

## Instructions for use

### Monosyn® Quick

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

#### Description

Monosyn® Quick is a sterile, synthetic, absorbable, monofilament surgical suture material made from a triblock copolymer comprising glycolide (72%), ε- caprolactone (14%) and trimethylene carbonate (14%), which is only available unpigmented. A polymer, with a lower molecular weight than the one used for regular Monosyn®, provides Monosyn® Quick with the characteristic rapid loss of tensile strength. Monosyn® Quick complies with all the requirements of the European Pharmacopoeia and the American Pharmacopoeia for sterile, absorbable, monofilament synthetic strands, apart from slight deviations in the diameter of the strand.

#### Maximum Suture Oversize in Diameter (mm) From USP

USP suture size designation	Maximum oversize (mm)
6-0	0.026
5-0	0.034
4-0	0.036
3-0	0.036
2-0	0.036
0	0.036
1	0.046

#### Indications

Monosyn® Quick Synthetic Absorbable Surgical Suture is intended for general soft tissue approximation of the skin and mucosa, where only short term wound support (6-7 days) is required. Monosyn Quick suture is not indicated for use in cardiovascular or neurosurgery.

#### Actions

There is a very slight inflammatory reaction typical of the normal tissue reaction to foreign bodies after the application of Monosyn® Quick. Hydrolysis results initially in a loss of tensile strength, followed by absorption of the Monosyn® Quick filaments. Studies *in vitro* demonstrate that approximately 60-70% of the original tensile strength remains after 5 days of implantation. At 10 days, 25-35% of the original tensile strength remains. All of the original tensile strength is lost by approximately at 14-21 days post-implantation.

	<b>Approximated remaining tensile strength</b>
<b>5 days</b>	60-70%
<b>7 days</b>	45-60%
<b>10 days</b>	25-35%
<b>14 days</b>	7-11%
<b>21 days</b>	2-8%

The *in vivo* study showed that mass absorption of Monosyn® Quick is essentially completed after 56 days, when the tissue is normally perfused.

### **Contraindications**

Monosyn® Quick is contraindicated for the adaptation of tissues that are under tension and for fixing synthetic/biologic implants. Monosyn® Quick is unsuitable, if wound support is required for more than 7 days. Monosyn Quick is not intended for ligations.

### **Warning note**

- Do not resterilized. 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 the surgical procedures and techniques involving absorbable sutures when using Monosyn® Quick, as the risk of wound dehiscence may vary depending upon the site of application and the type of material used.
- Usage of Monosyn® Quick may not be advised in case of elderly or malnourished or debilitated patients, or in patients suffering from diseases or conditions which delay the wound healing process.
- Delayed absorption is possible in poorly perfused tissues.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention, or which may require additional support.
- As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts may result in calculus formation.
- As an absorbable suture, Monosyn® Quick suture may act transiently as a foreign body.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

### **Precautions**

- Skin sutures which remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.
- Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply 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.
- When working with Monosyn® Quick 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.
- 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.
- Monosyn® Quick should be used applying the standard surgical suturing and knotting techniques, taking into account the surgeon’s experience with the respective surgical procedure. Care should be taken that the knots are positioned properly and adequate knot security is given.

### **Adverse Reactions**

Adverse effects associated with the use of Monosyn® Quick include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. 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**

To be used in accordance with surgical requirements:

The suture material is selected on the basis of the wound size, the condition of the patient, the suturing technique and the experience of the surgeon.

### **Sterilization**

Monosyn® Quick is sterilized using ethylene oxide. 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**

Monosyn® Quick sutures are available in USP 1 to 6/0 (metric 4 to 0.7). 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 Monosyn® Quick 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:

**Tissue Seal, LLC**

4401 Varsity Drive, Suite D  
Ann Arbor, MI 48108 – U.S.A.

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