

REF: WA90500US

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

Not made with natural latex rubber.



Rx Only



Indication for Use

The PneumoLiner device is intended for use as a multiple instrument port and tissue containment system during minimally invasive gynecologic laparoscopic surgery to enable the isolation and containment of tissue, considered benign, resected during single-port or multi-site laparoscopic surgery during power morcellation and removal. When used in women with fibroids, the PneumoLiner is for women who are pre-menopausal and under age 50. The PneumoLiner is compatible with bipolar or electromechanical laparoscopic power morcellators that are between 15mm and 18mm in shaft outer diameter and 135mm and 180mm in shaft working length and which have an external component that allows for the proper orientation of the laparoscope to perform a contained morcellation.

Contraindications

1. Do not use on tissue that is known or suspected to contain malignancy.
2. Do not use for removal of uterine tissue containing suspected fibroids in patients who are: post-menopausal or over 50 years of age; or candidates for en bloc tissue removal, through the vagina or via a mini-laparotomy incision.
3. Do not use in women with undiagnosed uterine bleeding.
4. Do not use this device on patients with known or suspected allergies to polyurethane.
5. Do not use where the abdominal wall thickness is larger than 10cm.

Warnings

Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk.

1. The risk of occult cancer, including uterine sarcoma, increases with age, particularly in women >50 years of age. This information should be shared with patients when considering surgery with the use of these devices.
2. Do not cut, puncture or scrape the PneumoLiner with the morcellator tip or tenaculum/grasper.
3. Do not use if package or printed information is damaged. The device is supplied sterile; inspect the package to ensure it is intact.
4. This device is single-use only. Do not re-sterilise or reuse any portion of this device.
5. Re-use or re-sterilisation may create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
6. Check for and remove adhesions that may inhibit proper placement of the device.
7. The PneumoLiner must be fully inflated (12 – 15 mmHg) to minimize the risk of damage to the bag and adjacent organs during morcellation.
8. At all times prior to morcellating, make sure the tenaculum/grasper is within view when grasping tissue, to prevent it contacting the PneumoLiner.
9. The tip of the morcellator must be brought into view, prior to and during each activation to provide confirmation of the position of the morcellator tip and its proximity to the PneumoLiner.
10. With the tip of the morcellator in view, prior to activating the morcellator, confirm that the tissue specimen is centered within the PneumoLiner.
11. Do not bring the morcellator tip into contact with the PneumoLiner.
12. To prevent risk of contamination, do not re-attach the Boot following removal of the PneumoLiner.
13. Any abdominal incision introduces a risk of abdominal hernia.

Precautions

1. Please read all instructions prior to use.
2. Device should only be used with 5mm laparoscopes with ≥30° lens angle or deflectable tip.
3. Only use an atraumatic grasper to manipulate the PneumoLiner.
4. Appropriate pre-operative diagnostic testing should be completed prior to using this device.
5. This device should only be used by surgeons with advanced training in laparoscopic techniques.
6. This device should only be used by surgeons who have successfully completed the validated training programme.
7. Regarding the grasper/tenaculum used, teeth which are curved proximally to shield their sharp tips may help reduce the risk of damage to the bag from the grasper/tenaculum. However, a lower risk grasper does not alter the risk of damage to the bag from the morcellator tip. Careful adherence to the training provided and the Instructions for Use regarding placement and visualization of the tip remains critical.
8. To prevent risk of contamination, do not re-use the Laparoscope following removal of the PneumoLiner.
9. After use, the device is a potential biohazard. Handle and dispose of as required by hospital policy and applicable laws.

