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PDSYNTH®

FILO DA SUTURA CHIRURGICA RIASSORBIBILE USP (SINTETICO) (POLIDIOXANONE MONOFILAMENTO)

ABSORBABLE SURGICAL SUTURE (SYNTHETIC) (MONOFILAMENT POLYDIOXANONE)

SUTURE CHIRURGICALE RÉSORBABLE (SYNTHÉTIQUE) (MONOFILAMENT POLYDIOXANONE)

RESORBIERBARES CHIRURGISCHES NAHTMATERIAL (SYNTHETISCH) (MONOFILES POLYDIOXANON)

SUTURA QUIRÚRGICA ABSORBIBLE (SINTÉTICA) (MONOFILAMENTO POLYDIOXANONE)

SUTURA CIRÚRGICA ABSORVÍVEL (SINTÉTICO) (MONOFILAMENTO POLYDIOXANONE)

ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΡΑΜΜΑ (ΣΥΝΘΕΤΙΚΟ) (ΜΟΝΟΚΛΩΝΗ POLYDIOXANONE)

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

ENGLISH

DESCRIPTION

PDSynth (Polydioxanone), monofilament synthetic absorbable suture is prepared from the polyester, poly (p-dioxanone). The empirical formula of the polymer is (C4H603)X. Polydioxanone polymer has been found to be non antigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption. It is colored violet, dyed with D&C Violet. PDSynth sutures comply with USP requirements, except for diameter.

INTENDED PURPOSE

PDSynth, monofilament synthetic absorbable sutures are indicated for use in all types of soft tissue approximation, including use in ophthalmic surgery. PDSynth sutures is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

ACTION

PDSynth synthetic absorbable suture has been formulated to minimize the variability of these characteristics and to provide wound support through an extended healing period. The results of implantation studies of PDSynth monofilament suture in animals indicate that approximately 80% of its original strength remains two weeks after implantation. At four weeks post - implantation, approximately 70% of its original strength is retained and at six weeks, approximately 25% of the original strength is retained. Data obtained from implantation studies in rats show that the absorption of these sutures is minimal until about the 90th post - implantation day. Absorption is essentially complete approximately 180days.

CONTRA INDICATIONS

These sutures being absorbable, are not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required these sutures are not to be used in conjunction with prosthetic devices, i.e., heart halves or synthetic grafts.

WARNINGS

The safety and effectiveness of PDSynth (Polydioxanone) sutures have not been established in neural tissue, adult cardiovascular tissue or for use in microsurgery. Under certain circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon. Do not reuse.

PRECAUTIONS

The PDSynth suture knots must be properly placed to be secure. As with other synthetic sutures, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the surgeon. As with any suture, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needle holders and forceps to the strand except when grasping the free end of the suture during an instrument tie. Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated. Subcuticular sutures should be placed as deeply as possible in order to minimize the erythema and induration normally associated with absorption. Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds. Discard used needle in sharps containers.

ADVERSE REACTIONS

Due to prolonged suture absorption, some irritation and bleeding has been observed in the conjunctiva and mild irritation has been observed in the vaginal mucosa.

SUPPLY

PDSynth 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 (Warings) sorgfältig lesen **ES -** Precaución: lea las instrucciones (advertencias) cuidadosamente **PT -** Cuidado: leia as instruções (avisos) cuidadosamente **GR -** Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ενστάσεις)
	**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 -** Fabbricante **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 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
	**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
	**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

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