Meril
Endo Surgery

Meril Endo Surgery Private Limited

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

FILAMIDE™

INSTRUCTION FOR USE

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DESCRIPTION

FILAMIDE™ suture is a non-absorbable, sterile, synthetic, monofilament surgical suture composed of polyamide 6 [(NH-CO-$(CH_2)_5$]n and Polyamide 6,6 (NH$(CH_2)_6$-NH-CO-$(CH_2)_4$-CO)n. FILAMIDE™ sutures are either undyed or dyed with logwood extract.

Available in a broad range of suture sizes and lengths, FILAMIDE™ is either non-needled or attached to standard stainless steel needles of varying types and sizes.

FILAMIDE™ complies with the "Non absorbable suture (Polyamide Surgical Suture)" requirements as per the United States Pharmacopeia (U.S.P.) and "Sterile Polyamide 6,6 Strand" and "Sterile Polyamide 6 Strand" requirements as per the European Pharmacopeia (E.P.). However, it may be slightly oversize in diameter to U.S.P. requirement for some suture sizes. U.S.P. except for diameter.

INDICATION

FILAMIDE™ suture is indicated for approximation and/or ligation of Skin tissue, General soft tissue, Vascular tissue, Ophthalmic tissue

INTENDED USER GROUP

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

PATIENT TARGET GROUP

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

INTENDED PURPOSE

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

SELECTION CRITERIA

The suture should be selected and implanted depending on patient's condition, surgical experience, surgical technique, and wound size. Normally the skin sutures are removed within 30days depending on wound condition. The decision of physician is final in removing the skin sutures. The device is used by professional healthcare person only.

PERFORMANCE

FILAMIDE™ undergoes gradual encapsulation by fibrous connective tissues due to minimal initial inflammatory tissue reaction. While polyamide is not absorbed, progressive hydrolysis of the polyamide in vivo may result in gradual loss of tensile strength over time.

CONTRAINDICATIONS

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, FILAMIDE™ suture should not be used where permanent retention of tensile strength is required e.g. in fixation of intraocular lenses or synthetic vascular grafts.

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 FILAMIDE™ 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 FILAMIDE™ suture with salt solutions, to prevent calculus formation.

The safety and effectiveness of FILAMIDE™ 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 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 FILAMIDE™ Suture includes tissue reactions, transitory local irritation at wound site or transitory inflammatory foreign body response, Like all foreign bodies, FILAMIDE™ Suture may contribute in enhancing an existing infection.

STERILITY

FILAMIDE™ sutures are sterilized by gamma radiation as indicated on the package. Do not resterilize. 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

FILAMIDE™ suture is Long term permanent implantable device.

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 FILAMIDE™ 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

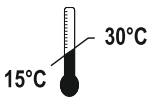

= Use by
(Use until Year & Month)

= Sterilized using Irradiation

= 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


= Dyed / Monofilament
Nonabsorbable

= Polyamide

= Authorised Representative
in the European Community

= CE mark and Identification
number of Notified Body

= Medical Device


= Single sterile barrier system
with protective packaging
inside

= MR Safe

= Unique Device Identifier