

INSTRUCTIONS FOR USE

**ARNILENE
MONOFILAMENT POLYPROPYLENE
NON-ABSORBABLE SURGICAL SUTURE U.S.P.**

DESCRIPTION:

ARNILENE suture is a monofilament, synthetic non-absorbable, sterile surgical suture, composed of an isotactic crystalline stereoisomer of Polypropylene, a synthetic linear Polyolefin. The molecular formula is (C₃H₆)_n.

ARNILENE suture is available as dyed blue with Pigment blue.

ARNILENE suture is available in a range of gauge sizes, and lengths, attached to stainless steel needles of various types, and sizes.

ARNILENE sutures comply all the requirements as per United States Pharmacopeia for non-absorbable Surgical suture. It is only available as dyed.

INTENDED USE:

ARNILENE suture is indicated for use in soft tissue approximation and /or ligation.

APPLICATIONS:

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

MECHANISM OF ACTION:

ARNILENE suture elicits a minimal, initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue.

ARNILENE suture is not absorbed, nor it is subject to degradation or weakening by the action of tissue enzymes. Due to its relative biological inertness, it is recommended for use where the least possible suture reaction is desired. As a monofilament it has been successfully employed in surgical wounds which could subsequently become infected or contaminated where it can minimize later sinus formation and suture extrusion. Because of its lack of adherence to tissue, **ARNILENE** suture is effective as a pull out suture.

CONTRAINDICATIONS:

None known.

WARNINGS/PRECAUTIONS/INTERACTIONS:

Users should be familiar with surgical procedures and techniques involving non absorbable sutures before employing **ARNILENE** suture for wound closures, as risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of any suture with salt solution such as those found in urinary and biliary tracts, may result in calculus formation. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Care should be taken to avoid damaging the surface of the material with surgical instruments as this could lead to fracture of the material in use. 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 circumstances and experience of the surgeon.

The use of additional throws may be particularly appropriate when knotting Polypropylene 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 the needle 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. Discard unused needles in “Sharps” containers.

ADVERSE REACTIONS:

Adverse effects associated with the use of **ARNILENE** suture include minimal initial

inflammatory tissue reaction and transient local irritation at the wound site.

Like all foreign bodies, **ARNILENE** suture may potentiate an existing infection.

STERILITY:

ARNILENE sutures are sterilized by Ethylene Oxide. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

SUPPLY:

ARNILENE sutures are available in U.S.P. sizes 10-0 to Size 5. 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:

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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