

INSTRUCTIONS FOR USE



LAPBOX - MANUAL

Rx Only

Caution: Federal (U.S.A) law restricts this device to sale by or on order of a physician



Indications for Use

The LapBox device is indicated to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation.

Contraindications

1. The LapBox is contraindicated for laparoscopic power morcellation during gynecologic procedures.
2. The LapBox is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.
3. Do not use on tissue that is known or suspected to contain malignancy.
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.
6. Do not use if specimen to be morcellated has a diameter larger than 12cm.

Warnings and Precautions

1. Please read all instructions prior to use
2. Ensure the tenaculum/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 tenaculum, grasper or scalpel.
3. 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. 
4. Do not use the device if the "Use by" date indicated on the package label has passed. 
5. 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.
6. Any abdominal incision introduces a risk of abdominal hernia.
7. LapBox should only be introduced through the umbilicus
8. The LapBox should only be used by physicians 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 manual morcellation.
9. The use of the LapBox should be based on the risk benefit factors as they apply to each individual patient.
10. If resistance is met during bag removal, the tissue has not been adequately morcellated. Insufficient morcellation of the specimen can lead to damage of the LapBox chamber upon removal
11. All manual morcellation should be completed extracorporeally. Cutting below the level of the Instrument Port may lead to patient injury.

LAPBox – INSTRUCTIONS FOR USE

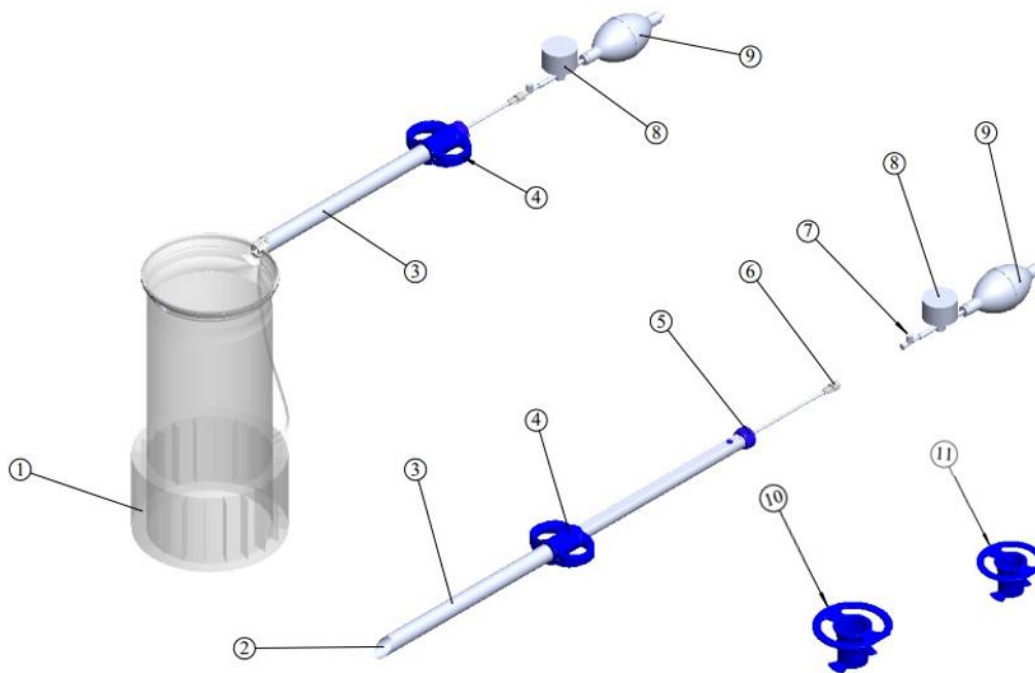
12. After use, the device is a potential biohazard. Handle and dispose of as required per hospital policy and applicable local laws and regulations

Complications

Potential complications associated with the use of the LapBox device 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.

