

## **TRUSYNTH®**

**FILO DA SUTURA CHIRURGICA RIASSORBIBILE USP (SINTETICO)**  
**(RIVESTITO IN POLYGLACTIN 910)**

**ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC)**  
**(COATED POLYGLACTIN 910)**

**SUTURE CHIRURGICALE RÉSORBABLE USP (SYNTHÉTIQUE)**  
**(POLYGLACTINE ENDUITE 910)**

**RESORBIERBARES CHIRURGISCHES NAHTMATERIAL U.S.P**  
**(SYNTHETISCH) (BESCHICHTETES POLYGLACTIN 910)**

**SUTURA QUIRÚRGICA ABSORBIBLE U.S.P. (SINTÉTICA)**  
**(CUBIERTA CON POLI GLACTINA 910)**

**SUTURA CIRÚRGICA ABSORVÍVEL U.S.P. (SINTÉTICO)**  
**(POLI GLACTINA REVESTIDA 910)**

**ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΠΑΜΜΑ U.S.P (ΣΥΝΘΕΤΙΚΟ)**  
**(ΕΠΙΚΑΛΥΜΜΕΝΟ ΜΕ ΠΟΛΥΓΛΑΚΤΙΝΗ 910)**

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

**ENGLISH**

### **DESCRIPTION**

Trusynth is an absorbable, sterile, surgical suture, composed of a co-polymer, made from 90% Glycolide and 10% Lactide, Polyglactin 910. Trusynth is colored violet with D & C Violet No. 2, conforming to U.S. Code of Federal regulations. Trusynth is available as undyed also. For added lubrication and smoothness, Trusynth is coated with unique combination of Polyglactin 370 and Calcium Stearate. Trusynth meets all the requirements, established by the United States Pharmacopeia for Absorbable Surgical suture (Synthetic) except for diameter.

### **INTENDED PURPOSE**

Trusynth is indicated for use in general soft tissue approximation and/or Ligation, including use in ophthalmic procedures but not for use in cardiovascular and neurological tissues.

### **ACTION**

Trusynth suture gets absorbed in the site of implementation, owing to the hydrolysis, where the polymer degrades to Glycolic acid and Lactic acid. It is slowly absorbed and metabolized in the body. Absorption begins with the loss of tensile strength followed by loss of mass. Approximately 70% of the original tensile strength is retained up to 14 days after surgery. Approximately 15% of the original tensile strength is retained up to 28 days after surgery. Absorption of Trusynth is minimal upto 10% in two weeks, 25% of the mass gets absorbed in four weeks, upto 75% in two months and absorption is essentially complete Approximately 80 days.

### **CONTRA INDICATION**

Trusynth suture being absorbable, should not be used where extended approximation of tissue is required.

### **WARNING**

Do not reuse, Discard open unused sutures. Prolonged contact of this suture or any other suture with salt solutions such as those found in urinary and binary tracts, may result in calculus formation. As an absorbable suture, it may act transiently as a foreign body. As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to storage with respect to drainage and closure of infected or contaminated wounds. USE of Trusynth suture may be inappropriate in patient suffering from conditions which may be delay wound healing.

### **PRECAUTIONS**

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 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. As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and experience of the surgeon. Discard used needle in sharps containers.

### **ADVERSE REACTIONS**

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

### **SUPPLY**

Trusynth 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.

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

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