VICRYL™

ar	خيط	fr	FIL DE SUTURE	pl	NICI
bg	КОНЕЦ	hr	KIRURŠKI KONAC	pt	FIO DE SUTURA
cs	ŠICÍ MATERIÁL	hu	VARRÓANYAG	ru	ШОВНЫЙ МАТЕРИАЛ
da	SUTUR	it	SUTURA	sk	NIŤ
de	NAHTMATERIAL	ko	봉합사	sl	KIRURŠKA NIT
el	ΡΑΜΜΑ	lt	SIŪLAS	sr	KONAC
en	SUTURE	lv	ĶIRURĢISKAIS DIEGS	sv	SUTURMATERIAL
es	SUTURA	mk	ХИРУРШКИ КОНЕЦ	tr	SÜTÜR
et	ÕMBLUSMATERJAL	nl	HECHTMATERIAAL	zh-cn	缝线
fi	OMMELAINE	no	SUTUR	zh-tw	縫合線

08/2019
8752795
LAB10043401Tv2

CE 2797

Johnson & Johnson International
c/o European Logistics Centre
Leonardo Da Vincilaan, 15
BE-1831 Diegem
Belgium
+1-513-337-6928

Instructions for use

en

VICRYL™
(Polyglactin 910)
sterile synthetic absorbable

suture

DESCRIPTION
VICRYL™ 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 $(C_2H_2O_2)_m(C_3H_4O_2)_n$.
Braided VICRYL™ sutures are coated with a mixture composed of equal parts of copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate. Polyglactin 910 copolymer and Polyglactin 370 with calcium stearate have been found to be nonantigenic, nonpyrogenic and elicit only a slight tissue reaction during absorption.
VICRYL™ sutures are dyed by adding D+C violet # 2 (Color Index number: 60725) during polymerisation. Sutures are also available in the undyed form.
VICRYL™ is available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes. Note that some sizes of VICRYL™ are available as a monofilament. The needles may be attached permanently or as CR-needles (control release), enabling the needles to be pulled off instead of being cut off. Full details are contained in the catalogue.
VICRYL™ complies with the requirements of the United States Pharmacopoeia for Absorbable Surgical Suture and the European Pharmacopoeia for Sterile Synthetic Absorbable Braided Sutures (except for an occasional slight oversize in some gauges).

INDICATIONS
VICRYL™ sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, peripheral nerve anastomosis and microsurgery for vessels less than 2 mm diameter. The safety and effectiveness of VICRYL™ sutures in cardiovascular tissue have not been established.

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

PERFORMANCE
VICRYL™ suture elicits a minimal initial inflammatory reaction in tissues and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of VICRYL™ 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 VICRYL™ suture is essentially complete between 56 and 70 days.

Days Implantation	Approximate % original Strength Remaining
14 days	75%
21 days (6-0 and larger)	50%
21 days (7-0 and smaller)	40%
28 days (6-0 and larger)	25%

CONTRAINDICATIONS
These sutures, being absorbable should not be used where extended approximation of tissues under stress is required.

WARNINGS/PRECAUTIONS/INTERACTIONS
Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing VICRYL™ 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 VICRYL™ 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 distension, or which may require additional support. Skin sutures which must remain in place longer than 7 days may cause localised irritation and should be snipped off or removed as indicated.
Under some circumstances, notably orthopaedic procedures, immobilisation 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 extrusion 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 debilated 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 in 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. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. All needles are magnetizable and should therefore not be used in an active magnetic field.
Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in 'Sharps' containers.
Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting any monofilament suture.
Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to infection or transmission of bloodborne pathogens to patients and users.

ADVERSE REACTIONS
Adverse reactions associated with the use of this device include transitory 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 VICRYL™ may potentiate an existing infection.

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

STORAGE
No special storage conditions required. Do not use after expiry date!

SYMBOLS USED ON LABELLING

= Do not reuse
= Number of units
= Use by – year and month
STERILE EO = Sterile unless package is damaged or opened
Method of sterilization: Ethylene Oxide
CE 2797 = CE-mark and identification number of Notified Body.
= The product meets the essential requirements of Medical Device Directive 93/42/EEC
LOT = Batch number
= Caution: See instructions for use
= Manufacturer
REF = Catalogue Number