

Coated VICRYL *RAPIDE*™ (Polyglactin 910) Suture

Synthetic Absorbable Suture, Undyed Braided

Non-U.S.P.

DESCRIPTION

Coated VICRYL *RAPIDE*™ (polyglactin 910) 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 of rapid loss of strength is achieved by use of a polymer material with a lower molecular weight than Coated VICRYL™ (polyglactin 910) suture.

Coated VICRYL *RAPIDE*™ sutures are obtained by coating the braided suture material with 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.

Coated VICRYL *RAPIDE*™ sutures are only available undyed.

Although this suture is a synthetic absorbable suture, its performance characteristics are intended to model the performance of collagen (surgical gut) suture. The knot tensile strength of Coated VICRYL *RAPIDE*™ suture meets U.S.P. knot tensile strength requirements for collagen sutures.

MAXIMUM SUTURE OVERSIZE IN DIAMETER (mm) FROM U.S.P. U.S.P. SUTURE SIZE DESIGNATION MAXIMUM OVERSIZE (mm)

6-0	.008
5-0	.016
4-0	.017
3-0	.018
2-0	.010
0	.022

INDICATIONS

Coated VICRYL *RAPIDE*™ synthetic absorbable suture is indicated only for use in superficial soft tissue approximation of the skin and mucosa, where only short term wound support (7–10 days) is required. Coated VICRYL *RAPIDE*™ suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.

ACTIONS

Coated VICRYL *RAPIDE*™ suture, when used in closure of skin and mucous membranes, typically begins to fall off 7 – 10 days post-operatively and can be wiped off subsequently with sterile gauze. Natural mechanical abrasion of the sutures while *in situ* may also accelerate this disappearance rate. Rapid loss of tensile strength may preclude the need for stitch removal.

Coated VICRYL *RAPIDE*™ elicits a minimal to moderate acute inflammatory reaction in tissue. Progressive loss of tensile strength and eventual absorption of Coated 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 tissue implantation studies of Coated VICRYL *RAPIDE*™ sutures 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. Intramuscular implantation studies in rats show that the absorption of these sutures occurs thereafter and is essentially complete by 42 days.

CONTRAINDICATIONS

Due to the rapid loss of tensile strength, this suture should not be used where extended approximation of tissues under stress is required or where wound support beyond 7 days is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Coated VICRYL *RAPIDE*™ suture for wound closure, as a risk of wound dehiscence may vary with the site of application and the suture material used.

Physicians should consider the *in vivo* performance when selecting a suture. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.

Do not resterilize. Discard opened packages and unused sutures.

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 *RAPIDE*™ suture 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 sites which may undergo expansion, stretching or distention, or which may require additional support.

PRECAUTIONS

Skin sutures which 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 extrusion and delayed absorption may occur.

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.

Coated VICRYL *RAPIDE*™ suture, which is treated with coating to enhance handling characteristics, requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Avoid prolonged exposure to elevated temperatures.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.

Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

Coated VICRYL *RAPIDE*™ sutures are available sterile, undyed and attached to stainless steel needles of varying types and sizes.

Coated VICRYL *RAPIDE*™ sutures are available in various lengths in sizes 6-0 to 1 (0.7 to 4.0 metric) in one and three dozen boxes.

 Method of Sterilization	 Batch number
 Do not reuse	 Use by – Year and month
 Do not resterilize	 Manufacturer
 Consult instructions for use	 See instructions for use
 Do not use if package is opened or damaged	

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