

**TRUSILK®****FILO DA SUTURA CHIRURGICA NON RIASSORBIBILE USP  
(SETA INTRECCIATA DI COLORE NERO)****NON-ABSORBABLE SURGICAL SUTURE U.S.P  
(BLACK BRAIDED SILK)****SUTURE CHIRURGICALE NON RÉSORBABLE USP  
(SOIE NOIRE TRESSÉE)****NICHT-RESORBIERBARES CHIRURGISCHES NAHTMATERIAL U.S.P  
(SCHWARZE, GEFLOCHTENE SEIDE)****SUTURA QUIRÚRGICA NO ABSORBIBILE U.S.P  
(SEDA NEGRA TRENZADA)****SUTURA CIRÚRGICA NÃO ABSORVÍVEL U.S.P  
(SEDA TRANÇADA PRETA)****ΜΗ ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΠΑΜΜΑ U.S.P  
(ΜΑΥΡΟ ΠΛΕΓΜΕΝΟ ΜΕΤΑΞΙ)****Manuale d'uso - User manual - Manuel de l'utilisateur  
Guía de uso - Gebrauchs- und instandhaltungsanleitung  
Guia para utilização - Οδηγίες χρήσης****ENGLISH****DESCRIPTION**

Trusilk is a nonabsorbable, sterile, surgical suture, composed of an organic protein, called fibroin. This protein is derived from the domesticated species *Bombyx mori* (B mori) of the family Bombycidae. Natural Silk contains approximately 30% extraneous material or gum which is removed by specially developed "Degumming" process. This process is essential for a compact braid while ensuring that the filaments retain their natural body and elasticity. Trusilk dyed with black Hematoxylin and coated with wax/ silicon. Trusilk meets all the requirements as per United States Pharmacopeia for Nonabsorbable Surgical suture.

**INTENDED PURPOSE**

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

**ACTION**

Trusilk elicits an initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. While Trusilk is not absorbed, progressive degradation of the proteinous silk fibres in vivo may result in gradual loss of the sutures over a period of time.

**CONTRA INDICATIONS**

Use of this suture is contra indicated in patients with known sensitivities or allergies to Silk. Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, Trusilk sutures should not be used where permanent retention of tensile strength is required as in fixation of vascular prostheses.

**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 nonabsorbable sutures before employing Trusilk 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. Discard used needles in 'Sharps' containers.

**ADVERSE REACTIONS**

















Adverse reactions associated with the use of the device, Trusilk include wound dehiscence, gradual loss of all tensile strength over time, allergic response in patients who are known to be sensitive to silk, calculi formation in urinary & biliary tracts when prolonged contact with salt solutions such as urine and bile juice, enhanced bacterial infectivity, acute inflammatory tissue reaction, pain, edema and erythema at the wound site.

**SUPPLY**

Trusilk 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. Non sterile reels are packed in 25 metres, six reels packed in a box.

