Meril Endo Surgery Private Limited
Artwork approval

IFU - MITSU FST
(62 X 300) mm

Date : 13.03.2025

INSTRUCTIONS FOR USE

MITSU FST™

MANUFACTURED BY

Endo-Surgery

MERIL ENDO SURGERY PVT. LTD.
Meril Park, F3 (E1-E3), Survey No.1575 and
Meril Park 2, F0, F1, F2 & F4, Survey No. 879,
Muktanand Marg, Chala, Vapi, Valsad
396191, Gujarat, India.
Customer Care No. : 18004194433,
E-mail : enquiry.endosurgery@merillife.com,
Web : www.merillife.com

CE 0297

EC REP
OBELIS S.A
Bd. Général Wahis, 53, 1030 Brussels, Belgium
T : +32 2 732 59 54 **F. :** +32 2 732 60 03
E : mail@obelis.net **W. :** www.obelis.net

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

DESCRIPTION
MITSU FST™ 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 FST™ 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 $C_{36}H_{70}O_4Ca$.
The rapid loss of strength is achieved by using polymer material with lower molecular weight than that of regular MITSU™ suture.
Poly(glycolide/l-lactide) copolymer and poly(glycolide/l-lactide) with calcium stearate exhibit non-pyrogenic properties and elicit only slight tissue reaction during absorption. MITSU FST™ sutures are available in undyed form.
Available in a broad range of suture sizes and lengths, MITSU FST™ comes with standard stainless steel needles of varying types and sizes.
MITSU FST™ 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, there may be occasional minimum oversize in diameter to U.S.P. requirement for some suture sizes. U.S.P. except for diameter.

INDICATIONS
MITSU FST™ sutures are used only where short term wound support is required and also where the rapid absorption of the suture is desirable. The rapid absorption profile is particularly useful for applications such as skin closure including episiotomy repair, closure of oral mucosa.

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

INTENDED PURPOSE
MITSU FST™ sutures are used for soft tissue approximation and/or ligation where only short term wound support is required and also where the rapid absorption of the suture is desirable.

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 FST™ leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. MITSU FST™ 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. 50% of the original is retained until initial 5 days. However, by approximately 10-14 days post implantation, the original tensile strength is completely lost. Complete absorption of MITSU FST™ suture usually takes place by 42 days.

CONTRAINDICATIONS
Due to rapid loss of tensile strength, MITSU FST™ suture should not be used where extended approximation of tissue under stress is required or wound support beyond 7 days is essential. These sutures are not to be used in ligation, cardiovascular, and neurological tissues. MITSU FST™ 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 FST™ 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 FST™ suture with salt solutions, to prevent

(CONT.)

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 FST™ 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 FST™ 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 FST™ may enhance an existing infection.

STERILITY
MITSU FST™ sutures are sterilized by irradiation 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 FST™ 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 R = Sterilized using Irradiation
LOT = Batch Code (Number)
= Consult electronic instructions for use
= Do not resterilize
= 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
= Undyed / Braided Coated / Absorbable
CE 0297 = CE mark and Identification number of Notified Body
MD = Medical Device
= Single sterile barrier system with protective packaging outside
UDI = Unique Device Identifier
MR = MR Safe

ARTWORK No.	REV.
ME/IFU/181	00

PANTONE SHADE
PANTONE 271 C
PANTONE 361 C
BLACK