

**PRODUCT DESCRIPTION:** PMI Disposable Site Closure Kits

PMI512 – PMI Disposable Site Closure Kit (3 Piece)

- (1) PMI Disposable Suture Grasper
- (1) PMI Disposable 10/12mm Suture Guide
- (1) PMI Disposable 5/8mm Suture Guide

PMI12 – PMI Disposable Site Closure Kit (2 Piece)

- (1) PMI Disposable Suture Grasper
- (1) PMI Disposable 10/12mm 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**

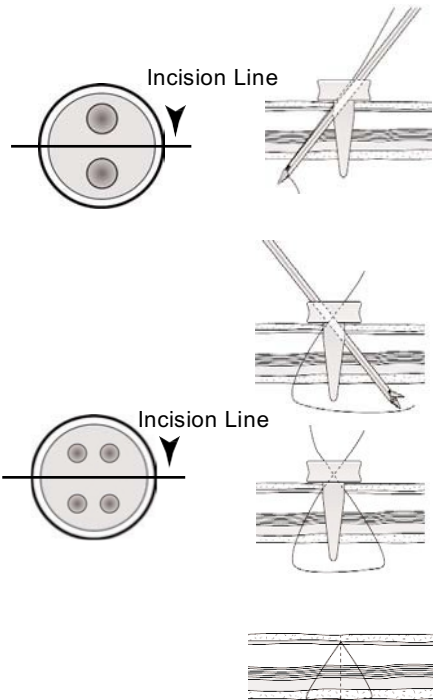
For single patient use only. Do not attempt to clean or re-sterilize this product. The design of this device may not perform as intended by the manufacturer if it is reused. The manufacturer cannot guarantee the performance, safety and reliability of a reprocessed device. After use, this product may 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.

The PMI Suture Grasper can also be used in conjunction with the PMI Suture Guide to close trocar site incisions 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.



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 DO NOT RE-USE

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 PROFESSIONAL USE ONLY

 CONSULT INSTRUCTIONS FOR USE

DO NOT USE IF PACKAGE IS DAMAGED