



Polysorb™

Coated Braided Absorbable Suture

PT00129889



(92)PT00129889



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Polysorb™ braided sutures are composed of Lactomer™ glycolide/lactide copolymer which is a synthetic polyester composed of glycolide and lactide (derived from glycolic and lactic acids). Polysorb™ sutures are prepared by coating the suture with a mixture of a caprolactone/glycolide copolymer and calcium stearoyl lactylate. Polysorb™ sutures are colored violet to increase visibility and are also available undyed.

Polysorb™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) except for minor variations in suture diameter.

Such variations are:

Maximum Suture Oversize in Diameter (mm) from USP		
USP Size	USP Size Designation (mm)	Maximum Overage (mm)
8-0	0.040 - 0.049	0.020
7-0	0.050-0.069	0.030
6-0	0.070-0.099	0.050
5-0	0.10-0.149	0.050
4-0	0.15-0.199	0.050
3-0	0.20-0.249	0.050
2-0	0.30-0.339	0.050
0	0.35-0.399	0.050
1	0.40-0.499	0.050
2	0.50-0.599	0.050

INDICATIONS

Polysorb™ sutures are indicated for use in soft tissue approximation or ligation and ophthalmic surgery, but not in cardiovascular or neural tissue.

ACTIONS

Polysorb™ sutures elicit a minimal acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue.

Progressive loss of tensile strength and eventual absorption of Polysorb™ sutures occurs by means of hydrolysis, where the Lactomer™ glycolide/lactide copolymer is broken down to glycolic and lactic acids which are subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Studies indicate tensile strength averages for Polysorb™ sutures are approximately 140% of USP and E.P. minimum knot strength initially, are approximately 80% at two weeks and in excess of 30% at three weeks post implant. Absorption of Polysorb™ sutures is essentially complete between the 56th and 70th day.

CONTRAINDICATION

Polysorb™ sutures, being absorbable, should not be used where extended approximation of tissue is required.

WARNINGS

Reprocessing and/or resterilization of this device may create the risk of contamination, patient infection, permanent impairment or life threatening injury. Do not reuse, reprocess or sterilize this device. Sterile unless packaging has been opened or damaged. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

In surgery of the urinary or biliary tracts, care should be taken to avoid prolonged contact of this, or any other, suture with salt solutions, as calculus formation may result.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Polysorb™ sutures for wound closure, as the 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 contaminated or infected wounds.

The use of this suture may be inappropriate in patients with any conditions which, in the opinion of the surgeon, may cause or contribute to delayed wound healing.

As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in closure of the abdomen, chest, joints or other sites subject to expansion or requiring additional support.

PRECAUTIONS

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. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Skin sutures which must remain in place longer than 7 days may cause irritation and should be snipped off or removed as indicated.

Under some circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Dispose of used instruments in accordance with the end-user's medical and biological waste disposal requirements. For RX Only. Federal law restricts this device to sale by or on the order of a license healthcare practitioner.

ADVERSE REACTIONS

Adverse effects: wound dehiscence, failure to provide adequate wound support in sites where expansion, stretching, or distention occur, failure to provide adequate wound support in patients with conditions which may delay wound healing, localized irritation when skin sutures are left in place greater than 7 days, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

HOW SUPPLIED

Polysorb™ sutures are available in USP sizes 2 (5 Metric) through 8-0 (0.4 Metric). They are available undyed (natural) or violet colored. The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needled or affixed to various needle types using both permanent and removable needle attachment techniques. The sutures are available in box quantities of one, two and three dozen.

