

AbClose

Port Site Closure Device

Instructions for Use

1. **DEVICE DESCRIPTION**

The AbClose Port Site Closure Device includes the following components:

- One (1) Suture Passer
- One (1) Suture Guide

The AbClose - Port Site Closure Device is a sterile, single-use device, which includes one Suture Guide and one Suture Passer. The Suture Guide has two channels to direct the Suture Passer with suture strand into the Suture Catcher. The Suture Catcher grasps the end of the suture strand. By withdrawing the Suture Guide from the abdominal cavity after the sutures are deployed, the device automatically creates a loop for closure. At the end, any standard knot tying technique may be performed by the physician to close the incision.

2. **INDICATION FOR USE**

The AbClose - Port Site Closure Device is intended for use in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing the incisions created by 10 mm, 12 mm or 15 mm trocars.

3. **CONTRAINDICATIONS**

Do not use where laparoscopic techniques are generally contraindicated.

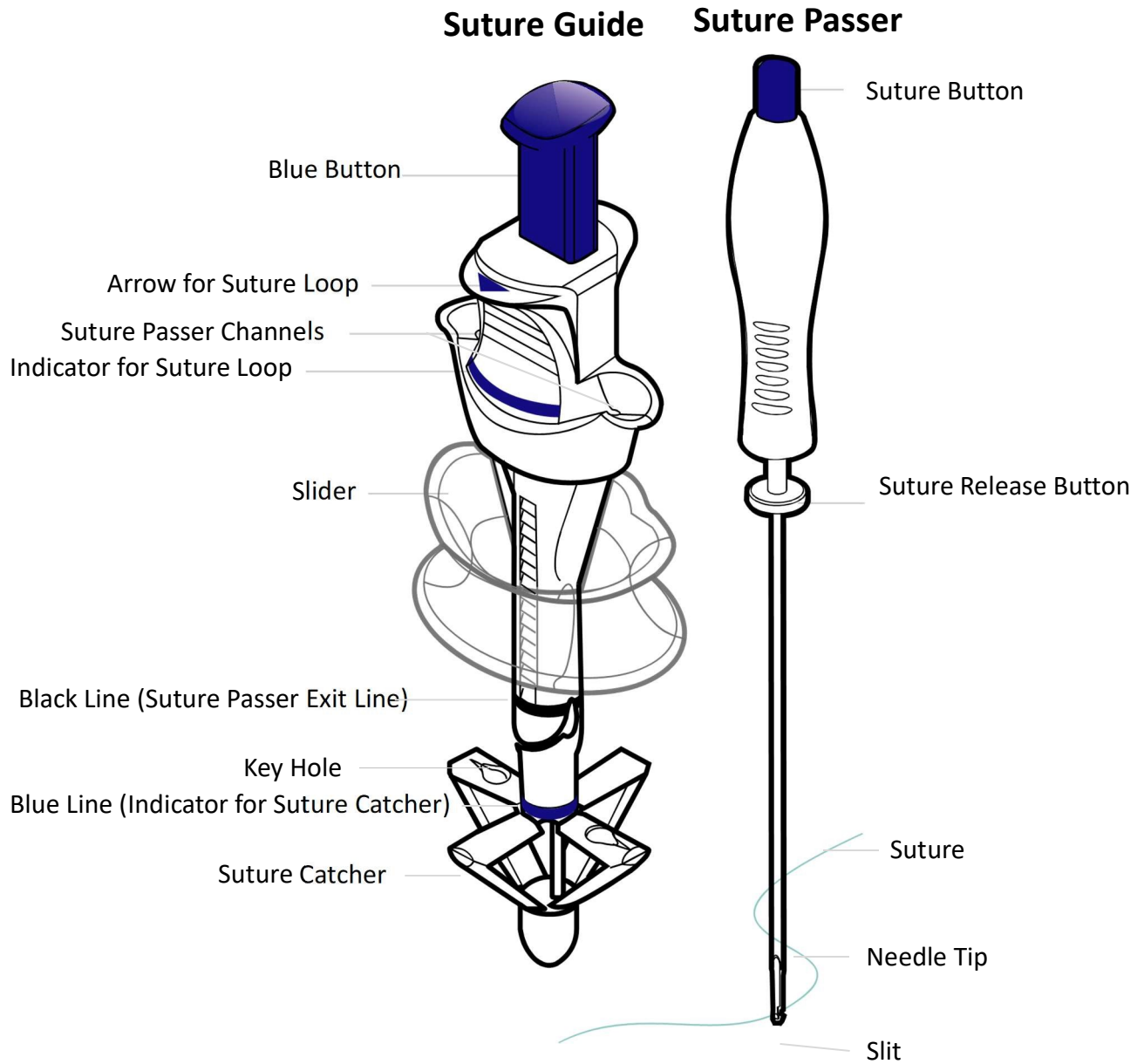
4. **WARNINGS AND PRECAUTIONS**

- A surgeon should not use the AbClose device without a full understanding of how the device functions and reading the instructions for use.
- The AbClose is not recommended for use in surgical procedures where the position of the needle tip cannot be clearly visualized.
- The AbClose is not recommended for use where surgical procedures may increase the wound size to greater than 15mm.
- The Slit of the Suture Passer must be retracted to expose the Needle Tip of the Suture Passer to pass suture through tissue.
- The Needle Tip of the Suture Passer can injure internal tissues and/or any personnel in contact with its pointed end. The tip of the Suture Passer should be protected at all times when the instrument is not in use.
- Dispose the device in accordance with all applicable Federal, State, and local Medical / Hazardous waste practices.
- **The device is provided STERILE for SINGLE USE ONLY.** It is not designed to be re-used or re-sterilized. Reprocessing may cause changes in material characteristics which may compromise device performance. Reprocessing may cause contamination leading to surgical site infections. These risks may potentially affect patient safety.

- Do not use if package is damaged.

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

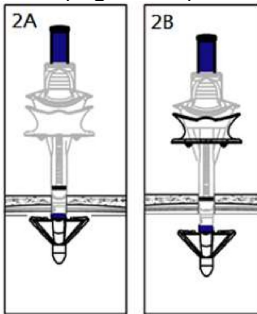
5. DIRECTIONS FOR USE



