

# INSTRUCTIONS FOR USE



## LAPBOX POWER TISSUE CONTAINMENT SYSTEM Rx Only

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

### Indications for Use

The LapBox Power Tissue Containment System 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. The LapBox is compatible with electromechanical laparoscopic power morcellators that are between 15 mm and 18 mm in shaft outer diameter and 135 mm and 180 mm in shaft working length and which have an external component that allows for the proper orientation of the laparoscope to perform a contained morcellation. When used in women with fibroids, the LapBox Power Tissue Containment System is for women who are pre-menopausal and under age 50.

### 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 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 in umbilicus is larger than 4cm for the small port and 3cm for the medium port.
6. Do not use if specimen to be morcellated has a diameter larger than 9cm for the medium port and 7cm for the small port.
7. Do not use if abdominal cavity is too small to contain the chamber in its inflated state (chamber height is 10 cm), i.e., if inflated device applies excessive pressure on adjacent organs or is unable to be fully inflated.

### 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 over 50 years of age. This information should be shared with patients when considering surgery with the use of these devices.
2. Before choosing to use the LapBox, visually assess abdominal cavity size to determine device size compatibility.
3. During inflation, if the chamber: (1) does not maintain a round shape or (2) applies pressure on adjacent organs or seems to be sunken into the intestine these are indications that there is insufficient space in the abdominal cavity. If these are observed, use a different device or convert to an open procedure
4. If following inflation the chamber appears to be compressing the intestine or the inflated walls are not vertical the device is too large for that abdomen and the device should be removed in order to prevent injury.
5. Check for and remove adhesions that may inhibit proper placement of the device.

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6. Please read all instructions prior to use.
7. Ensure the Claw/Atraumatic Grasper is within view when grasping tissue, to prevent it from contacting the LapBox chamber. Do not insert tools without direct visualization. Do not cut, puncture, or scrape the LapBox with the Claw/Atraumatic Grasper, morcellator, grasper or scalpel.
8. Do not use if package or printed information is damaged. The device is supplied sterile; inspect the package to ensure it is intact. If damage to the sterile barrier or the device is noted, DO NOT USE the device. Retain the package with the contents and notify your Ark Surgical Ltd. representative.
9. Do not use the device if the "Use by" date indicated on the package label has passed.
10. This device is single use only. Do not re-sterilize or reuse any portion of this device. Re-use or re-sterilization 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.
11. Any abdominal incision introduces a risk of abdominal hernia.
12. LapBox should only be introduced through the umbilicus and operated in an insufflated abdomen.
13. The LapBox should only be used by physicians who have been trained to use it and are thoroughly trained in laparoscopic, laparoscopic assisted and open surgery and familiar with the medical literature regarding techniques, complications, and hazards associated with the use of tissue containment bags and power morcellation.
14. The use of the LapBox should be based on the risk benefit factors as they apply to each individual patient.
15. The LapBox chamber must be fully inflated to 150mmHg as marked on the pressure gauge to minimize the risk of damage to the chamber and adjacent organs during morcellation.
16. With the tip of the morcellator in view, prior to activating the morcellator, confirm that the tissue specimen is centered within the LapBox chamber.
17. All tissue must be removed from the chamber before it is extracted. If resistance is met during bag removal, the tissue has not been completely removed. Insufficient morcellation of the specimen can lead to difficulty in chamber removal.

### During Power Morcellation:

18. Always ensure direct morcellator tip visualization during activation to provide confirmation of the position of the morcellator tip and its proximity to the LapBox chamber.
19. Do not bring the morcellator tip into contact with the LapBox chamber.
20. Always ensure direct visualization of grasper tip during the procedure and avoid direct contact of the grasper tip or morcellator blade with the LapBox chamber.
21. Ensure you only use atraumatic (claw) graspers.
22. Always ensure a clear pathway through the port to avoid cutting the chamber sleeve.
23. Mark the incision length before cutting depending on the port size; 23mm for the small port and 30mm for the medium port.

