

Carefully Read All Instructions Prior to Use.

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

PACKAGING & STORAGE

The SureCUT is sterile (using ethylene oxide gas) and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

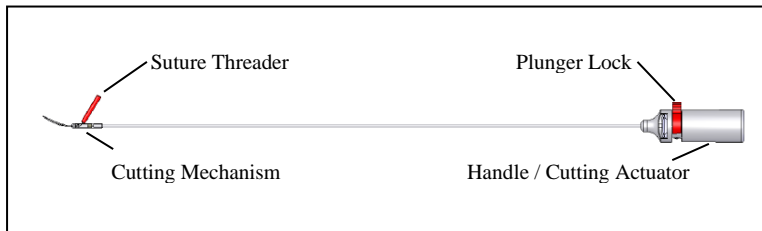
Handle with care. Do not store in excessive heat. After use, this product may be a potential biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

INDICATIONS

The SureCUT Suture Cutter is indicated for cutting multifilament, size "0" polyester suture.

DESCRIPTION

The SureCUT Suture Cutter is a single-use, sterile device. The device is comprised of a stainless steel suture threader; a flexible shaft with a stainless steel shaft that actuates an internal blade to cut suture in a single action. The handle includes a Plunger Lock for the cutting actuator to avoid premature cutting of the suture during device advancement.



COMPLICATIONS

When used as directed, no adverse effects are expected with use of this device.

WARNINGS

- Never advance, torque, or retract the SureCUT if significant resistance is encountered.
- The SureCUT has been qualified to cut size "0" multifilament polyester suture. Attempts to cut smaller, larger or monofilament suture may result in device damage or failure.
- After loading of suture and prior to advancing the SureCUT device, ensure the Suture Threader has been removed from the device and suture. Failure to do so could result in the introduction of a foreign body.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or

cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

PRECAUTIONS

- Care should be taken to avoid damage when handling the device. Do not use if the device is visibly kinked, damaged or deformed.
- Review the Instructions for Use before using.
- Do not remove the Plunger Lock from the device until after the suture has been loaded. If removed or missing, discard the device.
- Prior to advancing the SureCUT device, ensure the Plunger Lock is not removed to avoid premature cutting of the suture.
- Attempts to cut monofilament suture may result in undesired particulates and is not recommended.

INSTRUCTIONS FOR USE

Preparation

1. Carefully inspect the SureCUT Suture Cutter and the packaging prior to use. Do not use a device that is damaged in any way or if its packaging is damaged.
2. Remove the SureCUT from the packaging by the device handle end of the pouch.

CAUTION: Attempting to remove the SureCUT by the distal end of the device may result in damage to the device.

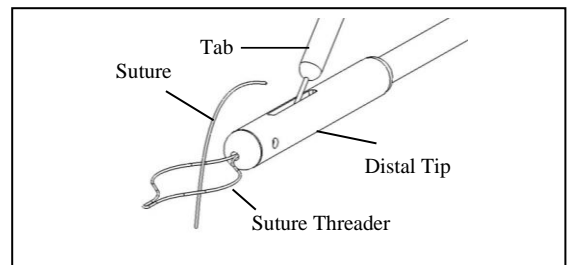
Loading Suture into the SureCUT Suture Cutter

NOTE: Do not remove the Red Plunger Lock on the handle until ready to cut suture. Removal prior to that may result in premature cutting of suture.

3. Insert approximately 1" (3.5cm) of the remnant suture tail through the arrowhead shaped Suture Threader wire and fold suture. (See FIG. 1)

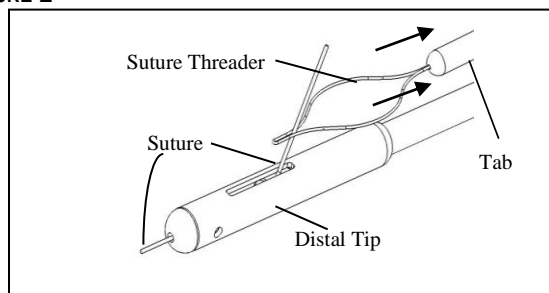
CAUTION: If the Suture Threader is missing or has been removed prior to loading the suture, discard the device and use another. Attempts to re-load the Suture Threader may damage the device.

