



**ALCALENE®**

**KATSAN PP**  
Polypropylene (PP)

Sterile non-absorbable surgical suture

**DESCRIPTION**

**ALCALENE®** sutures are synthetic non-absorbable sterile surgical sutures which are composed of isotactic crystallized polypropylene polymer of high molecular weight. Suture is pigmented blue to enhance visibility.

**ALCALENE®** sutures meet all requirements for synthetic non-absorbable surgical sutures specified at the European Pharmacopoeia (EP) and United States Pharmacopoeia (USP).

**ALCALENE®** 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-needed or attached to stainless steel needles of varying types and sizes.

**INDICATIONS**

**ALCALENE®** 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**

**ALCALENE®** suture elicits a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. **ALCALENE®** suture is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. As a monofilament, **ALCALENE®** suture resists involvement infection and has been successfully employed in contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion. The lack of adherence to tissues has facilitated removing of **ALCALENE®** suture. **ALCALENE®** suture provides permanent wound support.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

Users should be familiar with surgical procedures and techniques covering non-absorbable sutures before employing **ALCALENE®** 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. The safety and effectiveness of **ALCALENE®** sutures have not been established in neural tissue, cardiovascular tissue for use in microsurgery.

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 **ALCALENE®** 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**

**ALCALENE®** sutures are sterilized by Ethylene Oxide.

Do not re-sterilize!

Do not use if package is opened or damaged!

Discard opened unused sutures.

**STORAGE**

**ALCALENE®** 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**

**ALCALENE®** sutures are available as sterile, monofilament dyed (blue) 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**

	→	Polypropylene (PP)
	→	Monofilament Non-Absorbable Suture (Uncoated&Dyed)
	→	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 Number
	→	Product Code
	→	EO Sterilization Method - Ethylene Oxide (Single sterile barrier system with protective packaging inside)
	→	Caution
	→	Consult instructions for use
	→	Keep away from sunlight
	→	Protect from humidity
	→	Store between : 5°C - 25°C
	→	Single use
	→	Do not re-sterilize
	→	Do not use if package is damaged
	→	Unique Device Identifier (UDI)
	→	Medical Device

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