

# 10 mm and 12 mm R-Med® Disposable Plug

(U.S. Patent Nos. 5,562,688 and 5,716,369)  
PRODUCT INFORMATION DATA SHEET

Following information should be read before using this device

For use with Riza-Ribe® Needles or GraNee® Needles

- INTENDED USE:** The 10 mm or 12 mm R-Med® Disposable Plug is a single use product supplied sterile for use during laparoscopy to retain pneumoperitoneum and close 10 mm or 12 mm trocar defects.
- CONTRAINDICATIONS:** When Riza-Ribe® Needle or GraNee® Needle penetration cannot be visualized and when endoscopic techniques are contraindicated (Refer to endoscope labeling).
- WARNING:** Trocar defect closures are accomplished only under laparoscopic visualization.  
Read all instructions prior to using device

## **DIRECTIONS FOR USE:**

### **PNEUMOPERITONEUM RETENTION**

1. At the end of procedure, select plug that matches your trocar (e.g., 12 mm plug will match 12 mm trocar). Release Trocar and remove (Fig. 1).
2. Immediately place gloved finger over skin opening to retain pneumoperitoneum.
3. Place R-Med® Disposable Plug into defect (Fig. 2).
4. Under Laparoscopic visualization ensure that distal end of R-Med® Disposable Plug is aligned at the peritoneal surface (Fig. 3). This will align Riza-Ribe® Needle or GraNee® Needle to pass 16-17 mm above the peritoneum, which will be above the fascial level.

### **CLOSURE OF TROCAR DEFECTS**

5. Load Riza-Ribe® Needle (Fig. 4) or GraNee® Needle (Fig. 5) with a suture (e.g., Chromic, Vicryl O) as shown.
6. Thread the suture loaded Riza-Ribe® Needle or GraNee® Needle down the groove on one side of the R-Med® Disposable Plug (Fig. 6) through fascia on the opposite side of the plug, into the peritoneal cavity.
7. Release the suture, and withdraw the empty Riza-Ribe® Needle or GraNee® Needle back through the R-Med® Disposable Plug.
8. Thread the empty Riza-Ribe® Needle or GraNee® Needle down the remaining groove, through the fascia on the opposite side of the R-Med® Disposable Plug, into the peritoneal cavity.
9. Load the free suture end into the Riza-Ribe® Needle with the help of a grasper or a needle holder (Fig. 7a) or grab free suture with GraNee® Needle (Fig. 7b).
10. Withdraw loaded Riza-Ribe® Needle or GraNee® Needle back through the R-Med® Disposable Plug (Fig. 8), and release the suture.

### **SUTURE TYING**

11. After all sutures are in place; remove the R-Med® Disposable Plug while tightening on the sutures (Fig. 9).
12. Lower the abdominal pressure to reduce distention, allowing better approximation of the fascia under lower stresses.
13. Tie sutures under direct visualization (Fig. 10).
14. Subcutaneous and skin approximation can be performed to surgeon's choice.
15. For Single Patient Use only. Properly dispose of device in accordance with local regulations.

### **CLOSURE OF MULTIPLE TROCAR DEFECTS**

16. Place another R-Med® Disposable Plug into second defect (steps 1-4) to retain pneumoperitoneum.
17. Place sutures in additional R-Med® Disposable Plug as outlined above (steps 3-10).
18. Complete steps 11-15.

