Instructions for use

VICRYL™
(POLYGLACTIN 910)
STERILE SYNTHETIC ABSORBABLE SUTURE

DESCRIPTION
VICRYL™ suture is a synthetic absorbable sterile surgical suture made of a copolymer of glycolide and lactide. The empirical formula of the copolymer is (C₆H₈O₂)₉ x (C₆H₇O₂)₉. Braided VICRYL™ sutures are made with a mixture of equal parts of copolymer of glycolide and lactide (Polydioxanone 370) and calcium stearate. Polydioxanone 910 copolymer and Polydioxanone 370 with calcium stearate have been found to be nonantigenic, nonpyrogenic and elicit only a slight tissue reaction during absorption. VICRYL™ sutures are dyed using D+G (Color Index number: 60725) during polymerization. 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 needle 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 Sutures 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 within five years post implantation. Absorption of VICRYL™ sutures is essentially complete between 56 and 70 days.

<table>
<thead>
<tr>
<th>Days</th>
<th>Approximate % original Strength Remaining</th>
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<tbody>
<tr>
<td>14 days</td>
<td>75%</td>
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<tr>
<td>21 days (6-0 and larger)</td>
<td>50%</td>
</tr>
<tr>
<td>21 days (7-0 and smaller)</td>
<td>40%</td>
</tr>
<tr>
<td>28 days (6-0 and larger)</td>
<td>25%</td>
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</tbody>
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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 calcium 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 infusected 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 site which may undergo extension, 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 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 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) of one-half (1/2) of the distance from the handle to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the handle end could cause bending or breakage. Resharpening 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 transmission or bloodborne pathogens to patients and users.

ADVERSE REACTIONS
Adverse reactions associated with the use of this device include transient local irritation at the wound site, transitory inflammatory 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 damaged or opened! Discard opened, unused sutures!

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

SYMBOLS USED ON LABELLING

- (2) = Do not reuse
- (3) = Number of units
- (2) = Use by - year and month

STERILE 80 = Sterile unless package is damaged or opened
Method of sterilization: Ethylene Oxide

CE 0066 = CE-mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42/EEC

LOT = Batch number
- (2) = Caution: See Instructions for use
- (2) = Manufacturer
- (2) = Catalogue Number

EC REP = Authorised Representative in the European Community