ALCADINONE®

KATSAN PDO

Polydioxanone (PDO)

Sterile absorbable surgical suture

DESCRIPTION

ALCADINONE® sutures are synthetic absorbable sterile surgical sutures which are made of Polydioxanone.

ALCADINONE® sutures when implanted into a living organism, it is absorbed by that organism and cause no undue tissue irritation. **ALCADINONE®** sutures have been found to be non-antigenic, non-pyrogenic and elicit only a mild tissue reaction during absorption.

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

In order to ease of operation, **ALCADINONE®** sutures are coloured FDA approved D&C violet No: 2. **ALCADINONE®** 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

ALCADINONE® sutures are indicated for general use in soft tissue approximation where growth is expected occur up to 6 weeks. On the other hand, **ALCADINONE®** suture is not indicated in adult cardiovascular tissue, microsurgery, ophthalmic surgery and neural tissue.

ACTIONS

ALCADINONE® sutures elicit a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of **ALCADINONE®** suture occurs by means of hydrolysis, gradually and decreases the strength in the body. The absorption process begins a loss of tensile strength followed by a loss of mass. Implantation studies indicate that **ALCADINONE®** suture retains approximately 75% of the original tensile strength at 2 weeks and in excess of 50%-60% at 4 weeks post implantation. Absorption of **ALCADINONE®** suture is essentially complete between 180 to 210 days. Depending on the organism, changes may occur in the related ratios.

CONTRAINDICATIONS

Since **ALCADINONE®** sutures are absorbable, they should not be used where extended tissue approximation is required and in conjunction with prosthetic devices; for example, heart valves or synthetic grafts.

WARNINGS

Users should be familiar with surgical procedures and techniques covering absorbable sutures before employing **ALCADINONE®** sutures for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material is used. Users should consider the *in vivo* performance, under "ACTION" section, when selecting a suture.

As with any foreign body, in surgery of the urinary or biliary tracts, attention should be taken to avoid prolonged contact of any suture with salt solutions, as may result in calculus formation.

As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of contaminated or infected wounds.

The use of this suture may be inappropriate in elderly malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.

ALCADINONE® is an absorbable suture material, the use of supplemental non absorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching, or distention, or which may require additional support.

The safety and effectiveness of **ALCADINONE®** sutures have not been established in neural tissue, cardiovascular tissue for use in microsurgery. Under certain circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Sterility is preserved only when opened under sterile conditions.

Do not re-sterilize.

Store at room temperature and avoid prolonged exposure to elevated temperatures.

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 **ALCADINONE®** 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.

Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation. Subcuticular sutures should be placed as deeply as possible in order to minimize the erythema and induration normally associated with absorption.

Acceptable surgical practice should be followed with respect to drainage and closure infected wounds.

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

Due to prolonged suture absorption, some irritation and bleeding has been observed in conjunctiva and mild irritation has been observed in vaginal mucosa.

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, 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

ALCADINONE® sutures are sterilized by Ethylene Oxide.

Do not re-sterilize!

Do not use if package is opened or damaged!

Discard opened unused sutures.

STORAGE

ALCADINONE® 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!

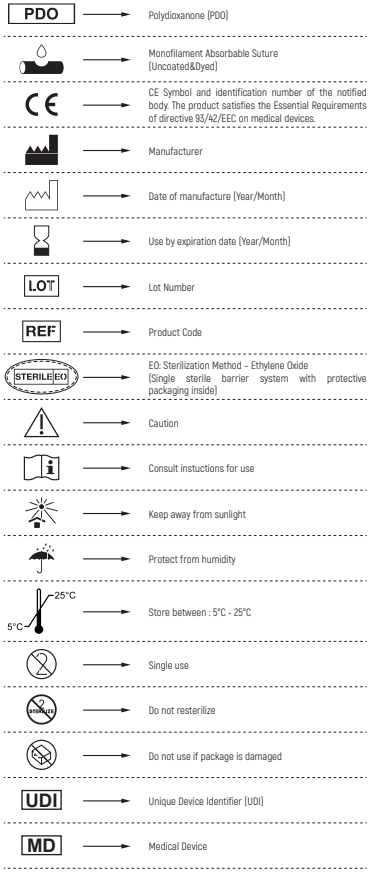
Protect from humidity.

HOW SUPPLIED

ALCADINONE® sutures are available as sterile, monofilament, dyed (violet) strands in sizes USP 6/0 through USP 2 (metric sizes 0, 7-5), in a variety of lengths from 10 cm to 150 cm, 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



KATSAN KATGUT SANAYI VE TICARET A.S.
AOSB 10041 Sk. No:22 Cigli, IZMIR / TURKIYE
Tel: +90 (232) 486 0910 **Fax:** +90 (232) 486 3379
Web: www.katsanas.com **E-mail:** info@katsanas.com