AQMEN®

Aqlon® (AQLON)

MONOFILAMENT POLYAMIDE NYLON STERILE NON-ABSORBABLE SURGICAL SUTURE U.S.P.

INSTRUCTION FOR USE

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Registered Office :
AQMEN MEDTECH PVT. LTD.
#205, Brigade Rubix, 2nd Floor,
HMT Road, Yeshwanthpur Hobli,
Jalahalli, Bangalore, Bangalore North,
Karnataka, India, 560013
Email: customercare@aqmen.co.in
Lic No:MFG/MD/2024/000629
Customer care # +91-080 23245324

EU REP
Amstermed B.V.
Burnhamstraat 279, Unit 032
2132 GZ Hoofddorp
The Netherlands
Email: info@amstermed.nl
Website: https://www.amstermed.nl

Manufactured at:
AQMEN MEDTECH PVT. LTD.
Sy No. 68/69, Varadanahalli Village,
Bashettihally Gram Panchayat,
Kasaba Hobli,Doddaballapur,
Bengaluru Rural, Karnataka, 561203
Email : customercare@aqmen.co.in
Lic No:MFG/MD/2024/000629
Customer care # +91-080 23245324

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Device Category: Non-Absorbable Polyamide (Nylon) Monofilament Surgical Suture.

Trade Names: AQLON

Product Description:

Suture:

Monofilament Polyamide (Nylon) Sterile Non-Absorbable surgical suture U.S.P is a, monofilament, synthetic, surgical suture composed of polyamide 6 and polyamide 6,6 (Nylon 6 & Nylon 6,6). Monofilament Polyamide (Nylon) Sterile Non- Absorbable surgical suture U.S.P is available in black and blue, black colour dyed with Hematine HCK and blue colour dyed with FD & C Blue 2(Conforming to US code of Regulations) to enhance visibility in the surgical field. Monofilament Polyamide Suture is available in a range of gauge sizes and lengths, non-needled or attached to needles of various types and sizes, and in presentations as described in the how supplied section.

Monofilament Polyamide (Nylon) 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 Polyamide (Nylon) Sterile Non-Absorbable Surgical Suture U.S.P is indicated 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 Polyamide. Monofilament Polyamide Suture is contraindicated for use in paediatric, lactating mothers and pregnant women.

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 Polyamide (Nylon) 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 Polyamide (Nylon) 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 Polyamide (Nylon) Sterile Non-Absorbable surgical suture U.S.P is composed of polyamide 6 and polyamide 6,6 (Nylon 6 & Nylon 6,6) The needle is made up of Stainless Steel 300 series Monofilament Polyamide suture is dyed: black colour-dyed with Hematein-Black logwood and blue colour-dyed with FD & C BLUE 2.

Device Dimensions:

Monofilament Polyamide (Nylon) Sterile Non-Absorbable surgical suture U.S.P is available in U.S.P. sizes, 12-0 to 5 (0.01metric to 7 metric).

Sterility:

Monofilament Polyamide sutures 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 condition 0 - 30°C, away from moisture and direct sunlight/heat. Do not use after expiry 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-12). 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 Polyamide (Nylon) 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 resterilize**
	**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**