### Precautions

1. Appropriate preoperative and intraoperative diagnostic testing and evaluations should be completed prior to using this device. Perform ultrasound measurements to assess abdominal wall thickness and organ size as well as visually assess abdominal cavity size to evaluate inflated abdominal cavity size for compatibility with the inflated chamber.
2. Only use atraumatic grasper to place the specimen into the LapBox chamber. Do not grab the bag using graspers.
3. This device should only be used by surgeons with advanced training in laparoscopic techniques.
4. This device should only be used by surgeons who have successfully completed the validated training program.
5. Regarding the Claw/Atraumatic Grasper used to place the specimen inside the LapBox chamber or to operate with the power morcellator, teeth which are curved proximally to shield their sharp tips may help reduce the risk of damage to the bag. However, a lower risk grasper does not negate 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.
6. After use, the device is a potential biohazard. Handle and dispose of as required per hospital policy and applicable local laws and regulations.

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7. To prevent contamination, do not re-insert the laparoscope into the abdomen after it has been in the chamber during morcellation.
  8. Observe the pressure gauge while inflating until 150 mmHg mark is reached. Overinflation beyond 150 mmHg will result in the pressure relief valve releasing excess pressure.
  9. Only inflate the chamber opening when it is facing upward.
  10. Monitor and maintain pneumoperitoneum throughout the insertion, deployment and use of the LapBox; maintain the pressure at 15 mmHg.
  11. The safety and effectiveness of this device has not been evaluated with bipolar morcellators.
  12. Device should only be used with a 5mm laparoscope with a 30-degree lens.
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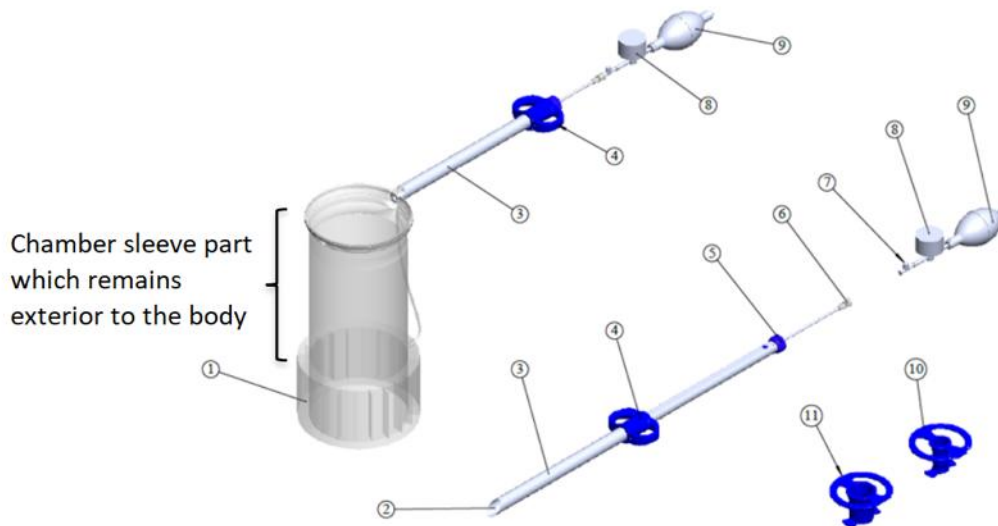
### Complications

Potential complications associated with the use of the LapBox are the same as these associated with the use of tissue and specimen bags, morcellation and laparoscopic surgery in general and include, but are not limited to: superficial lesions, injury to internal vessels, bleeding, hematoma, injury to the abdominal wall, injury to bowel, infection, peritonitis, and spread of benign or malignant tissue. Experience and recognition of the procedural and product limitations significantly reduce the incidence of complications.

Inflation of the device in a patient with insufficient abdominal space may result in circulatory abnormalities, delayed complications, and coagulative abnormalities which may further increase the risk of other complications such as deep vein thrombosis/pulmonary embolisms.

