

DAMALENE

Polypropylene
Monofilament, Synthetic
Non-absorbable sterile surgical suture

DESCRIPTION

DAMALENE suture is synthetic non-absorbable sterile surgical suture, composed of isotactic crystalline stereoisomer of Polypropylene, a synthetic linear polyolefin. It is Monofilament dyed sutures.

DAMALENE suture has high in vivo tensile strength and has the further advantages of being remarkably smooth & easy to handle resulting in minimal tissue trauma.

DAMALENE 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

DAMALENE suture is indicated for use in general soft tissue approximation and ligation, including use in cardio vascular, ophthalmic, plastic and neurological procedures.

CONTRAINDICATIONS

None known

WARNINGS

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

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. 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.

DAMALENE 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. The use of addition throws may be appropriate when knotting Mono filament Polypropylene sutures.

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, minimal acute inflammatory tissue reaction, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, gradual loss of tensile strength over time, transitory local irritation and edema at the wound site, and like all foreign bodies it may potentiate an existing infection

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

DAMALENE 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

IKITELLI OSB MAH. ISDOK
SOSYAL TESİS 2 SK. B BLOK 1 B
7 BASAKŞEHİR/ İSTANBUL
info@gmdgroup.com.tr
www.gmdgroup.com.tr