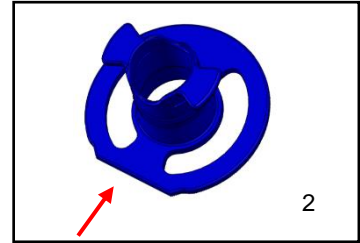
Device Components

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

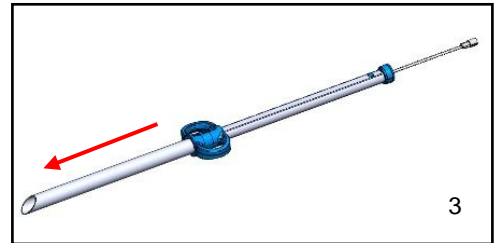


LapBox Deployment – Instructions for Use

1. Use the side of the desired port to mark the final incision length.
 - Medium port can be used for organs up to 400 grams / 9cm maximal diameter.
 - Big port can be used for organs up to 900 grams / 12cm maximal diameter.
2. For initial device insertion Increase the incision in the umbilicus to 25mm length.

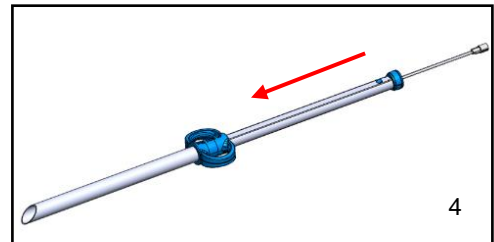


3. Insert the LapBox System under direct visualization through the created incision using rotating movements (Figure #3). Maintain pneumoperitoneum at 15 mmHg.

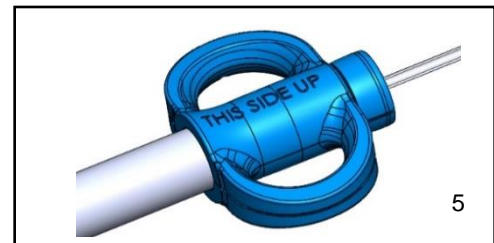


4. To deploy the LapBox Chamber, firmly hold the insertion shaft and push the handle forward to the maximum.

Note: Do not pull the tube back at any stage of the procedure (Figure #4).



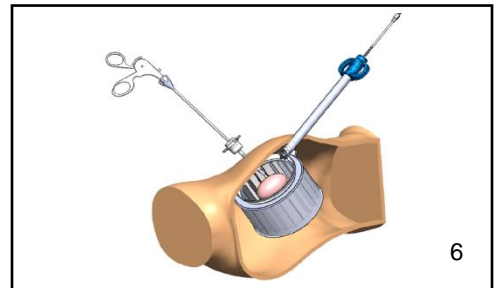
5. Ensure that the marking “this side up” on the distal handle is facing upwards (Figure #5).



6. Place the organ within the Chamber.

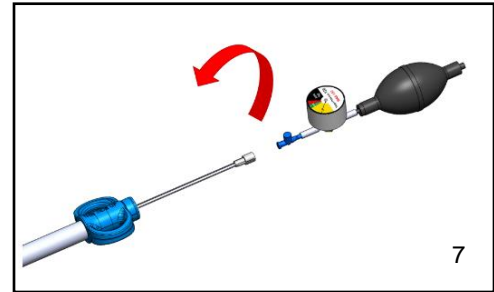
Note: Always use an atraumatic grasper (Figure #6).

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



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

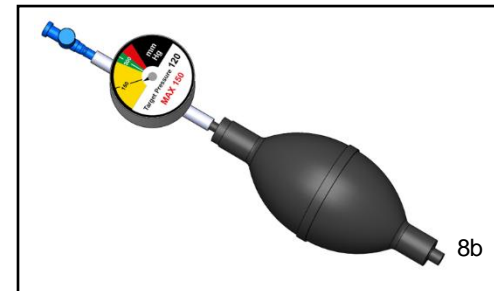
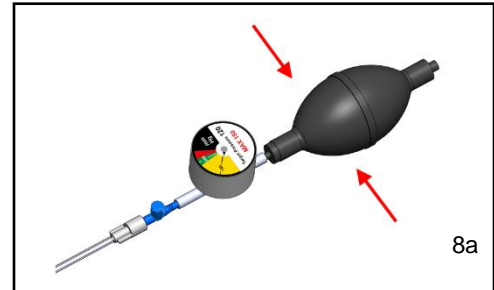
Note: when connecting the hand pump assembly hold the pressure relief valve for optimal connection