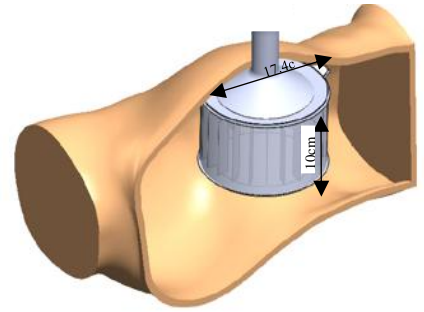
### Device Components

- |   |                              |
|---|------------------------------|
| 1. LapBox Inflatable Chamber                | 6. Hand Pump Connector       |
| 2. LapBox Inflatable Chamber (within shaft) | 7. Pressure Relief Valve     |
| 3. Insertion shaft                          | 8. Pressure Gauge            |
| 4. Handle (Distal)                          | 9. Hand Pump                 |
| 5. Handle (Proximal)                        | 10. Instrument Port (Small)  |
|   | 11. Instrument Port (Medium) |

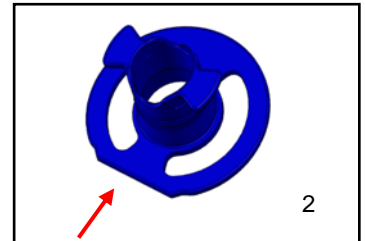


## LapBox Deployment – Instructions for Use

1. Before choosing to use the LapBox Power Tissue Containment System, visually assess abdominal cavity size to determine device size compatibility. Abdominal cavity space should allow for adequate inflation of a cylindrical shape measuring 17.4 cm width and 10 cm height.



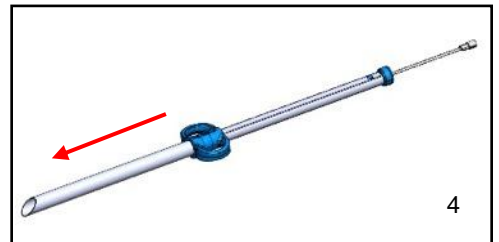
2. Use the side of the desired port to mark the final incision length.
  - Small port can be used for organs up to 250 grams / 7cm maximal diameter and abdominal wall thickness of 4cm.
  - Medium port can be used for organs up to 500 grams / 10 cm maximal diameter and abdominal wall thickness of 3cm.



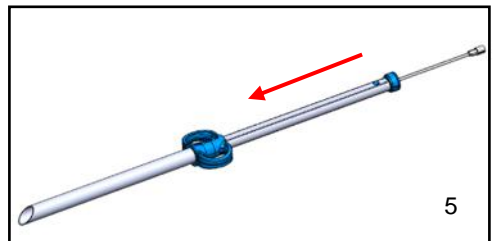
3. For initial device insertion, create an incision in the umbilicus. Using the straight edge of the small port, mark the incision length required for initial device insertion. If the medium size port will be used, use the straight edge of the medium port to mark the additional incision length required for its insertion (step #13 details the port insertion step).
4. Prior to and post device insertion, ensure that the marking "this side up" on the distal handle is facing upwards (Figure #3).



5. Insert the LapBox System under direct visualization through the created incision using rotating movements (Figure #4). Monitor and maintain pneumoperitoneum throughout the insertion, deployment, and use of the LapBox; keep the pressure at 15 mmHg.



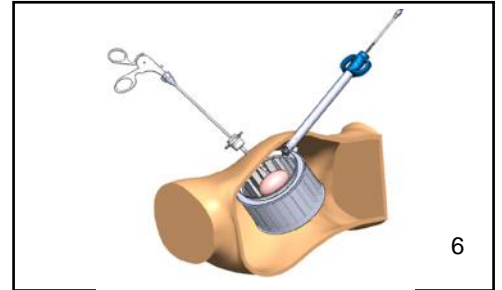
6. To deploy the LapBox Chamber, firmly hold the insertion shaft and push the handle forward to the maximum (Figure #5).



