

Laparoscopic Fascial Closure System  
Suture Ease, Inc.



**Before using this product, read the following information thoroughly.**

**Product Description:**

The CrossBow Fascial Closure System is a set of single-use instruments primarily intended for the use of closing soft tissue layers (fascia, muscle and peritoneum) of a trocar wound following laparoscopic surgery. The CrossBow system has two basic components: (1) a suture passer component used to pass suture through the abdominal wall, and (2) a guide used to repeatedly direct the needle through the abdominal wall using visual markers to reference the needle puncture location off the inner wall of the abdomen. The guide has two deployable snare loops used to secure and retrieve the free ends of suture passed by the suture passer.

**Indications for use:**

1. This product is intended to pass suture through soft tissue layers (fascia, muscle and peritoneum) of a trocar wound during laparoscopic surgery.
2. It is to be used only by surgeons trained in endoscopic/laparoscopic surgery.

**Contraindications:**

1. This device is not intended for use where endoscopic techniques are contraindicated.
2. Do NOT use the CrossBow device where it is not possible to visualize the tip of the needle during insertion or removal.
3. The device is not intended for use when the minimum tissue thickness does not reach the markings on the guide component.

**Warnings and Precautions:**

- 1) This device was designed, tested, and manufactured for single patient use only. 2) The device cannot be re-sterilized after use.
- 3) Re-use or re-processing of this device may lead to its failure and subsequent patient injury. 4) Store at room temperature. Avoid prolonged exposure to elevated temperatures.
- 5) Do not expose to temperatures above 54°C (130°F). 6) The needle tip of the suture passer can injure internal tissues and/or any personnel in contact with the device. Special attention should be paid to the tip of the suture passer when handling the device. 7) Always visualize the tip of the needle directly or indirectly (using a laparoscope) during insertion and removal to prevent unintended puncture of internal organs. 8) The device is not intended to be used more than 10 times per procedure

**Product Specifications:**

The closure system is supplied sterile. Do not use if the package is opened or damaged as sterility may be compromised.


**Instructions for Use:**

<p><b>1 Guide Insertion</b></p> <ol style="list-style-type: none"> <li>a) While holding the guide body steady, pull upward on the finger ring to retract the snare loops inside the guide.</li> <li>b) Insert the guide into the wound such that the distal tip of the guide is visible in the abdominal cavity.</li> <li>c) View the proximal end of the guide, ensuring the blue indicator stripe is positioned below the skin surface.</li> <li>d) Push the finger ring down completely to expose the snare loops.</li> <li>e) Holding the guide body perpendicular to the abdomen, recheck to ensure the blue indicator stripe is below the skin surface.</li> </ol> <p><b>2 Suture Loading</b></p> <ol style="list-style-type: none"> <li>a) Depress the actuator of the suture passer prior to loading suture in the distal tip.</li> <li>b) Position a free end of the suture into the tip of the suture passer needle, such that approximately 1 centimeter of suture tail remains on one side.</li> <li>c) Release the actuator to capture and secure the suture tail in the tip of the needle.</li> </ol>	<p><b>3 Suture Passing</b></p> <ol style="list-style-type: none"> <li>a) Insert the suture passer through one track of the guide until the needle tip can be seen inside the peritoneal cavity. Ensure that the needle and suture have passed through the snare loop.</li> <li>b) Release the suture by depressing the actuator. Withdraw the suture passer from the guide.</li> <li>c) Secure the remaining free end of the suture to the tip of the suture passer, as described previously in Steps (2a) - (2c).</li> <li>d) Insert the needle through the opposing track of the guide until the tip of the needle can be seen inside the peritoneal cavity. Ensure that the needle and suture have passed through the opposing snare loop.</li> <li>e) Depress the actuator to release the suture and withdraw the suture passer from the guide.</li> </ol> <p><b>4 Guide Removal/Suture Retrieval</b></p> <ol style="list-style-type: none"> <li>a) If necessary, release the remaining suture from both track slots at the proximal end of the guide.</li> <li>b) Hold the guide body steady. Then pull upward on the finger ring of the guide FIRMLY to retract the snares and grasp the suture.</li> <li>c) While letting go of the guide body, continue pulling upward on the finger ring to remove the entire guide from the wound, exposing the suture secured within the snares of the guide.</li> <li>d) Return the finger ring to the downward position, thus extending the snare loops to enable release of the suture from the guide. If the finger ring does not advance, manually pull on the suture to expose the snare loops and thus release the suture.</li> </ol> <p><b>Final Closure</b></p> <ol style="list-style-type: none"> <li>a) Tie appropriate knots in the suture to complete the closure.</li> <li>b) Inspect the wound to confirm proper closure of the fascia.</li> </ol>
---	--

**Disclaimer of warranties:**

Suture Ease warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including but not limited to, any implied warranties of merchantability or fitness. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact and since Suture Ease has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after it leaves its possession, Suture Ease does not warrant either a good effect or against an ill effect following its use. The manufacturer shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. Suture Ease will replace any device which is defective at the time of shipment. No representative of Suture Ease may change any of the foregoing or assume any additional liability or responsibility in connection with this device.










**Manufactured For:** Suture Ease

 1735 North First Street, Ste 300  
San Jose, CA 95112  
408-459-7595

**REF** : SE-CB

Assembled in Mexico

**EXPLANATION OF SYMBOLS:**

 <b>ATTENTION:</b> See instructions for use.	 Reorder Number.	 Batch Code.	 Sterilized Using Gamma. Contents sterile unless package has been opened or damaged. Do not use if sterile barrier has been breached.
 DO NOT REUSE Do not reuse.	 Manufacturer.	 Rx Only On order of Physician.	 Use By.
 Consult Instructions for Use			