

## INSTRUCTIONS FOR USE

### ***Polydioxanone Suture***

Absorbable - Monofilament - Synthetic - Sterile

#### **Description:**

PDO (Polydioxanone) monofilament synthetic absorbable suture is prepared from the polyester, poly(p-dioxanone). PDO (Polydioxanone) Sutures are also available dyed and undyed. PDO (Polydioxanone) suture has been found to be non allergenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

#### **Indications:**

These sutures are generally preferred where the combination of an absorbable suture and longer wound support is desired PDO (Polydioxanone) is generally used in ligation, skin sutures. Intestinal suture, uterus, pediatric surgery and plastic surgery it is not used for cardiovascular and neurology b tissue approximation.

#### **Actions:**

Two important characteristics describe the in vivo performance of absorbable sutures: first, tensile strength retention and second, the absorption rate (mass loss). PDO (Polydioxanone) sutures has been formulated to minimize the variability of these characterizes and to provide a wound support through an extended healing period. The results of in vitro studies of PDO (Polydioxanone) suture indicate that 50% of its original strength remains after 4 weeks and 25% of its original strength remains after 6 weeks. Absorption is essentially complete about 180-210 days.

#### **Contraindications:**

PDO (Polydioxanone) sutures, being absorbable, are 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).

#### **Warnings:**

PDO (Polydioxanone) should not be re-sterilized. Contents in the package have been already sterilized. Do not use if package is opened or damaged. Discard opened unused sutures. PDO (Polydioxanone) should be stored at room temperature away from moisture and direct heat. As with any other foreign substance, any

extended contact of PDO (Polydioxanone) or any other suture with salt solutions as those found in kidneys or in the liver can result in gallstones and kidney Stones. Users have to be familiar with surgical procedures including absorbable sutures. Do not use after the expiry date.

#### **Precautions:**

The PDO (Polydioxanone) sutures knots must be properly 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. If it's necessary extra sutures can be added. As with any suture, care should be taken to avoid damage when handing. 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. Avoid exposure to elevated temperature.

#### **Adverse Reaction:**

Due to prolonged suture absorption, some irritation and bleeding has been observed in the Conjunctiva and mide 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 sited where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions 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 an the wound site.















#### **How supplied:**

PDO (Polydioxanone) sutures are available from from USP2-7/0, and are supplied sterile, in a variety of lengths, lengths, non-needled or affixed to various needle types in one, two or three dozen per box.

#### **Storage Conditions:**

It is recommended that PDO (Polydioxanone) Sutures are stored below 23°C kept away from direct heat and moisture. Carefully observe the expiry date.

#### **Explanation of the Symbols on Packaging:**

	Do not re-use
	Gamma irradiation
	Ethylene Oxide irradiation
	Consult instructions for use
	Do not use if package is damaged
	Expiration Date
	Manufactured Date
	Catalogue Number
	Batch number
	Keep away from sunlight
	Keep dry
	Temperature Limitation
	Fragile: Handle with care
	CE Mark and identification number of Notified Body. Product conforms to the essential requirements of the medical device directive 93/42/EEC

#### **Manufacturer:**

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