7. Place the organ within the Chamber.

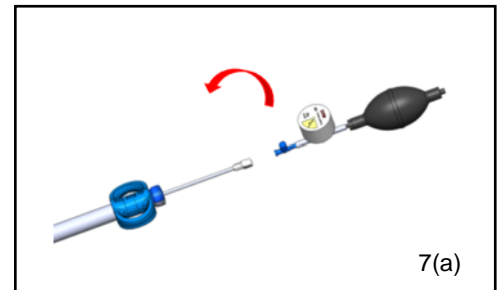
**Note: Always use an atraumatic grasper (Figure #6).**

**Note: After organ insertion hold the chamber's opening adjacent to the abdomen wall by lowering the insertion shaft to ensure encapsulation.**

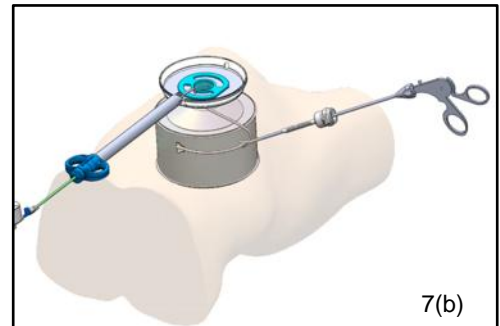


8. Attach the Hand Pump unit to the Chamber using the designated connector (Figure #7(a)).

**Note: when connecting the hand pump assembly hold the pressure relief valve for optimal connection.**

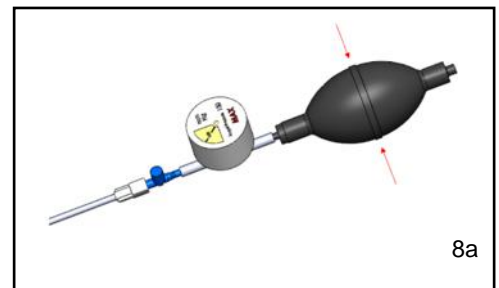


9. To ensure adequate inflation of the chamber prior to morcellation: using the atraumatic grasper, grasp the air tube adjacent to the air tube bend location (Figure 7(b)) and hold it to ensure proper airflow; ensure the air tube remains open throughout the inflation process. If during inflation the inflation rate reduces, manipulate the grasper to adjust tube and improve air flow.



**Note: Do not grab or touch the chamber wall with the grasper, grasp only the air tube.**

10. Under visualization, inflate the chamber by squeezing the LapBox hand pump until a pressure of 150 mmHg is noted on the pressure gauge and the chamber is fully inflated (Figures #8a and #8b).

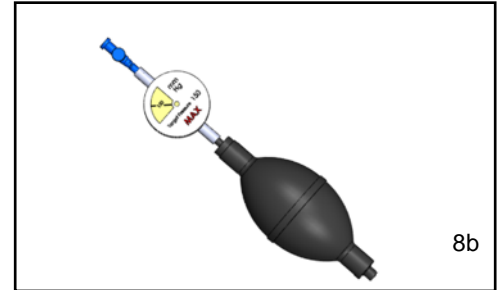


**Warning:**

**During inflation, if the chamber: (1) does not maintain a round shape or (2) applies pressure on adjacent organs or seems to be sunken into the intestine these are indications that there is insufficient space in the abdominal cavity. If these are observed, use a different device or convert to an open procedure.**

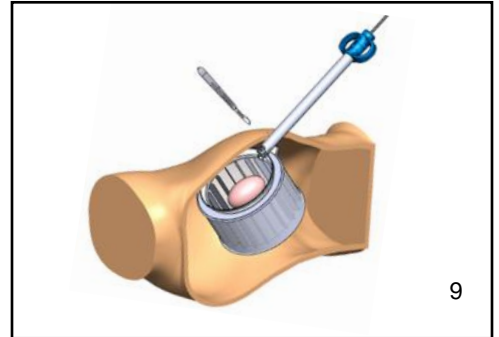
**Note:**

- **Visually confirming adequate inflation of the double wall chamber is imperative during the inflation process.**
- **Do not inflate more than 150mmHg.**
- **Do not block the pressure relief valve.**
- **Make sure the chamber opening is facing upward during inflation.**



8b

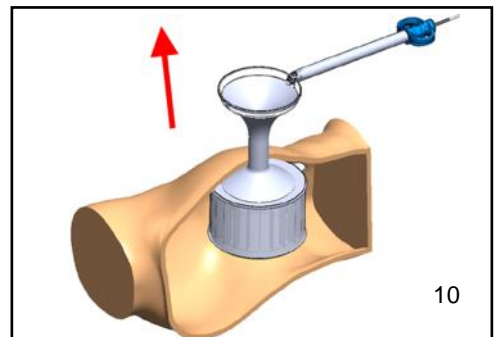
11. If the medium port was selected, increase the incision length to 30mm making sure not to damage the chamber.  
(Figure #9).



