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PROFESSIONAL MEDICAL PRODUCTS

TRUSYNTH® FAST

FILO DA SUTURA CHIRURGICA RIASSORBIBILE USP (SINTETICO) (RIVESTITO IN POLYGLACTIN 910) A RIASSORBIMENTO RAPIDO

ABSORBABLE SURGICAL SUTURE (SYNTHETIC) (COATED POLYGLACTIN 910) FAST ABSORBABLE

SUTURE CHIRURGICALE RÉSORBABLE (SYNTHÉTIQUE) (POLYGLACTINE 910 ENDUITE) RÉSORPTION RAPIDE

RESORBIERBARES CHIRURGISCHES NAHTMATERIAL (SYNTHETISCH) (BESCHICHTETES POLYGLACTIN 910) SCHNELL RESORBIERBAR

SUTURA QUIRÚRGICA ABSORBIBLE (SINTÉTICA) (CUBIERTA CON POLIGLACTINA 910) RÁPIDA ABSORCIÓN

SUTURA CIRÚRGICA ABSORVÍVEL (SINTÉTICO) (POLIGLACTINA 910 REVESTIDA) RÁPIDA ABSORVÍVEL

ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΡΑΜΜΑ (ΣΥΝΘΕΤΙΚΟ) (ΕΠΙΚΑΛΥΜΜΕΝΟ ΜΕ ΠΟΛΥΓΑΛΑΚΤΙΝΗ 910) ΤΑΧΕΙΑΣ ΑΠΟΡΡΟΦΗΣΗΣ

Manuale d'uso - User manual - Manuel de l'utilisateur
Guía de uso - Gebrauchs- und instandhaltungsanleitung
Guia para utilização - Οδηγίες χρήσης

za della ferita, reazione infiammatoria transitoria da corpo

ENGLISH

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 requirements, established by the United States Pharmacopeia for Absorbable Surgical suture (Synthetic) except for diameter. 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 surgery 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 absorption 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 metabolized in the body. Absorption begins as loss of tensile strength, followed by loss of mass. Subcutaneous and intra 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 10% of the original strength remains. The absorption of Trusynth Fast occurs thereafter and is essentially complete Approximately 42 days. Trusynth Fast sutures elicit minimal to moderate inflammatory tissue reaction.

CONTRA INDICATION

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 beyond 7 days is required. Trusynth Fast suture is not for use in ligation, cardiovascular and neurological tissues.

WARNING/ PRECAUTIONS/ 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 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 practice 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 non absorbable suture. Skin suture, 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 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. Sub cuticular sutures should be placed as deeply as possible to minimize erythema and induration normally associated with 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 additional throws as indicated by surgical circumstance and experience of the surgeon. Discard used needles in Sharps containers.

ADVERSE REACTIONS

Adverse effects associated with the use of Trusynth Fast include allergic response in certain patients, transient local irritation at the wound site, transient inflammatory foreign body response, erythema and induration during the absorp on process of subcuticular sutures.

STERILITY

Trusynth Fast suture is sterilized by ethylene oxide. Do not reuse. Do not use if package is opened or damaged. Discard opened unused sutures as well as unopened primary packs.

SUPPLY

Trusynth Fast is available in various U.S.P. sizes, The suture is supplied sterile in pre-cut lengths, both non- needled and attached to various needle type, shape and length. which are packed in a printed box quantity as indicated on the box label.

STORAGE

Recommended storage conditions: Below 30°C away from moisture and direct sunlight. Do not use after expiry.

