INSTRUCTIONS FOR USE

FILAXYN™

MANUFACTURED BY

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FILAXYN™
ABSORBABLE POLY(P-DIOXANONE) SURGICAL SUTURE

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.

SELECTION CRITERIA

The selection of suture for implantation depends upon patient condition, surgical technique, wound size, tissue characteristics and surgeon's preference.

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 75% of the original is retained until initial 14 days (4-0 & smaller) , 78% of the original is retained until initial 14 days (3-0 & larger), 66% of the original is retained until initial 28 days (4-0 & smaller) and 69% of the original is retained until initial 28 days (3-0 & larger). 53% of the original is retained until initial 42 days (4-0 & smaller) and 57% of the original is retained until initial 42 days (3-0 & larger) 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.

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

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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!

STORAGE

Recommended storage conditions: Between 15°C and 30°C, away from moisture and direct heat. Do not use after expiry date.

RISK OF REUSE

The product is instructed to be used single time only. If used multiple times it may lead to cross contamination / infection.

SYMBOLS USED ON LABELLING


= Do not reuse


= Date of Manufacture


= Use by
(Use until Year & Month)

= Sterilized using Ethylene Oxide

= Batch Code (Number)


= Consult Instruction 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

= Authorised Representative in the European Community

= CE mark and Identification number of Notified Body