Syneture™

STERILE EO

en: Sterilized using ethylene oxide **fr:** Stérilisé à l'oxyde d'éthylène
de: Mit Ethylenoxid sterilisiert **it:** Sterilizzato con ossido di etilene **es:** Esterilizado con óxido de etileno **pt:** Esterilizado com óxido de etileno
nl: Gesteriliseerd met ethyleenoxide **sv:** Steriliserad med etylenoxid
da: Steriliseret med ethylenoxid **fi:** Steriloitu eteenioksidilla. **el:** Αποστειρωμένο με οξείδιο του αιθυλενίου **pl:** Sterylizowano przy użyciu tlenku etylenu **tr:** Etilen oksit kullanılarak sterilize edilmiştir
ru: Стерилизовано этиленоксидом **cs:** Sterilizováno ethylenoxidem
hu: Etilén-oxidál sterilizálva **sk:** Sterilizované etylénoxidom **no:** Sterilisert med etylenoksid **sl:** Sterilizirano z etilen oksidom **bg:** Стерилизирано с етиленов оксид **ro:** Sterilizat cu oxid de etilenă **et:** Steriliseeritud etüleenoksiidiga **lv:** Sterilizēts, izmantojot etilēnoksidu
hr: Sterilizirano etilen-oksidad **sr:** Sterilisano etilen oksidom **lt:** Sterilizuota etileno oksidu **zh:** 使用环氧乙烷灭菌 **zht:** 使用環氧乙烷滅菌 **ko:** 산화에틸렌으로 멸균처리 **id:** Disterilkan menggunakan etilena oksida **vi:** Được tiệt trùng bằng ethylene oxide



en: Single Use **fr:** Usage unique **de:** Einmalgebrauch **it:** Monouso
es: Un solo uso **pt:** Uso único **nl:** Voor eenmalig gebruik **sv:** För engångsbruk **da:** Engangsbrug **fi:** Kertakäyttöinen **el:** Μίας χρήσης
pl: Produkt jednorazowego użytku **tr:** Tek Kullanımlık **ru:** Для одноразового использования **cs:** Na jedno použití **hu:** Egyszer használatos **sk:** Na jedno použitie **no:** Engangsbruk **sl:** Za enkratno uporabo **bg:** За еднократна употреба **ro:** De unică folosință **et:** Ühekordselt kasutatav **lv:** Vienreiz lietojams **hr:** Za jednokratnu uporabu **sr:** Za jednokratnu upotrebu **lt:** Vienkartinė **zh:** 单一用途 **zht:** 單次用 **ko:** 1회용 **id:** Sekali Pakai **vi:** Dùng một lần

**Rx
ONLY**

en: Caution: U.S. Federal law restricts this device to sale by or on the order of a physician. **fr:** Mise en garde : La loi fédérale des États-Unis n'autorise la vente de ce dispositif que par un médecin ou sur ordonnance médicale. **de:** Vorsicht: Gemäß US-Bundesgesetz darf dieses Gerät nur durch einen Arzt oder auf ärztliche Verschreibung abgegeben werden. **it:** Attenzione: la legge federale statunitense limita la vendita di questo dispositivo a medici o dietro prescrizione medica. **es:** Precaución: La ley federal de EE. UU. restringe la venta de este dispositivo a un médico o por prescripción facultativa. **pt:** Cuidado: A lei federal dos EUA restringe a venda deste produto à prescrição de um médico. **nl:** Let op: Krachtens de federale wetgeving van de Verenigde Staten mag dit hulpmiddel