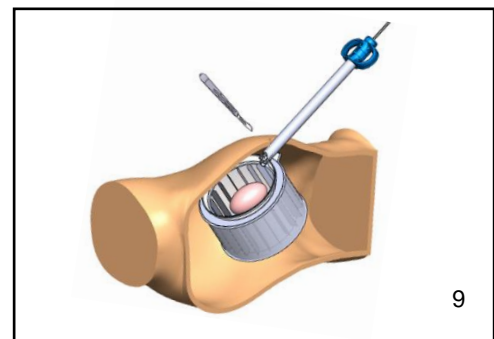
8. Inflate the chamber by squeezing the LapBox hand pump until a pressure of 120 mmHg is noted on the pressure gauge and the chamber is fully inflated (Figures #8a and #8b).

Note:

- **Do not inflate more than 150mmHg.**
- **Do not block the pressure relief valve**
- **Make sure the chamber opening is facing Upward during inflation**

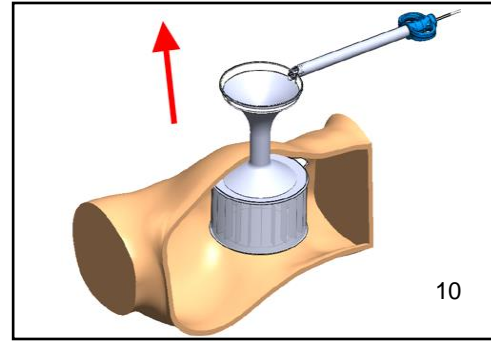


9. Increase the incision length according to the desired port. making sure not to damage the chamber (Figure #9).



10. 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.

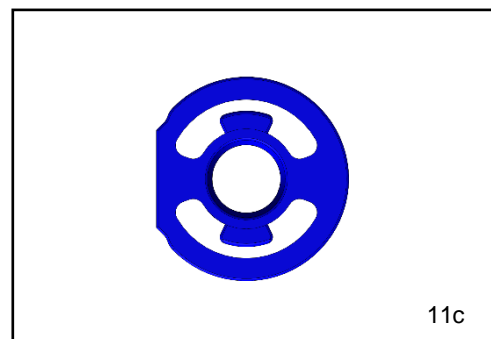
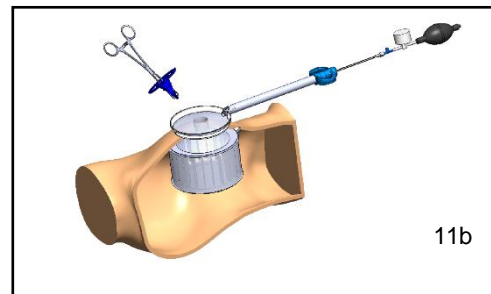
Note: *If the chamber is twisted, further extract the chamber sleeve and adjust it by rotating it until it is in the correct orientation (Figure #10)*



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

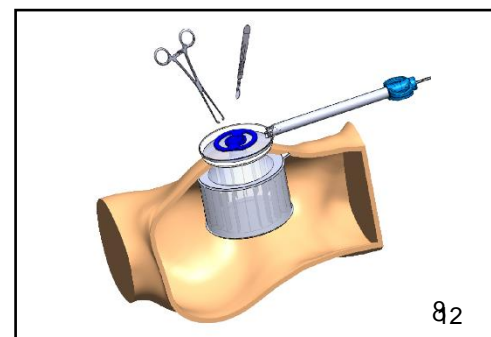
Note:

- *If following port insertion, the port opening is not round – (Figures 11c) increase incision size to allow full deployment of port*
- *If following port insertion there is not a clear vision of the organ, further extract the chamber's sleeve.*
- *If following extraction of the chamber's sleeve the chamber is not fully round – the sleeve was over extracted and need reinserting.*



12. **Under direct visualization**, utilizing a grasper and scalpel, perform manual morcellation.