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12. Extract the chamber's sleeve from the abdomen. After chamber sleeve is revealed grip the chamber sleeve and complete extraction until the double-walled chamber is adjacent to the abdominal wall.

**Note: If the chamber is twisted, further extract the chamber sleeve and adjust it by rotating it until it is in the correct orientation (Figure #10).**



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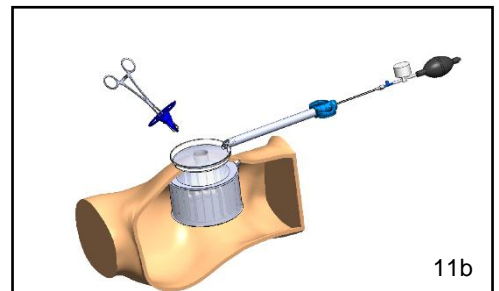
13. Utilizing Allis forceps, grasp the instrument port and insert through the LapBox opening (Figures 11a and 11b).

**Note:**

- **If following port insertion the port opening is not round (Figures 11c), make sure fascia was cut to allow full deployment of port**
- **If following port insertion chamber sleeve inside the abdomen is blocking visualization of the organ, further extract the chamber's excess sleeve.**
- **If following extraction of the chamber's sleeve the chamber is not fully round or was pulled more to one side – the sleeve was over extracted and needs reinserting.**

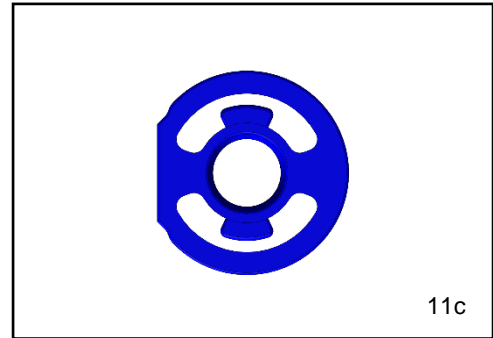


11a



11b

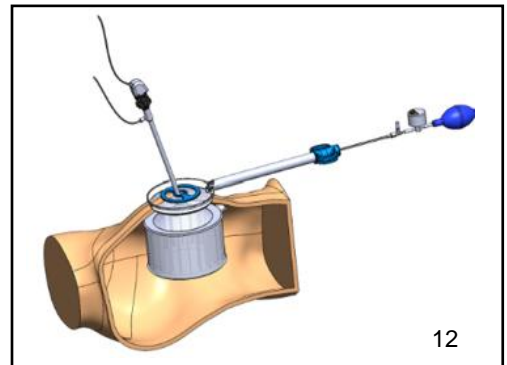




14. Prior to initiating the morcellation procedure, visually confirm again there is adequate space for the device. If the device (1) does not maintain a round shape or (2) applies pressure on adjacent organs or seems to be sunken into the intestine these are indications that there is insufficient space in the abdominal cavity. If these are observed, use a different device or convert to an open procedure

15. Insert a 5mm 30° laparoscope to the inflated chamber prior to inserting the morcellator and maintain visualization of the morcellator at all times (Figure 12).