uitsluitend worden verkocht door of op voorschrift van een arts. **sv:** Viktigt! Enligt federal lag i USA får denna produkt endast säljas av läkare eller på läkares ordination. **da:** Forsigtig: Amerikansk lovgivning begrænser denne anordning til salg af eller på ordination af en læge. **fi:** Huomio: Yhdysvaltain lantovalltion lain mukaan tämä laite saa myydä vain lääkäri tai lääkäriin määräksestä. **el:** Προσοχή: Η ομοσπονδιακή νομοθεσία των Η.Π.Α. επιτρέπει την πώληση αυτού του προϊόντος μόνον σε ιατρό ή κατόπιν εντολής ιατρού. **pl:** Przestroga: Prawo federalne Stanów Zjednoczonych dopuszcza niniejsze urządzenie do sprzedaży tylko przez lub na zlecenie lekarza. **tr:** Dikkat: ABD federal yasalarına göre bu cihaz sadece bir hekim tarafından veya hekim talimatıyla satılabilir. **ru:** Внимание! Федеральное законодательство США разрешает продажу этой продукции только врачам или по их заказу. **cs:** Upozornění: Podle federálních zákonů USA smí být tento prostředek prodáván pouze lékařem nebo na jeho objednávku. **hu:** Figyelem: Az USA szövetségi törvényei alapján ez a készülék kizárólag orvos által vagy orvosi rendelvényre értékesíthető. **sk:** Upozornenie: Federálne zákony (USA) obmedzujú predaj tohto zariadenia na lekára alebo na lekársky predpis. **no:** Forsiktig: I følge amerikansk føderal lovgivning (USA) kan denne enheten kun selges av eller på ordre av en lege. **sl:** Pozor: Z zvezno zakonodajo ZDA je prodaja tega pripomočka dovoljena le zdravnikom ali na zdravniški recept. **bg:** Внимание! Според федералното законодателство на САЩ продажбата на това устройство може да стане само по поръчка на лекар. **ro:** Atenție! Legislația federală din S.U.A. permite comercializarea acestui dispozitiv exclusiv de către sau la recomandarea unui medic. **et:** Ettevaatus! USA föderaaliseaduste kohaselt võib käesolevat seadet müüa vaid arsti tellimisel või korraldusel. **lv:** Uzmanību! Federālās likums (ASV) nosaka, ka šo ierīci drīkst pārdot tikai ārstiem vai pēc ārsta pasūtījuma. **hr:** Oprez: Savezni zakon Sjedinjenih Američkih Država ograničava prodaju ovog uređaja samo na liječnika ili na njegov nalog. **sr:** Oprez: Savezni zakon SAD-a ograničava prodaju ovog sredstva na lekara ili po nalogu lekara. **it:** Atsargai. Pagal JAV federalinius įstatymus ši priemonė gali būti parduodama tik gydytojui paskyrus arba užsakius. **zh:** 小心: 美国联邦法律限定本器械只能由医生销售或遵照医嘱销售。 **zh:** 小心: 美国联邦法规规定此装置仅能由医生或遵照医嘱销售。 **ko:** 주의: 미국 연방 법률은 본 기기를 의사에 의한 판매 또는 의사의 지시에 따른 판매로 제한합니다. **id:** Perhatian: Federal A.S. membatasi penjualan perangkat ini hanya oleh dokter atau atas perintah dokter. **vi:** Thân trọng: Luật liên bang (Hoa Kỳ) giới hạn thiết bị này chỉ được bán bởi hoặc theo yêu cầu của bác sĩ.



