Meril
Endo Surgery

Meril Endo Surgery Private Limited

ABSORBABLE POLY(P-DIOXANONE) SURGICAL SUTURE U.S.P.

FILAXYN™

INSTRUCTION FOR USE

CE 0297

ME/eIFU/EN/E/007
Rev No: 00

Issue Date: 19-06-2025

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PANTONE 279 C PANTONE 1235 C PANTONE 7543 C PANTONE 7543 C(40%) BLACK

DESCRIPTION

FILAXYN™ is a sterile synthetic absorbable monofilament suture composed of Poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_n$.

Polydioxanone polymer has non-pyrogenic properties. FILAXYN™ sutures are available in undyed or dyed (D and C Violet No.2) form. FILAXYN™ is available in a range of gauge sizes and lengths, attached to standard stainless steel needles of varying types and sizes.

FILAXYN™ 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

FILAXYN™ sutures are intended for use in general soft tissue approximation including use in ophthalmic surgery. These sutures are particularly useful where an absorbable suture with prolonged wound support (up to 42 days) is required.

INTENDED USER GROUP

Healthcare professionals, general physicians and surgeons those perform surgery.

PATIENT TARGET GROUP

FILAXYN™ Suture is intended to be used in both men and women and all the general population including infants, children, and adults of all age groups for soft tissue approximation and/or ligation.

INTENDED PURPOSE

FILAXYN™ suture is intended for use as an absorbable surgical suture in general soft tissue approximation and/or ligation.

SELECTION CRITERIA

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

PERFORMANCE

FILAXYN™ leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. FILAXYN™ gradually loses tensile strength and is finally absorbed by hydrolytic process. During hydrolysis, the copolymer degrades to monomeric acid (2-hydroxyethoxyacetic acid) which are then absorbed and metabolized in the body. Significant tensile strength i.e 71% of the original is retained until initial 14 days, 54% of the original is retained until initial 28 days and 33% of the original is retained until initial 42 days. There is a subsequent minimal absorption until about 90th post implantation day and complete absorption usually takes place between 180-220 days.

CONTRAINDICATIONS

- These sutures being absorbable, should neither be used where prolonged (beyond 42 days) approximation of tissues under stress is required nor in conjunction with prosthetic devices, for example heart valve or synthetic grafts.
- Suture cannot be used for direct contact with the heart, the central circulatory system or the 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 FILAXYN™ 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 FILAXYN™ 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.
Conjunctival, cuticular and vaginal epithelium sutures which remain in place longer than 10 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 FILAXYN™ 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 FILAXYN™ 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, FILAXYN™ may contribute in enhancing an existing infection.

STERILITY
FILAXYN™ 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 lifetime of the FILAXYN™ suture is 7 to 42 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 FILAXYN™ 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

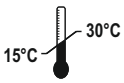
 = Use by (Use until Year & Month)

= 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

= PDO

= CE mark and Identification number of Notified Body

= Medical Device

 = Single sterile barrier system with protective packaging outside

= Unique Device Identifier

= MR Safe