

DAMASILK

Non-absorbable Silk
Braided, Coated
Sterile surgical suture

DESCRIPTION

DAMASILK suture is synthetic non-absorbable sterile surgical suture, composed of approximately 70% fibroin protein fibers & 30% extraneous material or gum. Specially developed process removes extraneous material amounting to 30% of the original weight of the raw silk. It is braided, silicone coated, dyed sutures.

DAMASILK suture loses most of its tensile strength in one year and elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue.

DAMASILK suture is not absorbed nor is it subjected to degradation or weakening by the action of tissue enzymes. It is Coated with Silicone to allow easy passage through tissue

DAMASILK 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

DAMASILK suture is indicated for use in general soft tissue approximation and ligation, and used in a wide variety of surgical procedures.

CONTRAINDICATIONS

DAMASILK is contraindicated in patients with known allergies and sensitivities to Silk. It should also not be used where permanent retention of tensile strength is required as in fixation of intraocular lenses or synthetic vascular grafts, due to gradual loss of tensile strength which may occur over prolonged periods in vivo.

WARNINGS

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing **DAMASILK** 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.

DAMASILK 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.

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, gradual loss of tensile strength over time, allergic response in patients who are known to be sensitive to silk, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, transitory local irritation 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 blood borne pathogens.

STERILITY

DAMASILK 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: KABAKIBI SABBAGH MED.

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