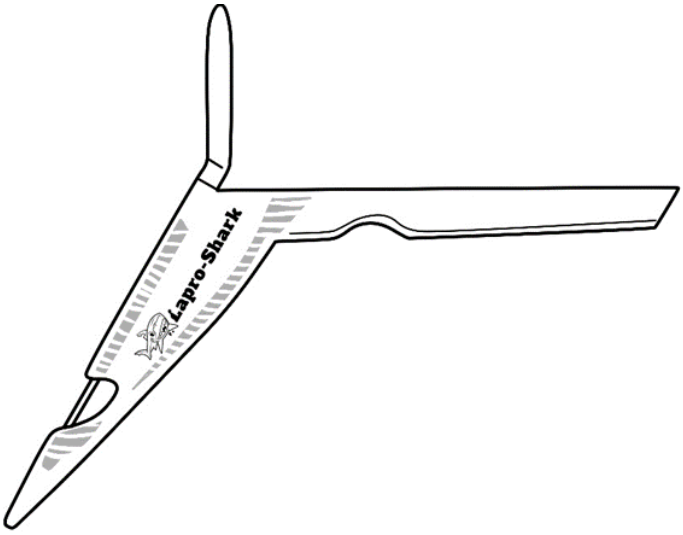
# LAPRO-SHARK™

## Instructions For Use




**Description of the Device**

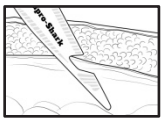
The Fascial Closure Device is used as a closure guide to direct the suturing to ensure adequate closure and avoid injury to the intra-abdominal contents. The system consists of a guide and a needle that is used to close incision sites that are 10 – 15mm in size.

**Operating Principles**

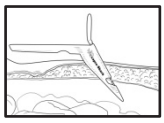
The Fascial Closure Device is designed to distract the skin and subcutaneous fat in the location where the suture is being placed thus maximizing fascial tissue capture and minimizing capture of subcutaneous fat. The elliptical closure guide has a notch cut out on one side at around the midpoint into which the fascial tissue to be sutured is captured.
The closure guide has two guide holes, one for directing the needle and the second as a suture guide. The needle guide is oriented to capture the maximum amount of tissue and ends bluntly in a pocket at the tip of the closure guide device. This pocket ensures that the needle is not free in the abdominal cavity and cannot injure organs or tissue within the abdominal cavity. The suture guide is curved in such a way to direct the suture through the plastic guide and further direct the suture through the eye of the needle. This avoids the need to capture the suture within the abdominal cavity. Lastly the closure guide has a handle to enhance tissue manipulation and improve tissue capture.

### Instructions for Use

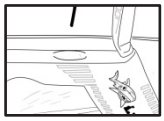
**Step 1:** At the conclusion of the procedure, the trocar is removed and replaced with the Fascial Closure Device.



**Step 2:** The device is then advanced through the defect created by the trocar to ensure that the notch of the device is below the skin and subcutaneous fat.
The device is then manipulated so as to capture the maximal amount of fascia (1cm) into the notch of the device. Manipulating the device can be aided by exerting pressure on the handle of the device.

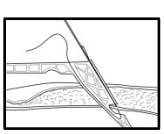


**Step 3:** Once satisfied that adequate tissue has been captured, the needle is introduced through the needle guide driving the needle through the tissue and coming to rest in the pocket at the bottom of the device. The surgeon must ensure that the needle handle is completely seated in the needle guide channel.



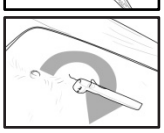
**Step 4:** A suture is then passed via the suture guide. A black indicator mark encircles the suture guide opening. The suture guide is oriented in such a way as to direct the suture down the device and through the eye of the needle and then exit the device at a 90 degree angle.

**Step 5:** Once the surgeon suture exits the device this confirms that it is captured in the eye of the needle.

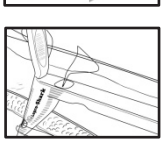


**Step 6:** The needle is then extracted from the device thereby pulling the suture through the tissue.

**Step 7:** The device is rotated180 degrees and captures the opposite side of the defect's fascia into the notch on the device similar to step 2.



**Step 8:** Repeat steps 3-5 but pass the other end of the same suture through the suture guide as in Step 4



**Step 9:** The device is removed resulting in a "U" type suture through full thickness of fascia on either side of the defect. The suture is tied in the usual fashion thereby closing the defect.

### Indications for Use

To close wounds following general surgery and/or minimally invasive surgery.

### Adverse Reactions

Adverse effects associated with the use of this device may include, wound dehiscence, failure to provide adequate wound support in closure of the site 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, suture extrusion and delayed absorption in tissue with poor blood supply. 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. The use of absorbable sutures is highly recommended with the Fascial Closure Device.

### Sterility

The Fascial Closure Device is provided sterile and is a single use device. Do not re-sterilize. Do not use if package is opened or damaged. Do not use after expiration date.

### Contraindications

The Fascial Closure Device is not be used where extended approximation of tissues under stress is required or in cases of a preexisting hernia.

### Warnings

Do not re-sterilize. Discard opened unused components.
Users should be familiar with surgical procedure and techniques involving sutures before employing the Fascial Closure Device for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. The use of this device may be inappropriate in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing.

### Precautions

Care should be taken to avoid damage when handling. Avoid crushing or crimping the suture material with surgical instruments, such as needle holders and forceps. Acceptable surgical practice should be followed with respect to drained and closure of infected wounds.
Store product at room temperature. Dispose or discard in accordance with local laws and regulations.
**CAUTION: Federal law restricts this device to sale by or on the order of a healthcare professional.**

STERILE R Sterile Using Gamma Radiation

Do Not Reuse

Rx ONLY Prescription Required

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