

GraNee[®] Needle

(Riza-Ribe[®] Needle Open Loop Grasper)

(U.S. Patent # 5,501,692)

PRODUCT INFORMATION DATA SHEET

Following information should be read before using this device

INTENDED USE: The **GraNee[®] Needle** (Riza-Ribe[®] Needle Open Loop Grasper) is a single use product supplied sterile. This device is used during laparoscopy or under direct visualization. It has a sharp end. Precaution is advised to prevent self inflicted needle wounds. It has an ambidextrous locking mechanism that can be activated by twisting the thumb. Under direct visualization, insert the grasper/needle into the abdominal wall. When the tip of grasper/needle is visualized, lock the open loop grasper/needle (**GraNee[®] Needle**) by pushing the plunger and twist the thumb. The open loop will be fully extended and ready to use. To unlock, reverse the order of the steps to this maneuver.

CONTRAINDICATIONS: This device is not intended for use when endoscopic techniques are contraindicated or needle penetration is not visualized.

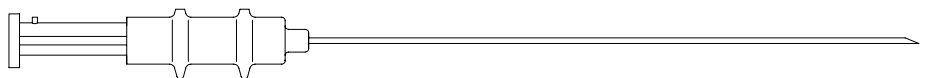
WARNING: This device is not a trocar sleeve. Extreme caution is recommended and when in abdominal cavity the open loop grasper/needle (**GraNee[®] Needle**) should be in locked position. Refer to endoscopy labeling.

Read all instructions prior to using device.

This device is used as an adjunct to laparoscopic surgical procedures: its primary uses are in those procedures where it is necessary to grasp the free end of a suture / ligature under laparoscopic visualization, and either complete an intra-corporeal tie or bring the suture to the skin surface for an extra-corporeal tie.

Operation Preparation :

- 1 - Prepare abdominal wall or surgical field.
- 2 - Open package and remove the **GraNee[®] Needle** (Riza-Ribe[®] Needle Open Loop Grasper) in sterile fashion.
- 3 - Remove protective plastic from tip of needle.
- 4 - Test for proper function of needle by pushing plunger several times and visualize the open loop. **If parts do not move easily, discard the unit.**
- 5 - Load ligature to the **GraNee[®] Needle** (Riza-Ribe[®] Needle Open Loop Grasper) by pushing plunger, threading ligature in open loop and releasing plunger (Fig. 1 and 2).



GraNee[®] Needle (Riza-Ribe[®] Needle Open Loop Grasper)



Locked Position : To lock open loop, push plunger and twist thumb.

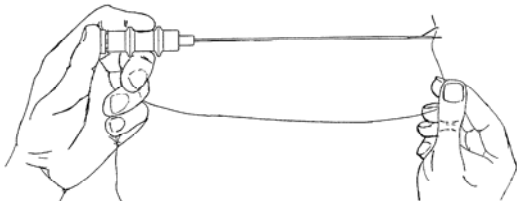


Fig. 1 - Loading with suture

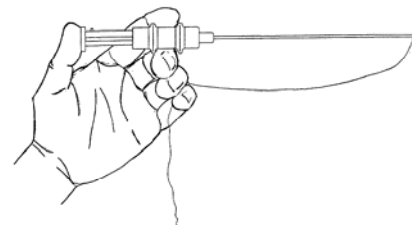


Fig. 2 - Loaded with suture

This device is used during laparoscopy :

- A.) Securing Abdominal Wall Bleeders due to Trocar Injury (See Fig. 3, 4, 5, 6, 7 and 8).
- B.) For Securing Trocar Induced Fascial Defects and Prevention of Herniae (See Fig. 9, 10, 11, 12 and 13).
- C.) Laparoscopic Total Extra-Peritoneal (T.E.P) Hernia Repair : 3-Point Fixation Technique.
- D.) For the Repair of Incisional or Preperitoneal Herniae . . . Securing the Mesh.
- E.) Transfer of Suture under Laparoscopic or Direct Visualization.

