

Riza-Ribe® Needle
U.S. Patent No.s: 5,501,692 and 5,817,111
PRODUCT INFORMATION DATA SHEET

Following information should be read before using this device

The Riza-Ribe® Needle is a single use product supplied sterile. This device is used during laparoscopy or under direct visualization to transfer a ligature. It has an ambidextrous locking mechanism that can be activated by twisting the thumb to stabilize the loop, and a spring to help loop retraction. Curved end gives easy access to tissue. **Contraindications:** This device is not intended for use when endoscopic techniques are contraindicated or needle penetration is not visualized. Refer to endoscopy labeling.

This device is used during laparoscopy:

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| <p>A) Securing abdominal wall bleeders due to trocar Injury.
 C) Pre-peritoneal bladder-neck suspension for urinary stress incontinence.</p> | <p>B) Closure of fascial trocar defects.
 D) Transfer of suture under laparoscopic or direct visualization.</p> |
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A) Securing abdominal wall bleeders due to trocar injury.

- 1 - Prepare abdominal wall or surgical field.
- 2 - Open package and remove Riza-Ribe® Needle 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 preformed wire loop. **If parts do not move easily, discard the unit.**
- 5 - Load ligature to Riza-Ribe® Needle by pushing plunger, threading end of ligature to wire loop and releasing plunger.
- 6 - Under laparoscopic visualization, pass loaded needle through one side of

- the injured blood vessel (Fig. 1). Free ligature from the needle and withdraw the empty needle.
- 7 - Pass the empty needle through the other side of the injured blood vessel. Thread end of ligature to wire loop of needle with the help of a grasper (Fig. 2) and withdraw loaded needle.
- 8 - Tie ends of ligature over a folded 4x4 gauze (Fig. 3). The gauze protects the skin and augments the tourniquet effect.
- 9 - Repeat steps 6, 7 and 8 at a small distance in opposite side of the blood vessel injury to arrest bleeding (Fig. 4, 5 and 6).
- 10 - Upon completion of endoscopic procedure, dispose of Riza-Ribe® Needle in accordance with local regulations.

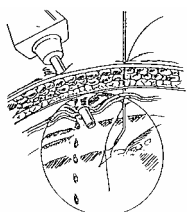


Fig. 1

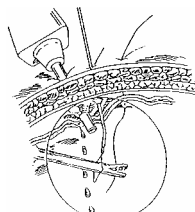


Fig. 2

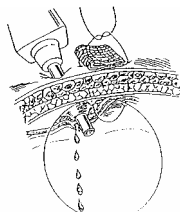


Fig. 3

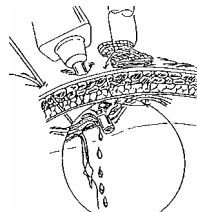


Fig. 4

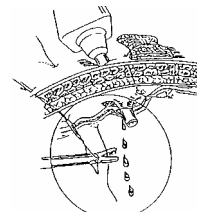


Fig. 5

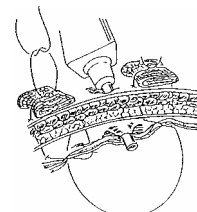


Fig. 6

References:

1. Penfield AJ: Trocar and needle injuries, in laparoscopy. Edited by JM Phillips. Baltimore, Williams & Wilkins, 1977, pp. 236-241.
2. Hulka JF: Textbook of laparoscopy, Orlando, FL Grune & Stratton, 1985, pp. 61-63.
3. Yuzpee AA: Pneumoperitoneum needle and trocar injuries in Laparoscopy. The Journal of Reproductive medicine. Volume 35, Number 5, May 1990.
4. Parker WH: LAVH: Approach with Caution. Contemporary Ob/Gyn, Volume 38, Number 9, September 1993.
5. Riza, E.D., Deshmukh, A., An Improved Method of Securing Abdominal Wall Bleeders During Laparoscopy. Journal of Laparoendoscopic Surgery. Volume 5, Number 1 1995.

B) Closure of fascial trocar defects:

- 1 - After laparoscopic procedure is completed, remove the trocar and the gripper if used. Insert either a 10 or 12 mm R-Med® Plug into defect. This will prevent loss of gas and will assist positioning Ribe-Ribe® Needle passes subcutaneously

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

- 2 - Thread a 0 vicryl ligature to a Ribe-Ribe® Needle. Pass the loaded needle through the fascial edge into the peritoneal cavity. Free the end of ligature from Ribe-Ribe® Needle and withdraw the empty needle (Fig. 1).

