Coated VICRYL™ Suture

(polyglactin 910) Suture

U.S.P., EXCEPT FOR DIAMETER

DESCRIPTION

Coated VICRYL™ Suture (polyglactin 910) is a synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. Coated VICRYL™ Suture is prepared by coating Coated VICRYL™ Suture material with a mixture composed of equal parts of copolymer of glycolide and lactide (polyglactin 370) with calcium stearate. The copolymers used in this product have been found to be nonantigenic, nonpyrogenic and elicit only a mild tissue reaction during absorption. The sutures are available dyed and undyed (natural). Coated VICRYL™ Sutures meet U.S.P. except for diameters in the following sizes:

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	.004
0	.022

INDICATIONS

Coated VICRYL™ Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

ACTIONS

Coated VICRYL™ Suture elicits a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Coated VICRYL™ Suture 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. Implantation studies in rats indicate that Coated VICRYL™ Suture retains approximately 75% of the original tensile strength at two weeks post implantation. At three weeks, approximately 50% of the original strength is retained for sizes 6-0 and larger and approximately 40% of its original strength is retained for sizes 7-0 and smaller. At four weeks, approximately 25% of the original strength is retained for sizes 6-0 and larger. All of the original tensile strength is lost by five weeks post implantation. Absorption of Coated 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

This suture, being absorbable, should not be used where extended approximation of tissue is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Coated VICRYL™ Suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) 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. 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 distention, or which may require additional support.

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. 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™ Suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

PRECAUTIONS

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 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™ Sutures, which are treated to enhance handling characteristics, require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

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" container.

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 blood-borne pathogens.

STORAGE

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

HOW SUPPLIED

Coated VICRYL™ Suture are available sterile, as braided dyed (violet) and undyed (natural) strands in sizes 8-0 through 3 (metric sizes 0.4-6), in a variety of lengths, with or without needles, and on LIGAPAK™ Dispensing Reels.

Coated VICRYL™ Suture are also available in size 8-0 (metric size 0.4) with attached beads for use in ophthalmic procedures. Coated VICRYL™ sutures are also available in sizes 4-0 through 2 (metric sizes 1.5-5.0) attached to CONTROL RELEASE™ Removable Needles. Coated VICRYL™ Suture are available in one, two, and three dozen boxes.

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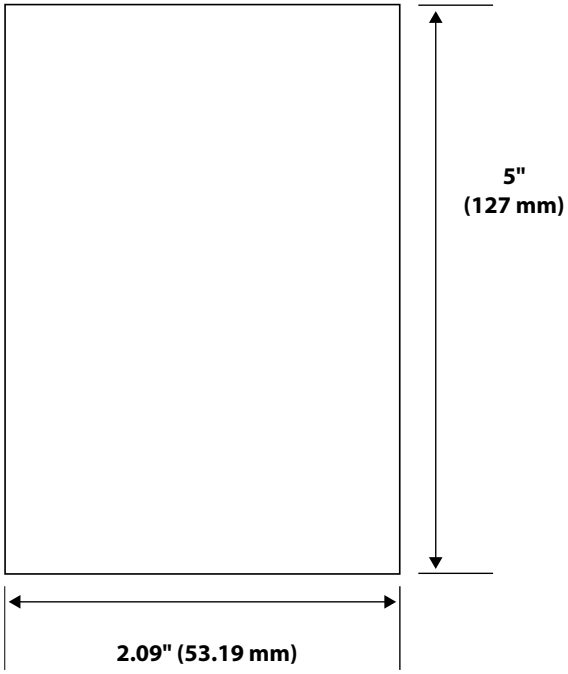
IFU PRINTING SPECIFICATION SHEET

PAGE LAYOUT



Flat Size

TITLE	DESCRIPTION	LAB NUMBER	SPECIAL INSTRUCTIONS/COMMENTS	BINDING	COLORS
Coated VICRYL™ Suture	**IFU**	**LAB100203142v2**	**n/a**	**n/a**	**Black, PMS 264 (purple)**

FLAT SIZE	FOLDED SIZE	RMC NUMBER	PAGE COUNT	LANGUAGES	SELF COVER	PLUS COVER	SEALING METHOD	WAFER SEAL
2.09" x 5" **53.19 mm x 127 mm**	**2.09" x 5"** **53.19 mm x 127 mm**	**390283R02**	**2 (front & back)**	**EN**	[X]	☐	**n/a**	☐

BLEED SIZE .5" (12.7 mm)	.125" (3.175 mm)	NONE	BLEED ALL SIDES	BLEED TOP	BLEED RIGHT	BLEED LEFT	BLEED BOTTOM
☐	☐	[X]	☐	☐	☐	☐	☐

DRAWING IS NOT TO SCALE: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK.

STOCK
9 pt. Monadock Suture Stock

ETHICON