Meril
Endo Surgery

Meril Endo Surgery Private Limited

ABSORBABLE POLY(GLYCOLIDE-CO-CAPROLACTONE) SURGICAL SUTURE U.S.P

FILAPRON™

INSTRUCTION FOR USE

CE 0297

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PANTONE 279 C PANTONE 1235 C PANTONE 197 C PANTONE 197 C(40%) BLACK

DESCRIPTION

FILAPRON™ is a sterile synthetic absorbable monofilament suture is composed of poly(glycolide-co-caprolactone). The empirical molecular formula of the polymer is $(C_2H_2O_2)_m$ $(C_6H_{10}O_2)_n$ poly(glycolide-co-caprolactone) has non-pyrogenic properties. FILAPRON™ sutures are available either in undyed or dyed (D and C violet No. 2) form.

FILAPRON™ is available in a range of gauge sizes and lengths and attached to standard stainless steel needles of varying types and sizes.

FILAPRON™ complies with the requirements of the United States Pharmacopeia for "Absorbable Surgical Suture" and the European Pharmacopeia for "Sterile Synthetic 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.

INDICATIONS

FILAPRON™ sutures are intended for use in general soft tissue approximation and/or ligation where an absorbable material is indicated.

INTENDED USER GROUP

Healthcare professionals, general physicians and surgeons those perform surgery.

PATIENT TARGET GROUP

FILAPRON™ sutures are intended to be used in both men and women.

INTENDED PURPOSE

FILAPRON™ Sutures are intended for use as absorbable surgical sutures in general soft tissue approximation and/or ligation.

SELECTION CRITERIA

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

PERFORMANCE

FILAPRON™ leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. FILAPRON™ gradually loses tensile strength and is finally absorbed by hydrolytic process. During hydrolysis, the copolymer degrades to adipic acid which are then absorbed and metabolized in the body. In dyed FILAPRON™ suture, significant tensile strength i.e 60-80% of the original is retained until initial 7 days and 30-40% of the original is retained until initial 14 days. In undyed FILAPRON™ suture, significant tensile strength, i.e.: 50-60% of the original is retained until initial 7 days and 20-30% of original is retained until initial 14 days. The initial tensile strength is essentially lost by 28 days post-implantation for dyed suture while for undyed sutures the initial tensile strength is essentially lost by 21 days post-implantation. Complete absorption of FILAPRON™ dyed and undyed suture usually takes place between 90 to 120 days.

CONTRAINDICATIONS

These sutures (Dyed and Undyed) should not be used where extended approximation of tissues under stress is required. However, FILAPRON™ undyed must not be used for abdominal or facial tissue closure These sutures can not be used in opthalmic surgery,cardiovascular Surgery and central nervous System.

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 FILAPRON™ 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 FILAPRON™ 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 that must be in a place for longer than 7 days may cause localised irritation and therefore should be snipped off or removed as indicated.
In some cases, particularly orthopaedic 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 erythema and induration normally associated with the absorption process.
In handling FILAPRON™ 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 FILAPRON™ 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, FILAPRON™ may contribute in enhancing an existing infection.

STERILITY
FILAPRON™ 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

The effective life time of the device is 7 - 21 days.

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 FILAPRON™ 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

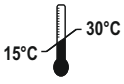
 = Use by (Use until Year & Month)

= 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

 = Manufacturer

 = Do not use if Package is Damaged

 = Caution

= Authorised Representative in the European Community

 = Dyed / Monofilament / Absorbable

 = Undyed / Monofilament / Absorbable

= Polyglycolic Acid Caprolacton

= CE mark and Identification number of Notified Body

= Medical Device

 = Single sterile barrier system with protective packaging outside

= Unique Device Identifier

= MR Safe