

PMI SURGLINE®

PMI CLASSICCLOSE™ Port Site Closure Kit INSTRUCTIONS FOR USE



IMPORTANT INFORMATION – PLEASE READ BEFORE USE!

Please read all information contained in this insert. The use of an instrument for a task other than that for which it is intended, incorrect handling, improper care, failure to adhere to all warning and precautions and misuse can lead to premature wear and/or have serious clinical consequences to the user or patient, such as injury, contamination, cross-infection, or death. Federal (USA) law restricts this device to sale by or on the order of a physician. Before using, read the following information thoroughly. This IFU is designed to assist in using this product. It is not a reference to surgical techniques.

INSTRUCTIONS FOR USE: PMI CLASSICCLOSE™ Port Site Closure Kit

DEVICE DESCRIPTION: PMI CLASSICCLOSE™ Suture Passer and Bariatric Length CLASSICCLOSE™ Suture Passer are sterile, single-case use, hand-held suture grasping device, designed to pass suture through soft tissue.

The PMI CLASSICCLOSE™ is available in three configurations consisting of the following components:

PMICC512:

- (1) Classic Close Suture Passer
- (1) 5mm Suture Guide
- (1) 10/12mm Suture Guide

PMICC512S:

- (1) Classic Close Suture Passer
- (1) 5mm Suture Guide
- (1) 10/12mm Suture Guide
- (1) Trocar Cleaning Swab Pack (5-8mm and 10-12mm swabs) PMITS

PMICCXLKIT:

- (1) Bariatric Length Classic Close Suture Passer
- (1) 10/12mm Suture Guide
- (1) 15mm Bariatric Suture Guide

INDICATION FOR USE: The **PMI CLASSICCLOSE™** is intended to pass suture through soft tissues of the body during endoscopic/laparoscopic surgery. It is to be used only by surgeons trained in endoscopic/laparoscopic surgery.

PRECAUTIONS:

- A surgeon should not begin clinical use of the PMI Classic Close without a full understanding of the directions for use.
- The PMI Classic Close is not recommended for use in surgical procedures where the position of the needle tip cannot be clearly determined.
- The jaws of the instrument must be closed completely in order to form a needle point to pass suture through tissue. Passage of the PMI Classic Close through tissue without pressure on the thumb ring may result in losing grasp of the suture or the inadvertent capture of tissue.
- The suture passer jaws can injure internal tissues and/or any personnel in contact with the pointed end of the instrument. The suture passer jaw should be protected at all times with the protective cap when the instrument is not in use.

PMI CLASSICCLOSE Suture Passer Instructions for Use:

The suture passer has two operating positions: Jaws Open and Jaws Closed (see illustrations).



1. To suture, open the needle point tip to grasp the suture by pulling back on the thumb ring.
2. Place suture in the jaw depression opening nearest the hinge point.
3. Close the jaws around the suture by releasing the thumb ring, thus forming a needlepoint.
4. Pass the needle point with the suture through tissue by pushing distally on the handle while maintaining gentle pressure on the thumb ring to keep the needle tip closed.
5. Open the jaw to drop the suture.
6. Close the jaw and remove the suture passer.
7. With the jaws closed, reinsert the suture passer in proximity to the first entry point.
8. Open the jaws to retrieve the suture by pulling back on the thumb ring.
9. Close the jaws by releasing the thumb ring to form a needle tip.
10. While removing the suture passer (suture in place) maintain gentle pressure on the thumb ring.

STEP 1

Insert PMI Suture Guide with holes aligned perpendicular to the incision. Insert PMI Classic Close through PMI Suture Guide, maintaining gentle pressure on the thumb ring, fascia, muscle, peritoneum and into the abdomen. Release the suture and remove PMI Classic Close.

STEP 2

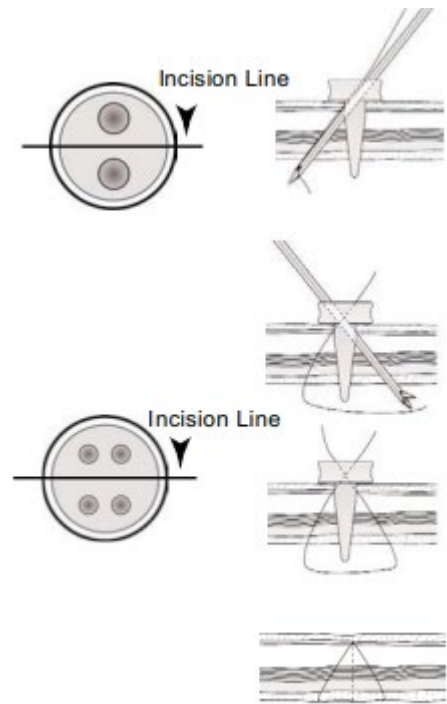
Push PMI Classic Close through opposite side of PMI Suture Guide. Grasp suture.