Retractor Introducer

1. Introducer Plunger
2. Introducer Shaft

Retractor

3. Removal Ribbon
4. Retracting Sleeve
5. Inner Proximal Ring
6. Outer Proximal Ring
7. Gradations (for indication only)
8. Distal Ring

Boot Assembly

9. Large Instrument Valve (Yellow)
10. Boot
11. Insufflation/Venting Port
12. 5mm Instrument Valve (Blue)
13. 5mm Reducer
14. Reducer Tab
15. Removal Tab

PneumoLiner Introducer

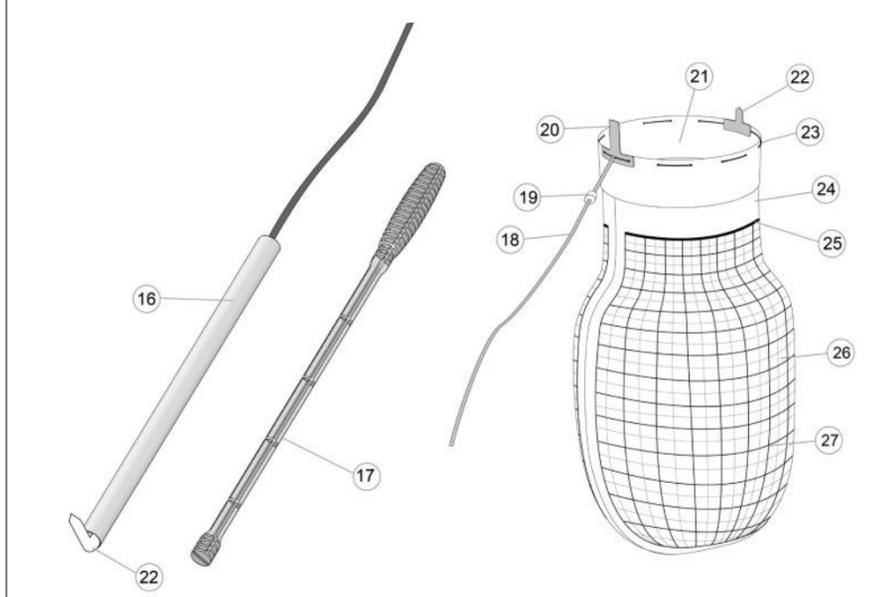
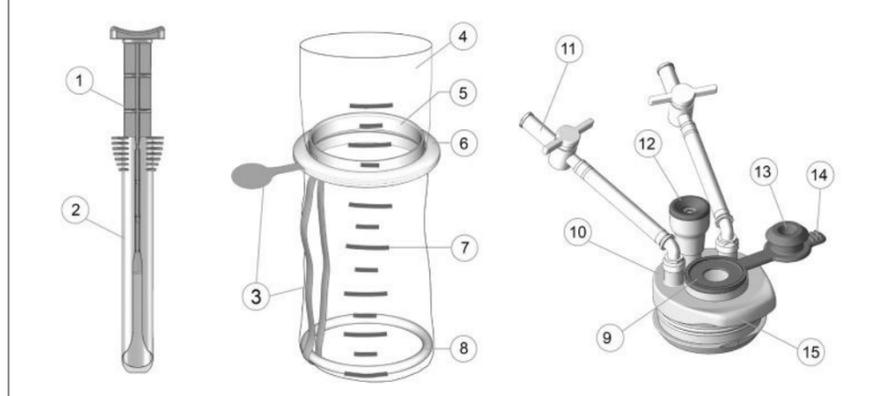
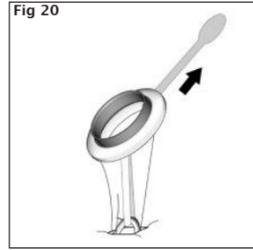
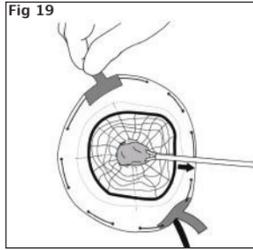
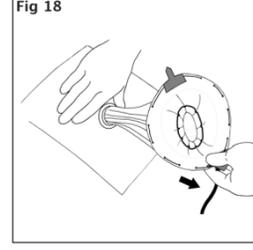
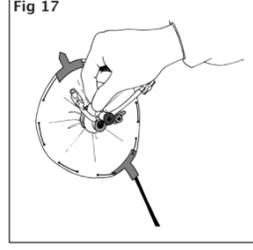
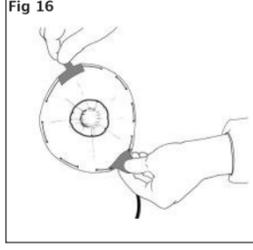