**STORAGE**

Recommended storage conditions: Below 30°C away from moisture and di-

	<b>IT</b> - Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso <b>GB</b> - Caution: read instructions (warnings) carefully <b>FR</b> - Attention: lisez attentivement les instructions (avertissements) <b>DE</b> - Achtung: Anweisungen (Warnings) sorgfältig lesen <b>ES</b> - Precaución: lea las instrucciones (advertencias) cuidadosamente <b>PT</b> - Cuidado: leia as instruções (avisos) cuidadosamente <b>GR</b> - Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ενστάσεις)
	<b>IT</b> - Codice prodotto <b>GB</b> - Product code <b>FR</b> - Code produit <b>DE</b> - Erzeugniscode <b>ES</b> - Código producto <b>PT</b> - Código produto <b>GR</b> - Κωδικός προϊόντος
	<b>IT</b> - Dispositivo monouso, non riutilizzare <b>GB</b> - Disposable device, do not re-use <b>FR</b> - Ne pas réutiliser <b>DE</b> - Für einmaligen Gebrauch, nicht wiederverwenden <b>ES</b> - Dispositivo monouso, no reutilizable <b>PT</b> - Dispositivo descartável, não reutilizar <b>GR</b> - Προϊόν μιας χρήσεως. Μην το χρησιμοποιείται εκ νέου
	<b>IT</b> - Numero di lotto <b>GB</b> - Lot Number <b>FR</b> - Numéro de lot <b>DE</b> - Chargennummer <b>ES</b> - Número de lote <b>PT</b> - Número de lote <b>GR</b> - Αριθμός παρτίδας
	<b>IT</b> - Data di fabbricazione <b>GB</b> - Date of Manufacturing <b>FR</b> - Date de fabrication <b>DE</b> - Herstellungsdatum <b>ES</b> - Fecha de fabricación <b>PT</b> - Data de fabrico <b>GR</b> - Ημερομηνία παραγωγής
	<b>IT</b> - Data di scadenza <b>GB</b> - Expiration date <b>FR</b> - Date d'échéance <b>DE</b> - Ablaufdatum <b>ES</b> - Fecha de Caducidad <b>PT</b> - Data de validade <b>GR</b> - Ημερομηνία λήξεως
	<b>IT</b> - Sterilizzato con ossido di etilene <b>GB</b> - Sterilized using ethylene oxide <b>FR</b> - Stérilisé à l'oxyde d'éthylène <b>DE</b> - Sterilisiert mit Ethylenoxid <b>ES</b> - Esterilizado con óxido de etileno <b>PT</b> - Esterilizado com óxido de etileno <b>GR</b> - Αποστειρωμένο με αιθυλενοξείδιο
	<b>IT</b> - Rappresentante autorizzato nella Comunità europea <b>GB</b> - Authorized representative in the European community <b>FR</b> - Représentant autorisé dans la Communauté européenne <b>DE</b> - Autorisierter Vertreter in der EG <b>ES</b> - Representante autorizado en la Comunidad Europea <b>PT</b> - Representante autorizado na União Europeia <b>GR</b> - Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση
	<b>IT</b> - Fabbricante <b>GB</b> - Manufacturer <b>FR</b> - Fabricant <b>DE</b> - Hersteller <b>ES</b> - Fabricante <b>PT</b> - Fabricante <b>GR</b> - Παραγωγός
	<b>IT</b> - Non ri-sterilizzare <b>GB</b> - Do not re-sterilize <b>FR</b> - Ne pas restériliser <b>DE</b> - Nicht erneut sterilisieren <b>ES</b> - No reesterilizar <b>PT</b> - Não reesterilize <b>GR</b> - Μην αποστειρώνετε
	<b>IT</b> - Conservare in luogo fresco ed asciutto <b>GB</b> - Keep in a cool, dry place <b>FR</b> - À conserver dans un endroit frais et sec <b>ES</b> - Conservar en un lugar fresco y seco <b>DE</b> - An einem kühlen und trockenen Ort lagern <b>PT</b> - Armazenar em local fresco e seco <b>GR</b> - Διατηρείται σε δροσερό και στεγνό περιβάλλον
	<b>IT</b> - Conservare al riparo dalla luce solare <b>GB</b> - Keep away from sunlight <b>FR</b> - À conserver à l'abri de la lumière du soleil <b>DE</b> - Vor Sonneneinstrahlung geschützt lagern <b>ES</b> - Conservar al amparo de la luz solar <b>PT</b> - Guardar ao abrigo da luz solar <b>GR</b> - Κρατήστε το μακριά από ηλιακή ακτινοβολία
	<b>IT</b> - Limite superiore di temperatura <b>GB</b> - Upper limit of temperature <b>FR</b> - Limites supérieure de température <b>DE</b> - Obergrenze der Temperatur <b>ES</b> - Limitaciones superiorde temperatura <b>PT</b> - Limitação superior de temperatura <b>GR</b> - Ανώτερο όριο θερμοκρασίας
	<b>IT</b> - Non utilizzare se l'imballaggio è danneggiato <b>GB</b> - Don't use if package is damaged <b>FR</b> - Ne pas utiliser si le colis est endommagé <b>DE</b> - Nicht verwenden, wenn das Paket beschädigt ist <b>ES</b> - No usar si el paquete está dañado <b>PT</b> - Não use se o pacote estiver danificado <b>GR</b> - Μην το χρησιμοποιείτε αν η συσκευασία είναι κατεστραμμένη
	<b>IT</b> - Leggere le istruzioni per l'uso <b>GB</b> - Consult instructions for use <b>FR</b> - Consulter les instructions d'utilisation <b>DE</b> - Gebrauchsanweisung beachten <b>ES</b> - Consultar las instrucciones de uso <b>PT</b> - Consulte as instruções de uso <b>GR</b> - Διαβάστε προσεκτικά τις οδηγίες χρήσης
	<b>IT</b> - Dispositivo medico conforme alla Direttiva 93/42/CEE <b>GB</b> - Medical Device complies with Directive 93/42/EEC <b>FR</b> - Dispositif médical conforme à la directive 93/42 / CEE <b>DE</b> - Medizinprodukt gemäß Richtlinie 93/42/CEE <b>ES</b> - Dispositivo médico según a la Directiva 93/42 / CEE <b>PT</b> - Dispositivo médico em conformidade com a Diretiva 93/42/CEE <b>GR</b> - Ιατρική συσκευή σύμφωνα με την οδηγία 93/42 / CEE

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**STERILE EO**

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