Meril
Endo Surgery

Meril Endo Surgery Private Limited

ABSORBABLE POLY(GLYCOLIDE/L-LACTIDE) SURGICAL SUTURE U.S.P.

MITSU™

INSTRUCTION FOR USE

CE 0297

ME/eIFU/EN/E/003
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PANTONE 279 C PANTONE 1235 C PANTONE 271 C PANTONE 271 C(40%) BLACK

DESCRIPTION

MITSU™ is a braided coated synthetic absorbable sterile poly(glycolide/l-lactide) surgical suture. It is composed of a copolymer made from 90% glycolide and 10% L-lactide.

MITSU™ sutures are coated with a mixture containing equal parts of copolymer of glycolide and lactide and calcium stearate. The empirical formula of the copolymer is $(C_2H_2O_2)_m$ $(C_3H_4O_2)_n$ and calcium stearate is $C_{36}H_{70}O_4Ca$.

Poly(glycolide/l-lactide) copolymer and poly(glycolide/l-lactide) with calcium stearate exhibit non-pyrogenic properties. MITSU™ sutures are available in undyed and dyed (D and C violet No. 2) form.

Available in a broad range of suture sizes and lengths, MITSU™ comes with standard stainless steel needles of varying types and sizes. MITSU™ complies with the "Absorbable Surgical Suture" requirements as per the United States Pharmacopeia (U.S.P.) and "Sterile Synthetic Absorbable braided Strands" requirements as per the European Pharmacopeia (E.P.). However, it may be slightly oversize in diameter to U.S.P. requirement for some suture sizes.

U.S.P. except for diameter.

INDICATIONS

MITSU™ sutures are intended for use in general soft tissue approximation and/or ligation. The safety and effectiveness of MITSU™ sutures in microsurgery and cardiovascular have not been established.

INTENDED USER GROUP

MITSU™ sutures are intended to be used by Healthcare professionals, general physicians and surgeons who are well-trained in performing soft tissue approximation and ligation.

INTENDED TARGET GROUP

MITSU™ sutures are intended to be used in both men and women including adults and elderly age groups.

INTENDED PURPOSE

MITSU™ suture is intended for use in general soft tissue approximation and/or ligation.

SELECTION CRITERIA

The selection of suture for implantation in the surgery depends upon patient condition, surgical technique, wound size, tissue characteristics and surgeon's preference. The device is used by professional healthcare person only.

PERFORMANCE

MITSU™ leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. MITSU™ gradually loses tensile strength and is finally absorbed by hydrolytic process. During hydrolysis, the copolymer degrades to glycolic and lactic acids which are then absorbed and metabolized in the body. Significant tensile strength i.e 75% of the original is retained until initial 14 days, 40% - 55% of the original is retained until initial 21 Days (6-0 and larger) & (7-0 and smaller) and 24% of the original is retained until initial 28 Days (6-0 and larger). There is a subsequent loss between four to five weeks post implantation. Complete absorption of MITSU™ suture usually takes place between 56 to 70 days.

CONTRAINDICATIONS

Being absorbable, MITSU™ Suture is not recommended where extended

approximation of tissues under stress is required. MITSU™ suture is not to be used in ligation of cardiovascular or neurological tissues. MITSU™ suture is not recommended to be used in children, infants and pregnant or breastfeeding women.

WARNINGS

Surgeons should consider the in vivo performance (under 'PERFORMANCE' section) and should be familiar with surgical procedures and techniques involving absorbable sutures before employing MITSU™ 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 MITSU™ suture with salt solutions, to prevent calculus formation.

This suture may be inappropriate in patients suffering from conditions which may delay wound healing e.g. patients that are elder, malnourished or debilitated. As this is an absorbable suture, the use of supplemental non-absorbable sutures should be considered by the surgeons in the closure of the abdomen, chest, joints or other sites subject to expansion or requiring additional support.

PRECAUTIONS

Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

Skin sutures which remain in place longer than 7 days may cause localised irritation and should be snipped off or removed.

In some cases, particularly orthopedic procedures, immobilization of joints by external support may be employed at surgeon's discretion.

In tissue with poor blood supply, care should be taken while using absorbable suture as suture extrusion and delayed absorption may occur. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with the absorption process.

In handling MITSU™ or any other 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 MITSU™ include transitory local irritation at the wound site, transitory inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures. Like all foreign bodies, MITSU™ may enhance an existing infection.

STERILITY

MITSU™ sutures are sterilized by ethylene oxide (EtO) as indicated on the package.

Do not re-sterilize! If re-sterilized, product may degrade and not perform as intended. 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.

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 MITSU™ 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)

STERILE EO = Sterilized using Ethylene Oxide

LOT = Batch Code (Number)

= Consult electronic Instructions for use

= Do not resterilize

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

= Keep away from Sunlight

= Keep Dry

= Do not use if Package is Damaged

= Caution

= Manufacturer

EC REP = Authorised Representative in the European Community

= Dyed / Braided Coated / Absorbable

= Undyed / Braided Coated / Absorbable

CE 0297 = CE mark and Identification number of Notified Body

MD = Medical Device

= Single sterile barrier systemwith protective packaging outside

UDI = Unique Device Identifier

MR = MR Safe