Meril
Endo Surgery

Meril Endo Surgery Private Limited

NON-ABSORBABLE POLYPROPYLENE SURGICAL SUTURE U.S.P.

FILAPROP™

INSTRUCTION FOR USE

CE 0297

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PANTONE 279 C PANTONE 1235 C PANTONE 278 C PANTONE 278 C(40%) BLACK

DESCRIPTION
FILAPROP™ suture is a monofilament, synthetic non-absorbable, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The molecular formula of polypropylene is $(C_3H_6)_n$.
FILAPROP™ sutures are either undyed or dyed with phthalocyanine blue.
FILAPROP™ is available in a range of gauge sizes and lengths attached to standard stainless steel needles of various types and sizes.
FILAPROP™ complies with the requirements of the United States Pharmacopeia for "Non Absorbable Surgical Suture" and the European Pharmacopeia for "Sterile Synthetic Non Absorbable monofilament Strand." However, it may be slightly oversize in diameter to U.S.P. for some suture sizes. U.S.P. except for diameter.

INDICATION
FILAPROP™ Sutures are indicated for approximation and/or ligation of:
- Skin tissue
- Soft tissues including cardiac

INTENDED USER GROUP
FILAPROP™ Sutures are intended to be used by Healthcare professionals, general physicians and surgeons who performs skin closures, soft tissue approximation and/or ligation.

INTENDED TARGET GROUP
FILAPROP™ Suture is intended to be used in both men and women and in all general populations including infants, children, and adults of all age groups.

INTENDED PURPOSE
FILAPROP™ Sutures are intended to be used for skin closure and soft tissue (internal 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
FILAPROP™ suture initially elicits a minimal inflammatory reaction in tissues followed by gradual encapsulation of the suture by fibrous connective tissue. FILAPROP™ suture is neither absorbed, nor subjected to degradation or weakening by the action of tissue enzymes. It is recommended for use in wounds where the least possible suture reaction is desired as it is relatively biologically inert. Being a monofilament suture, FILAPROP™ has been successfully employed in surgical wounds which may subsequently become infected or contaminated and thus minimising later sinus formation and suture extrusion. FILAPROP™ is effective pull-out suture due to its lower adherence to tissue.

CONTRAINDICATIONS
The use of FILAPROPTM suture is contraindicated in patients with known sensitivities or allergies to polypropylene.

WARNING
1. 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 FILAPROP™ suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. Inappropriate surgical procedures and techniques may lead to Pseudoaneurysm formation.
2. In surgery of the urinary or biliary tracts, care should be taken to avoid prolonged contact of FILAPROP™ suture with salt solutions, to prevent calculus formation.
3. Do not re-sterilize and/ or reuse FILAPROP™ suture. Reuse of FILAPROP™ suture result in device failure and/ or cross-contamination, which may lead to infection or transmission of blood borne pathogens to patients and users.
4. Use of FILAPROP™ suture beyond indications can cause poor or delayed healing and lead to various surgical complications and may not serve intended purpose.

PRECAUTION

1. Acceptable surgical practice should be followed for the management of contaminated or infected wounds. Failure to this may lead to Hemiparesis.
2. 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. Suture breakage or reduction in strength that leads to early device failure may occur due to crushing or crimping.
3. 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. Inadequate knotting may lead to suture loosening, wound perfusion, bleeding, leakage or resurgery.
4. 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.
5. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.
6. Users should exercise caution while handling surgical needles to avoid inadvertent needle stick injury.
7. Discard the used needles appropriately.
8. Broken needles may result in foreign body residual which may require additional surgery.
9. Reuse of needle may result in transmission of blood borne pathogens to patients and users.

ADVERSE REACTIONS

Adverse reactions associated with the use of FILAPROP™include

- Transitory local irritation at the wound site or transitory inflammatory foreign body response and transient inflammatory tissue reactions.
- wound dehiscence
- calculi formation in urinary or biliary tracts when prolonged contact with salt solutions such as urine or bile occurs.
- Like all foreign bodies, FILAPROP™ may contribute in enhancing an existing infection.

INFORMATION TO PATIENT

- Keep the wound site dry and clean.
- Consult the doctor if a suture opens, loosens or breaks.
- Consult the doctor in case of post operative bleeding or leakage.
- Consult doctor/ surgeon in case of persistent pain and discomfort, fever, headache, nausea and vomiting.

STERILITY

FILAPROP™ 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.

DEVICE LIFETIME
FILAPROP™ 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 government policy.

SSCP SUMMARY
A summary of safety and clinical performance for FILAPROP™ 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

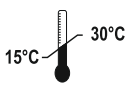

= Use by
(Use until Year & Month)

= Sterilized using
Ethylene Oxide

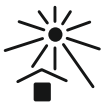
= Batch Code (Number)

= Consult electronic
instructions for use


= Do not resterilize



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


= Keep away from
Sunlight


= Keep Dry


= Do not use if Package is
Damaged


= Caution


= Manufacturer


= Dyed / Monofilament
Nonabsorbable

= Polypropylene

= Authorised Representative
in the European Community

= CE mark and Identification
number of Notified Body

= Medical Device


= Single sterile barrier
system with protective
packaging outside

= MR Safe

= Unique Device Identifier