en: Do not resterilize **fr:** Ne pas restériliser **de:** Nicht resterilisieren **it:** Non risterilizzare **es:** No reesterilizar **pt:** Não reesterilize **nl:** Niet opnieuw steriliseren **sv:** Får inte omsteriliseras **da:** Må ikke reesteriliseres **fi:** Ei saa steriloida uudelleen **el:** Μην επανοστεριώνετε **pl:** Nie sterylizować ponownie **tr:** Tekrar sterilize etmeyin **ru:** Повторная стерилизация запрещена **cs:** Opakovaně nesterilizujte. **hu:** Tilos újraszterilizálni **sk:** Nesterilizujte opakovane **no:** Skal ikke reesteriliseres **sl:** Ne sterilizirajte ponovno **bg:** Да не се стерилизира повторно **ro:** A nu se reesteriliza **et:** Mitte resteriliseerida **lv:** Nesterilizēt atkārtoti **hr:** Nemojte ponovno sterilizirati **sr:** Nemojte ponovo sterilisati **lt:** Nesterilizuoti pakartotinai **zh:** 请勿重新灭菌 **zh:** 請勿重複滅菌。 **ko:** 재멸균하지 마십시오 **id:** Jangan disterilkan ulang **vi:** Không tiệt trùng lại



en: Do not use if package is opened or damaged. **fr:** Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage. **de:** Bei geöffneter oder beschädigter Verpackung nicht verwenden. **it:** Non utilizzare se la confezione è aperta o danneggiata. **es:** No usar el dispositivo si la envoltura está abierta o dañada. **pt:** Não utilizar se a embalagem estiver aberta ou danificada. **nl:** Niet gebruiken als de verpakking beschadigd of geopend is. **sv:** Får ej användas om förpackningen är öppnad eller skadad. **da:** Må ikke anvendes, hvis emballagen er åbnet eller beskadiget. **fi:** Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut. **el:** Μην χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά. **pl:** Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone. **tr:** Ambalaj açılmış ya da zarar görmüşse kullanmayın. **ru:** Не используйте изделие, если упаковка вскрыта или повреждена. **cs:** Pokud je balení otevřené nebo poškozené, produkt nepoužívejte. **hu:** Tilos felhasználni, ha a csomagolás kinyílt vagy megsérült. **sk:** Nepoužívajte, ak je obal otvorený alebo poškodený. **no:** Skal ikke brukes hvis emballasjen er åpnet eller skadet. **sl:** Ne uporabljajte, če je embalaža odprta ali poškodovana. **bg:** Не използвайте, ако опаковката е отворена или повредена. **ro:** A nu se utiliza în cazul în care ambalajul este deschis sau deteriorat. **et:** Ärge kasutage, kui pakend on avatud või kahjustatud. **lv:** Nelietot, ja iepakojums ir atvērts vai bojāts. **hr:** Ne koristite ako je pakiranje otvoreno ili oštećeno. **sr:** Ne koristiti ako je pakovanje otvoreno ili oštećeno. **lt:** Nenaudokite, jei pakuotė atidaryta arba pažeista. **zh:** 如果果包装已打开或破损, 请勿使用。 **zh:** 如果包装已開啟或損毀, 則請勿使用。 **ko:** 포장 이 개봉되어 있거나 손상된 경우에는 사용하지 마십시오. **id:** Jangan digunakan jika kemasan terbuka atau rusak. **vi:** Không sử dụng nếu bao bì bị bóc mở hoặc hư hỏng.




en: Caution, consult accompanying documents **fr:** Mise en garde
: consulter les documents joints **de:** Vorsicht, Begleitdokumente
beachten **it:** Attenzione: consultare la documentazione di
accompagnamento **es:** Precaución, consultar documentación adjunta
pt: Cuidado, consulte os documentos que acompanham o produto
nl: Let op, raadpleeg de bijgevoegde documenten **sv:** OBS! Läs
medföljande dokumentation **da:** Forsigtig, læs de medfølgende
dokumenter **fi:** Huomio, lue liitteenä olevat asiakirjat **el:** Προσοχή,
συμβουλευτείτε τα συνοδευτικά έγγραφα **pl:** Przestroga: należy
zapoznać się z załączonymi dokumentami **tr:** Dikkat, beraberindeki
belgelere bakın **ru:** Внимание! Сверьтесь с сопроводительной
документацией **cs:** Pozor, prostudujte si přiloženou dokumentaci **hu:**
Figyelem, tanulmányozza a mellékelt dokumentumokat **sk:** Pozor,
prečítajte si priložené dokumenty **no:** Forsiktig, les medfølgende
dokumenter **sl:** Pozor, preberite priložene dokumente **bg:** Внимание,
направете справка с приложените документи **ro:** Atenție, consultați
documentele însoțitoare **et:** Ettevaatus! Lugege kaasasolevaid
dokumente! **lv:** Uzmanību, iepazīstieties ar pievienotajiem
dokumentiem **hr:** Oprez, pročitajte prateću dokumentaciju **sr:**
Oprez, pogledajte prateća dokumenta **lt:** Atsargiai, žr. lydimuosius
dokumentus **zh:** 小心, 請參閱隨附文件 **zht:** 注
意 · 請參閱隨附文件 **ko:** 주의, 함께 제공된
설명서를 참조하십시오. **id:** Perhatian, baca dokumen
pendamping **vi:** Thận trọng, tham khảo các tài liệu đi kèm



en: Package quantity **fr:** Quantité par paquet **de:** Anzahl pro Packung
it: Quantità confezione **es:** Cantidad por paquete **pt:** Quantidade na
embalagem **nl:** Hoeveelheid per verpakking **sv:** Antal i förpackningen
da: Antal anordninger i pakken **fi:** Määrä pakkauksessa **el:** Ποσότητα
συσκευασίας **pl:** Liczba sztuk w opakowaniu **tr:** Paket miktar **ru:**
Количество в упаковке **cs:** Počet v balení **hu:** Csomagokénti
mennyiség **sk:** Množstvo v balení **no:** Antall enheter i pakningen **sl:**
Količina v pakiranju **bg:** Количество в опаковка **ro:** Cantitate per
pachet **et:** Kogus pakendis **lv:** Izstrādājumu skaits iepakojumā **hr:**
Količina u pakiranju **sr:** Količina u pakovanju **lt:** Kiekis pakuotėje **zh:**
包裝數量 **zht:** 包裝數量 **ko:** 포장 수량 **id:** Jumlah
kemasan **vi:** Số lượng đóng gói

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