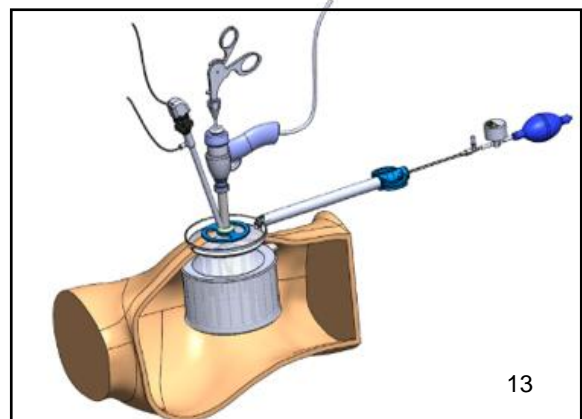
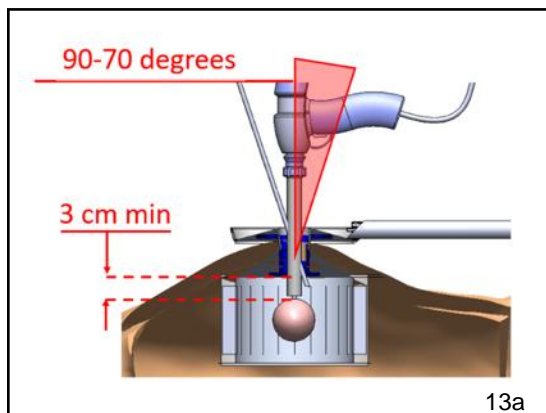
16. Insert a power morcellator with an obturator through the port, remove the obturator and perform morcellation.



**Note:**

***Make sure to hold the morcellator perpendicular to the abdominal wall with a maximal angle of entry of 90-70 degrees – in order to prevent contact with chamber (Figure 13 and 13(a))***

***Do not reinsert the laparoscope or any instrument (morcellator, Claw/Atraumatic Grasper, etc.) into the abdomen after morcellation has taken place in the chamber to mitigate the risk of contamination and transit of cellular debris.***

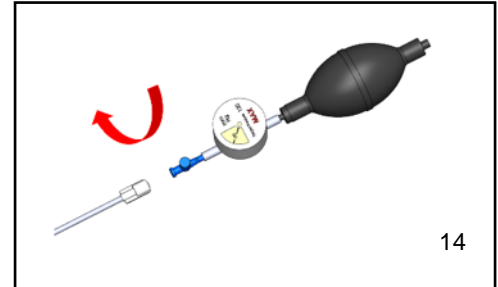


17. Once the morcellation process is complete and **all** **tissue** was extracted from the chamber, the chamber can be deflated and extracted.

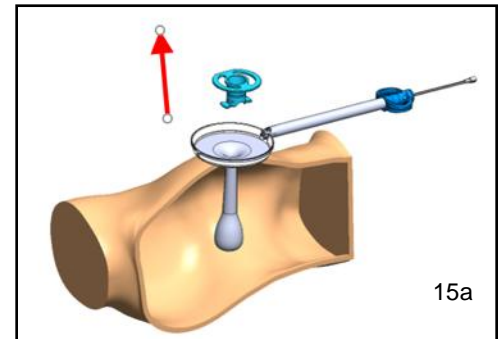
**Note:**

***Do not remove the port or extract the chamber before it has been fully emptied and deflated – this should be laparoscopically verified prior to extraction.***

To deflate the Chamber, disconnect the hand pump and wait until the chamber is fully deflated before removing port (Figure #14). Visually inspect the deflation process laparoscopically to ensure the device has fully deflated prior to extraction.



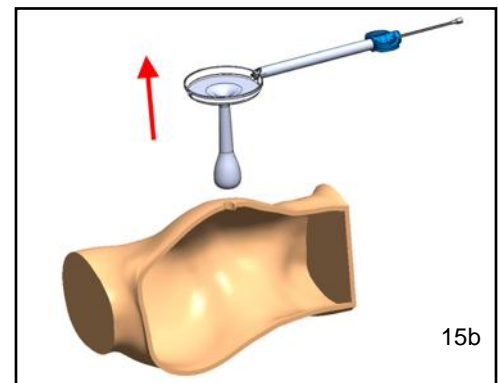
18. Once the chamber is completely deflated the LapBox System can be extracted:
- Take out the port from within the LapBox (Figure #15a)



- Grasp the chamber's sleeve and gently retract from the abdomen (Figure #15b).

At this stage the bag should be completely empty. If excessive resistance is encountered, extend the incision and remove the bag.

***Note: following removal of the chamber, survey the abdominal cavity for signs of adjacent tissue compression and, if noted, consider additional patient monitoring for clinical sequelae***



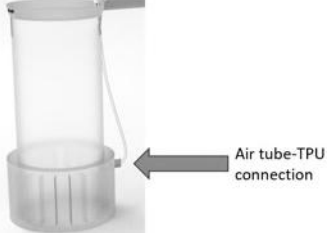
19. Discard of the LapBox per administrative and/or local, state, and federal laws and regulations.

