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VICRYL RAPIDE™

ar	خيط	fr	FIL DE SUTURE	ru	ШОВНЫЙ МАТЕРИАЛ
cs	ŠICÍ MATERIÁL	hu	VARRÓANYAG	sk	NIŤ
da	SUTUR	it	SUTURA	sv	SUTUR
de	NAHTMATERIAL	ko	봉합사	tr	SÜTÜR
el	PAMMA	nl	HECHTMATERIAAL	zh-cn	缝线
en	SUTURE	no	SUTUR	zh-tw	縫合線
es	SUTURA	pl	NICI		
fi	OMMELAINE	pt	FIO DE SUTURA		

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Instructions for use

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VICRYL RAPIDE™
(POLYGLACTIN 910)

STERILE SYNTHETIC ABSORBABLE

SUTURE

DESCRIPTION
VICRYL RAPIDE 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 $(C_2H_2O_2)_m(C_3H_4O_2)_n$. The characteristic rapid loss of strength is achieved by use of a polymer material with a lower molecular weight than regular VICRYL™ (polyglactin 910) suture.
VICRYL RAPIDE sutures are obtained by coating the braided suture material with a copolymer composed of 90% caprolactone and 10% glycolide followed by a mixture composed of equal parts of copolymer of glycolide and lactide (polyglactin 370) and calcium stearate. Polyglactin 910 copolymer and its coatings have been found to be nonantigenic, nonpyrogenic and elicit only a mild tissue reaction during absorption.
VICRYL RAPIDE sutures are available undyed as well as dyed by adding D&C violet No. 2 (Colour Index Number 60725) during polymerisation.
VICRYL RAPIDE is available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes. Full details are listed in the catalogue.
VICRYL RAPIDE sutures meet United States Pharmacopoeia (USP) and European Pharmacopoeia (EP) requirements for synthetic absorbable sutures, with the exception of an occasional slight oversize in some gauges and the exception of knot tensile strength. Knot tensile strength meets the USP and EP for collagen sutures (Chorda resorbilis sterilis).

INDICATIONS
VICRYL RAPIDE is intended for use in soft tissue approximation where only short term wound support is required and where the rapid absorption of the suture would be beneficial. Due to its absorption profile VICRYL RAPIDE is useful for skin closure, particularly in paediatric surgery, episiotomies, circumcision and closure of oral mucosa. VICRYL RAPIDE is also successfully used in ophthalmic surgery for conjunctival sutures.

APPLICATION
Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.
VICRYL RAPIDE typically falls off 7–10 days post-operatively or can be wiped off subsequently with sterile gauze. Normally the removal of the suture is not required.

PERFORMANCE
VICRYL RAPIDE suture elicits a minimal to moderate initial inflammatory tissue reaction. Progressive loss of tensile strength and eventual absorption of VICRYL RAPIDE 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.
Subcutaneous and intramuscular implantation studies of VICRYL RAPIDE in rats show that 5 days post-implantation approximately 50% of the original tensile strength remains. All of the original tensile strength is lost by approximately 10 to 14 days post-implantation. The absorption of VICRYL RAPIDE occurs thereafter and is essentially complete by 42 days.

CONTRAINDICATIONS
Due to the rapid loss of tensile strength, VICRYL RAPIDE should not be used where extended approximation of tissues under stress is required or where wound support or ligation beyond 7 days is required. VICRYL RAPIDE suture is not for use in cardiovascular and neurological tissues.

WARNINGS/PRECAUTIONS/INTERACTIONS
Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing VICRYL RAPIDE for wound closure, as the 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 RAPIDE may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
As VICRYL RAPIDE is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of sites which may undergo expansion, stretching or distension, or which may require additional support.
Skin sutures which remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.
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.
The use of VICRYL RAPIDE may be inappropriate in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.
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.
For adequate knot security VICRYL RAPIDE, which is treated with coating to enhance handling characteristics, requires the accepted surgical technique of flat and square ties with additional throws as indicated by surgical circumstance and experience of the surgeon.
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 resistent to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard used needles in 'Sharps' containers.
Do not re-sterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.

ADVERSE REACTIONS
Adverse reactions associated with the use of VICRYL RAPIDE 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 VICRYL RAPIDE may enhance an existing infection.

STERILITY
VICRYL RAPIDE violet is sterilized by ethylene oxide gas. VICRYL RAPIDE undyed is sterilized by irradiation. 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	REF	Catalogue Number
	Use by – year and month		Manufacturer
CE 0086	CE-mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42/EEC	LOT	Batch number
			See instructions for use
STERILE EO / R	Sterile unless package is damaged or opened. Method of sterilization: Ethylene Oxide or Irradiation	EC REP	Authorised Representative in The European Community
	Number of units		