Box size: 2.25 x 5
Overall size: 18 x 21
Folds to: 2.25 x 4.2

COVIDIEN

Polysorb™

Coated Braided Absorbable Suture

1300577

EN

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

Do not resterilize. 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.

ADVERSE REACTIONS

Adverse effects, which may be associated with the use of this product, include: 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.

FR
Suture résorbable tressée et recouverte

DE
Beschichtetes geflochtenes resorbierbares Nahtmaterial

IT
Sutura assorbibile intrecciata rivestita

ES
Sutura reabsorbible trenzada y revestida

PT
Sutura absorvível trançada e revestida

NL
Gevlochten absobeerbare hechtdraad met coating

SV
Ytbehandlad, flätad, resorberbar sutur

DA
Flettet, resorberbar sutur med belægning

FI
Päällystetty punottu resorboituva ommelaine

EL
Επικαλυμμένο, πλεκτό, απορροφήσιμο ράμμα

PL
Powlekane plecione szwy wchłanialne

TR
Kaplamalı Örgülü Emilebilir Dikiş İpliği

RU
Рассасывающийся плетеный шовный материал с покрытием

CS
Opletaný vstřebatelný šicí materiál s povrchovou úpravou

HU
Bevont fonott felszívódó fonalak

SK
Vrstvené pletené vstrebateľné chirurgické nite

NO
Flettet resorberbar sutur med belegg

SL
Prevlečena, pletena vpojna sutura

ZH
带涂层多股可吸收缝合线

ZH-T
帶塗層辮狀可吸收縫合線

KO
코팅된 브레이드 흡수성 봉합사

BG
Сплетен абсорбируем хирургически конец с покритие

RO
Sutură absorbabilă împletită, cu înveliş

ET
Punutud absorbeeruv kattega haavaõmblusniit

LV
Pīta absorbējama šuve ar pārklājumu

HR
Isprepleteni resorptivni kirurški konac s oblogom

SR
Obloženi pleteni resorptivni konac

LT
Padengti supinti absorbuojamieji siūlai

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

Syneture™

STERILE EO

Rx ONLY

Caution, consult accompanying documents

Upper temperature limit 130°F 54°C

CE 0123

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