

POLYDIOXANONE (PDO) MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES

DESCRIPTION

Polydioxanone monofilament synthetic absorbable suture is prepared from the polyester, poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_6H_8O_3)_x$. Polydioxanone polymer has been found to be non-antigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption. Polydioxanone Sutures are U.S.P. with the exception of diameter for sizes 2 to 6/0 which comply with the European Pharmacopeia for diameter.

INDICATIONS

Polydioxanone sutures are indicated for use in soft tissue approximation. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 42 days) is desirable.

ACTIONS

Two important characteristics describe the in vivo performance of absorbable sutures: tensile strength retention and the absorption rate (loss of mass). Polydioxanone synthetic absorbable suture has been formulated to minimize the variability of these characteristics and to provide wound support through an extended healing period.

The result of implantation studies of Polydioxanone monofilament suture in animals indicate that approximately 75% of its original strength remains 14 days after implantation. At 28 days post-implantation, approximately 66% of its original strength is retained, and at 42 days, approximately 53% of the original strength is retained. Data obtained from implantation studies in rats show that the absorption of these sutures is minimal until about the 90th post-implantation day. Absorption is essentially complete within 180-220 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.

Polydioxanone is contraindicated in adult cardiovascular tissue, in pediatric cardiovascular tissue where growth is expected to occur

and also in ophthalmic surgery. Polydioxanone suture is not indicated in cardiovascular tissue, microsurgery and neural tissue.

The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions, which may delay wound healing.

WARNINGS

User should be familiar with surgical techniques involving absorbable sutures before employing Polydioxanone sutures for wound closure as a risk wound dehiscence may vary with the site of application and suture material used.

The safety and effectiveness of Polydioxanone sutures have not been established in neural tissues, 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 use if package is open or damaged or the expiration date has been exceeded. Discard open, unused suture.

Do not resterilize; resterilization may alter the physical properties of this suture, which will result in adverse patient reaction.

Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in a "sharps" container.

Store in a cool dry environment.

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, Polydioxanone suture may act transiently as a foreign body.

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

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

PRECAUTIONS

Polydioxanone suture knots must be properly placed to be secure. In handling this or any other surgical suture, care should be taken to avoid damage from handling. Avoid crushing or crimping damage

during the use of surgical instruments such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, squared ties with additional throws as warranted by surgical circumstance and experience of the surgeon. The use of additional throws may be particularly appropriate when tying monofilaments.

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.

ADVERSE REACTIONS

Due to prolonged suture absorption, some irritation and bleeding has been observed in the conjunctiva and mild irritation has been observed in the vaginal mucosa.

Discuss the potential for allergic reaction in patients that are known to be sensitive to Polydioxanone suture.

HOW SUPPLIED

Polydioxanone (PDO) sutures are available in various USP sizes. PDO sutures are supplied in a wide range of lengths affixed to a diverse assortment of needle types.

DISPENSING (racetrack cartridge only):

For best results, pull the suture from the racetrack cartridge using a slow, steady pull. If binding occurs, the suture can be removed from the card by removing the press-fit label and opening the plastic hinges.


CAUTION


Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

SYMBOL DEFINITIONS

 Lot Number

 Expiration Date


 Do Not Reuse

 Do Not Resterilize

 See Instructions For Use

 Sterilized By Ethylene Oxide

 Keep away from sunlight and heat

 Do not use if package is damaged

 Keep dry

 Manufacturer

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