INSTRUCTIONS FOR USE

ARNIGLYDE MONO

MONOFILAMENT POLYGLECAPRONE 25
ABSORBABLE SURGICAL SUTURE (SYNTHETIC)

DESCRIPTION:
Monofilament Polyglecaprone 25 suture is a sterile, monofilament synthetic absorbable suture, composed of a co-polymer, made from Glycolide and caprolactone.
The Co-polymer Poliglecaprone 25 has been found to be non-antigenic, non-pyrogenic and elicits only a slight tissue reaction during absorption.

Monofilament Polyglecaprone 25 sutures are dyed by adding D & C Violet # 2, color index No. 60725 during polymerization. Sutures are also available in undyed form. Monofilament Polyglecaprone 25 suture is available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes.

Monofilament Polyglecaprone 25 suture complies with the requirements, established in the United States Pharmacopeia, under the monograph, "Absorbable Surgical suture, Synthetic", except for diameter.

INTENDED USE:
Monofilament Polyglecaprone 25 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.

MECHANISM OF ACTION:
Monofilament Polyglecaprone 25 suture elicits a minimal initial inflammatory reaction in tissues and is eventually replaced with an ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Monofilament Polyglecaprone 25 sutures occurs by means of hydrolysis, where the copolymer degrades to adipic acid, which is 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 show the rate of loss of tensile occurs as stated below:

Suture type	No. of days.	% retention of T.S.
Dyed	7 days	60%
Dyed	14 days	20%
Undyed	7 days	50 %
Undyed	14 days	20 %

All the original tensile strength is lost by 21 days post implantation. Absorption is essentially complete between 90 and 120 days.

CONTRAINDICATIONS:
Monofilament Polyglecaprone 25 (Dyed or Undyed) sutures, being absorbable, should not be used where extended approximation of tissues under stress is required. Monofilament Polyglecaprone 25 Undyed sutures should not be used for abdominal closure or to close facial tissue.

WARNINGS/PRECAUTIONS/INTERACTIONS:
The safety and effectiveness of Monofilament Polyglecaprone 25 has not been established in neural tissues, cardiovascular, microsurgery and ophthalmic surgery. Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Monofilament Polyglecaprone 25 sutures 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 Mechanism of Action section) when selecting a suture. This suture may be inappropriate in elderly, malnourished, diabetic patients or in patients suffering from conditions which may delay wound healing.

As with any foreign body, prolonged contact of this suture or any other suture with salt solutions such as those found in urinary and biliary tracts may result in calculus formation. As an absorbable suture, it 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 sites undergoing expansion, stretching or distention which may require additional support.

Skin suture, which remain in place for more than 7 days may cause localized irritation and should be snipped off or removed as indicated. Sub-cuticular 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 suture in tissue with poor blood supply as suture extrusion and delayed absorption may occur.

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. Adequate knot security requires the standard surgical techniques of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. 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 the needle in the point area, could impair the penetration performance and cause fracture of the needle. Grasping the needle 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. Discard unused needles in "Sharps" containers.

ADVERSE REACTIONS:
Adverse effects associated with the use of Monofilament Polyglecaprone 25 suture include transient local irritation at the wound site, transient inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures. Like all foreign bodies, Monofilament Polyglecaprone 25 sutures may potentiate an existing infection.

STERILITY:
Monofilament Polyglecaprone 25 sutures are sterilized by Ethylene Oxide. Do not re-sterilize. Do not use if package is found opened or damaged. Discard the opened or unused sutures.

SUPPLY:
Monofilament Polyglecaprone 25 (Dyed and Undyed) is available in U.S.P. sizes, 2 to 6-0. Suture is supplied sterile in pre-cut lengths and attached to various needle type, shape and length.

STORAGE:
Recommended storage conditions:
Below 30° C away from moisture and direct sunlight.
Do not use after expiry.

DISPOSAL:
To be disposed as per user's country disposal regulations and Hospital/Clinic protocol.

Manufactured by:
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EXPLANATION OF SYMBOLS	
Symbol	**Explanation**
	Manufacturer
	Date of Manufacture
	Use-By Date
	Sterilization by Ethylene Oxide
	Do not re- use
	Do not re-sterilize
	Batch number
	Keep away from Sunlight
	Keep dry
	Warning
	Temperature Limit
	Do not use if package is damaged
	Read Instructions for use