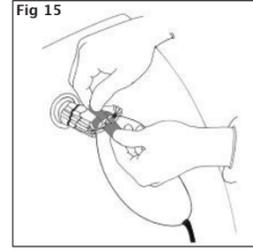
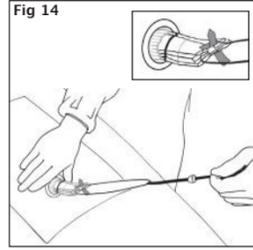
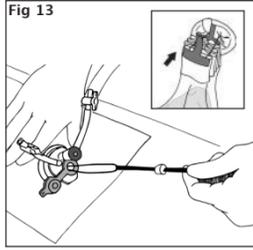
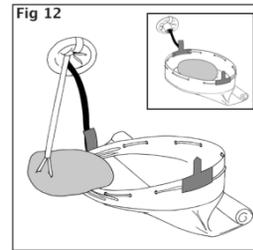
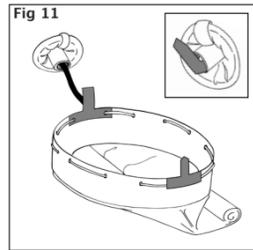
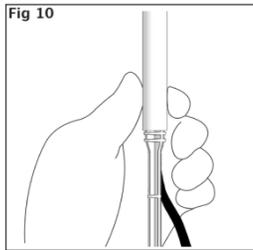
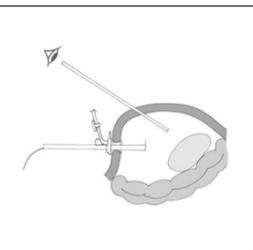
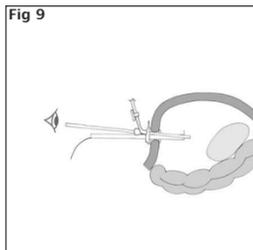
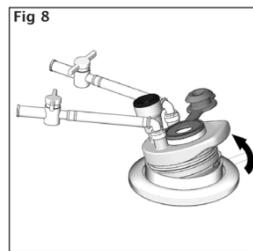
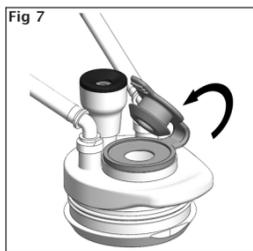
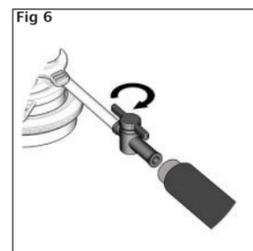
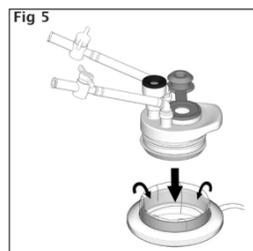
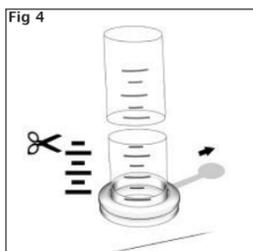
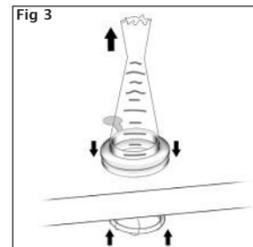
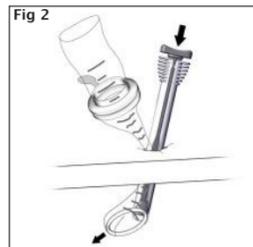
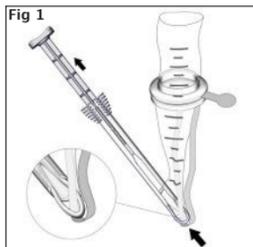
16. Introducer Shaft
17. Introducer Plunger

