

# Dafilon®

**Caution: Federal (USA) law restricts this device to sale or use by or on the order of a physician.**

## Description

Dafilon® is a sterile, monofilament, non-absorbable surgical suture material produced from polyamide. Dafilon® is available in blue (polyamide 6/6.6), coloured with [Phthalocyaninato(2-)] copper at a concentration of  $\leq 0.5\%$  by weight of the suture, or in black (polyamide 6/6), coloured with Logwood extract at a concentration of  $\leq 1.0\%$  by weight of the suture to make it more readily recognizable. Dafilon is also available undyed in the natural beige colour. Dafilon® fulfils all the requirements of the European Pharm. and the United States Pharm. current edition for sterile, nonabsorbable sutures.

## Indications

Dafilon® Nonabsorbable Polyamide Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neurological procedures.

## Mode of action

Suture materials are used primarily for adaptation of the wound edges to render possible an undisturbed wound healing. When Dafilon® suture materials are employed, a minimal inflammatory tissue reaction will occur followed by a gradual encapsulation of the suture material by fibrous connective tissue.

Like all polyamide materials, over a long period of time Dafilon® in vivo is subject to a gradual loss of total suture strength through the action of body enzymes.

## Contra-indications

On account of the gradual loss of strength, which can occur in vivo over a longer period, the use of Dafilon® is contraindicated when a permanent retention of suture strength is of importance.

## Warning note

- Do not resterilize. Sterile unless packaging has been opened or damaged.
- Single use only. Discard opened packages and unused sutures.
- Users should be familiar with surgical suturing techniques, before employing Dafilon® suture materials for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.
- As with all other suture materials, long contact with salt solutions such as urine and bile, can lead to lithiasis.
- Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

## Precautions

- When working with Dafilon® suture materials great care should be taken to ensure that the use of surgical instruments, such as forceps and needle holders, do not cause any crushing or crimping damage to the suture material. Adequate knot security requires the standard surgical technique of flat, square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon.
- Avoid prolonged exposure to elevated temperatures.
- Care should be taken to avoid damage when 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. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury
- Discard needles in "Sharps" containers.

**Adverse reactions**

Adverse effect associated with the use of this device include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solution occurs, enhanced bacterial infectivity, infection, minimal acute inflammatory reaction and transitory local irritation. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

**Application**

Sutures should be selected depending on the tissue to be sutured, the specific duration of wound support needed, the size of the wound, the patient's condition and the specific suturing technique.

**Sterilization**

Dafilon® is sterilized by gamma radiation and ethylene oxide gas. Do not resterilize the sutures. In case that the individual suture container has been damaged or opened before the actual use, discard the affected suture.

**Storage**

Store at room temperature. Avoid exposure to extreme temperatures over a long period of time. Do not use after the expiry date.

**How supplied**

Dafilon® polyamide sutures are available in USP 2 to 11/0 (metric 5 to 0.1). The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needled or attached to various types of stainless steel needles, with permanent needle attachment techniques. The boxes contain 1, 2 or 3 dozens of sutures.

**CUSTOMER SERVICE**

For further information regarding Dafilon® Suture please contact Tissue Seal, LLC's Customer Service at 1-877-754-6458 or [customerservice@tissue seal.com](mailto:customerservice@tissue seal.com)

Distributed by:

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