

TRULENE®

**FILÒ DA SUTURA CHIRURGICA NON RIASSORBIBILE USP
(MONOFILAMENTO POLIPROPILENE)**

**NONABSORBABLE SURGICAL SUTURE U.S.P
(MONOFILAMENT POLYPROPYLENE)**

**SUTURE CHIRURGICALE NON RÉSORBABILE USP
(POLYPROPYLÈNE MONOFILAMENT)**

**NICHT-RESORBIERBARES CHIRURGISCHES NAHTMATERIAL U.S.P
(MONOFILES POLYPROPYLEN)**

**SUTURA QUIRÚRGICA NO ABSORBIBILE U.S.P
(POLIPROPILENO DE MONOFILAMENTO)**

**SUTURA CIRÚRGICA NÀO ABSORVÍVEL U.S.P
(MONOFILAMENTO (POLIPROPILENO))**

**ΜΗ ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΠΑΜΜΑ U.S.P
(ΜΟΝΟΚΛΩΝΟ POLYPROPYLENE)**

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

ENGLISH

DESCRIPTION

Trulene is a nonabsorbable, sterile, surgical suture, composed of Polypropylene, a synthetic linear Polyolefin. The molecular formula is (C₃H₆)_n. Trulene is colored blue with Phthalocyanine Copper blue, Color Index No.74160, and U.S.F.D.A.approved dye. Trulene is monofilament and it is uncoated. Trulene meets all the requirements as per United States Pharmacopeia for nonabsorbable surgical suture.

INTENDED PURPOSE

Trulene is indicated for use in soft tissue approximation and or ligation, including use in cardiovascular, ophthalmic and neurological tissues.

ACTION

TRULENE being a monofilament suture is remarkably smooth and easy to handle. It does not have interstices in its structure. It elicits an initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. Trulene is neither absorbed, nor it is subjected to degradation or weakening by the action of tissue enzymes. Due to its relative biological inertness, it is recommended for use where the least possible suture reaction is desired. Because of its lack of adherence to tissue, Trulene is effective as a pull out suture. Trulene, being a monofilament has been successfully employed in surgical wounds which could subsequently become infected or contaminated where it can minimize later sinus formation and suture extrusion.

CONTRA INDICATIONS

None known.

WARNINGS

Do not resterilise. Discard open, unused sutures. Prolonged contact of this suture or any other suture with salt solution such as those found in urinary and biliary tracts may result in calculus formation. Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing Trulene for wound closures, as risk of wound dehiscence may vary with the site of application and the suture material used. 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.

PRECAUTIONS

In handling this 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 holder. 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. The use of additional throws may be particularly appropriate when knotting with Trulene being a monofilament. Discard used needles in 'Sharps' containers.

ADVERSE REACTIONS

Adverse effects associated with the use of Trulene include minimal initial inflammatory tissue reaction and transient local irritation at the wound site, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile juice etc. Like all foreign bodies, TRULENE may potentiate an existing infection.

SUPPLY

TRULENE 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 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 αιθυλενοξειδίο
	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 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 superiores 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 καταστραμμένη
	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
Customercare 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