	**IT -** Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso **GB -** Caution: read instructions (warnings) carefully **FR -** Attention: lisez attentivement les instructions (avertissements) **DE -** Achtung: Anweisungen (Warings) sorgfältig lesen **ES -** Precaución: lea las instrucciones (advertencias) cuidadosamente **PT -** Cuidado: leia as instruções (avisos) cuidadosamente **GR -** Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ενστάσεις)
	**IT -** Codice prodotto **GB -** Product code **FR -** Code produit **DE -** Erzeugniscode **ES -** Código producto **PT -** Código produto **GR -** Κωδικός προϊόντος
	**IT -** Dispositivo monouso, non riutilizzare **GB -** Disposable device, do not re-use **FR -** Ne pas réutiliser **DE -** Für einmaligen Gebrauch, nicht wiederverwenden **ES -** Dispositivo monouso, no reutilizable **PT -** Dispositivo descartável, não reutilizar **GR -** Προϊόν μιας χρήσεως. Μην το χρησιμοποιείται εκ νέου
	**IT -** Numero di lotto **GB -** Lot Number **FR -** Numéro de lot **DE -** Chargennummer **ES -** Número de lote **PT -** Número de lote **GR -** Αριθμός παρτίδας
	**IT -** Data di fabbricazione **GB -** Date of Manufacturing **FR -** Date de fabrication **DE -** Herstellungsdatum **ES -** Fecha de fabricación **PT -** Data de fabrico **GR -** Ημερομηνία παραγωγής
	**IT -** Data di scadenza **GB -** Expiration date **FR -** Date d'échéance **DE -** Ablaufdatum **ES -** Fecha de Caducidad **PT -** Data de validade **GR -** Ημερομηνία λήξεως
	**IT -** Sterilizzato con ossido di etilene **GB -** Sterilized using ethylene oxide **FR -** Stérilisé à l'oxyde d'éthylène **DE -** Sterilisiert mit Ethylenoxid **ES -** Esterilizado con óxido de etileno **PT -** Esterilizado com óxido de etileno **GR -** Αποστειρωμένο με αιθυλενοξείδιο
	**IT -** Rappresentante autorizzato nella Comunità europea **GB -** Authorized representative in the European community **FR -** Représentant autorisé dans la Communauté européenne **DE -** Autorisierter Vertreter in der EG **ES -** Representante autorizado en la Comunidad Europea **PT -** Representante autorizado na União Europeia **GR -** Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση
	**IT -** Fabbricante **GB -** Manufacturer **FR -** Fabricant **DE -** Hersteller **ES -** Fabricante **PT -** Fabricante **GR -** Παραγωγός
	**IT -** Non ri-sterilizzare **GB -** Do not resterilize **FR -** Ne pas restériliser **DE -** Nicht erneut sterilisieren **ES -** No reesterilizar - **PT -** Não re-esterilize **GR -** Μην αποστειρώνετε
	**IT -** Conservare in luogo fresco ed asciutto **GB -** Keep in a cool, dry place **FR -** Á conserver dans un endroit frais et sec **ES -** Conservar en un lugar fresco y seco **DE -** An einem kühlen und trockenen Ort lagern **PT -** Armazenar em local fresco e seco **GR -** Διατηρείται σε δροσερό και στεγνό περιβάλλον
	**IT -** Conservare al riparo dalla luce solare **GB -** Keep away from sunlight **FR -** Á conserver à l'abri de la lumière du soleil **DE -** Vor Sonneneinstrahlung geschützt lagern **ES -** Conservar al amparo de la luz solar **PT -** Guardar ao abrigo da luz solar **GR -** Κρατήστε το μακριά από ηλιακή ακτινοβολία
	**IT -** Limite superiore di temperatura **GB -** Upper limit of temperature **FR -** Limites supérieure de température **DE -** Obergrenze der Temperatur **ES -** Limitaciones superiorde temperatura **PT -** Limitação superior de temperatura **GR -** Ανώτερο όριο θερμοκρασίας
	**IT -** Non utilizzare se l'imballaggio è danneggiato **GB -** Don't use if package is damaged **FR -** Ne pas utiliser si le colis est endommagé **DE -** Nicht verwenden, wenn das Paket beschädigt ist **ES -** No usar si el paquete está dañado **PT -** Não use se o pacote estiver danificado **GR -** Μην το χρησιμοποιείτε αν η συσκευασία είναι κατεστραμμένη
	**IT -** Leggere le istruzioni per l'uso **GB -** Consult instructions for use **FR -** Consulter les instructions d'utilisation **DE -** Gebrauchsanweisung beachten **ES -** Consultar las instrucciones de uso **PT -** Consulte as instruções de uso **GR -** Διαβάστε προσεχτικά τις οδηγίες χρήσης
	**IT -** Dispositivo medico conforme alla Direttiva 93/42/CEE **GB -** Medical Device complies with Directive 93/42/EEC **FR -** Dispositif médical conforme à la directive 93/42 / CEE **DE -** Medizinprodukt gemäß Richtlinie 93/42/CEE **ES -** Dispositivo médico segun a la Directiva 93/42 / CEE **PT -** Dispositivo médico em conformidade com a Diretiva 93/42/CEE **GR -** Ιατρική συσκευή σύμφωνα με την οδηγία 93/42 / CEE

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