

TRULENE MESH™

RETE CHIRURGICA SINTETICA NON RIASSORBIBILE, IN POLIPROPILENE, STERILE

POLYPROPYLENE NON ABSORBABLE SYNTHETIC SURGICAL MESH, STERILE

POLYPROPYLÈNE SYNTHÉTIQUE NON RÉSORBABLE FILET CHIRURGICAL, STÉRILE

POLYPROPYLEN NICHT-RESORBIERBARER KUNSTSTOFF CHIRURGISCHES NETZ, STERIL

POLIPROPILENO SINTÉTICO NO ABSORBIBILE MALLA QUIRÚRGICA ESTERILIZADA

POLIPROPILENO NÃO ABSORVÍVEL SINTÉTICO MALHA CIRÚRGICA, ESTERILIZADA

ΜΗ ΑΠΟΡΡΟΦΗΣΙΜΟ ΣΥΝΘΕΤΙΚΟ ΠΟΛΥΠΡΟΠΥΛΕΝΟ ΧΕΙΡΟΥΡΓΙΚΟ ΠΛΕΓΜΑ, ΑΠΟΣΤΕΙΡΩΜΕΝΟ

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

DESCRIPTION

Trulene mesh is constructed of knitted filaments of extruded Polypropylene, identical in composition with that used in Trulene polypropylene suture, Non absorbable surgical suture U.S.P. Trulene Mesh is available undyed in a variety of square and rectangular sizes for surgical procedures. This material, when used as sutures has been reported to be nonreactive and to retain its strength for an indefinite period in clinical use.

Trulene mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The fiber junctions are not subject to the same work – fatigue exhibited by more rigid metallic meshes. This bi-directional elastic properly allows adaptation to various stresses encountered in the body.

ACTIONS

Trulene mesh is a non absorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. This mesh elicits minimum inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into the adjacent tissue. The mesh remains soft, pliable and the wound healing is not noticeably impaired. The mesh is not absorbed nor is subject to degradation or weakening by the action of tissue enzymes.

INTENDED PURPOSE

Trulene Mesh used for the repair of hernia. Types of Hernia: Inguinal Hernia and Ventral Hernia.

CONTRAINDICATIONS

When this mesh is used in infants or children with future growth potential and pregnant women, the surgeon should be aware that this product will not stretch significantly as the patient grows. Trulene Mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.

WARNING

Trulene mesh is supplied as a sterile product. Re sterilization is not recommended.

RISK OF REUSE

Reprocessing or sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize the Trulene mesh.

PRECAUTIONS

Users should be familiar with surgical procedures and techniques involving the use of non-absorbable meshes before employing Trulene mesh in wound repair or reinforcement and brief the patients about contraindications and precautions. A minimum of 6.5 mm inside the edge mesh extend beyond the suture line.

ADVERSE REACTIONS

Potential adverse reactions with Trulene mesh implantation are those typically associated with surgical implantable materials which including seroma formation, inflammation, adhesion formation, fistula formation, extrusion and potentiation of infection.

INSTRUCTIONS FOR USE

Mesh is implanted according to currently accepted surgical mesh procedures.

Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away.

















Adequate mesh fixation is required to minimize post-operative complications and recurrence. The fixation technique method and products used should follow the current standard of care. Careful attention to fixation and spacing will help prevent excessive tension or disruption between the mesh materials and connective tissue. When fixating with non-absorbable sutures or other mechanical fixation devices, a safe from the edge of the mesh of not less than 6.5mm (¼”) should be maintained. 6.5 mm to 12.5mm (¼” to ½”) must be left between fixation points.

SUPPLY


Trulene mesh is available in various sizes 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 (επιδείξεις)
	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 - Fabricante 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 όρσοερό 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

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