

**TRUWAX®**

**CERA STERILE PER OSSA 2,5GM**  
**STERILE BONEWAX 2.5GM**  
**CIRE D'OS STÉRILE 2,5GM**  
**STERILES KNOCHENWACHS 2,5G**  
**CERA ÓSEA ESTÉRIL 2.5GM**  
**BONEWAX ESTÉRIL 2.5GM**  
**ΑΠΟΣΤΕΙΡΩΜΕΝΟΣ ΟΣΤΙΚΟΣ ΚΗΡΟΣ 2.5GM**

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

ENGLISH

**DESCRIPTION**

TRUWAX is sterile bone wax, a sterile mixture of White Bees wax, Hard Paraffin and Isopropyl Palmitate, a wax - softening agent. Truwax is opaque and has a waxy odor.

**INDICATIONS**

TRUWAX may be used for the control of bleeding from bone surfaces.

**ACTION**

TRUWAX achieves local haemostasis of bone by acting as a mechanical (tamponade) barrier. It does not act bio chemically and is minimally resorbable.

**CONTRAINDICATIONS**

TRUWAX should not be used where rapid osseous regeneration and fusion are desired.

**WARNINGS**

TRUWAX should not be re sterilized or subjected to excessive heat. TRUWAX may inhibit osteogenesis and may act as a physical barrier to the reparative process. Do not use if package is opened or damaged. Discard opened, unused bonewax.

**PRECAUTIONS**

TRUWAX should be used sparingly. Excess Truwax should be re-moved from the operative site. The package should be opened just prior to use to minimize the possibility of contamination and excessive drying.

**ADVERSE REACTIONS**










Mild inflammatory reactions have been reported in tissues immediately adjacent to the site of implantation. Studies have suggested that bone wax as a foreign body may impair the ability of cancellous bone to clear bacteria. In animal models, the local accumulation of foreign body giant cells has been observed and histologic examination has revealed the appearance of macrophages and occasionally polymorphonuclear leukocytes and lymphocytes.

**DOSAGE ADMINISTRATION**

TRUWAX should be used immediately after removal from the package. Using aseptic technique, Truwax should be warmed to desired consistency by manipulation with the fingers or by immersion of the unopened foil packet in a warm sterile solution.

**HOW SUPPLIED**

TRUWAX is available sterile in individual foil envelopes, each containing 2.5 grams and packed in an individually sealed overwrap packet.

	<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> - Διαβάστε και ακολουθήστε προσεκτικά τις οδηγίες χρήσης
<b>REF</b>	<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 μίας χρήσεως. Μην το χρησιμοποιείται εκ νέου
<b>LOT</b>	<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>STERILE R</b>	<b>IT</b> - Sterilizzato per irradiazione <b>GB</b> - Sterilized using irradiation <b>FR</b> - Stérilisé par irradiation <b>DE</b> - Durch Bestrahlung steril gemacht <b>ES</b> - Esterilizado por irradiación <b>PT</b> - Esterilizado por irradiação <b>GR</b> - Αποστειρωμένο μέσω ακτινοβολίας
<b>EC REP</b>	<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 re-esterilize <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 εάν η συσκευασία παρουσιάζει φθορά
	<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>CE</b>	<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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