



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

INSTRUCTION FOR USE



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Device Category: Non-Absorbable Polypropylene Monofilament Surgical Suture

Trade Names: AQLENE

Product Description:

Suture:

Monofilament Polypropylene Sterile Non-Absorbable surgical suture U.S.P is a, synthetic composed linear polyolefin, polypropylene. Monofilament Polypropylene sterile Non- Absorbable Surgical Suture U.S.P is coloured blue, dyed with Phthalocyanine Copper blue (colour index no.74160), and U.S.F.D.A approved dye. Monofilament Polypropylene sterile Non-Absorbable Surgical Suture U.S.P also be supplied with PTFE (Polytetrafluoroethylene) pledgets for use as a pad between the suture and the tissue surface to increase the load bearing area.

Monofilament Polypropylene sterile Non-Absorbable Surgical Suture U.S.P complies with the requirements of the European Pharmacopoeia (EP) for Sterile Non-Absorbable suture and United States Pharmacopeia (USP) for Non-Absorbable Surgical Suture.

Needle:

The surgical needle attached to the suture acts as a delivery device designed to carry the suture through tissue to facilitate soft tissue approximation and/or ligation. It is constructed from Stainless Steel grade SS 302. The structural anatomy of the surgical needle consists of the needle point, the needle body, and the swage (the attachment end where the suture is secured). Key dimensional design parameters include the needle length, needle chord length, needle radius, and wire/needle diameter. To accommodate various surgical applications and tissue types, the needle designs include multiple point and body profiles such as Round Body (Taper Point), Reverse Cutting, Conventional Cutting, Taper Cutting, and Round Body Blunt Point. Furthermore, the needle design encompasses a variety of curvatures, including 1/2 Circle, 3/8 Circle, 1/4 Circle, 5/8 Circle, Straight Needle, J Shape, Ski Needle, and Compound Curve.

Intended Purpose:

Monofilament Polypropylene sterile Non-Absorbable Surgical Suture U.S.P is intended for use in soft tissue approximation and/or ligation.

Indication:

The device is indicated for wound closure and ligation during surgical procedures.

Contraindication:

The use of this suture is contraindicated in patients with known sensitivities or allergies to polypropylene, Phthalocyanine Copper Monofilament Polypropylene suture is contraindicated for use in lactating mothers, pregnant women and paediatric population.

Intended users:

Surgeons who know the surgical technique and procedure for non-absorbable sutures.

Intended patient population:

The device is intended for use in adult patients (≥ 18 years), both male and female, requiring wound closure and ligation during surgical procedures.

The safety and performance of this device have not been established for paediatric patients (< 18 years), pregnant women, or breastfeeding women. No specific limitations are identified for use in elderly patients; however, caution should be exercised in patients with conditions that may impair wound healing, including elderly patients, malnourished patients, or patients with malignancy.

Performance:

Monofilament Polypropylene sterile Non-Absorbable Surgical Suture U.S.P is not absorbed nor is it subjected to degradation or weakening by the action of enzymes. The device (suture) may be used permanently or for temporary fixation which is decided by the surgeon/ doctor depending on the area or type of usage. Depending upon the nature of the wound the follow up will be decided by the doctor. In case the suture is used superficially then the wound management instruction should be given by the surgeon.

Applications:

Monofilament Polypropylene sterile Non-Absorbable Surgical Suture U.S.P should be selected and implanted depending on the patient's condition, surgeon experience, wound size and surgical technique used for that particular procedure.

Residual risks:

- Surgical site infection
- Wound dehiscence
- Infection
- Allergic reaction
- Inflammation

Side effects:

Local inflammatory tissue reaction, local transitory irritation in response to foreign body, erythema or induration, wound dehiscence.

Material of Construction:

Monofilament Polypropylene sterile Non-Absorbable Surgical Suture U.S.P is composed of linear polyolefin, Polypropylene. The needle is made up of Stainless Steel 300 series Monofilament Polypropylene suture dyed with Phthalocyanine Copper blue

Device Dimensions:

Monofilament Polypropylene suture is available in U.S.P. sizes, 12-0 to 5 (0.01 metric to 7 metric).

Sterility:

Monofilament Polypropylene suture are sterilized by ethylene oxide. Do not re – sterilize. Do not use if package is opened or damaged. Discard opened unused sutures.

Storage:

Recommended storage conditions: temperature 0 - 30°C, keep away from moisture and sunlight/ heat. Do not use after expiration date.

Shelf Life:

The product has a shelf life of 05 years.

Summary of Safety and Clinical Performance Referred:

Summary of Safety and Clinical Performance (Doc No: AMPLSSCP-11). The link will be provided here once EUDAMED is fully functional. The SSCP will be provided to the public upon request from users.

Precautions:

- When handling this or any other suture, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or sharp needle holders.
- Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard the used needle in designated biohazard “sharps” containers.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- 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 point.

Warnings:

- This suture may be inappropriate in patients suffering from conditions which may delay wound healing e.g., patient that are elder, malnourished, cancer.
- For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury or illness.
- Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Surgeons should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing suture for wound

closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

Supply:

Monofilament Polypropylene sterile Non-Absorbable Surgical Suture U.S.P is available in various U.S.P. sizes and E.P Metric sizes. Sutures are supplied sterile in pre-cut lengths, both non needled and attached to various needle type, shape and length. Sutures are packed in a printed box with quantity indicated on the box label.

Disposal:

Discard used sutures and needles contaminated with blood in the container meant infectious waste. Opened pack, unused sutures, unused expired packs should be incinerated. Follow the local governing laws for disposal.

Notes for Users and Patients:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Note: To open the package, carefully tear along the perforated line marked ‘Tear’.

Symbols used on Label

	Manufacturer
	Model number
	Do not re-use
	Date of manufacture
	Sterilized using ethylene oxide
	Temperature limit
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Single Sterile barrier system with protective packaging inside.
	Catalogue number
	Authorized representative in the European Community European Union
	Batch code
	Use-by date
	Do not re-sterilize
	Consult instructions for use
	Keep dry
	Caution: See Instruction for Use
	Medical device
	Country of Manufacturer
	Unique device identifier
	European conformity mark and identification of Notified Body