Absorbable Monofilament Polydioxanone Surgical Suture

DSI PDO Suture

INSTRUCTIONS FOR USE

DESCRIPTION

DSI Suture PDO is a sterile synthetic absorbable monofilament suture composed of Polydioxanone. The 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. during polymerization.

The needles are attached permanently to the suture. Entire detail of the product range is contained in the company catalogue.

INDICATIONS

Polydioxanone monofilament synthetic absorbable sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur, ophthalmic and dental surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

SELECTION

The sutures should be selected and implanted depending on the patient's condition, surgical experience, surgical technique and wound size.

PERFORMANCE

The suture leads to the ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. DSI PDO gradually loses tensile strength and is finally absorbed by the hydrolytic process. During hydrolysis, the co-polymer degrades monomeric acid to 2 hydroxyethoxyacetic acid which is subsequently absorbed and eliminated by the body. Absorption begins as a loss of tensile strength followed by a loss of mass. Absorption pattern for suture when tested on rats:

Approx 78.45 % of tensile strength at 14 days,

Approx 69.7 % tensile strength after 28 days,

Approx 57.95 % tensile strength after 43 days.

Approx 40.55 % tensile strength after 57 days.

ADVERSE REACTIONS

Adverse reaction, associated with the use of the device include 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, DSI PDO suture may enhance an existing infection.

CONTRAINDICATIONS

PDO 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. The use of this suture is contraindicated in patients with known sensitivities or allergies to polydioxanone.

WARNINGS

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

b. 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.

c. 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 and illness.

d. Reuse, reprocessing or re-sterilization may 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.

e. Contamination of the device may lead to injury, and illness of the patient.

PRECAUTIONS

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

b. 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.

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

d. 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.

e. 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.

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

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

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

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

STERILITY

Sutures are sterilized by ethylene oxide. The sterility of undamaged, unopened packs is guaranteed. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.

STORAGE

Recommended storage condition 5°C-25°C, away from moisture and direct heat. Do not use after the expiry date.

DISPOSAL

Discard used sutures and needles contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

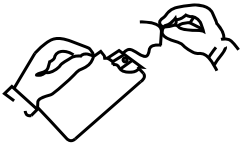
INSTRUCTIONS FOR USE

A. Technique for opening the over wrap

1. The scrub nurse should hold the sterile pack in their 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 containing sutures.

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.

PACKAGING

2/0 USP (metric EP 3.0)	**Ref: DS-PDS20**
3/0 USP (metric EP 2.0)	**Ref: DS-PDS30**
4/0 USP (metric EP 1.5)	**Ref: DS-PDS40**
5/0 USP (metric EP 1.0)	**Ref: DS-PDS50**

SYMBOLS

	Consult instructions for use		Do not resterilize
	Caution, consult accompanying documents		Do not re-use/ for single use only
	Temperature limit		Manufacturer
	Keep away from sunlight	REF	Catalogue number
	Keep dry	LOT	Batch code
STERILE OE	Sterilized by ethylene oxide		Use by
	Do not use if package is damage		Date of Manufacture

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material.
The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.