List of Acceptable Tools

- FDA Cleared electromechanical Morcellators
- Atraumatic 5mm Graspers
- Clamp and Allis Grasper
- 10mm Claw/Atraumatic Grasper (to be used with morcellator)
- 5mm, 30° Laparoscope




















## Troubleshooting

#	Problem	Reason	Action
1.	Pneumoperitoneum cannot be maintained following port insertion.	The incision is too wide.	Use a clamp grasper to decrease the incision length.
2.	Following the deployment, the chamber opening is upside down.	The handle was inserted with the “this side up” marking facing down.	(a) Rotate the outer tube until the chamber is in the correct position. (b) Visually inspect that the chamber is not entangled.
3.	Organ is too big	Organ size exceeds 10cm	The LapBox cannot be used with organs greater than 10cm. Either convert to manual morcellation or laparotomy.
4.	Hand pump assembly disconnected	Connecting tube detached	Reconnect unit and continue inflation
5.	During inflation, the chamber does not inflate.	Tube might be kinked.	Gently pull air tube to release kink and continue inflating.
6.		Tube might be kinked or the air tube-TPU connection might be twisted (see diagram below). 	Extract the chamber to straighten the kink and sort the twist.
		One of the walls in the inflated section has ruptured.	(a) Extract the organ from chamber. (b) Remove and replace device.
		Abdominal cavity size is too small to accommodate the LapBox.	Use a different device or convert to an open procedure.
7.	Difficulties in port insertion.	Incision is too small at the skin or fascia.	Increase the incision in the fascia to the same length that was marked on the skin making sure not to puncture the chamber.
8.	Chamber's sleeve is obstructing the view through the port.	Chamber sleeve is not completely extracted.	Hold the port in its place and pull the chamber's sleeve upwards until clear visualization is achieved.
9.	Chamber is not round/fully deployed	Chamber sleeve was over extracted.	Remove port, reinsert sleeve and insert port and inflate bag to target pressure.
10.	Chamber ruptured prior to initiation of morcellation.	One of the walls of the inflated section has ruptured.	(a) Extract the organ from chamber. (b) Remove and replace device.
11.	Pressure gauge indicates “0” (zero) or indicates constant pressure loss during procedure.	Tube might be kinked.	Visually inspect that the chamber walls are inflated, if no problem is detected gently pull the air tube 2-3 cm.

## LAPBox POWER TISSUE CONTAINMENT SYSTEM – INSTRUCTIONS FOR USE

#	Problem	Reason	Action
12.		Puncture /leak in the double chamber wall.	Increase the incision length and extract the chamber without further morcellation.
13.	During morcellation, an accidental tear in the chamber occurs.	Puncture of both chamber's walls.	Increase the incision length and extract the chamber
14.		Puncture in the inner chamber wall.	Increase the incision length and extract the chamber without further morcellation
15.	During deflation, the chamber does not deflate.	Tube might be kinked.	Gently pull the air tube that is outside the patient to release kink and continue deflating. If the chamber cannot be easily removed, extend the incision, and remove the chamber.
		Tube might be kinked or the air tube-TPU connection might be twisted (see diagram below). <div data-bbox="711 653 1062 896" data-label="Image"> </div>	
16.	The chamber cannot be extracted due to excess tissue.	Specimen tissue was left in the chamber	Extend the incision and remove the chamber and contents intact.

## Symbols

	Batch Code		Sterilized Using ETO
	Catalogue Number		Consult Instructions For Use
	Use by Date		Keep dry
	Do Not Reuse		Keep Away from Sunlight
	Do Not Resterilize		Date of Manufacture
	Do Not Use if Package is Damaged		Quantity Per Box Any number can be presented in the box.
	Non-Pyrogenic		EU Authorized Representative:
	Legal Manufacturer		Not made with natural rubber latex
	Prescription Only. U.S. Federal Law Restricts This Device to Sale by or on the Order of a Physician.		



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