



Instructions for Use
SafePath™ SILK SUTURE
WITH SafePath SUTURING SYSTEM
NONABSORBABLE SURGICAL SUTURE

DESCRIPTION

SafePath™ silk suture is a nonabsorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species *Bombyx mori* (B. mori) of the family Bombycidae. SafePath sutures are processed to remove the natural waxes and gums. SafePath braided silk suture is dyed black and coated with silicone for lubricity.

The suture is available in USP sizes 2-0 and 3-0 and is attached to a single-armed 26mm reverse cutting needle pre-loaded in a single-patient-use suturing device.

SafePath suture meets requirements established by the United States Pharmacopeia (USP) for nonabsorbable surgical suture.

INDICATIONS

The SafePath Suturing System is intended for use in placement of a silk suture in the skin and subcutaneous tissues.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to silk.

Due to the 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 involving nonabsorbable sutures before employing SafePath suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

Silk sutures left in the skin for longer than 7-14 days may cause a “railroad track” scar consistent with the inflammatory process at the silk suture entrance and exit sites. For best cosmetic results the skin sutures should be removed after 7–14 days.

Closing avascular subcutaneous tissue with silk suture may increase the risk of surgical site infections especially in the presence of wound contamination.

SafePath suture elicits an acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. While silk sutures are not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of all of the suture’s tensile strength over time.

PRECAUTIONS

In handling this, or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, 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. The device design also provides a grasper feature that can be used to complete “instrument ties”, if desired.

SafePath silk suture is pre-loaded on a suturing device. It is not necessary to use any other instrument to grasp and drive the needle. In the event that the operator uses another instrument, always grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the needle point to the suture attachment area to avoid damaging needle points and suture.

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 sticks. Discard the entire device and any loose, used needles in "sharps" containers.

ADVERSE REACTIONS

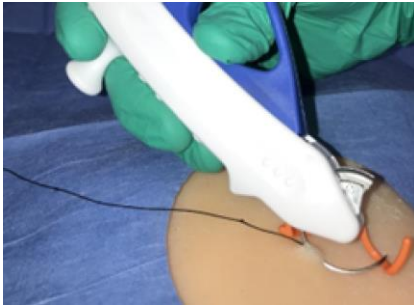
Adverse effects associated with the use of this suture include wound dehiscence, gradual loss of all tensile strength over time, allergic response in patients that are known to be sensitive to silk, infection, acute inflammatory tissue reaction, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

DIRECTIONS FOR USE

1. Remove device from pouch, hold the free length of suture, and pull suture card away from device to release suture.
2. Hold device between fingers and thumb. Place thumb in actuator lever facing towards user with the needle pointing down.
3. Fully squeeze and hold actuator lever to reveal needle.



4. The suturing device is used in the same manner as a traditional needle holder. Orient the device such that the needle point is always visible to the user. Rotate wrist to penetrate tissue with needle ensuring visualization of needle point. The orange needle guard is designed to identify the exit location of the needle and to prevent the user from contacting the needle point.



5. Rotate the needle through the tissue and advance the needle as far as it will travel. When the full length of the needle point is clearly visible, release the actuator and the needle gripper will engage the needle shaft. The user's hand should be relaxed in order to avoid applying sideways or forward pressure to the needle.



6. Squeeze and hold actuator a second time to extract the needle from the tissue. Draw and/or rotate the device away from tissue, pulling the suture through the skin leaving the desired suture "tail" for knot tying.



7. Release the actuator to reset the needle in the suturing device. Repeat steps 3 - 7 in order to place additional stitches.

- To cut suture: hold sutures gently taut and advance the device cutter slot (located at the top of the device) around the suture. Ensure that the suture is placed at the bottom of this slot and squeeze the grasper cutter lever.



- When all sutures have been placed, discard the used device into a sharps container

STERILITY

The SafePath Suturing System is provided sterile for single patient use. Product is sterile unless package has been opened or damaged.

DO NOT RESTERILIZE. Discard opened or unused containers.



Not made with natural rubber latex

HOW SUPPLIED

SafePath sutures are available in USP size 2-0 (metric size 3) and USP size 3-0 (metric size 2) with permanently attached needles.

SafePath suturing devices are available individually packaged in boxes of 5.

STORAGE AND HANDLING

Store in a cool, dry place in a manner that protects the integrity of the package and sterile barrier.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

The SafePath Suturing System is protected by U.S. patents 9,125,644; 9,554,793; 9,743,924; 10,258,323; 10,945,723 and other U.S. and foreign issued and pending patents.



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