Meril
Endo Surgery

Meril Endo Surgery Private Limited

NON-ABSORBABLE POLY(ETHYLENE TEREPHTHALATE) SURGICAL SUTURE U.S.P.

MERICRON XL™

INSTRUCTION FOR USE

CE 0297

ME/eIFU/EN/E/020
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PANTONE 279 C PANTONE 1235 C PANTONE 137 C PANTONE 137 C(40%) BLACK

DESCRIPTION

MERICRON XL™ suture is a coated, braided, non-absorbable sterile surgical suture composed of poly (ethylene terephthalate). The empirical molecular formula of the polymer is $(C_{10}H_8O_4)_n$. The suture is coated with bees wax / silicon which acts as a lubricant to mechanically improve the ease of passage through tissue and the overall handling quality of the suture.

MERICRON XL™ is available undyed or dyed green with D & C Green No.6.

MERICRON XL™ is available in a range of gauge sizes and lengths, or attached to standard stainless steel needles of various types and sizes.

MERICRON XL™ complies with the requirements of the United States Pharmacopeia for Non Absorbable Surgical Poly (Ethylene Terephthalate) Suture and European Pharmacopeia for Sterile Poly (ethylene Terephthalate) Strand. However, it may be slightly oversize in diameter to U.S.P. requirement for some suture sizes. U.S.P. except for diameter.

INDICATIONS

MERICRON XL™ suture is intended for use in general soft tissue approximation and/or ligation including cardiovascular surgery, neurosurgery and ophthalmic procedure.

INTENDED USER GROUP

Healthcare professionals, general physicians and surgeons those perform surgery.

PATIENT TARGET GROUP

MERICRON XL™ suture is intended to be used in both men and women and all the general population including infants, children, and adults of all age groups.

INTENDED PURPOSE

MERICRON XL™ suture is intended for use as non-absorbable surgical suture in general soft tissue approximation and/or ligation.

SELECTION CRITERIA

The selection of suture for implantation depends on patient condition, surgical experience, surgical technique and wound size. The device is used by professional healthcare person only.

PERFORMANCE

MERICRON XL™ undergoes gradual encapsulation by fibrous connective tissue due to minimal initial inflammatory tissue reaction.

CONTRAINDICATIONS

None

WARNING

Surgeons should consider the in vivo performance (under 'PERFORMANCE' section) and should be familiar with surgical procedures and techniques involving non absorbable sutures before

employing MERICRON XL™ suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. In surgery of the urinary or biliary tracts, care should be taken to avoid prolonged contact of MERICRON XL™ suture with salt solutions, to prevent calculus formation.

PRECAUTION

Acceptable surgical practice should be followed for the management of contaminated or infected wounds. In handling this suture material, care should be taken to avoid damage. Avoid crushing or crimping due to the application of surgical instruments such as forceps or needle holders. Adequate knot security requires the acceptable surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon.

Care should be taken to avoid damage while 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 sharp point. Grasping in the sharp point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause needle-suture detachment, bend or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.

Users should exercise caution while handling surgical needles to avoid inadvertent needle stick injury. Discard the used needles appropriately.

ADVERSE REACTIONS

Adverse reactions associated with the use of MERICRON XL™ include transitory local irritation at the wound site or transitory inflammatory foreign body response. Like all foreign bodies, MERICRON XL™ may enhance an existing infection.

STERILITY

MERICRON XL™ sutures are sterilized by irradiation as indicated on the package. Do not resterilize. Do not use if package is opened or damaged. Discard opened remaining unused sutures as per the local area discard procedure!

STORAGE

Recommended storage conditions: Between 15°C and 30°C, away from moisture and direct heat. Do not use after expiry date.

RISK OF REUSE

The product is instructed to be used single time only. If used multiple times it may lead to cross contamination / infection.

DEVICE LIFETIME

The effective lifetime of the MERICRON XL™ suture is 7 to 60 days.

DISPOSAL OF PRODUCT

Disposal of the unused/used product and packaging should be carried out

in accordance with hospital, administrative and/or local government policy.

SSCP SUMMARY

A summary of safety and clinical performance for MERICRON XL™ Suture can be found at the following link (once the EUDAMED will be activated.)

https://ec.europa.eu/tools/eudamed

"Contact Meril Endo Surgery Pvt. Ltd. and Competent authority of the member state in case of any serious incident occur with the device"

SYMBOLS USED ON LABELLING

 = Do Not Reuse

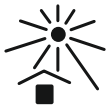
= Date of manufacture

 = Use By (Use until Year & Month)

LOT = Batch code (Number)

= Consult electronic instructions for use

= Do Not Resterilize

 = Keep away from Sunlight

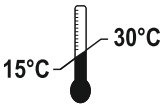
 = Do Not use if Package is damaged

 = Dyed / Braided Coated / Nonabsorbable

 = Undyed / Braided Coated / Nonabsorbable

 = Manufacturer

STERILE R = Sterilized using irradiation



= Temperature limit (Store between 15 °C and 30 °C)

 = Keep Dry

 = Caution

 = Single sterile barrier system with protective packaging outside

MD = Medical Device

MR = MR Safe

UDI = Unique device identifier

PET = Polyester

= CE mark and Identification number of Notified Body

EC REP = Authorised Representative in the European community