Instructions for use

Coated VICRYL™ PLUS ANTIBACTERIAL
(POLYGLACTIN 910)
STERILE SYNTHETIC ABSORBABLE
SUTURE

DESCRIPTION
Coated VICRYL™ PLUS Antibacterial suture is a synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. The empirical formula of the copolymer is (C₅H₆O₂)ₓ(C₅H₇O₂)ᵧ. Braided Coated VICRYL™ PLUS Antibacterial sutures are coated with a mixture composed of equal parts of copolymer of glycolide and lactide (Poliglecaprone 25) and calcium stearate. Poliglecaprone 25 copolymer and Poliglecaprone 370 with calcium stearate have been found to be nonantigenic, nonpyrogenic and eliciting only a slight tissue reaction. Coated VICRYL™ PLUS Antibacterial suture contains Irgacare™ MP (Triclosan), a broad spectrum antibacterial agent at no more than 25 µg/g. Coated VICRYL™ PLUS Antibacterial sutures are dyed with a color index number of 60725 (color Index number: 60725) during polymerization. Sutures are also available in the undyed form. Coated VICRYL™ PLUS Antibacterial sutures are available in a range of gauge sizes and lengths, non-needed or attached to stainless steel needles of varying sizes. The needles may be attached permanently or as CR-needles (control release), enabling the needle to be pushed over instead of being cut off. Full details are contained in the catalogue. Coated VICRYL™ PLUS Antibacterial sutures comply with the requirements of the United States Pharmacopeia for Absorbable Suture and the European Pharmacopeia for Sterile Synthetic Absorbable Braided Sutures. (except for an occasional slight variation in some gauges).

INDICATIONS
Coated VICRYL™ PLUS Antibacterial sutures are intended for use in general soft tissue approximation and/or ligation. The safety and effectiveness of Coated VICRYL™ PLUS Antibacterial sutures in cardiovascular tissue, ophthalmic tissue and neurotissue have not been established.

APPLICATION
Sutures should be selected and implanted on patient condition, surgical experience, surgical technique and wound size.

PERFORMANCE
Coated VICRYL™ PLUS Antibacterial suture elicits a minimal initial inflammatory reaction in tissues and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Coated VICRYL™ PLUS Antibacterial sutures occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass. All of the original tensile strength is lost by five weeks post implantation. Absorption of Coated VICRYL™ PLUS Antibacterial Suture is essentially complete between 56 and 70 days.

Days

Approximate % Original Strength Remaining
14 days
21 days
28 days
75%
50%
25%

Coated VICRYL™ PLUS Antibacterial suture has been shown to inhibit colonization of the suture by Staphylococcus aureus, Staphylococcus epidermidis and their Methicillin resistant strains. The clinical significance of this finding is unknown.

CONTRAINDICATIONS
These sutures, being absorbable should not be used where extended approximation of tissues under stress is required. Coated VICRYL™ PLUS Antibacterial suture should not be used in patients with known allergic reactions to Irgacare™ MP (Triclosan).

WARNINGS/PRECAUTIONS/INTERACTIONS
Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Coated VICRYL™ PLUS Antibacterial suture for wound closure. As risk of wound dehiscence may vary with the site of application and the suture material used. Surgeons should consider the in vivo performance (under PERFORMANCE section) when selecting a suture. 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 Coated VICRYL™ PLUS Antibacterial suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds. The use of Coated VICRYL™ PLUS Antibacterial suture does not substitute normal observance of hygiene and/or otherwise needed antibiotic treatment. As this is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of the sites which may undergo endoprostheses, stretching or distention, or which may require additional support. Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Under some circumstances, notably orthopaedic 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 tissues with poor blood supply as suture extension and delayed absorption may occur. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with the absorption process. This suture may be inappropriate in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing. When handling this or any other suture material, care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the attachment end to the point. Grasping the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Repositioning needles may cause them to lose strength and be less resistant to bending and breaking.

ADVERSE REACTIONS
Adverse reactions associated with the use of this device include transient local irritation at the wound site, transitory inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures. Like all foreign bodies Coated VICRYL™ PLUS Antibacterial suture may potentiate an existing infection.

STERILITY
Coated VICRYL™ PLUS Antibacterial sutures are sterilized by ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

STORAGE
Recommended storage conditions: Store at or below 25°C. Do not use after expiry date.

SYMBOLS USED ON LABELING

Do not reuse
Use by — year and month
Uterine End
Sterile unless package is damaged or opened. Method of sterilization: Ethylene Oxide
Manufacturer
Sachets
CE-mark and Identification Number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42/EEC
Catalogue Number
Upper limit of temperature 77°F
LOT
Batch number

Comment: See instructions for use

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Coated VICRYL™ PLUS
- ANTIBACTERIAL -
SUTURE

bg KOHEÇ
cs ŠICÍ MATERIÁL
da SUTUR
de NAHTMATERIAL
el ΠΑΜΜΑ
en SUTURE
es SUTURA
et ÕMPLUSMATERIJAL
fi OMMELAINE
fr FIL DE SUTURE
hr KONAC
hu VARRÓANYAG
it SUTURA
ko 봉합사
lt SIULAS
lv KIRURĢISKĀS DIEGS
nl HECHTDRAAD
no SUTUR
pl NICI
pt FIO DE SUTURA
ro FIR DE SUTURĂ
ru ШОВНЫЙ МАТЕРИАЛ
sk CHIRURGICKÁ NÍT
sl KIRURŠKA NIT
sr KONAC
sv SUTUR
tr SÜTÜR
zh-cn 缝线
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