



GIMA

PROFESSIONAL MEDICAL PRODUCTS

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TRUGLYDE FAST®

**FILO DA SUTURA CHIRURGICA RIASSORBIBILE USP
(SINTETICO) IN ACIDO POLIGLICOLICO, INTRECCIATO
E RIVESTITO A RIASSORBIMENTO RAPIDO**

**ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC)
(BRAIDED AND COATED POLYGLYCOLIC ACID) (FAST
ABSORBABLE)**

**SUTURE CHIRURGICALE RÉSORBABLE USP
(SYNTHÉTIQUE) (ACIDE POLYGLYCOLIQUE TRESSÉ
ET ENDUIT) (RESORPTION RAPIDE)**

**RESORBIERBARES CHIRURGISCHES NAHTMATERIAL
U.S.P (SYNTHETISCH) (GEFLOCHTENE UND
BESCHICHTETE POLYGLYKOLSÄURE) (SCHNELL
RESORBIERBAR)**

**SUTURA QUIRÚRGICA ABSORBIBLE U.S.P. (SINTÉTICA)
(ÁCIDO POLIGLICÓLICO TRENZADO Y RECUBIERTO)
(RÁPIDA ABSORCIÓN)**

**SUTURA CIRÚRGICA ABSORVÍVEL U.S.P. (SINTÉTICO)
(ÁCIDO POLIGLICÓLICO TRANÇADO E REVESTIDO)
(ABSORVÍVEL RAPIDAMENTE)**

**ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΡΑΜΜΑ U.S.P
(ΣΥΝΘΕΤΙΚΟ) (ΠΛΕΓΜΕΝΟ ΚΑΙ ΕΠΙΚΑΛΥΜΜΕΝΟ
ΠΟΛΥΓΛΥΚΟΛΙΚΟ ΟΞΥ) (ΤΑΧΕΙΑΣ ΑΠΟΡΡΟΦΗΣΗΣ)**

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

the site of implantation. Absorption begins with loss of tensile strength followed by loss of mass. Truglyde Fast shows 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 Truglyde Fast occurs thereafter and is essentially complete. Approximately 42 days.

CONTRA INDICATIONS

Truglyde Fast should not be used where extended approximation of tissues under stress is required or where wound support beyond 7 days is required due to the rapid loss of tensile strength.

WARNINGS/PRECAUTIONS/ INTERACTIONS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Truglyde Fast for wound closure as risk of wound dehiscence may vary with the site of application and the suture material used. Surgeons should consider the *in vivo* performance 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 Truglyde Fast is an absorbable suture materials, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of sites which may undergo expansion, stretching or distention or which may require additional support. 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. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with the absorption process. The use of Truglyde Fast may be inappropriate in elderly, malnourished or debilitated patients, or patients suffering from conditions, which may delay wound healing. In handling Truglyde 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. As with any suture material, adequate knot security requires the accepted surgical techniques of flat and square ties, with additional throws as warranted 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 & cause fracture of the needle.

Grasping at the butt or attachment end could cause bending or breakage of the needle. Reshaping needles may cause them to lose strength and make 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.

ADVERSE REACTIONS

Adverse reactions associated with the use of the Truglyde Fast include: allergic response in certain patients, transient local irritation at the wound site, followed by moderate transient inflammatory foreign body response, erythema and induration during the absorption process of subcuticular su-

ENGLISH

DESCRIPTION

Truglyde Fast is an absorbable, sterile, surgical suture, composed of homopolymers of Glycolide (100%). For added lubrication and smoothness, Truglyde Fast is coated with unique combination of Polycaprolactone and Calcium Stearate. Truglyde Fast meets all the requirements, established by the United States Pharmacopeia for Absorbable Surgical suture. Truglyde Fast is available as undyed. Truglyde Fast is available in range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes.

INTENDED PURPOSE

Truglyde Fast is intended for use in soft tissue approximation where only short-term wound support is required and where the rapid absorption would be beneficial. Due to the absorption profile Truglyde Fast is useful for skin closure, particularly in pediatric surgery, episiotomies, circumcision and closure of oral mucosa. Truglyde Fast is not intended for use in ophthalmic surgery cardiovascular and neurological procedures.

APPLICATION

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size. Truglyde Fast typically falls off in 7 – 10 days post operatively or can be wiped off subsequently with sterile gauze. Normally the removal of the sutures is not required.

PERFORMANCE

Truglyde Fast sutures elicit a minimal to moderate initial inflammatory tissue reaction. Progressive loss of tensile strength and eventual absorption of Truglyde Fast sutures occur by means of hydrolysis, where the polymer degrades to Glycolic acid. It gets absorbed quickly and metabolized in

tures. Like all foreign bodies, Truglyde Fast may enhance an existing infection.

STERILITY

Do not reuse. Do not use if package is opened or damaged. Discard opened unused sutures.

SUPPLY

Truglyde 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 (Warnings) sorgfältig lesen ES - Precaución: lea las instrucciones (advertencias) cuidadosamente PT - Cuidado: leia as instruções (avisos) cuidadosamente GR - Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ειδοστάσεις)
	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 χρησιμοποιείτε 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 reesterilize GR - Μην αποστειρώνετε
	IT - Conservare in luogo fresco ed asciutto GB - Keep in a cool, dry place FR - À 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 - À 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 superior de 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 προσεκτικά 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 según 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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STERILE EO

