USAGE INSTRUCTION DAMACRYL

DAMACRYL
Polyglycolic Acid
Coated & Braided
Synthetic absorbable sterile surgical suture

DESCRIPTION

DAMACRYL suture is synthetic absorbable sterile surgical suture. It is composed of homo polymer prepared and synthesized from 100% Polyglycolic Acid. This sutures are braided, dyed (violet) or undyed and coated with polycaprolactone and calcium stearate.

DAMACRYL suture is non-antigenic, non-pyrogenic and elicits only a mild tissue reaction during the absorption process, and is completely absorbed in 60-90 days. The In vitro retention of strength is more than 65% in two weeks.

DAMACRYL 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

DAMACRYL suture is indicated for use in general soft tissue approximation and ligation, including the use in ophthalmic procedures. **DAMACRYL** is not for use in cardiovascular or neurological tissues.

CONTRAINDICATIONS

DAMACRYL suture, being absorbable, should not be used where extended approximation of tissue is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing **DAMACRYL** 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, **DAMACRYL** 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.
DAMACRYL 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.
Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.
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 distension 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 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 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

DAMACRYL 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 ºC. 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	
LOT	Batch Number	STERILE EO	Ethylene Oxide Sterilized Product
Avoid Moisture		Do Not Re-sterilize	
Avoid Direct Sunlight		Temperature Limitation	
Consult Instructions For Use		Manufacturer	

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