

PDS* Plus

Antibacterial

(Polydioxanone) Suture

DYED and CLEAR MONOFILAMENT
SYNTHETIC ABSORBABLE SUTURES,
U.S.P., except for diameter.

DESCRIPTION

PDS* Plus Antibacterial (polydioxanone) monofilament synthetic absorbable suture is prepared from the polyester, poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_x$. The suture contains Irgacare MP** (triclosan), a broad-spectrum antibacterial agent, at no more than 2360 $\mu\text{g}/\text{m}$. PDS Plus Antibacterial dyed suture is dyed with D&C Violet No. 2.

Polydioxanone polymer has been found to be nonallergenic, nonpyrogenic and elicits only a slight tissue reaction during absorption. PDS Plus Antibacterial sutures are U.S.P., except for diameter.

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

U.S.P. SUTURE SIZE

DESIGNATION

MAX. OVERSIZE (mm)

6-0	0.015
5-0	0.029
4-0	0.029
3-0	0.056
2-0	0.029
0	0.071
1	0.047

INDICATIONS

PDS Plus Antibacterial sutures are indicated for use in soft tissue approximation, and ophthalmic surgery (other than contact with cornea and sclera). PDS Plus is not indicated in pediatric tissue, and 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: first, tensile strength retention, and second, the absorption rate (loss of mass). PDS Plus Antibacterial suture has been formulated to minimize the variability of these characteristics and to provide wound support through an extended healing period.

Data obtained from an implantation study in rats shows that PDS Plus Antibacterial suture is essentially absorbed between 182 and 238 days post-implantation.

The results of implantation studies indicate the percentage of original strength is retained as follows:

DAYS IMPLANTATION	APPROXIMATE % ORIGINAL STRENGTH REMAINING 4-0 and SMALLER	APPROXIMATE % ORIGINAL STRENGTH REMAINING 3-0 and LARGER
14 DAYS	60%	80%
28 DAYS	40%	70%
42 DAYS	35%	60%

Irgacare MP (triclosan) in PDS Plus Antibacterial suture has been shown to inhibit colonization of the suture by *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Methicillin Resistant S. aureus*, *Methicillin Resistant S. epidermidis*, *Escherichia coli*, and *Klebsiella pneumoniae* which are microorganisms known to contribute to surgical site infections. Animal studies have demonstrated that PDS Plus Antibacterial suture inhibits bacterial colonization of suture after direct in vivo challenge with bacteria.

CONTRAINDICATIONS

PDS Plus Antibacterial suture, being absorbable, is not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required and is not to be used in conjunction with prosthetic devices (i.e., heart valves or synthetic grafts).

PDS Plus Antibacterial Suture should not be used in patients with known allergic reactions to Irgacare MP (triclosan).

WARNINGS

The safety and effectiveness of PDS Plus Antibacterial sutures have not been established in neural tissue, pediatric tissue, and adult cardiovascular tissue, microsurgery, or for contact with cornea or sclera.

Under certain circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Do not resterilize. Discard open packages and unused sutures.

PRECAUTIONS

The PDS Plus Antibacterial 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 circumstance and the experience of the operator.

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.

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.

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

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

Adverse effects associated with the use of synthetic absorbable sutures 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, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary

tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site, as well as allergic reaction to Irgacare MP (triclosan). Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

STORAGE

Recommended storage conditions: Store at or below 25°C. Do not use after expiry date.

HOW SUPPLIED

PDS Plus Antibacterial sutures are available as sterile, monofilament dyed (violet) strands in sizes 6-0 thru 1 (metric sizes 0.7-4) and sterile, monofilament undyed (clear) strands in sizes 6-0 thru 1 (metric sizes 0.7-4) in a variety of lengths, with a variety of needles.

PDS Plus Antibacterial sutures are available in one, two and three dozen boxes.



Do not re-use



Upper limit of temperature



Caution



Do not re-sterilize



Use-by date



Batch code



Sterilized using ethylene oxide

ETHICON, LLC

a *Johnson & Johnson* company

Guaynabo, Puerto Rico 00969

*Trademark of ETHICON, Inc.

**Trademark of Ciba Specialty Chemical Corporation.

© ETHICON, Inc. 2009

LAB0012338v3

11/2017



389898R03