INSTRUCTIONS FOR USE

ARNISILK

BLACK BRAIDED SILK

NON-ABSORBABLE SURGICAL SUTURE U.S.P.

DESCRIPTION:

ARNISILK suture is a non-absorbable, sterile, surgical braided and coated suture, composed of an organic protein called Fibroin. This protein is derived from (Silk bees) the domesticated species of Bombyx mori of the family Bombycidae. Silk sutures are processed to remove the natural waxes and gum.

ARNISILK suture is colored black with FDA approved Haematin HCK dye. Color Index No.75290.

ARNISILK suture is coated with white beeswax which acts like a lubricant to mechanically improve the ease of passage through the tissue and the overall handling qualities of the suture.

ARNISILK complies with all the requirements, established by the United States Pharmacopeia for Non-absorbable Surgical suture.

INTENDED USE:

ARNISILK suture is indicated for use in general soft tissue approximation and or ligation.

APPLICATION:

ARNISILK suture should be selected and implanted depending on patient's condition, surgical experience, surgical technique and wound size.

MECHANISM OF ACTION:

ARNISILK suture elicits an acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue.

ARNISILK suture is not absorbed. However progressive degradation of the proteineous silk fiber in vivo may result in gradual loss of all the tensile strength over a period of time.

CONTRAINDICATIONS:

Use of this suture is contra indicated in patients with known sensitivities or allergies to silk.

Due to the gradual loss of tensile strength which may occur over prolonged period in vivo silk suture should not be used where

permanent retention of tensile strength is required.

WARNINGS/PRECAUTIONS/INTERACTIONS:

Users should be familiar with surgical procedures and techniques involving non absorbable sutures before employing **ARNISILK** 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 for the management 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 warranted by surgical circumstances and experience of the surgeon.

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 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 reactions associated with the use of this suture include wound dehiscence, gradual loss of tensile strength over time, allergic response in patients who are known to be sensitive to silk, calculi formation in urinary and biliary tracts where prolonged contact with salt solutions such as urine and bile occurs,

infection, acute inflammatory tissue reaction and transitory local irritation at the wound site.

Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in transmission of blood-borne pathogens.

STERILITY:

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

SUPPLY:

ARNISILK sutures are available in U.S.P. sizes 6-0 to Size 2. 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