Meril
Endo Surgery

Meril Endo Surgery Private Limited

NATURAL NON-ABSORBABLE SILK SURGICAL SUTURE U.S.P.

FILASILK™

INSTRUCTION FOR USE

CE 0123

ME/eIFU/EN/E/001
Rev No: 00

Issue Date: 30-04-2025

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. DOMESTIC : 18004194433, **CUSTOMER CARE NO. EXPORT** :+91-260-2408005
E : enquiry.endosurgery@merillife.com **W** : www.merillife.com

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

PANTONE 279 C PANTONE 1235 C PANTONE 311 C PANTONE 311 C(40%) BLACK

DESCRIPTION

FILASILK™ silk suture is a non-absorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. FILASILK™ sutures are processed to remove the natural waxes and gums. FILASILK™ suture is available undyed or dyed black with Logwood extract and coated with bees wax. FILASILK™ suture meets requirements established by the United States Pharmacopeia (U.S.P.) for non-absorbable surgical suture and European pharmacopeia (E.P) for sterile braided Silk strand. However, it may be slightly oversize in diameter to U.S.P. requirement for some suture sizes. U.S.P. except for diameter.

INDICATION

FILASILK™ Suture is indicated for approximation and/or ligation of Skin closure, General soft tissues, Abdominal tissues, Ophthalmic tissues.

MODE OF ACTION/ PERFORMANCE

The function of a surgical suture in wound care is to attach tissue to tissue. FILASILK™ Silk suture elicits an acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. While silk sutures are not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of all of the suture's tensile strength over time.

INTENDED USER GROUP

Healthcare professionals, cardiologists, general surgeons, gynaecologists, urologists who are performing skin closure, soft tissue approximation and ligation during various surgical procedures.

PATIENT TARGET GROUP

FILASILK™ Suture is intended to be used in both men and women and in all general populations including children, adults and elderly patients.

INTENDED PURPOSE

FILASILK™ Suture is intended to be used for skin closure and general soft tissue (internal tissue) approximation and/or ligation.

APPLICATION

FILASILK™ sutures are available in range of gauge sizes and lengths, non-needled or attached to standard stainless steel needles of varying types and sizes.

SELECTION CRITERIA

The suture should be selected and implanted depending on patient's condition, surgical experience, surgical technique, and wound size. The device is used by professional healthcare person only.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to silk. Since silk sutures experience a gradual loss of tensile strength over prolonged periods of time, it should not be used in indications where permanent retention of tensile strength is required.

Do not expose the pack of chemical disinfectants containing oxidizing agents like Hydrogen Peroxide or other similar chemicals. This may affect product quality.

WARNINGS

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 FILASILK™ 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 this or any other suture with salt solutions, to prevent calculus formation.

The safety and effectiveness of FILASILK™ suture has not been evaluated in anatomical location like heart, central circulatory system and central nervous system."

PRECAUTIONS

Acceptable surgical practice should be followed for the management of contaminated or infected wounds. In handling this 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 Reaction associated with the use of FILASILK™ Suture includes tissue reactions, transitory local irritation at wound site or transitory inflammatory foreign body response, swelling, suture toxic reaction and surgical complications may lead to fistula formation. Like all foreign bodies, FILASILK™ may contribute in enhancing an existing infection.

STERILITY

FILASILK™ sutures are sterilized by gamma radiation 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.

DEVICE LIFE TIME
FILASILK™ Suture is Long term permanent implantable device.

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 unused / used product and packaging should be carried out in accordance with hospital, administrative and / or local goverment policy.

SSCP SUMMARY
A summary of safety and clinical performance for FILASILK™ 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 with country code

= Use by (Use until Year & Month)

STERILE R = Sterilized using Irradiation

LOT = Batch Code (Number)

= Consult electronic instructions for use

= Do not resterilize

= Dyed / Braided Coated / Nonabsorbable

SILK = SILK

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

CE 0123 = CE mark and Identification number of Notified Body

MD = Medical Device

= Single sterile barrier system with protective packaging inside

MR = MR Safe

UDI = Unique Device Identifier