INSTRUCTIONS FOR USE

ARNISYNTH

BRAIDED & COATED POLYGLACTIN 910
ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC)
VIOLET/UNDYED

DESCRIPTION:

Braided and coated Polyglactin 910 suture is a synthetic, absorbable, sterile, surgical suture, composed of the co-polymer, Polyglactin 910, made from 90% Glycolide and 10% Lactide.

Braided and coated Polyglactin 910 sutures are coated with a mixture, composed of equal parts of the co-polymer Polyglactin 370 (Glycolide 30% and Lactide 70%), and Calcium Stearate.

Co-polymers, Polyglactin 910 and Polyglactin 370, with Calcium Stearate have been found to be non-antigenic, non-pyrogenic and elicit only slight tissue reaction during absorption.
Braided and coated Polyglactin 910 sutures are dyed by adding D & C Violet # 2, color index No. 60725 during polymerization. Sutures are also available in undyed form.

Braided and coated Polyglactin 910 is available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes.

Braided and coated Polyglactin 910complies with requirements, established in the United States Pharmacopeia, under the monograph, "Absorbable Surgical suture, Synthetic".

INTENDED USE:

Braided and coated Polyglactin 910 sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, peripheral nerve anastomosis and micro surgery for vessels, less than 2mm diameter. The safety and effectiveness of Braided and coated Polyglactin 910 sutures in cardio-vascular tissues have not been established.

APPLICATION:

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

MECHANISM OF ACTION:

Braided and coated Polyglactin 910 suture elicits a minimal initial inflammatory reaction in tissues and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Braided and coated Polyglactin 910 sutures occurs by means of hydrolysis, where the copolymer degrades to Glycolic acid and Lactic acid which are subsequently absorbed and metabolized in the body. Absorption begins as loss of tensile strength followed by loss of mass. All of the original tensile strength is lost between four- and five-weeks post implantation. Absorption of Braided and coated Polyglactin 910 sutures is essentially complete between 56 and 70 days.

Days Implantation	% Original strength remaining
14 days (6-0 & larger)	75%
21 days (6-0 & larger)	60%
28 days (6-0 & larger)	25%

CONTRAINDICATIONS:

Being absorbable Braided and coated Polyglactin 910 sutures should not be used where extended approximation of tissues under stress is required.

WARNING/PRECAUTIONS/INTERACTIONS:

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Braided and coated Polyglactin 910 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. 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. 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. 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, diabetic 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 from handling. 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) 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 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.

STERILITY:

Braided and coated Polyglactin 910 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:

Braided and coated Polyglactin 910 (Dyed/Undyed) sutures are available in U.S.P. sizes, 2 to 6-0. The suture is supplied dyed violet and also in undyed form. The suture is supplied sterile in pre-cut lengths, non-needled or attached with 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.
V Square, 4th floor, Plot No.50, Sai Nagar Colony,
Madhapur, Hyderabad - 500 081.
+91 97367-39999 | care@arnimedica.com
www.arnimedica.com

Manufactured at:
No.15/1,2,3, Acharya Indl. Complex, Andrahalli Main Road,
Vishwaneedam Post, Bangalore - 560091.

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