COATED VIOLET ANTIBACTERIAL MONOFILAMENT POLYDIOXANONE SYNTHETIC ABSORBABLE SUTURE WITH CHLORHEXIDINE DIACETATE

DESCRIPTION

Polydioxanone monofilament synthetic absorbable suture is prepared from the polyester, poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_x$. Polydioxanone polymer has been found to be non-antigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption. This antibacterial suture contains ≤ 60 µg/m of a common antimicrobial agent, chlorhexidine diacetate. Polydioxanone Sutures are U.S.P., except for slight oversize in diameter.

MAXIMUM SUTURE OVERSIZE IN DIAMETER (mm) from U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (mm)	U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (mm)
7-0	0.025	3-0	0.081
6-0	0.026	2-0	0.041
5-0	0.031	-0-	0.091
4-0	0.041	-1-	0.051
		-2-	.006

INDICATIONS

Polydioxanone sutures are indicated for use in animals in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and also in 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.

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 two weeks after implantation. At four weeks post-implantation, approximately 66% of its original strength is retained, and at six weeks, 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 six months.

This suture is coated with chlorhexidine diacetate, an antimicrobial agent which is intended to reduce or inhibit the colonization of *Staphylococcus aureus* and *Staphylococcus epidermidis*, and methicillin-resistant *S. aureus* (MRSA) and *S. epidermidis* (MRSE) that may be present at the surgical site.

CONTRAINDICATIONS

These absorbable sutures 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 suture is not indicated in adult cardiovascular tissue, microsurgery or neural tissue. For use in animals only, not for use in humans.

WARNINGS

Do not use if package is open or damaged or if the expiration date has been exceeded. Discard open, unused suture.

Do not resterilize. Resterilization may alter the physical properties of this suture Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in a "sharps" container.

Avoid storing product at elevated temperatures.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Acceptable surgical practice should be followed with respect to drainage and closure 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. As with other synthetic sutures, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstances and the experience of the operator. The use of additional throws may be particularly appropriate when tying monofilaments.

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.

A reduction in the colonization of or microbial growth on this device has not been shown to directly correlate with a reduction of infections in patients; acceptable surgical practice should be followed with respect to aseptic technique and the drainage and closure of infected wounds.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, wound infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation. Do not use this product on patients with a potential for hypersensitivity or a history of allergies to chlorhexidine diacetate.

HOW SUPPLIED

Polydioxanone suture is a synthetic absorbable monofilament and is dyed (violet) or undyed (milk white). It is available in sizes 7-0 through 2 (metric sizes 0.5-5). The suture is supplied sterile in precut lengths attached to various needle types in one- to three-dozen boxes.

CAUTION

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

FOR VETERINARY USE ONLY

SYMBOL DEFINITIONS

REF Part Number

LOT Lot Number

Expiration Date

Do Not Reuse

Do Not Resterilize

See Instructions For Use

Manufacturer

STERILE EO Sterilized By Ethylene Oxide

PUB202 R04

Effective Date 02/17/2016