

TRUGLYDE®

FILÒ DA SUTURA CHIRURGICA RIASSORBIBILE USP (SINTETICO)

IN ACIDO POLIGLICOLICO, INTRECCIATO E RIVESTITO

ABSORBABLE SURGICAL SUTURE U.S.P (SYNTHETIC)

BRAIDED AND COATED POLYGLYCOLIC ACID

SUTURE CHIRURGICALE RÉSORBABLE USP (SYNTHÉTIQUE)

ACIDE POLYGLYCOLIQUE TRESSÉ ET ENDUIT

RESORBIERBARES CHIRURGISCHES NAHTMATERIAL U.S.P

**(SYNTHETISCH) GEFLOCHTENE UND BESCHICHTETE POLY-
GLYKOLSÄURE**

SUTURA QUIRÚRGICA ABSORBIBLE U.S.P (SINTÉTICA)

ÁCIDO POLIGLICÓLICO TRENZADO Y RECUBIERTO

SUTURA CIRÚRGICA ABSORVÁÍEL U.S.P (SINTÉTICA)

ÁCIDO POLICLICÓLICO TRANÇADO E REVESTIDO

ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΠΑΜΜΑ U.S.P (ΣΥΝΘΕΤΙΚΟ)

ΠΛΕΓΜΕΝΟ ΚΑΙ ΕΠΙΚΑΛΥΜΜΕΝΟ ΠΟΛΥΓΛΥΚΟΛΙΚΟ ΟΞΉ

Manuale d'uso - User manual - Manuel de l'utilisateur

Guía de uso - Gebrauchs- und Instandhaltungsanleitung

Guia para utilização - Οδηγίες χρήσης

DESCRIPTION

Truglyde Suture is an absorbable, sterile, synthetic surgical suture, composed of homopolymers of Glycolide(100%). Truglyde is colored violet with D & C Violet No.2, conforming to U.S.Code of Federal regulations. Truglyde is available undyed also. For added lubrication and smoothness, Truglyde is coated with unique combination of polycaprolactone and calcium stearate. Truglyde meets all the requirements as per United States Pharmacopoeia for Absorbable Surgical suture (Synthetic).

INTENDED PURPOSE

Truglyde is indicated for use in soft tissue approximation and or ligation, including use in plastic and ophthalmic procedures but not for use in cardiovascular and neurological tissues.

ACTION

Truglyde suture gets absorbed in the site of implantation, owing to the hydrolysis, where the polymer degrades to Glycolic acid. It is slowly absorbed and metabolized in the body. Absorption begins with 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 Truglyde suture is minimal up to 10% in two weeks. 25% of the mass gets absorbed in four weeks, upto 75% in two months and absorption is essentially complete Approximately 70 days.

CONTRA INDICATION

Truglyde 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 biliary 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 drainage and closure of infected or contaminated wounds. The use of this suture may be inappropriate in patients suffering from conditions which may delay wound healing. Discard used needle in sharps container.

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. Under some circumstances, notably orthopaedic Procedure, immobilisation by external support may be employed at the discretion of the surgeon. Skin suture, which remain in place for more than 7 days may cause localized irritation and should be snipped off or removed. Discard used needle in sharps containers.

ADVERSE REACTIONS

Adverse effects associated with the use of Truglyde 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

Truglyde 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 (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 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 re-sterilize 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 όρσορό 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 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 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

Healthium Medtech Limited

Plot No.1600, R-6 West, Sri City(SEZ), Cherivi Village,
Irrugulam Post, Satyavedu Mandal, Chittoor District,
Andhra Pradesh-517588, India
Email: care@healthiummedtech.com
Customer care number: +91-80-41868198
Mfg. Lic. No.: MFG/MD/2021/000435

MED DEVICES LIFESCIENCES B.V.

Krajenhoffstraat 137 A, 1018RG Amsterdam, Netherlands
Email: info@meddevices.net Phone: +31-202254558