<p>Step 1 Press the Blue Button of the Suture Guide (Figure A) and insert the device through the trocar incision site (Figure B). Warning: If the trocar incision is a slit instead of a round shape hole, face the Arrow of the Suture Loop toward one end of the incision slit. DO NOT attempt to release the Push Button while inserting the device.</p>	<p>Step 2 Once the Blue Line is visible below the peritoneum under laparoscope visualization, release the Blue Button to open the Suture Catcher. Pull the Suture Guide against the peritoneum and ensure that the Black Line is below the skin level under direct visualization*.</p>	<p>Step 3 Advance the Slider to the skin surface to stabilize the Suture Guide**.</p>	<p>Step 4 Place suture in the Slit of the Suture Passer, leaving approximately 1-3 cm of the suture end over the Slit (Figure A). Press the Suture Button to advance the Needle Tip and grasp the suture. (Figure B)***.</p>

<p>Step 5 While the Suture Guide is kept steady, insert the Suture Passer into one of the two Suture Passer Channels (Figure A). Continuously advance the Suture Passer to activate the Suture Release Button, releasing the suture end in the Key Hole****. Repeat Steps 4-5 to introduce the other end of the suture (Figure B). Make sure the upper suture loop remains on the same side of the Arrow for Suture Loop. Warning: DO NOT hold or pull the suture outside human cavity while inserting the Suture Passer.</p>	<p>Step 6 Press the Push Button on the Suture Guide to close the Suture Catcher. The Suture Catcher will automatically grasp the two ends of the suture.</p>	<p>Step 7 Withdraw the Suture Guide and detach the suture by pulling the proximal end of the device. Warning: DO NOT attempt to release the Push Button (Blue) while withdrawing the device.</p>	<p>Step 8 Use standard knot tying techniques to obtain the desired closure. Warning: After suture closure, inspect the site for hemostasis</p>

*In Step 2, ensure the Black Line is right below the skin level under direct visualization. If the Black Line is above the skin level (Figure 2A), advance the Suture Guide down into the wound to position the Black Line below the skin level (Figure 2B).



**In Step 3, keep the Slider at the original location (as Figure 2B), manually hold the Suture Guide steadily.

***In Step 4, it is recommended that a nurse assistant load the suture into Suture Passer.

****In Step 5, if the released suture end does not securely stay in the Key Hole of the Suture Catcher, withdraw the suture and repeat Steps 4-5 to introduce the same end of the suture into the same Guide Channel.

6. STORAGE CONDITIONS

AbClose - Port Site Closure Device should be stored under the following condition: 20~25 °C, 30%~60% RH.

STERILE EO



Rx Only

7. PATENTS

This product and / or its use are covered by one or more of the following United States Patents: 9,241,613. Additional patents pending.

AbClose is a registered trademark of Medeon BioDesign, Taiwan.

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