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# MERSILENE™



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ar	خيوط جراحية	fr	FIL DE SUTURE	ru	ШОВНЫЙ МАТЕРИАЛ
cs	ŠÍČÍ MATERIÁL	hu	VARRÓANYAG	sk	NIŤ
da	SUTUR	it	SUTURA	sv	SUTUR
de	NAHTMATERIAL	ko	봉합사	tr	SÜTÜR
el	PAMMA	nl	HECHTMATERIAAL	zh-cn	缝线
en	SUTURE	no	SUTUR	zh-tw	缝合線
es	SUTURA	pl	NICI		
fi	OMMELAINE	pt	FIO DE SUTURA		

## Instructions for use

en

### MERSILENE™ (POLYESTER) STERILE SYNTHETIC NON ABSORBABLE SUTURE

#### DESCRIPTION

MERSILENE™ suture is a monofilament or braided, non absorbable sterile surgical suture composed of poly (ethylene terephthalate). The empirical molecular formula of the polymer is  $(C_{10}H_8O_4)_n$ .  
MERSILENE™ is available undyed (white) or dyed green with D & C Green No. 6, Colour Index No. 61565.

MERSILENE™ is available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of various types and sizes. The needles may be attached permanently or as CR-needles (control release), enabling the needles to be pulled off instead of being cut off. Full details of the product range are contained in the catalogue.

MERSILENE™ complies with the requirements of the European Pharmacopoeia for Sterile Poly (ethylene Terephthalate) Suture and the United States Pharmacopoeia for Non Absorbable Surgical Sutures (except for an occasional slight oversize in some gauges).

#### INDICATIONS

MERSILENE™ sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures, and also for the fixation of soft tissue to bone tissue.

#### APPLICATION

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.

#### PERFORMANCE

MERSILENE™ suture elicits a minimal initial inflammatory reaction in tissue followed by a gradual encapsulation of the suture by fibrous connective tissue. Subcutaneous tissue implantation in rats shows that no significant change in the retention of tensile strength of the suture occurs during the entire evaluation period of 180 days.

#### CONTRAINDICATIONS

None known.

#### WARNINGS/PRECAUTIONS/INTERACTIONS

Users should be familiar with surgical procedures and techniques involving non absorbable sutures before employing MERSILENE™ 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 infected or contaminated wounds.

In handling this or any other suture material, care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and the experience of the surgeon. The use of additional throws is particularly appropriate when knotting any monofilament suture.

Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one third (1/3) to one half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. All needles are magnetizable and should therefore not be used in an active magnetic field. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in Sharps' containers. Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to infection or transmission of bloodborne pathogens to patients and users.

#### ADVERSE REACTIONS

Adverse reactions associated with the use of this device include minimal, initial inflammatory tissue reaction and transient local irritation at the wound site. Like all foreign bodies MERSILENE™ may potentiate an existing infection.

#### STERILITY

MERSILENE™ sutures are sterilized by irradiation. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened, unused sutures!

#### STORAGE


No special storage conditions required. Do not use after expiry date!

#### SYMBOLS USED ON LABELLING

 = Do not reuse

 = Number of units

 = Use by – year and month

 = Sterile unless package is damaged or opened.  
Method of sterilization: Irradiation

 0086 = CE mark and identification number of Notified Body.  
The product meets the essential requirements of Medical Device Directive 93/42/EEC

 = Batch number

 = Caution: See instructions for use

 = Manufacturer

 = Catalogue Number

 = Authorised Representative in the European Community