- 3 - Pass the empty needle through the fascial edge on the opposite side. Thread end of ligature to Ribe-Ribe® Needle with the help of a grasper in **endo-loop** fashion (Fig. 2) and withdraw loaded needle (Fig. 3).

- 4 - After sutures are in place (Fig. 4), remove the 10 or 12 mm R-Med® Plug while tightening on the sutures.

- 5 - Tie suture subcutaneously (Fig. 5). Proceed with skin closure of your choice.

- 6 - Repeat with same technique to secure other trocar sites.

- 7 - Dispose of Riza-Ribe® Needle in accordance with local regulations.

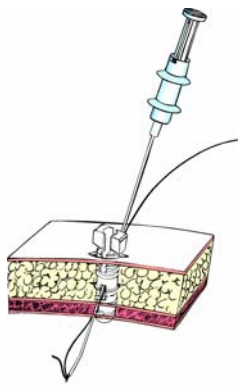


Fig. 1

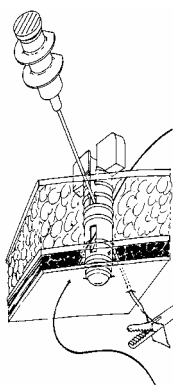


Fig. 2

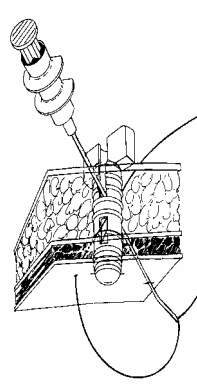


Fig. 3

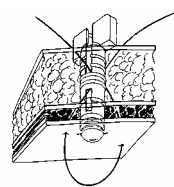


Fig. 4

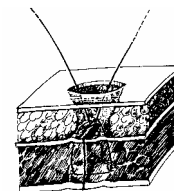


Fig. 5

References:

1. Schiff I, Naftolin F., Small bowel incarceration after uncomplicated laparoscopy. Obstet. Gynecol. 1974; 43: 674-675.
2. Bourke J.B. Small intestinal Obstruction from a Richter's hernia at site of insertion of a laparoscope. Br. Med. J. 1972; 2: 1393-1394.
3. Bishop H.L. and Halpin T.F., Dehiscence following Laparoscopy: Report of an unusual complication. Am. J. Obstet. Gynec. Volume 114, Number 4, June 15, 1973.
4. Barton M., Laparoscopic Complications, Prevention and Management. Edited by F.A. Friedman. Toronto, Philadelphia: B.C. Decker Inc., 1986: 352-358.
5. Kiillhoma P., Makinen J., Incarcerated Richter's hernia after laparoscopy. Eur. J. Obstetrics Gynec. Prod. Biolog. 1988; 28: 75-77.
6. Riza, E.D., Deshmukh, A., A technique for prevention of Richter's hernia through a laparoscopic incision. For a copy contact E.D. Riza at R-Med, Inc.

C) Pre-peritoneal bladder-neck suspension for urinary stress incontinence.

This operative procedure is described in the Journal of Laparoendoscopic Surgery, Vol. 4, #5, 1994. "A Laparoscopic-Assisted Extraperitoneal Bladder Neck Suspension; An Initial Experience". E.D. Riza, M.D. and A.S. Deshmukh, M.D. For further details you may contact: E.D. Riza, M.D. at R-Med, Inc., 3465 Navarre Avenue, P. O. Box 167636, Oregon, OH 43616-7636.

A weighted speculum is inserted into the vagina, and the labia are sutured laterally. A zero Prolene suture is passed through the vaginal mucosa in a helical manner starting well above the bladder neck and going toward the midurethra (Fig. 2). At this stage, a small suprapubic incision is made just above the pubic crest, and dissection is performed down to the fascia. A Riza-Ribe® Needle is used in the Vagina to grasp the sutures. The first pass of the needle is made at 0.5 cm lateral to the bladder neck. The second pass is made 1 cm lateral and caudal to the first pass (Fig. 3). The loop of the Riza-Ribe® Needle in the vagina grasps the suture ends that were used previously to plicate the vaginal mucosa and pull it into the suprapubic wound (Fig. 4).

