

## INFORMATION INSERT

### Disposable Suture Grasper Needle for Laparoscopic Trocar Sites

Sterile – contents sterile unless package is opened, damaged or expired.



**STERILE EO**

Sterilized Using Ethylene Oxide

Not Made  
With Natural  
Rubber Latex

**INDICATIONS FOR USE:** The Suture Grasper Needle is used to facilitate the placement of sutures during the closure of laparoscopic wound sites and laparoscopic fixation of mesh materials used in the repair of hernia defects or soft tissue deficiencies.

**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.

**CAUTION:** This product is for single-use only. It has not been designed to be re-used/re-sterilized. Reprocessing may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single-use instruments can also cause cross-contamination leading to patient infection. These risks may potentially affect patient safety. 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 regulations. Carefully place the used needle in a sharps biohazard container after the procedure is completed.

Test device with suture to ensure that it retracts completely without damaging the suture prior to use. Don't allow plunger cap to snap back while retracting the grasper arms. Ensure grasper arms can completely retract into lumen. If not, adjust one arm to create a misalignment between the arm ends to allow for full retraction.

#### **DIRECTIONS FOR USE**

1. Acquire a suture of sufficient length. 2.0 Nylon braided suture type is recommended for this device. Remove the needle guard from the Suture Grasper Needle. 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 midpoint of the suture between the grasping arms. Release the plunger to retract the suture into the needle. Pull the two lengths of suture back along the needle towards the handle end of the device and hold in place with gentle tension.
2. With the trocar still in place, position the needle at one edge of the wound site. Angle the trocar in a position that allows for precise needle advancement. 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 wound. Angle the trocar in a position that allows for precise needle advancement. 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. Remove the trocar from the wound site. 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 of in accordance with applicable laws and regulation. Carefully place the used needle in a sharps biohazard container after the procedure has been completed.

#### **Transperitoneal fixation of mesh materials**

1. Before the introduction of the mesh, position sutures on the wall side of the mesh material. The length of both arms of the suture should be adapted to the thickness of the abdominal wall.
2. Remove the needle guard from the Suture Grasper Needle. The arrow indicator mark is aligned with and designates the beveled side of the needle. For the curved configuration, the bevel face is rotated 90° from the arrow indicator mark.
3. When the mesh is well positioned inside the abdominal cavity, advance the Suture Grasper needle through the abdominal tissue and into the body cavity under laparoscopic visualization.
4. Depress the plunger on the proximal end of the device to advance the grasper arms past the distal end of the needle.
5. Place the midpoint of the suture between the grasping arms. Release the plunger to retract the suture into the needle.
6. Withdraw the Suture Grasper Needle.
7. Depress the plunger to release the suture. Grasp and retain the suture with an instrument.
8. Repeat steps 2-6 for placement of the second arm of the suture as desired.
9. Tie the suture.
10. Dispose in accordance with applicable laws and regulation. Carefully place the used needle in a sharps biohazard container after the procedure has been completed.

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



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Re-Order Catalog No.: RSG-14

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