MONOCRYL™ PLUS

– ANTIBACTERIAL –

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cs	ŠICÍ MATERIÁL	fi	OMMELAINE	no	SUTUR	zh-cn	缝线
da	SUTUR	fr	FIL DE SUTURE	pl	NICI	zh-tw	縫合線
de	NAHTMATERIAL	hu	VARRÓANYAG	pt	FIO DE SUTURA	bg	ШЕВЕН МАТЕРИАЛ
el	ΡΑΜΜΑ	it	SUTURA	ro	FIR DE SUTURĂ	ko	봉합사
en	SUTURE	lt	SIŪLAS	sk	NIŤ	ru	ШОВНЫЙ МАТЕРИАЛ
es	SUTURA	lv	DIEGS	sv	SUTUR	kk	ТІГУ МАТЕРИАЛЫ

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Instructions for use

MONOCRYL™ PLUS ANTIBACTERIAL

(POLIGLECAPRONE 25)
STERILE SYNTHETIC ABSORBABLE SUTURE
VIOLET MONOFILAMENT OR UNDYED MONOFILAMENT

DESCRIPTION

MONOCRYL™ Plus Antibacterial Suture is a sterile, synthetic, absorbable, monofilament suture prepared from a copolymer of glycolide and ε-caprolactone. The empirical molecular formula of the polymer is $(C_2H_2O_2)_m$ $(C_6H_{10}O_2)_n$. Poliglecaprone 25 copolymer has been found to be non-antigenic, non-pyrogenic, and elicits only a slight tissue reaction during absorption. MONOCRYL™ Plus Antibacterial Suture contains Irgacare®‡ MP (Triclosan), a broad-spectrum antibacterial agent, at no more than 2360 µg/m.

MONOCRYL™ Plus Antibacterial Sutures are available dyed [with D&C Violet No.2 (Color Index Number 60725)] and are also available in the undyed form. MONOCRYL™ Plus Antibacterial Suture is available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes. The needles may be attached permanently or as CONTROL RELEASE™, which enables the needles to be pulled off instead of being cut off. Full details of the product range are contained in the catalogue. MONOCRYL™ Plus Antibacterial Suture complies with all the requirements of the European Pharmacopoeia for Sterile Synthetic Absorbable Monofilament Sutures and the requirements of the United States Pharmacopoeia for Absorbable Surgical Sutures except for a slight oversize in diameter.

INDICATIONS

MONOCRYL™ Plus Antibacterial Sutures are intended for use in general soft tissue approximation and/or ligation where an absorbable material is indicated.

APPLICATION

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

PERFORMANCE

MONOCRYL™ Plus Antibacterial Suture elicits a minimal initial inflammatory reaction in tissues and is eventually replaced with an in-growth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of MONOCRYL™ Plus Antibacterial Sutures 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

Post Implantation	Approx. Original Strength Remaining
7 days	60 %
14 days	30 %

All of the original tensile strength is essentially lost by 28 days post implantation.

UNDYED

Post Implantation	Approx. Original Strength Remaining
7 days	50 %
14 days	20 %

All of the original tensile strength is essentially lost by 21 days post implantation.

Absorption is essentially complete between 91 and 119 days.

Using zone of inhibition studies, MONOCRYL™ Plus Antibacterial Suture has been shown to inhibit colonization of the suture by *Staphylococcus aureus, Staphylococcus epidermidis,* Methicillin-Resistant *S. aureus,* Methicillin-Resistant *S. epidermidis, Escherichia coli* and *Klebsiella pneumoniae.* The clinical significance of this finding is unknown.

CONTRAINDICATIONS

These sutures (dyed and undyed), being absorbable, should not be used where extended approximation of tissues under stress is required. Undyed MONOCRYL™ Plus Antibacterial Sutures, in particular, should not be used to close fascial tissue.

MONOCRYL™ Plus Antibacterial Suture should not be used in patients with known allergic reactions to Irgacare®‡ MP (Triclosan).

WARNINGS/PRECAUTIONS/INTERACTIONS

The safety and effectiveness of MONOCRYL™ Plus Antibacterial 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™ Plus Antibacterial 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. 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 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, MONOCRYL™ Plus Antibacterial 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 non-absorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distension, 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. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with the absorption process.

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.

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.

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

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 resistant 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 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.

ADVERSE REACTIONS

Adverse effects associated with the use of synthetic absorbable sutures include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distention occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, minimal acute inflammatory tissue reaction, transitory local irritation or transient inflammatory foreign body response at the wound site, suture extrusion, 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 allergic reaction to Irgacare®‡ MP (Triclosan). Like all foreign bodies MONOCRYL™ Plus Antibacterial Suture may potentiate an existing infection. Broken needles and needle pull-offs that result in lost needles or needle fragments 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.

STERILITY

MONOCRYL™ Plus Antibacterial Sutures are sterilized by ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

STORAGE

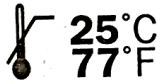
Recommended storage conditions: Store at or below 25°C. Do not use after expiry date.

SYMBOLS USED ON LABELING


Dyed absorbable monofilament


Undyed absorbable monofilament


Caution: See instructions for use



Upper limit of temperature

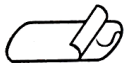
Sterilized using Ethylene Oxide

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


Do not reuse


Use by – year and month


Manufacturer


Number of units

Catalogue Number

Batch number

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