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TRUSTEEL™

FILO DA SUTURA CHIRURGICA NON RIASSORBIBILE USP FILO DA SUTURA CHIRURGICA STERILE, MONTATO SU AGO MONOFILAMENTO IN ACCIAIO INOX LVM 316

NONABSORBABLE SURGICAL SUTURE, U.S.P. STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT STAINLESS STEEL LVM 316 GRADE WIRE

SUTURE CHIRURGICALE NON RÉSORBABLE, USP SUTURE CHIRURGICALE STÉRILISÉE, AIGUILLETÉE FIL MONOFILAMENT EN ACIER INOXYDABLE LVM 316

NICHT-RESORBIERBARES CHIRURGISCHES NAHTMATERIAL, U.S.P STERILISIERTES CHIRURGISCHES NADELNAHTMATERIAL MONOFILER EDELSTAHL LVM 316 GRADE DRAHT

SUTURA QUIRÚRGICA NO ABSORBIBLE, U.S.P. SUTURA QUIRÚRGICA ESTERILIZADA CON AGUJA MONOFILAMENTO DE ACERO INOXIDABLE, GRADO DEL FILAMENTO LVM 316

SUTURA CIRÚRGICA NÃO ABSORVÍVEL, U.S.P. SUTURA AGULHADA CIRÚRGICA ESTERILIZADA FIO MONOFILAMENTO DE AÇO INOXIDÁVEL CLASSE LVM 316

ΜΗ ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΡΑΜΜΑ U.S.P ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΧΕΙΡΟΥΡΓΙΚΟ ΡΑΜΜΑ ΜΕ ΒΕΛΟΝΑ ΜΟΝΟΚΛΩΝΟ ΣΥΡΜΑ ΑΠΟ ΑΝΟΞΕΙΔΩΤΟ ΧΑΛΥΒΑ ΚΑΤΗΓΟΡΙΑΣ LVM 316

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

ENGLISH

DESCRIPTION

Trusteel (Stainless Steel), is a sterile synthetic monofilament non absorbable surgical suture prepared from 316 LVM grade Stainless Steel. 316 LVM grade Stainless Steel alloy contains iron, copper, manganese.
Molybdenum, Nickel and Chromium. Trusteel sutures comply with the requirements established by the European Pharmacopoeia (E.P) for Sterile Non-Absorbable sutures, and United States Pharmacopeia (U.S.P) for Non-Absorbable Surgical Suture.

INTENDED USE

Trusteel suture is intended for use In abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

INDICATION

Indicated for surgical procedures which require sutures with high tensile strength, such as in conditions like abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

CONTRAINDICATIONS

The use of the suture is contra indicated in patients with known sensitivities or allergies to 316 LVM Stainless Steel, or its constituent metals such as chromium and nickel.

INTENDED USERS

Trained and registered health care professional only.

INTENDED PATIENT POPULATION

This suture can be used in patlents irrespective of age and sex, in line with the intended use, indications and contraindications.

PERFORMANCE

Trusteel suture elicitis a minimal initial inflammatory reaction in tissues and is not absorbed

APPLICATION

Suture should be selected and implanted depending on patient's condition, surgical experience, surgical technique and wound size.

WARNINGS

This suture is intended to be used by a trained and registered health care professional.
Users should be familiar with surgical procedures and surgical suturing techniques involving non-absorbable stainless steel sutures before using Trusteel suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.
Users must apply their professional judgment when determining the appropriate sized suture based on the specific indication, wound size, preferred surgical technique, patient's condition and history.
As a non absorbable suture, it may act as a foreign body and as with any foreign body, presence of bacterial contamination may enhance bacterial infectivity. Thus, acceptable surgical practice should be followed with respect to drainage and closure of infected or contaminated wounds.
Wound dehiscence may occur when suture fails to provide adequate wound support inclosure of the sites where expansion, stretching or distension occur. Postoperatively and until healing is complete, fixation provided by this suture should be considered as temporary and may not withstand weight bearing or other unsupported stress.
The fixationion provided by this suture should be protected. The postoperative regimen prescribed by the surgeon should be strictly followed to avoid adverse stresses applied to the suture.
Under certain circumstances, notably orthopaedic procedures, Immobilization by external support may be employed at the disc. retion of the user.
Device removal when required, should be followed by adequate postoperative management.

PRECAUTIONS

Care should be taken to awoid damage when handing 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 penatration performance & cause facture of the needle. Grasping at the butt or attachment end could cause bending or breakage of the needle. Reshaping needles may cause them to loose strength and make less resistant to bending and breaking. Broken needles may result in extended or additional surgeries or residual foreign bodies.
Users should execise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in 'Sharps' containers.
When handling this suture, care should be taken to avoid damage from handing, 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 user.
Do not tie bands around pouches/packs of sutures as it may damage the pouches/pack.
Store the suture pouches/pack as supplied and avoid bending of the suture pouches/pack during transport or storage, as bending of suture before usage may lead to suture breakage.
Do not re-sterilize, do not reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.

SIDE EFFECTS

Side effects associated with the use of Trusteel suture include allergic response in patients with known sensitivities to 316 LVM Stainless Steel, or its constituent metals such as chromium and nickel; transient local irritation at the wound site, minimal initial inflammatory tissue reaction, pain, edema, and erythema at the wound site, and wound dehiscence. Like all foreign bodies, Trusteel suture may enhance an existing infection.

STERILITY

Trusteel suture is sterilized by ethylene oxide gas. Do not re-sterilize, do not reuse, Do not use if package is opened or clamaged.

REF	**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
LOT	**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
STERILE EO	**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
EC REP	**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
STERILIZE	**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
30°C	**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
CE	**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

UDI	**IT -** Identificatore univoco del dispositivo **GB -** Unique device identifier **FR -** Identifiant unique de l'appareil **ES -** Identificador de dispositivo único **DE -** Eindeutige Gerätekennung **PT -** Identificador exclusivo do dispositivo **GR -** Μοναδικό αναγνωριστικό συσκευής
	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)

REF **TS661P4 (GIMA 22790)**
TS650P4 (GIMA 22791)
TS652P4 (GIMA 22792)
TS659P4 (GIMA 22793)
TS649P4 (GIMA 22794)
TS644P2 (GIMA 22795)
TS657P4 (GIMA 22796)

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