

## INSTRUCTIONS FOR USE

### ARNISYNTH FAST

#### FAST ABSORBABLE BRAIDED & COATED POLYGLACTIN 910

#### ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC)

#### DESCRIPTION:

Fast Absorbable Braided and coated Polyglactin 910 suture is a synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. The empirical formula of the copolymer is  $(C_2H_2O_2)_m (C_3H_4O_2)_n$

The characteristic rapid loss of strength is achieved by use of a polymer material with a lower molecular weight than regular Braided and coated Polyglactin 910

Fast Absorbable Braided and coated Polyglactin 910 sutures are available undyed and dyed by adding D&C violet No. 2 color Index No. 60725 during polymerization.

The braided threads are treated with a coating so that they slide easily without causing a sawing effect.

Fast Absorbable Braided and coated Polyglactin 910 fulfils all of the requirements of United States Pharmacopoeias current edition for sterile synthetic braided absorbable sutures.

#### INTENDED USE:

Fast Absorbable Braided and coated Polyglactin 910 suture - is intended for use in soft tissue approximation and/or ligation.

#### MECHANISM OF ACTION:

Suture materials are used primarily for adaptation of the wound edges to render possible and undisturbed wound healing.

During the use of Fast Absorbable Braided and coated Polyglactin 910 sutures a mild inflammatory reaction may occur, which is typical of an endogenous reaction to foreign bodies. As time passes the suture material is encapsulated by fibrous connective tissue. Fast Absorbable Braided and coated Polyglactin 910 is metabolized to Glycolic and Lactic acid

by hydrolysis without causing any enduring change in the region of the wound. Absorption begins as a decline in tensile strength followed by a loss of mass.

Subcutaneous and intramuscular implantation studies of Fast Absorbable Braided and coated Polyglactin 910 show that at 7 days post-implantation approximately 50% of the initial tensile strength remains and 14 days post-implantation almost all the initial tensile strength is lost. Most of the suture mass absorption of Fast Absorbable Braided and coated Polyglactin 910 takes place after approximately 42 days.

#### APPLICATION:

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

#### CONTRAINDICATION:

Due to its rapid loss of tensile strength, Fast Absorbable Braided and coated Polyglactin 910 suture materials are contraindicated where extended approximation of tissues under stress is required or where prolonged support of wound closure is required.

#### WARNING:

Do not re-sterilize. Discard open unused sutures. 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. As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds. The use of this suture may be inappropriate in patients suffering from conditions which may delay wound healing.

#### PRECAUTIONS:

As this is an absorbable suture, the surgeon in the closure of sites undergoing expansion, stretching or distention, which may require additional support, should consider the use of supplemental non absorbable suture. Under some circumstances, notably orthopedic

procedure, immobilization by external support may be employed at the discretion of the surgeon. Skin suture, which remain in place for more than 7 days may cause localized irritation and should be snipped off or removed.

#### ADVERSE REACTIONS:

Adverse effects associated with the use of Fast Absorbable Braided and coated Polyglactin 910 suture include allergic response in certain patients, transient local irritation at the wound site, transient inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures.

#### SUPPLY:

Fast Absorbable Braided and coated Polyglactin 910 is available in U.S.P. sizes and EP Metric Sizes. The 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:

 ARNI MEDICA PVT. LTD.














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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