GIMA Trusynth Fast Instructions

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GIMA Trusynth Fast

DESCRIPTION

Trusynth Fast is an absorbable, sterile, surgical suture, composed of a co-polymer, made from 90% Glycolide and

10% Lactide, Polyglactin 910. Trusynth Fast is available as undyed. For added lubrication and smoothness, Trusynth Fast is coated with unique combination of Polyglactin 370 and Calcium Stearate. Trusynth Fast meets all the require- ments, established by the United States Pharmacopeia for Absorbable Surgical suture (Synthetic) except for diame- ter. The characteristic rapid loss of strength is achieved by use of a polymer material with lower molecular weight then Trusynth

INTENDED PURPOSE

Trusynth Fast is indicated for use in general soft tissue approximation where only short term wound support is required and where rapid absorption of the suture would be beneficial. Due to the rapid absorption profile, Trusynth Fast is useful for skin closure, particularly in pediatric surgery, episiotomies, circumcision and closure of oral mucosa. Trusynth Fast is also successfully used in ophthalmic sur- gery for conjunctival sutures.

APPLICATION

Sutures should be selected and implanted depending on the patient condition, surgical experience, surgical technique and wound size. Trusynth Fast typically falls off seven to ten days post operatively or can be wiped off subsequently with sterile gauze. Normally removal of the suture is not required.

PERFORMANCE

Progressive loss of tensile strength and eventual absorp- tion of Trusynth Fast sutures occurs by means of hydrolysis, where the copolymer gets degraded to Glycolic acid and lactic acid which are subsequently absorbed and me- tabolized in the body. Absorption begins as loss of tensile strength, followed by loss of mass. Subcutaneous and in- tra muscular implantation studies of Trusynth Fast in rats show that 7 days post implantation approximately 50% of the original strength remains and 14 days post implantation approximately 100/0 of the original strength remains. The ab- sorption of Trusynth Fast occurs thereafter and is essential- ly complete Approximately 42 days. Trusynth Fast sutures elicit minimal to moderate inflammatory tissue reaction.

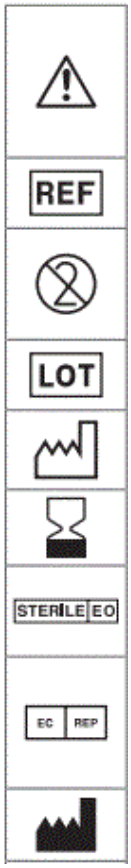
CONTRAINDICATION

Due to the rapid loss of tensile strength, Trusynth Fast suture should not be used where extended approximation of tissue under stress is required or where wound support be- yond 7 days is required. Trusynth Fast suture is not for use in ligation, cardiovascular and neurological tissues.

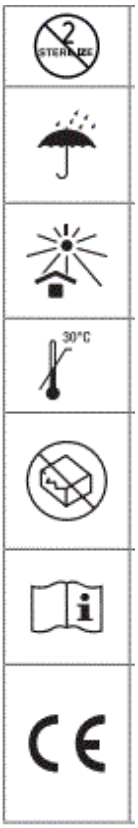
WARNING/ PRECA UTIONS/ INTERACTIONS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Trusynth Fast suture for wound closure, as risk Of wound dehiscence may vary with the site of application and the suture used. Surgeons should consider the in-vivo performance (under the PERFORMANCE section) when selecting a suture. As with any foreign body prolonged contact Of this suture or any other suture with salt solutions such as those found in urinary and biliary tracts, may result in calculus formation. As an absorbable suture, it may act transiently as a foreign body. Acceptable surgical practices should be followed for the management of contaminated or infected wounds. As this is an absorbable suture, the surgeon in the closure of sites undergoing expansion, stretching or distention, which may require additional support, should consider the use of supplemental nonabsorbable suture. Skin sutures, which remain in place for more than 7 days may cause localized irritation and should be snipped off or removed. In handling Trusynth Fast suture or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders. Reshaping which remains in place for more than 7 days may cause localized irritation and should be snipped off or removed. In handling Trusynth Fast suture or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders. Reshaping sutures in tissues with poor blood supply as suture extrusion and delayed absorp on may occur. Subcuticular sutures should be placed as deeply as possible to minimize the- ma and induration normally associated with the absorption process. Use of Trusynth Fast sutures may be inappropriate in elderly, malnourished and debilitated patients or in

patients suffering from conditions which may delay wound healing. For adequate knot security Trusynth Fast sutures which is coated to enhance handling characteristics, requires the accepted surgical technique of flat and square es with ad- ditional throws as indicated by surgical circumstance and experience of the surgeon. Discard used needles in Sharps containers.



- **Caution:** read instructions (warnings) carefully
- Product code
- Disposable device, do not re-use
- Lot Number
- Date of Manufacturing
- Expiration date
- Sterilized using ethylene oxide
- Authorized representative in the European community
- Manufacturer



- Do not resterilize
- Keep in a cool, dry place
- Keep away from sunlight
- Upper limit of temperature
- Do not use if the package is damaged
- Consult instructions for use
- Medical Device complies with Directive 93/42/EEC F

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Documents / Resources

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Trusynth Fast Suture, Trusynth, Fast Suture, Suture