INSTRUCTIONS FOR USE OF UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO (POLYDIOXANONE)

DESCRIPTION

UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）are sterile synthetic absorbable monofilament sutures made from the polyester poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_5O_3)_n$. Polydioxanone polymer has been found to be non-antigenic, non-pyrogenic and elicits only a slight tissue reaction during absorption.

UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）are dyed by adding D&C Violet No.2 (Color Index number 60725) during polymerisation.

UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）are available in a range of gauge sizes and lengths, attached to stainless steel needles of varying types and sizes. The needles may be attached permanently or as C-R needles (control release), which enables the needles to be pulled off instead of being cut off. The material may also be supplied with beads and collars to anchor the ends of the suture for subcuticular closure. Full details of the product range are contained in the catalogue.

UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）comply with all the requirements of the European Pharmacopoeia for Sterile Synthetic Absorbable Monofilament Sutures and the requirements of the United States Pharmacopoeia for Absorbable Surgical Sutures except for a slight oversize in diameter.

INDICATIONS

UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）are intended for use in general soft tissue approximation, including use in paediatric cardiovascular tissue, in microsurgery and in ophthalmic surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

APPLICATION

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.

PERFORMANCE

UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）elicit a minimal initial inflammatory reaction in tissues and are eventually replaced with an in-growth of fibrous connective tissue. Progressive loss of tensile strength and eventually absorption of UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）occur by means of hydrolysis, where the polymer degrades to the monomeric acid 2-hydroxyethoyacetic acid which is subsequently absorbed and eliminated by the body. Absorption begins as loss of tensile strength followed by a loss of mass. Implantation studies in rats show the following profile.

Post Implantation		**Approx. Original Strength Remaining**
14 days	M1.5 (4/0) and smaller	60%
	M2.0 (3/0) and larger	75%
28 days	M1.5 (4/0) and smaller	50%
	M2.0 (3/0) and larger	70%
42 days	M1.5 (4/0) and smaller	35%
	M2.0 (3/0) and larger	50%

Absorption is minimal until about the 90th post implantation day and is essentially complete between 180 and 210 days.

CONTRA-INDICATIONS

These sutures, being absorbable, should not be used where prolonged approximation of tissues under stress is required or in conjunction with prosthetic devices, for example, heart valves or synthetic grafts.

WARNINGS/PRECAUTIONS/INTERACTIONS

The safety and effectiveness of UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO (POLYDIOXANONE）have not been established in contact with the central nervous system, in adult cardiac tissue or in large vessels.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Surgeons should consider the in-vivo performance (under PERFORMANCE section) when selecting a suture. This suture may be inappropriate in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）may act transiently as a foreign body.

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

As this is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distension, or which may require additional support.

Conjunctival, cuticular and vaginal epithelium sutures which remain in place longer than 10 days may cause localized irritation and should be snipped off or removed.

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

Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

Consideration should be given to the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.

In handling this or any other suture material, care should be taken to avoid damage.

Avoid crushing or crimping damage due to application of 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 experiences of the surgeon. The use of additional throws may be particularly appropriate when knotting any monofilament suture.

Care should be taken to avoid damage when 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. Grasping in the point area could impair the penetration performance and cause fracture of the needles. Grasping at the butt or attachment end could cause bending or breakage. Reshaping needles may cause them to loose strength and be less resistant to bending and breaking. Users should exercise caution when handing surgical needles to avoid inadvertent needle stick injury. Discard used needles in "Sharps" containers.

ADVERSE REACTIONS

Adverse reactions associated with this device include: transient local irritation at the wound site, transient inflammatory foreign body response and erythema and induration during absorption with subcuticular sutures. Like all foreign bodies UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO (POLYDIOXANONE may enhance an existing infection.

STERILITY

UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）is sterile by ethylene oxide gas. Do not re-sterilize. Do not use if package is opened or damaged. Discard any opened sutures.

STORAGE

UNIFY® SYNTHETIC ABSORBABLE SUTURES PDO（POLYDIOXANONE）should be stored at a temperature below 25 degrees Centigrade, away from moisture and direct heat. Do not use after expire date.

SYMBOLS USED ON LABELLING

	Do not reuse
	Used by- year and month
	Sterile unless the package is damaged or opened. Method of sterilization- Ethylene Oxide
	Batch number
	See introduction for use
	Keep away from heat
	Keep dry
	Upper limit of temperature
	Date of manufacture

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