## Instructions for use

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# MONOCRYL™

## Poliglecaprone 25 (MONOFILAMENT)
## STERILE SYNTHETIC ABSORBABLE SURGICAL SUTURE

### DESCRIPTION

MONOCRYL™ Suture is a sterile, monofilament, synthetic, absorbable surgical suture composed of a copolymer of glycolide and (epsilon) ε-caprolactone. The empirical molecular formula of the polymer is $(C_4H_4O_3)_m$ $(C_6H_{10}O_2)_n$.

Poliglecaprone 25 copolymer has been found to be nonantigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

MONOCRYL™ Suture is available undyed and dyed with D&C Violet No. 2 (Color Index 60725) to enhance visibility in the surgical field.

MONOCRYL™ Suture is available in a range of gauge sizes and lengths, non-gseeded or attached to needles of varying types and sizes as described in the HOW SUPPLIED section.

MONOCRYL™ Suture complies with the requirements of the European Pharmacopoeia (Ph. Eur.) for Sterile Synthetic Absorbable Monofilament Sutures and United States Pharmacopeia (USP) for Absorbable Surgical Sutures except for a slight oversize in diameter for all gauges as shown in the table below.

| USP Suture Size | Metric Suture Size | Maximum Oversize |
|---|---|---|
| 6-0 | 0.7 | 0.049 mm |
| 5-0 | 1 | 0.033 mm |
| 4-0 | 1.5 | 0.045 mm |
| 3-0 | 2 | 0.067 mm |
| 2-0 | 3 | 0.055 mm |
| 0 | 3.5 | 0.088 mm |
| 1 | 4 | 0.066 mm |

The European Pharmacopoeia recognizes units of measure Metric and Ph. Eur. Sizes as equivalent, which is reflected on the labeling.

### INDICATIONS

MONOCRYL™ Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

### APPLICATIONS

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

### PERFORMANCE / ACTIONS

MONOCRYL™ Suture elicits a minimal initial inflammatory reaction in tissues and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption occurs by means of hydrolysis, where the polymer degrades to adipic acid, which is subsequently absorbed and metabolized in the body. Absorption begins as loss of tensile strength followed by a loss of mass. Implantation studies in rats show the following profile:

| DYED | | UNDYED | |
|---|---|---|---|
| Post Implantation | Approx. Original Strength Remaining | Post Implantation | Approx. Original Strength Remaining |
| 7 days | 60% to 70% | 7 days | 50% to 60% |
| 14 days | 30% to 40% | 14 days | 20% to 30% |
| All of the original tensile strength is essentially lost by 28 days post-implantation. | | All of the original tensile strength is essentially lost by 21 days post-implantation. | |

Absorption is essentially complete between 91 and 119 days.

### CONTRAINDICATIONS

This suture (dyed and undyed), being absorbable, should not be used where extended approximation of tissues under stress is required.

Undyed MONOCRYL™ Sutures, in particular, should not be used to close fascial tissue.

### WARNINGS

The safety and effectiveness of MONOCRYL™ Sutures has not been established in the following areas – neural tissue, cardiovascular tissue, microsurgery and ophthalmic surgery.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing MONOCRYL™ Suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Medical professionals should consider the in vivo performance (under PERFORMANCE/ACTIONS section) when selecting a suture.

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 distension, or that may require additional support.

Do not resterilize/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.

As an absorbable suture, this suture may act transiently as a foreign body. Like all foreign bodies, this product may potentiate infection.

### PRECAUTIONS

In 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.

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 orthopedic 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 that may delay wound healing.

As with any suture material, adequate knot security requires the standard surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilament sutures.

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 attachment end could cause bending or breakage. 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 stick injury. 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. Discard used needles in "sharps" containers.

### ADVERSE REACTIONS

Adverse reactions associated with the use of this device include wound dehiscence, calculi formation in urinary or biliary tracts when prolonged contact with salt solutions such as urine or bile occurs, transient inflammatory tissue reaction, and transient local irritation at the wound site.

### STERILITY

MONOCRYL™ Suture is 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.

### HOW SUPPLIED

Please note that not all sizes are available in all markets. Please contact your local sales representative for size availability.

MONOCRYL™ Suture is available as sterile, monofilament strands in sizes 6-0 through 1 (metric sizes 0.7 - 4), in a variety of lengths, with and without permanently attached needles.

MONOCRYL™ Suture is also available in sizes 3-0 through 1 (metric sizes 2 - 4) as sterile strands attached to CONTROL RELEASE™ removable needles, which enable the needles to be pulled off instead of being cut off.

MONOCRYL™ Suture is available in one, two or three dozen units per box.

For recognized legal manufacturer, refer to product label.


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