PMI SURGLINE®

PMI Disposable Bariatric 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 DISPOSABLE BARIATRIC SITE CLOSURE KIT

DESCRIPTION:

PMI DISPOSABLE BARIATRIC SITE CLOSURE KIT consists of the following components:

PMITCSGXLKTS includes:

- (1) PMI Disposable Bariatric Length Suture Grasper (PMITCSGXL)
- (1) PMI Disposable 10/12mm Suture Guide
- (1) Disposable 15mm, 4-Hole Bariatric Suture Guide
- (1) Trocar Cleaning Swab Pack (5-8mm and 10-12mm swabs) PMITS

INDICATIONS FOR USE:

PMI DISPOSABLE BARIATRIC SITE CLOSURE KIT is indicated to be used during endoscopic and laparoscopic surgery to keep the trocar valves and laparoscopic lens clean and free of biomatter (debris) and additionally, to facilitate the placement of sutures for secure closure of trocar sites as determined by a licensed surgeon familiar with potential indications, side effects, limitations, and contraindications of performing such procedures.

CLINICAL BENEFITS:

The preassembled **PMI DISPOSABLE BARIATRIC 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:
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 DISPOSABLE BARIATRIC SUTURE GRASPER in its protective sleeve when not in use. This will prevent injuries from the possibility of an exposed needle.
- DO NOT USE the PMI DISPOSABLE BARIATRIC SUTURE GRASPER in surgical procedures where the position of the BARIATRIC SUTURE GRASPER cannot be clearly determined.
- DO NOT USE the PMI DISPOSABLE BARIATRIC SUTURE GRASPER 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.

INSTRUCTIONS FOR USE FOR PMI TROCAR CLEANING SWABS:

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 PMI TROCAR CLEANING SWABS upon removal.
   NOTE: PMI TROCAR CLEANING SWABS must be used under direct vision.
6. Check the cannula to ensure all debris has been removed. If not, repeat the process until acceptable.
7. 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.
8. Upon completion of the procedure, PMI TROCAR CLEANING SWABS should be discarded in biohazardous waste as per standard procedure.

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INSTRUCTIONS FOR USE for PMI DISPOSABLE BARIATRIC SUTURE GRASPER (Included in PMI DISPOSABLE BARIATRIC SITE CLOSURE KIT):

PRODUCT DESCRIPTION:

- **PMI DISPOSABLE BARIATRIC SUTURE GRASPER (PMITCSGXL)**
- **PMI DISPOSABLE SUTURE GUIDES (Included in PMI DISPOSABLE BARIATRIC SITE CLOSURE KIT)**
- **(1) PMI Disposable 10/12mm Suture Guide**
- **(1) PMI Disposable 15mm, 4-Hole Bariatric Suture Guide**

INDICATION FOR USE

To facilitate the placement of sutures for secure closure of trocar sites as determined by a licensed physician familiar with the possible side effects, typical finding, limitations, indications and contraindications of performing such a procedure.

CONTRAINDICATIONS

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

CAUTIONS

For single patient use only. Do not attempt to clean or re-sterilize this product. The design of this device may not perform as intended by the manufacturer if it is reused. The manufacturer cannot guarantee the performance, safety and reliability of a reprocessed device. After use, this product may be a potential biohazard. Handle in a manner which will prevent accidental puncture. Dispose of in accordance with applicable laws and regulation. Carefully place the used needle in a sharps biohazard container after the procedure is completed.

DIRECTIONS FOR USE

The PMI Suture Grasper has specific indications for use as noted above. In that context, the surgeon is best advised to use a method which his/her own practice and discretion dictates to be best for the patient, consistent with the indications and contraindications outlined above. The following instructions are recommended for the proper function of the Suture Grasper. This is not a reference for trocar closure techniques.

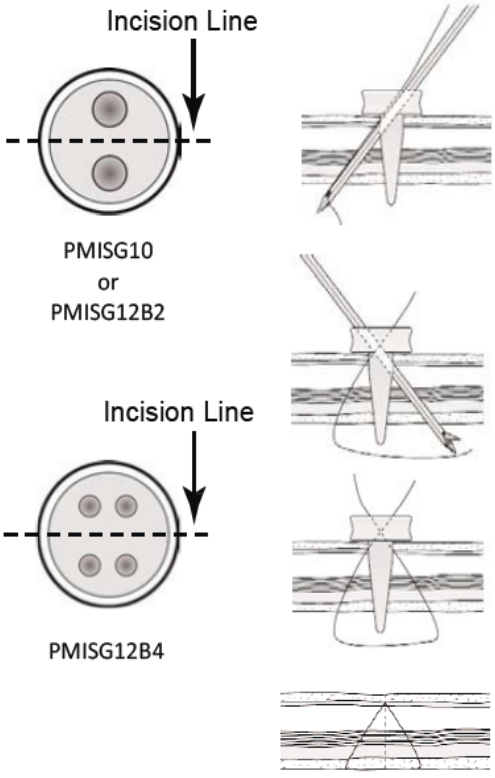
1. Acquire a suture at least 24 inches in length. Remove the needle guard from the Suture Grasper. The arrow indicator mark is aligned with and designates the beveled side of the needle. Depress the plunger on the proximal end of the device to advance the grasper arms past the distal end of the needle. Place the suture between the grasping arms, approximately 1-2cm from the suture end. Release the plunger to retract the suture into the needle. Pull the long end of suture back along the needle towards the handle end of the device and hold in place with gentle tension.
2. Position the needle at one edge of the trocar defect. Hold the needle at the preferred angle and advance the needle through the subcutaneous tissue and fascia. Keep the needlepoint in direct visualization after it has entered the abdominal cavity. Briefly depress the plunger to release the suture. Withdraw the device.
3. Position the needle at the opposite edge of the trocar defect. Hold the needle at the preferred angle and advance the needle through the subcutaneous tissue and fascia. Keep the needlepoint in direct visualization after it has entered the abdominal cavity. Depress the plunger to advance the grasping arms. Grasp the previously placed suture loop with the arms. Release the plunger to retract the suture into the needle. Hold one of the two ends of the suture to prevent movement. Withdraw the needle to pull the suture through the tissue. Continue to retract the suture loop until the other end of the suture exits the grasping arms.
4. Using manual traction on the suture withdraw any excess length that may remain in the abdominal cavity. Use standard technique to tie the suture.
5. Dispose in accordance with applicable laws and regulation. Carefully place the used needle in a sharps biohazard container after the procedure has been complete.

Indications for Use

The PMI Suture Guide is intended for use during endoscopic / laparoscopic surgery. It is to be used only by surgeons trained in endoscopic / laparoscopic surgery.

Instructions for Use

The PMI Suture Guide can be used in conjunction with the PMI Trocar Closure-Suture Grasper to close trocar wounds in the following manner (see figures below):



Step 1

Insert PMI Suture Guide with holes aligned perpendicular to the incision. Push PMI Trocar Closure-Suture Grasper through PMI Suture Guide, fascia, muscle, peritoneum and into abdomen. Drop suture and remove PMI Trocar Closure-Suture Grasper.

Step 2

Push PMI Trocar Closure-Suture Grasper through opposite side of PMI Suture Guide. Pick up suture.

Step 3

Pull the suture up through the peritoneum, muscle, fascia & PMI Suture Guide.

Step 4

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

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	