Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

PROFESSIONAL MEDICAL PRODUCTS

TRULON®

FILO DA SUTURA CHIRURGICA NON RIASSORBIBILE USP (POLIAMMIDE MONOFILAMENTO)

NONABSORBABLE SURGICAL SUTURE U.S.P (MONOFILAMENT POLYAMIDE)

SUTURE CHIRURGICALE NON RÉSORBABLE USP (POLYAMIDE MONOFILAMENT)

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

SUTURA QUIRÚRGICA ABSORBIBLE U.S.P (MONOFILAMENTO POLIAMIDA)

SUTURA CIRÚRGICA NÃO ABSORVÍVEL U.S.P (POLIAMIDA DE MONOFILAMENTO)

ΜΗ ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΡΑΜΜΑ U.S.P (ΜΟΝΟΚΛΩΝΟ POLYAMIDE)

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

ENGLISH

DESCRIPTION

Trulon is a nonabsorbable, sterile, surgical suture, composed of long chain-aliphatic polymers, Nyon 6 and Nylon 6.6. The monofilament Polyamide sutures attached needles are available in black and blue, colors dyed with FDA approved dyes. Polyamide 6.6 is formed by Polycondensation of hexamethylene diamine and adipic acid. Polyamide 6 is formed by polymerisation of epsilon caprolactum. Blue Nylon sutures is dyed with a blue pigment, colour Index No.69800 and Black Nylon suture is dyed with Haematin HCK, colour Index No. 75290. Trulon meets all the requirements, established by the United States Pharmacopeia for Nonabsorbable Surgical Suture.

INTENDED PURPOSE

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

ACTION

Trulon suture elicits a minimal acute inflammatory reaction in tissue which is followed by gradual encapsulation of suture by fibrous connective tissue. While it is not absorbed, progressive hydrolysis of Nylon in vivo may result in gradual loss of tensile strength over a period of time.

CONTRA INDICATIONS

Due to gradual loss of tensile strength which may occur over prolonged periods in vivo Trulon suture should not be used where permanent retention of tensile strength is required as in fixation of intraocular lenses or synthetic vascular grafts.

WARNINGS

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. Users should be familiar with surgical procedures and techniques involving non absorbable sutures before employing Trulon 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 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. The use of additional throws may be particularly appropriate when knotting with Trulon being a monofilament. Discard used needles in 'Sharps' containers.

ADVERSE REACTIONS

Adverse effects associated with the use of Trulon include wound dehiscence, gradual loss of tensile strength over time, minimal acute inflammatory tissue reaction, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile juice etc. occurs, enhanced bacterial infectivity, pain, edema and erythema at wound site.

SUPPLY

Trulon 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

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

GM/IFU/08 Rev.00 Date:01/01/2022