

## Optilene® Instructions for use

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



The Optilene Nonabsorbable Polypropylene/Polyethylene Surgical suture is MR Safe.

### Description

Optilene® is a sterile, non-absorbable, monofilament surgical suture material produced from polypropylene and polyethylene. Optilene® is coloured blue with copper phthalocyanine [Phthalocyaninato(2-)copper] for better visibility. Optilene® fulfils all the requirements of the European Pharm. and the United States Pharm. current edition for sterile, non-absorbable sutures. Optilene® sutures are available in USP 2 to 10/0 (metric 5 to 0.2), cut to different lengths and attached to various types and sizes of stainless steel needles. Optilene® is available with pledgets. The pledgets are made from 100% polytetrafluoroethylene (PTFE).

### Indications

Optilene® sutures are indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.

### Actions

Optilene® suture materials are used primarily for adaptation of the wound edges to render possible an undisturbed wound healing. When Optilene® suture materials are employed, there is a mild acute inflammation reaction, which is typical for an endogenous reaction to a foreign body. As time passes the suture material is encapsulated by fibrous connective tissue. Optilene® is not absorbed, nor is any significant change in tensile strength known to occur in vivo.

### Contraindications

None known.

### Warnings

- Do not resterilize. Sterile unless packaging has been opened or damaged.
- Single use only. Discard opened packages and unused sutures.
- Do not use after expiry date.
- Users should be familiar with surgical suturing techniques, before employing Optilene® 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 should be followed for the management of contaminated or infected wounds.

### Precautions

- When working with Optilene® 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. The use of additional throws may be particularly appropriate when knotting monofilaments.
- 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 used needles in “Sharps” containers.

### **Adverse reactions**

Adverse effect associated with the use of this Optilene® include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solution such as urine and bile occurs, enhanced bacterial infectivity, 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**

Optilene® is sterilized by 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**

Optilene® sutures are available in USP 2 to 10/0 (metric 5 to 0.2). The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needed or attached to various types of stainless steel needles, with permanent or removable (take-off) needle attachment techniques. The boxes contain 4, 6, 24 or 36 sutures.

Optilene® is supplied sterile.

### **CUSTOMER SERVICE**

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

Distributed by:

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