 45 days and 30% after 60 days of implantation and the suture is essentially absorbed completely between 180 to 210 days.

**ADVERSE REACTIONS**

Adverse reaction, associated with the use of the device includes 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, Polydioxanone barbed suture may enhance an existing infection.

**CONTRAINDICATIONS**

Polydioxanone barbed 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.

**WARNINGS**

**a.** Surgeons should be familiar with surgical procedures and techniques involving absorbable sutures before employing Polydioxanone barbed 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 many 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 or 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.** Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

**c.** Under some circumstances, notably orthopaedic procedures, immobilization of joints by external

support may be employed at the discretion of the surgeon.

**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.** Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration, normally associated with the absorption process.

**f.** 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.

**g.** 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.

**h.** Grasping in the point area could impair the penetration performance and cause fracture of the needle.

**i.** Grasping at the butt or attachment end could cause bending or breakage.

**j.** Reshaping the needles may cause them to loose strength and make less resistant to bending and breaking.

**k.** Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard the needles after use.

**STERILITY**

Polydioxanone barbed 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 is 10°C-35°C, away from moisture and direct heat. Don't 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.

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**SYMBOLS USED ON THE LABELS**

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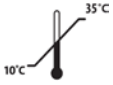
|---|---|---|---|
|  | Do not reuse |  | Batch number |
|  | Date of manufacture |  | Date of expiry |
|  | Sterilized by ethylene oxide |  | Do not resterilize |
|  | Temperature limitation |  | Consult instructions for use |
|  | Do not use if package is damaged |  | Avoid Moisture |
|  | Avoid direct sunlight | | |