

MONOGLYDE®

**FILO DA SUTURA CHIRURGICA RIASSORBIBILE USP
(SINTETICO) (POLIGLECAPRONE 25 MONOFILAMENTO)**

**ABSORBABLE SURGICAL SUTURE (SYNTHETIC)
(MONOFILAMENT POLIGLECAPRONE 25)**

**SUTURE CHIRURGICALE RÉSORBABLE (SYNTHÉTIQUE)
(MONOFILAMENT POLIGLECAPRONE 25)**

**RESORBIERBARES CHIRURGISCHES NAHTMATERIAL
(SYNTHETISCH) (MONOFILE POLIGLECAPRONE 25)**

**SUTURA QUIRÚRGICA ABSORBIBLE (SINTÉTICA)
(POLIGLECAPRONE 25 DE MONOFILAMENTO)**

**SUTURA CIRÚRGICA ABSORVÍVEL (SINTÉTICO)
(MONOFILAMENTO POLIGLECAPRONE 25)**

**ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΡΑΜΜΑ (ΣΥΝΘΕΤΙΚΟ)
(ΜΟΝΟΚΛΩΝΟ POLIGLECAPRONE 25)**

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

ENGLISH

DESCRIPTION

Monoglyde (Poliglecaprone25), is a monofilament synthetic absorbable suture, composed of a Polymer (Glycolide co – caprolactone). Monoglyde sutures are available undyed in beige color and in violet color, dyed with D & C violet. Poliglecaprone 25 copolymer has been found to be nonantigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption. MONOGLYDE sutures comply with USP requirements, except for diameter.

INTENDED PURPOSE

Monoglyde sutures are indicated for use in general soft tissue approximation. but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

ACTIONS

Monoglyde suture is a monofilament which elicits a minimal acute inflammatory reaction in tissues and in-growth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Monoglyde sutures occurs by means of hydrolysis. Absorption begins as loss of tensile strength followed by loss of mass. Implantation studies in rats indicate that Monoglyde suture retains approximately 45% of its original tensile strength 7 days post implantation and approximately 15% of its original tensile strength at 14 days post implantation. All of the original tensile strength is lost by 21 days post implantation. The absolute strength remaining 14 days post implantation meets or exceeds that historically observed with plain and chromic gut sutures. Absorption of MONOGLYDE absorbable synthetic suture is essentially complete approximately 90 days.

CONTRA INDICATIONS

Monoglyde sutures being absorbable, should not be used where extended approximation of tissue under stress is required, such as in fascia.

WARNINGS

Users should be familiar with the surgical procedures and techniques involving absorbable sutures before employing Monoglyde suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance when selecting a suture for use in patients. The use of this suture may be inappropriate in elderly, malnourished

or debilitated patients or in patients suffering from conditions which may delay wound healing. Do not reuse. Discard opened packages and unused sutures. As with any foreign body, prolonged contact of any suture with salt solutions such as those found in the urinary or biliary tracts may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds. As this is an absorbable suture material the use of supplemental sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention or which may require additional support.

PRECAUTIONS

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Sub cuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with absorption. Under some circumstances, notably orthopedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon. Consideration should be taken in the use of absorbable sutures in tissue with poor blood supply as suture extrusion and delayed absorption may occur. In handling this 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. Monoglyde suture knots must be properly placed to be secure. Adequate knot security requires the accepted surgical technique 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 monofilaments. Avoid prolonged exposure to elevated temperature.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharp" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of synthetic absorbable sutures include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distention occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, localized irritation when skin sutures are left in place for more than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies.














Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood-borne pathogens.

SUPPLY

Monoglyde 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 (Warnings) sorgfältig lesen ES - Precaución: lea las instrucciones (advertencias) cuidadosamente PT - Cuidado: leia as instruções (avisos) cuidadosamente GR - Προσοχή: διαβάστε προσεκτικά τις οδηγίες (εισαγωγές)
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 αιθυλενοξειδίο
	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 re-sterilize 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 δροσερό 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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