STEP 3

While maintaining gentle pressure on the thumb ring, pull the suture up through the peritoneum, muscle, fascia & PMI Suture Guide.

STEP 4

Remove PMI Suture Guide. Tie suture to complete the closure.



INSTRUCTIONS FOR USE FOR PMI TROCAR CLEANING SWABS (Included in PMICC512S):

1. Using sterile technique, remove the PMI TROCAR CLEANING SWABS from the packaging. Inspect the devices for any type of damage or contamination, and discard if any is suspected. If the devices are acceptable, deliver them to the sterile field.
2. During the procedure, anytime the scope is removed from the body, clean the scope lens using the PMI TROCAR CLEANING SWABS.
3. When removing debris from trocar valves, use the small trocar swab for 5-8mm trocars, and the larger trocar swab for 10-12mm trocars. NOTE: Trocar must be fully inserted into the abdominal cavity prior to use of PMI TROCAR CLEANING SWABS.
4. Select the appropriately sized trocar swab and insert the swab head into the trocar valve. Advance the swab into the valve, but do not extend the swab head beyond the distal end of the trocar. Move the swab back and forth to absorb fluid and clean debris from the cannula. Do not release the trocar swab. NOTE: PMI TROCAR CLEANING SWABS must be used under direct vision.
5. When cleaning a trocar with a flap valve, ensure that the valve is held open when withdrawing the swab, thereby preventing difficulty with withdrawing the Trocar Cleaning Swab upon removal. NOTE: PMI TROCAR CLEANING SWABS must be used under direct vision.
5. Check the cannula to ensure all debris has been removed. If not, repeat the process until acceptable.
6. Before disposal of the PMI TROCAR CLEANING SWABS, visually inspect the devices to ensure they are intact and ensure that all components have been retrieved.
7. Upon completion of the procedure, PMI TROCAR CLEANING SWABS should be discarded in biohazardous waste as per standard procedure.

CLINICAL BENEFITS:

The preassembled: **PMI CLASSICCLOSE™ Port Site Closure Kit** can minimize the incidence of complications and costs associated with post-operative port site hernias, by providing a fast, complete, and repeatable method of fascial closure. The PMI Trocar Cleaning Swabs improve endoscopic visualization during the procedure and may reduce procedure time by enabling a quick and simple way of maintaining clear vision through laparoscopic lens cleaning.

CONTRAINDICATIONS:

This device is not intended for use, except as indicated, and when laparoscopic and other minimally invasive surgical techniques are contraindicated.












CAUTIONS/WARNINGS:

The device should be used only by surgeons trained in proper techniques for laparoscopic surgery and minimally invasive procedures.

- Device is sterile if the package is dry, unopened, and undamaged. Do not use if the pouch is compromised in any way or if the package seal is broken.
- Discard these devices if there is possible damage or contamination, or if the device has passed the expiry date.
- These devices are for SINGLE PATIENT USE ONLY. If reused or reprocessed, the manufacturer cannot guarantee the performance, safety, and reliability of these devices.
- These devices should not be re-sterilized or re-used. Re-sterilization may compromise the integrity of the device and may create the risk of contamination as well as an opportunity for patient infection.
- Protect the **PMI CLASSICCLOSE™ Suture Passer** in its protective sleeve when not in use. This will prevent injuries from the possibility of an exposed needle.
- DO NOT USE the **PMI CLASSICCLOSE™ Suture Passer** in surgical procedures where the position of the suture passer cannot be clearly determined.
- DO NOT USE the **PMI CLASSICCLOSE™ Suture Passer** if the device is not functioning properly or if the plunger is malfunctioning.
- Ensure compatibility with the endoscope/laparoscope and trocar and avoid sharp edges that could interfere with the components of **PMI TROCAR CLEANING SWABS'** microfiber. For additional instructions, follow the complete IFU for **PMI TROCAR CLEANING SWABS**.
- **PMI TROCAR CLEANING SWABS** should not be inserted at an angle or beyond the distal end of the trocar.

Any serious incident related to any of these devices should be reported to the manufacturer and the local representative.

SYMBOLS:

	Caution		Consult Instructions for Use
	Catalog Number		Authorized for sale or use by physician only
	Expiration Date		Manufacture Date
	Lot Number		Sterilized by Ethylene Oxide (EO)
	Single Patient User Only		Do Not Re-Sterilize
	Do Not Use if Package is Damaged	Intentionally left blank	