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PROFESSIONAL MEDICAL PRODUCTS

TRUBARB™

SUTURA CHIRURGICA RIASSORBIBILE CON AGO.
DISPOSITIVO DI CHIUSURA DEI TESSUTI SENZA NODI (SINTETICO).
MONOFILAMENTO IN POLIDIOSSANONE.

ABSORBABLE SURGICAL NEEDLED-SUTURE (SYNTHETIC).
KNOTLESS TISSUE-CLOSURE DEVICE
MONOFILAMENT POLYDIAXANONE.

SUTURE CHIRURGICALE NON RÉSORBABLE MONTÉE SUR AIGUILLE (SYNTHÉTIQUE)
DISPOSITIF DE FERMETURE TISSULAIRE SANS NŒUDS.
POLYDIOXANONE MONOFILAMENT.

RESORBIERBARE CHIRURGISCHE NADEL-NAHT (SYNTHETISCHES).
KNOTENLOSES GEWEBEVERSCHLUSSINSTRUMENT
MONOFILAMENT POLYDIAXANON.

SUTURA QUIRÚRGICA ABSORBIBLE CON AGUJA.
DISPOSITIVO DE CIERRE DE TEJIDO SIN NUDOS (SINTÉTICO).
POLIDIAXANONA MONOFILAMENTO.

DISPOSITIVO DE FECHO DE TECIDO SEM NÓS (SINTÉTICO).
SUTURA DE AGULHA CIRÚRGICA, ABSORVÍVEL.
MONOFILAMENTO POLIDIOXANONA.

ΑΠΟΡΡΟΦΗΣΙΜΟ ΧΕΙΡΟΥΡΓΙΚΟ ΡΑΜΜΑ ΜΕ ΒΕΛΟΝΑ (ΣΥΝΘΕΤΙΚΟ).
ΣΥΣΤΗΜΑ ΣΥΓΚΛΙΣΗΣ ΙΣΤΩΝ ΧΩΡΙΣ ΚΟΜΠΟ.
ΜΟΝΟΚΛΩΝΟ ΑΠΟ ΠΟΛΥΔΙΟΞΑΝΟΝΗ.

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

DESCRIPTION

The Polydiaxanone Knotless Tissue-Closure Device is comprised of barbed dyed Polydiaxanone (PDO) suture material, armed with a surgical needle on one end and end stopper at the other end. The Polydiaxanone Knotless Tissue-Closure Device barbs are oriented in one direction to allow for tissue approximation without the need to tie surgical knots. Polydiaxanone Knotless Tissue-Closure Device is consisting of dyed (violet) polyester, poly(p-dioxanone). The empirical molecular formula of which is (C4H6O3)X. The pigment for the violet dye is D&C Violet No. 2. Polydiaxanone has been found to be nonantigenic, nonpyrogenic and to elicit only a slight tissue reaction during absorption. While the formation of barbs in the Polydioxanone Knotless Tissue- Closure Device reduces the tensile strength relative to non- barbed suture material of the same size, tying of knots in non- barbed suture materials also reduce their effective strength. For this reason, the strength of the Polydiaxanone Knotless Tissue- Closure Device can be compared to USP knot strength of non- barbed sutures. Additionally, USP designations for diameter are used to describe the Polydioxanone Knotless Tissue-Closure Device prior to barbing, except for minor variation in suture diameter with a maximum overage of 0.14mm.

Tensile Strength/Size Equivalency

Polydiaxanone Knotless Tissue-Closure Device size	Pre-Barbing Suture Size	Equivalent Non-Barbed Size(USP)/ Tensile Strength(Kgf)
1	2	1/5.08
0	1	0/3.90
2-0	0	2-0/2.68
3-0	2-0	3-0/1.77
4-0	3-0	4-0/0.95
5-0	4-0	5-0/0.68

ACTIONS
Two important characteristics describe the in vivo performance of absorbable sutures: first, tensile strength retention and second, the absorption rate (loss of mass). Polydiaxanone Knotless Tissue-Closure Device has been formulated to minimize the variability of these characteristics and to provide wound support through the critical wound healing period and an extended healing period.

The results of implantation studies in animals using Polydiaxanone Knotless Tissue-Closure Device indicate that

Days Implantation	Approximate % Original Strength Remaining
14 days	75%
28 days	65%
42 days	55%

Absorption of Polydiaxanone Knotless Tissue-Closure Device is essentially complete between 180 to 220 days.

INTENDED PURPOSE
Polydiaxanone Knotless Tissue-Closure Device is indicated for use in soft tissue approximation where use of Polydiaxanone absorbable suture is appropriate.

CONTRAINDICATIONS
Polydioxanone Knotless Tissue-Closure Device is not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required and is not to be used in conjunction with or for fixation of prosthetic devices (e.g. heart valves or synthetic grafts) that are non-absorbable in nature.