Note: *make sure to only use a #10 scalpel blade (Figure #12).*

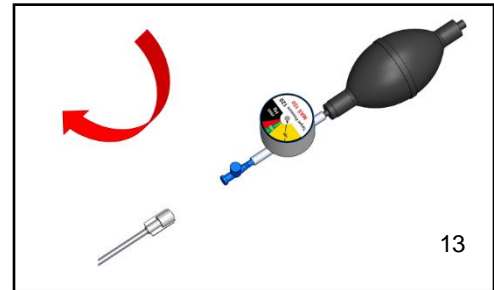


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14. Once the morcellation process is complete the chamber must be deflated prior to removal. Before deflation make sure remaining tissue, size will not prevent extraction.

To deflate the Chamber, disconnect the hand pump and wait 30 seconds before removing port. (Figure #13).

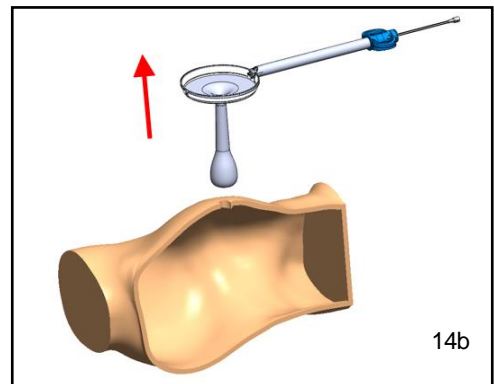
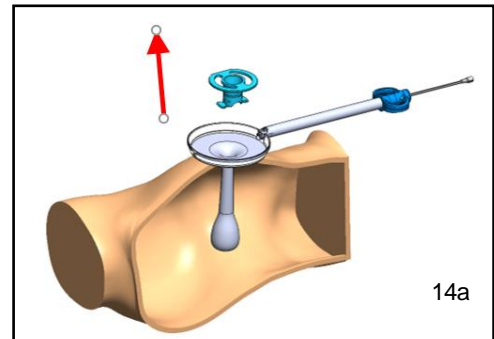
Note: make sure not remove the port before deflation.



15. Once the chamber is completely deflated the LapBox System can be extracted:

- (a) Take out the port from within the LapBox (Figure #14a)
- (b) Grasp the chamber's sleeve and gently retract from the abdomen (Figure #14b)

If excess material prevents the LapBox extraction, reinsert chamber and inflate, place port, and continue manual morcellation.




















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

Trouble Shooting

	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 to fit the chamber.	Organ size exceeds 12cm.	The LapBox is contraindicated, remove, and discard the device.
4	Hand pump assembly disconnected	Connecting tube was loss	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	During inflation, the chamber does not inflate.	One of the walls in the inflated section has ruptured.	(a) Extract the organ from chamber. (b) Remove and replace device.
7	Difficulties in port insertion.	Incision is too small.	Increase the incision 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) during procedure.	Tube might be kinked.	Visually inspect that the chamber walls are inflated, if no problem is detected gently pull the air tube 1”.
12	Pressure gauge indicates “0” (zero) during procedure.	Leak.	Increase the incision length and extract the chamber
13	During morcellation, an accidental tear in the chamber occurs.	Puncture of both of the chamber’s walls	Increase the incision length and extract the chamber
14	The chamber cannot be extracted due to excess tissue.	Specimen remaining in the chamber is too large.	(a) Reinsert chamber and inflate. (b) Place port. (c) Continue morcellation until the remaining specimen is small enough to allow chamber extraction.

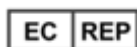
Symbols

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



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