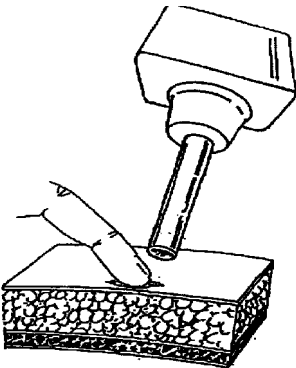


Fig. 1

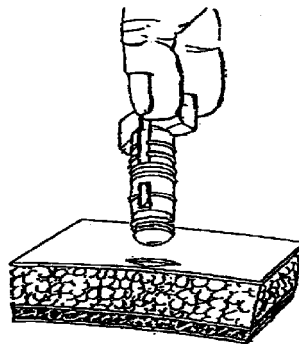


Fig. 2

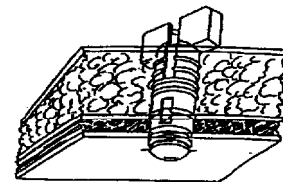


Fig. 3

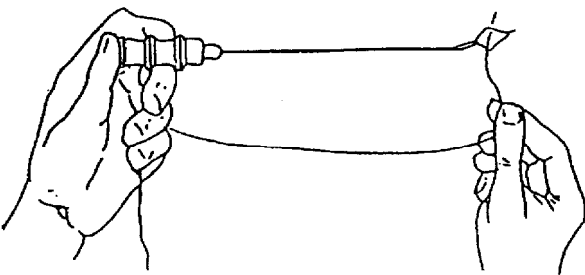


Fig. 4

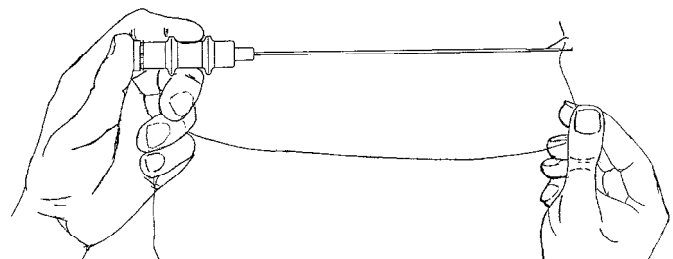
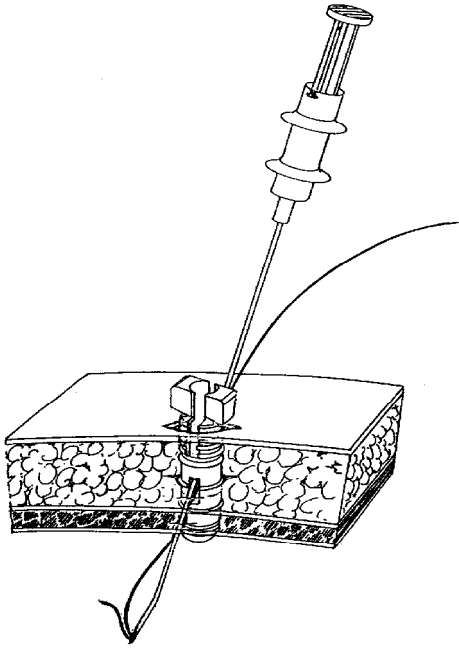
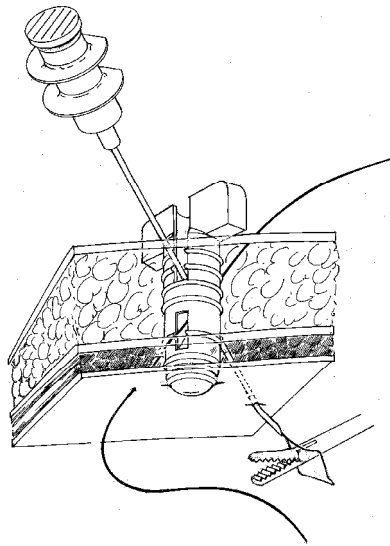


Fig. 5

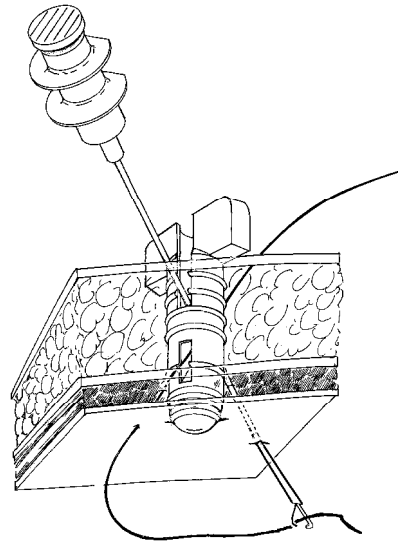


**Fig. 6**



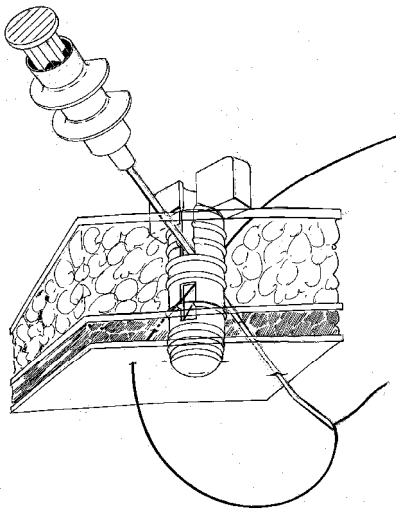
**Fig. 7a**

with Riza-Ribe® Needle

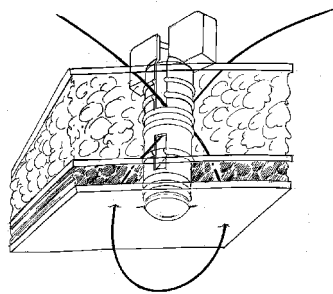


**Fig. 7b**

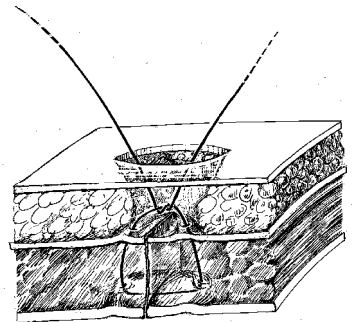
with GraNee® Needle



**Fig. 8**



**Fig. 9**



**Fig. 10**

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