The adequacy and accuracy of placement of the sutures are provided by visualization of the passage of the needle on the screen and endoscopic evaluation. When the placement of the sutures is deemed to be satisfactory, they are tied suprapubically. Simultaneously, the bladder neck is evaluated by cystoscopy for satisfactory occlusion.

The vagina and the retropubic space are thoroughly irrigated with an antibiotic solution throughout the procedure. The fascia in the large trocar wound is closed with one suture of 0 PDS. The rest of the wounds are closed with subcutaneous and subcuticular sutures. The use of a drain through the 5-mm incision is an option in case excess bleeding in the retropubic space.

The patient is discharged the same evening or the next morning with an indwelling catheter. She is kept on an oral cephalosporin and is examined on the fourth postoperative day after removal of the catheter.

A follow-up examination consists of wound inspection and a determination of residual urine. A urine culture is obtained if deemed necessary. A pelvic examination is performed to check for any bleeding and to check for an enterocele.

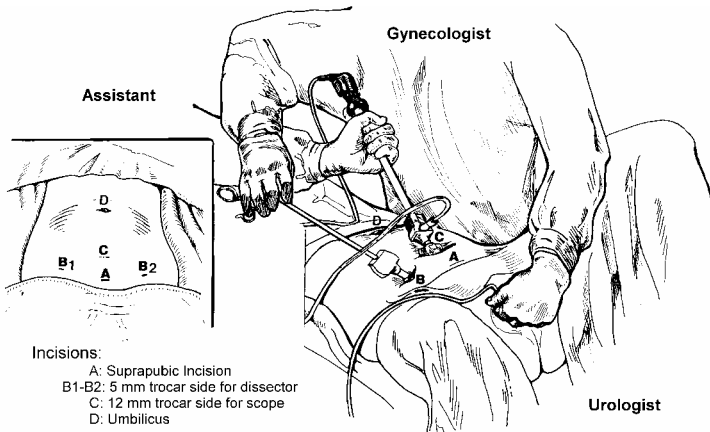


Fig. 1 A schematic illustration of abdominal trocar placement sites; suprapubic incision; and positions of gynecologist, urologist and assistant.

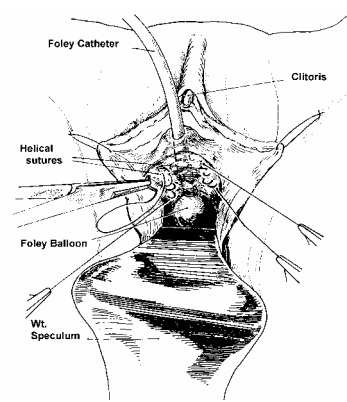


Fig. 2 Placement of helical sutures with 0 prolene.

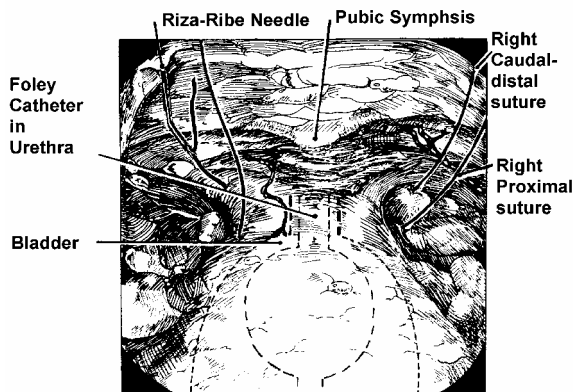


Fig. 3 View after two proximal and one caudal sutures were retrieved. Left caudal suture retrieved with Riza-Ribe® Needle.

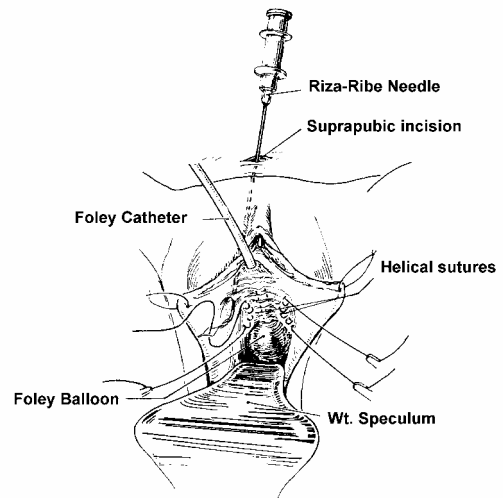


Fig. 4 Sutures retrieved with Riza-Ribe® Needle.

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