

DAMADIOXANONE

Poly(P-dioxanone)
Monofilament Synthetic
Absorbable sterile surgical suture

DESCRIPTION

DAMADIOXANONE suture is synthetic absorbable sterile surgical suture. It is composed of polymers made from 100% homo polymer of polydioxanone. It is Monofilament sutures dyed (violet) or undyed.

DAMADIOXANONE suture is non-antigenic, non-pyrogenic and elicits only a mild tissue reaction during the absorption process, and is completely absorbed in 180-240 days. The In vitro retention of strength is more than 65% in four weeks.

DAMADIOXANONE suture complies with the requirements of the United States pharmacopoeia U.S.P. and European pharmacopoeia Ph. Eur. and European Medical Device Directive 93/42/EEC.

INDICATIONS

DAMADIOXANONE suture is indicated for use in general soft tissue approximation and ligation, including use in pediatric cardiovascular tissue and ophthalmic surgery. It is also particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

DAMADIOXANONE is not for use in microsurgery, adult cardiovascular or neural tissues.

CONTRAINDICATIONS

DAMADIOXANONE suture, being absorbable, should not be used where prolonged approximation of tissue under stress is required (beyond six weeks), or in conjunction with prosthetic devices, i.e., heart valves or synthetic grafts.

WARNINGS

The safety and effectiveness of Polydioxanone have not been established in neural tissue, adult cardiovascular tissue or for use in microsurgery.

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

Users should consider the in vivo performance when selecting a suture. 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.

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

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, **DAMADIOXANONE** suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds. Discard opened packages and unused sutures.

Do not re-use.
Do not re-sterilize.

PRECAUTIONS

In handling this or any other suture material, 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.

DAMADIOXANONE sutures, which are treated to enhance handling characteristics, require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Conjunctival and vaginal mucosal sutures remaining in place for extended periods (more than 10 days) may be associated with localized irritation and should be removed as indicated. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with absorption.

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

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

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" container.

Avoid prolonged exposure to elevated temperatures.

Don't use after expiry date.

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 distention 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 conjunctival and vaginal sutures are left in place for greater than 10 days, erythema and induration during absorption with subcuticular sutures, 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. 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.

STERILITY

DAMADIOXANONE sutures are sterilized by ethylene oxide.

Sterility is preserved only when opened under sterile conditions.

Do not re-sterilize.

Do not use if package is opened or damaged.

Discard opened unused sutures.

STORAGE

Keep away from moisture and direct heat. Recommended storage condition is below 25 °C. Don't use after expiry date

SYMBOLS USED ON THE PRODUCT

	Date Of Manufacture		Do Not Use If Pack Is Opened Or Damaged
	Date Of Expiry		Do Not Reuse
	Batch Number		Ethylene Oxide Sterilized Product
	Avoid Moisture		Do Not Re-sterilize
	Avoid Direct Sunlight		Temperature Limitation
	Consult Instructions For Use		Manufacturer

Manufactured By:
GMD GROUP MEDİKAL SANAYİ VE TİCARET ANONİM ŞİRKETİ

İKİTELLİ OSB MAH. ISDOK
SOSYAL TESİS 2 SK. B BLOK 1 B
7 BASAKSEHIR/ İSTANBUL
Info@gmdgroup.com.tr
www.gmdgroup.com.tr

