KATSAN
MEDICAL DEVICES

INSTRUCTIONS FOR USE

ALCASILK®

KATSAN SILK
Silk
Sterile non-absorbable surgical suture

DESCRIPTION
ALCASILK® sutures are non-absorbable sterile surgical sutures which are produced of an organic protein called fibroin. This organic protein is derived from the domesticated species Bombyx mori of the family Bombyciade. **ALCASILK®** sutures are processed to remove the natural oil and viscous. **ALCASILK®** sutures are dyed black and coated wax (KAHLWAX 1540).
ALCASILK® sutures meet all requirements for non-absorbable surgical sutures specified at the European Pharmacopoeia (EP) and United States Pharmacopoeia (USP).
ALCASILK® sutures have been presented in USP 6/0 – USP 2 gauge sizes in a variety of lengths from 10 cm to 150 cm , as non-needled or attached to stainless steel needles of varying types and sizes.

INDICATIONS
ALCASILK® sutures are indicated for general use in soft tissue approximation or ligation, but not for use in cardiovascular or neural tissue and ophthalmic surgery.

ACTIONS
ALCASILK® suture elicits a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While **ALCASILK®** sutures are not absorbed, progressive degredation of the proteinaceous silk fiber *in vivo* may result in gradual loss of all of the suture's tensile strength over time.**ALCASILK®** suture provides permanent wound support.

CONTRAINDICATIONS
The use of this suture is contraindicated in patients with known sensitivities or allergies to silk. Due to gradual loss of tensile strength which may occur over prolonged periods *in vivo*, silk should not be used where permanent retention of tensile strength is required.

WARNINGS
Users should be familiar with surgical procedures and techniques covering non-absorbable sutures before employing **ALCASILK®** sutures for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material is used.
As with any foreign body, prolonged contact of this or any other suture with salt solutions such as those found in the urinary or biliary tracts, may result in calculus formation.
Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or infected wounds.
Sterility is preserved only when opened under sterile conditions.
Do not re-sterilize.
Discard opened packages and unused sutures.
Do not use opened or damaged products.+ Surgeons should use the needle holder or forceps to pass the curved needle through the tissue. Needle holders or forceps should be made from stainless steel, high strength, good quality steel alloy with jaws designed to hold the surgical needle securely. Needle holder jaws can be short or flat, concave or convex, smooth or serrated.
Katsan surgical needles are designed for optimal needle holder stability. There is a flattened area on the surgical needles approximately one-third to one-half of the distance from the swaged area to the needle tip to operate with the needle holder.
The selected needle holder should be in the proper size for the needle. If the surgeon is working deep within the body cavity, a longer needle holder will be appropriate.

PRECAUTIONS
In handling **ALCASILK®** or any other suture material, care should be taken to avoid damage from handling. Especially avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
In order to adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

In order to prevent damaging needle points and swage areas, the needle should be grasped on its flattened area which is one-third (1/3) to one-half (1/2) of the distance from the swaged area of the needle. Reshaping needle may result in loss of strength of the needles and may result in less resistance of the needle to bending and breaking. To prevent inadvertent needle sticks, users should pay attention when handling surgical needles. Discard used needles and surgical sutures in "sharps" container.
Do not use expired products.

ADVERSE REACTIONS
Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal 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 the transmission of blood borne pathogens.

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

STORAGE
ALCASILK® product should be kept in dry and clean conditions.
Recommended storage conditions: Store between 5°C-25°C, away from moisture and direct heat.
Do not use after expiry date!

HOW SUPPLIED
ALCASILK® sutures are available as sterile, multifilament, black strands in sizes USP 6/0 through USP 2 (metric sizes 0,7-5), in a variety of lengths, with various types of stainless steel needles or without needle.
Sutures are presented as pieces or as 1/2/3 dozen units per boxes.

SYMBOLS USED ON THE LABELS

SILK	Silk
	Multifilament Non-Absorbable Suture (Braided&Coated&Dyed)
CE	CE Symbol and identification number of the notified body. The product satisfies the Essential Requirements of directive 93/42/EEC on medical devices.
	Manufacturer
	Date of manufacture (Year/Month)
	Use by expiration date (Year/Month)
LOT	Lot Number
REF	Product Code
STERILE EO	EO: Sterilization Method – Ethylene Oxide (Single sterile barrier system with protective packaging inside)
	Caution
	Consult instuctions for use
	Keep away from sunlight
	Protect from humidity
5°C 25°C	Store between : 5°C - 25°C
	Single use
	Do not resterilize
	Do not use if package is damaged
UDI	Unique Device Identifier (UDI)
MD	Medical Device

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