FIGURE 1



4. Grasping the red tab located on the Suture Threader, gently pull the tab out of the slot and grasp the delivered suture remnant. (See FIG. 2)

FIGURE 2



- Remove the Suture Threader from the delivered suture remnant and dispose of appropriately.

CAUTION: Failure to remove the Suture Threader from the suture could result in the introduction of a foreign body once the suture is cut.

SURECUT ADVANCEMENT AND POSITIONING

NOTE: Do not remove the Red Plunger Lock on the handle until ready to cut suture. Removal prior to that may result in premature cutting of suture.

- Grasping the remnant suture end, advance the SureCUT to the desired location to cut the suture. The cutting mechanism is located 7mm proximal from the distal tip.

NOTE: Care should be taken not to over-rotate, torque or excessively bend the SureCUT as this may affect the ability to advance or cut.

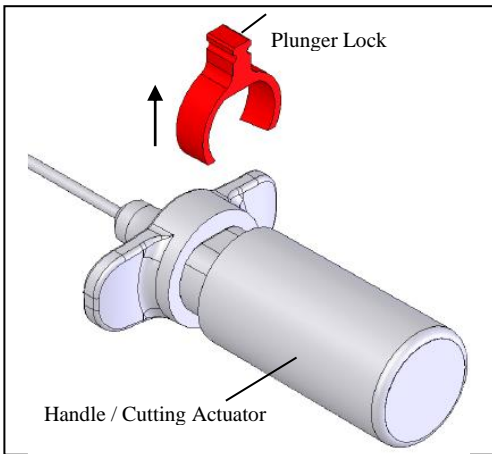
NOTE: If resistance is felt while advancing the SureCUT, determine the cause prior to proceeding.

CUTTING SUTURE WITH THE SURECUT

- Hold SureCUT in a stable position and remove the Red Plunger Lock from the handle. (See FIG 3).

NOTE: Failure to remove the Plunger Lock will result in the inability to cut the suture.

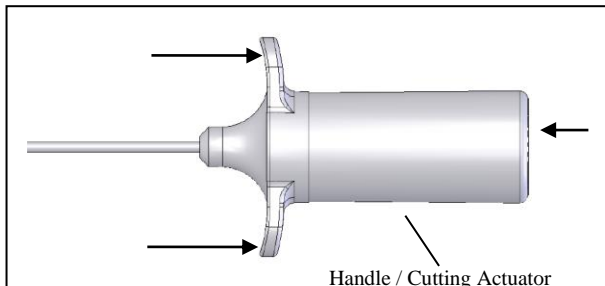
FIGURE 3



- Gently grasping the remnant suture tail with light tension, completely actuate the Handle / Cutting Actuator as shown in FIG 4 and then release.

NOTE: Failure to fully actuate the Handle / Cutting Actuator may result in incomplete cut.

FIGURE 4



- To confirm a successful suture cut, the remnant suture tail should no longer be in tension. Re-actuate the Handle / Cutting Actuator with the suture tail under light tension if necessary, to complete the suture cut.

NOTE: Ensure that the Handle / Cutting Actuator is released after actuation. Maintaining the actuator in the cut position may cause continuous tension to the suture tail until it is released.

- Withdraw the SureCUT and the remnant suture tail from the operative field.

NOTE: If resistance is met while withdrawing the SureCUT determine the cause prior to proceeding.

- Dispose of the SureCUT device as appropriate in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Catalog Number:



Batch Code:



Use By:



Contents of the package:



Do Not Reuse:



Do Not Resterilize:



Do not use if packaging is damaged:



Keep Away From Sunlight:



Keep Dry:



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



Caution



Consult Instructions For Use:



Sterilized using ethylene oxide:



Manufactured By:
AtriCure Inc
7555 Innovation Way
Mason, Ohio 45040
1.866.349.2342
www.atricure.com

