

## **Safil® Quick**

### **Description**

Safil® Quick is a synthetic absorbable sterile surgical suture material made of polyglycolic acid. A polymer, with a lower molecular weight than the one used for regular Safil®, provides Safil® Quick with the characteristic rapid loss of tensile strength. Safil® Quick sutures are available undyed.

The braided threads are treated with a coating so that they slide easily without causing a sawing effect. Safil® Quick fulfils all of the requirements of the European and American Pharmacopoeias current edition for sterile synthetic braided absorbable sutures.

Episio-Set consists of three needle-thread Safil® Quick combinations for closure of episiotomy.

### **Indications**

Safil Quick suture is indicated for use in general soft tissue approximation, including ophthalmic (e.g. conjunctiva) procedures, but not in cardiovascular or neurological procedures.

### **Mode of action**

Suture materials are used primarily for adaptation of the wound edges to render possible and undisturbed wound healing.

During the use of Safil® Quick sutures a mild inflammatory reaction may occur, which is typical of an endogenous reaction to foreign bodies. As time passes the suture material is encapsulated by fibrous connective tissue. Safil® Quick is metabolised to glycolic acid by hydrolysis without causing any enduring change in the region of the wound. Absorption begins as a decline in tensile strength followed by a loss of mass.

Subcutaneous and intramuscular implantation studies of Safil® Quick show that at 5 days post-implantation approximately 50% of the initial tensile strength remains and 14 days post-implantation almost all of the initial tensile strength is lost. Most of the suture mass absorption of Safil® Quick takes place after approximately 42 days, except sizes larger than USP 2/0 which are essentially absorbed after 56 days.

### **Contraindications**

Due to its rapid loss of tensile strength, Safil® Quick suture materials are contraindicated where extended approximation of tissues under stress is required or where prolonged support of wound closure is required. Use of Safil® Quick suture is contraindicated for ligation, and in cardiovascular or neurological procedures.

### **Warnings note**

The users should be familiar with surgical procedures and techniques involving absorbable sutures before using Safil® Quick synthetic absorbable suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions what may delay wound healing.

As with any foreign body, prolonged contact of this or any other suture with salt solutions such as those found in the urinary or biliary tracts may result in calculus formation.

Do not resterilize. Open, unused or damaged packs should be discarded. Store at room temperature. Do not expose to extreme temperatures for a prolonged period of time.

Accepted surgical practice should be followed with respect to drainage and closure of contaminated or infected wounds.

As this is an absorbable suture, the use of supplemental nonabsorbable suture should be considered by the surgeon in the closure of sites which may undergo expansion, stretching, or distension, or which may require additional support.

#### **Note/precautionary measures**

Great care must be taken when working with Safil® Quick in order to avoid damage as a result of crushing or snapping, due to the use of surgical instruments such as tweezers and needle holders. The user should be familiar with surgical suturing techniques, before employing Safil® Quick suture material. As with any suture material, adequate knot security requires the accepted surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Skin sutures which must 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. Under some circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

To avoid damaging needles points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should be careful when handling surgical needle to avoid inadvertent needle sticks. Discard needles in "sharps" containers.

#### **Adverse reactions**

Adverse effects associated with the use of this device 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 that may delay wound healing, wound infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures in place for longer than 7 days, calculi formation in urinary and biliary tracts when prolonged contact with urine or bile occurs, 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.

#### **How Supplied**

Safil Quick synthetic absorbable surgical suture is available in sizes USP 2 to 7/0 (metric 5 to 0,5). The sutures are supplied sterile, attached to needle, with permanent or removable (takeoff) needle attachment techniques. The boxes contain 1, 2 or 3 dozens of suture.

#### **Caution**

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

### Symbols used on labeling



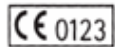
Do not reuse



Use by: Year + Month



Sterile unless package is opened or damaged. Method of Sterilization - Gamma radiation



CE-mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.



Batch number



See instructions for use

REF

Cat. No.

### CUSTOMER SERVICE

For further information regarding Safil® Quick Sutures please contact Aesculap, Inc. Customer Service at 1-800-282-9000.

Distributed by:

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