A) Securing abdominal wall bleeders due to trocar injury :

- 1 - Under laparoscopic visualization, pass loaded needle through one side of the injured blood vessel (Fig. 3). Free ligature from the needle and withdraw the empty needle.
- 2 - Pass the empty needle through the other side of the injured vessel. Grab end of ligature with open loop of needle or with the help of a grasper (Fig. 4) and withdraw loaded needle.
- 3 - Tie ends of ligature over a folded 4x4 gauze (Fig. 5). The gauze protects the skin and augments the tourniquet effect.
- 4 - Repeat steps 1, 2 and 3 at a small distance in opposite side of the blood vessel injury to arrest bleeding (Fig. 6, 7 and 8).
- 5 - Upon completion of endoscopic procedure, dispose of the **GraNee[®] Needle** (Riza-Ribe[®] Needle Open Loop Grasper) in accordance with local regulations.

Fig. 3

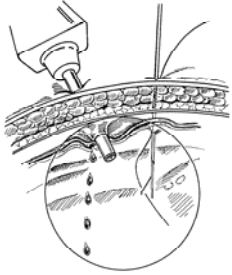


Fig. 4



Fig. 5



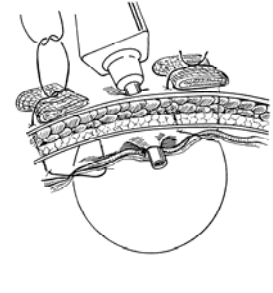
Fig. 6



Fig. 7



Fig. 8



B) Closing fascial defect :

- 1 - After laparoscopic procedure is completed, remove the trocar and the grasper if used. Insert either a 10 or 12 mm R-Med[®] plug into defect. This will prevent loss of gas and will assist positioning of the **GraNee[®] Needle** (Riza-Ribe[®] Needle Open Loop Grasper) passes subcutaneously.

Technical Tip : Make distal passes first. This will facilitate suture retrieval in endo-loop fashion.

- 2 - Thread a 0 vicryl ligature to the **GraNee[®] Needle** (Riza-Ribe[®] Needle Open Loop Grasper). Pass the loaded needle through the fascial edge into the peritoneal cavity (Fig. 9). Free the end of ligature from the **GraNee[®] Needle** (Riza-Ribe[®] Needle Open Loop Grasper) and withdraw the empty needle
- 3 - Pass the empty needle through the fascial edge on the opposite side (Fig. 10). Grab end of ligature the **GraNee[®] Needle** (Riza-Ribe[®] Needle Open Loop Grasper) in endo-loop fashion and withdraw loaded needle (Fig. 11).
- 4 - After sutures are in place (Fig. 12), remove the 10 or 12 mm R-Med[®] Plug while tightening on the sutures.
- 5 - Tie suture subcutaneously (Fig. 13). Proceed with skin closure of your choice.
- 6 - Repeat the same technique to secure other trocar sites.
- 7 - Upon completion of endoscopic procedure, dispose of the **GraNee[®] Needle** (Riza-Ribe[®] Needle Open Loop Grasper) in accordance with local regulations.

Fig. 9

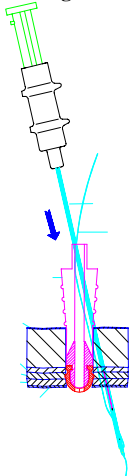


Fig. 10

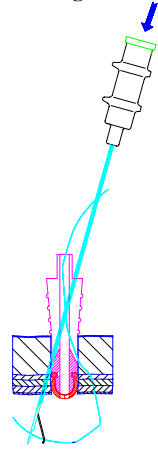


Fig. 11

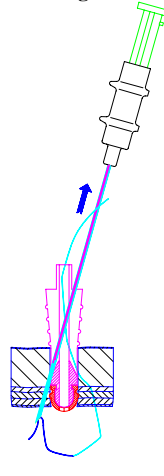


Fig. 12

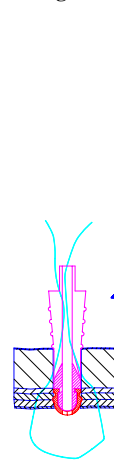


Fig. 13