PneumoLiner

18. Tether
19. Seal
20. Proximal Tab
21. Collar
22. Distal Tab
23. Opening Ring
24. Neck
25. Printed Line
26. Main Body
27. Printed Grid (20x20mm)

USE

1. Create incision (between 20 – 25 mm).
2. Insert the Distal Ring into the Retractor Introducer with the Removal Ribbon at its distal end. (Fig 1)
3. Pass the Retractor Introducer through the incision. Fully eject the Distal Ring into the abdominal cavity. Remove Retractor Introducer. (Fig 2)
4. While pulling upwards on the Retracting Sleeve, push down on the Outer Proximal Ring to slide it towards the abdomen. Continue until the incision is retracted. (Fig 3)
5. Pull gently on Removal Ribbon to remove excess inside the incision. Trim the Retracting Sleeve six gradations above the Inner Proximal Ring. (Fig 4)
6. Fold the Retracting Sleeve inside the Inner Proximal Ring and press the Boot into position. (Fig 5)
7. Insufflate through either of the Insufflation/Venting Ports. (Fig 6)
8. Fumes can be vented through the unused Insufflation/Venting Port.
9. A 5 mm instrument can be inserted through the Yellow Valve using the Reducer. (Fig 7)
10. The Boot can be removed using the Removal Tab, and re-attached. (Fig 8)
11. Insert a 5 mm laparoscope with a ≥ 30° lens angle or deflectable tip either through the Blue Valve or through a separate cannula. (Fig 9)
12. Insert PneumoLiner Introducer Shaft, white Distal Tab first, through the Yellow Valve. (Fig 9)
13. Insert PneumoLiner Introducer Plunger into shaft. Push Plunger to deploy PneumoLiner. Remove PneumoLiner Introducer. (Fig 10 & Fig 11)
- NOTE: The Distal Tab should point upwards to indicate correct orientation of the PneumoLiner. (Fig 11)**
- NOTE: Ensure free end of Tether remains external throughout procedure.**
14. Manipulate tissue into the PneumoLiner, ensuring it is contained within the Collar. (Fig 12)
- NOTE: Only use an atraumatic graspers to manipulate PneumoLiner.**
15. Using the Tether, pull the Opening Ring partially through Yellow Valve until PneumoLiner is closed. (Fig 13)
16. Remove all trocars and detach Boot, deflating abdomen. Remove Boot from Tether and keep within the sterile field.
17. Pull Tether until Printed Line is visible. (Fig 14)
18. Pull the Tabs apart to open PneumoLiner. (Fig 15 & Fig 16)
19. Re-attach Boot in desired orientation. (Fig 17)
- NOTE: Do not twist Boot while it is attached.**
20. Insufflate PneumoLiner using Insufflation Port, prior to insertion of instruments (12 – 15 mmHg).
21. Adequate insufflation is critical to the safety of contained morcellation, using the PneumoLiner, to ensure that the bag itself is at a safe distance from instrument tips. Ensure PneumoLiner is inflated, then insert laparoscope through the Blue Valve. In the case where the PneumoLiner is not adequately inflated or exhibits a leak the PneumoLiner (bag) can be replaced.
22. Insert morcellator, with obturator in place through the Yellow Valve. Morcellate and remove tissue, taking care not to damage the PneumoLiner with instruments.
- NOTE: Stop morcellation once gross tissue mass has been reduced to pieces, each smaller than four Printed Grid squares.**
23. Remove the instruments.
24. Detach Boot allowing the PneumoLiner to deflate. (Fig 8)
25. Gently remove PneumoLiner. (Fig 18)
- NOTE: Ensure PneumoLiner Neck remains open to allow gas to escape.**
26. If PneumoLiner is not easily removed, tissue pieces can be extracted using an atraumatic graspers at the incision. (Fig 19)
27. Remove the Retractor by pulling on the Removal Ribbon. (Fig 20)



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