WARNINGS
Do not resterilize. Discard opened, unused Polydioxanone Knotless Tissue-Closure Device and associated surgical needles. Users should be familiar with surgical procedure and techniques involving absorbable sutures before employing Polydioxanone Knotless Tissue-Closure Device 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 (under ACTIONS section) 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 delaywound healing.
The safety and effectiveness of Polydioxanone Knotless Tissue-Closure Device has not been established for use in fascial closures (including abdominal wall, thoracic and extremity fascial closures), gastrointestinal anastomoses, cardiovascular tissue, neural tissue, osseous tissue, tendinous tissue, ophthalmic surgery, or for use in microsurgery, therefore this product should not be used for these purposes.
As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts may result in calculus formation. As an absorbable suture, Polydioxanone Knotless Tissue-Closure Device 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 nonabsorbable 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
Polydioxanone Knotless Tissue-Closure Device contains unidirectionally oriented barbs to anchor tissues and does not require knots to approximate opposing edges of a wound. Tying knots on the barbed section of the material will damage the barbs and potentially reduce the suture tensile strength and barb e ectiveness. Additionally, when completing placement, an additional backstitch or bite of tissue lateral to the end of the incision is required to lock the device in place. Avoid contacting the Polydioxanone Knotless Tissue-Closure Device and associated needles with other materials (e.g. surgical gauze, drapes, etc.) in the surgical field to prevent ensnaring on the barbs. If the barbs catch, carefully pull the material in the opposite direction of the needle to disengage it from the barbs.
Care should be taken to avoid damage when handling. Avoid crushing or crimping the suture material with surgical instruments, such as needle holders and forceps. Do not pull the Polydioxanone Knotless Tissue-Closure Device out of the package by the needles as this can cause the barbs to catch on one another. Do not attempt to remove memory in the polymer.
by running fingers down the suture material as this can damage the barbs.
Infections, erythema, foreign body reactions, transient inflammatory reactions and in rare instances wound dehiscence are typical or foreseeable risks associated with any suture and hence are also potential complications associated with Polydiaxanone Knotless Tissue-Closure Device.
When using Polydiaxanone Knotless Tissue-Closure Device subcutaneously, the device should be placed as deeply as possible in order to minimize erythema and induration normally associated with absorption. Acceptable surgical practice should be followed with respect to drainage and Closure of infected wounds.
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 “sharps” containers.

ADVERSE REACTIONS
Adverse effects associated with the use of this device may include, wound dehiscence, failure to provide adequate wound support in closure of the site where expansion, stretching or distension 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, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater 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 infection 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 bloodborne pathogens. Due to prolonged suture absorption, some irritation and bleeding may occur.

APPLICATION
Polydiaxanone Knotless Tissue-Closure Device is designed to be used in continuous suture patterns and intended to be used without anchoring knots to begin or terminate the device line
Use as required per surgical procedure.
Secure the fixation end stopper portion to robust tissue by taking a bite in the designated tissue, passing the needle and pulling tautly around the anchoring tissue.
After Polydiaxanone Knotless Tissue-Closure Device is anchored into the tissue, grasp the strand and approximate tissue to the desired tension. Bites, or passes through the tissue, can be taken in a continuous suturing technique to approximate the wound. Care should be taken to utilize the Polydioxanone Knotless Tissue-Closure Device on the barbed segments only. Do not attempt to approximate wounds using the non-barbed segment near the needle, as the barbs are required for successful wound approximation with the Polydioxanone Knotless Tissue-Closure Device.
To complete the closure in subcuticular closure, take at least one pass in the reverse direction. Then pass the needle across the incision and take a split thickness bite perpendicular to the incision and exit the skin.
To complete the closure in all other tissue layers, take at least two passes in the reverse direction to complete the closure. Then gently pull on the free end of the device and cut flush with the surface of the tissue.

STERILITY
Polydiaxanone Knotless Tissue-Closure Device is sterilized by ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard opened unused sutures. Do not use after expiration date.

HOW SUPPLIED
Polydiaxanone Knotless Tissue-Closure Device is available sterile, in various sizes in unidirectional barb configurations attached with various needle type, shape and length which are packed in a printed box, quantity as indicated on the label.

STORAGE
Recommended storage conditions: Below 30° C away from moisture and direct sunlight. Do not use after expiry.

DISPOSAL
Discard used sutures and needles contaminated with blood in the container meant for infection waste. Unused expired pouches should be Incinerated or Disposal should be done as per local regulation.

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 **BSN0316U (GIMA 22890)**
BSN0326U (GIMA 22891)
BSN0315U (GIMA 22892)
BSN0325U (GIMA 22893)
BSN0615U (GIMA 22894)
BSN0624U (GIMA 22895)
BSN1100U (GIMA 22896)

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STERILE EO 30°C

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