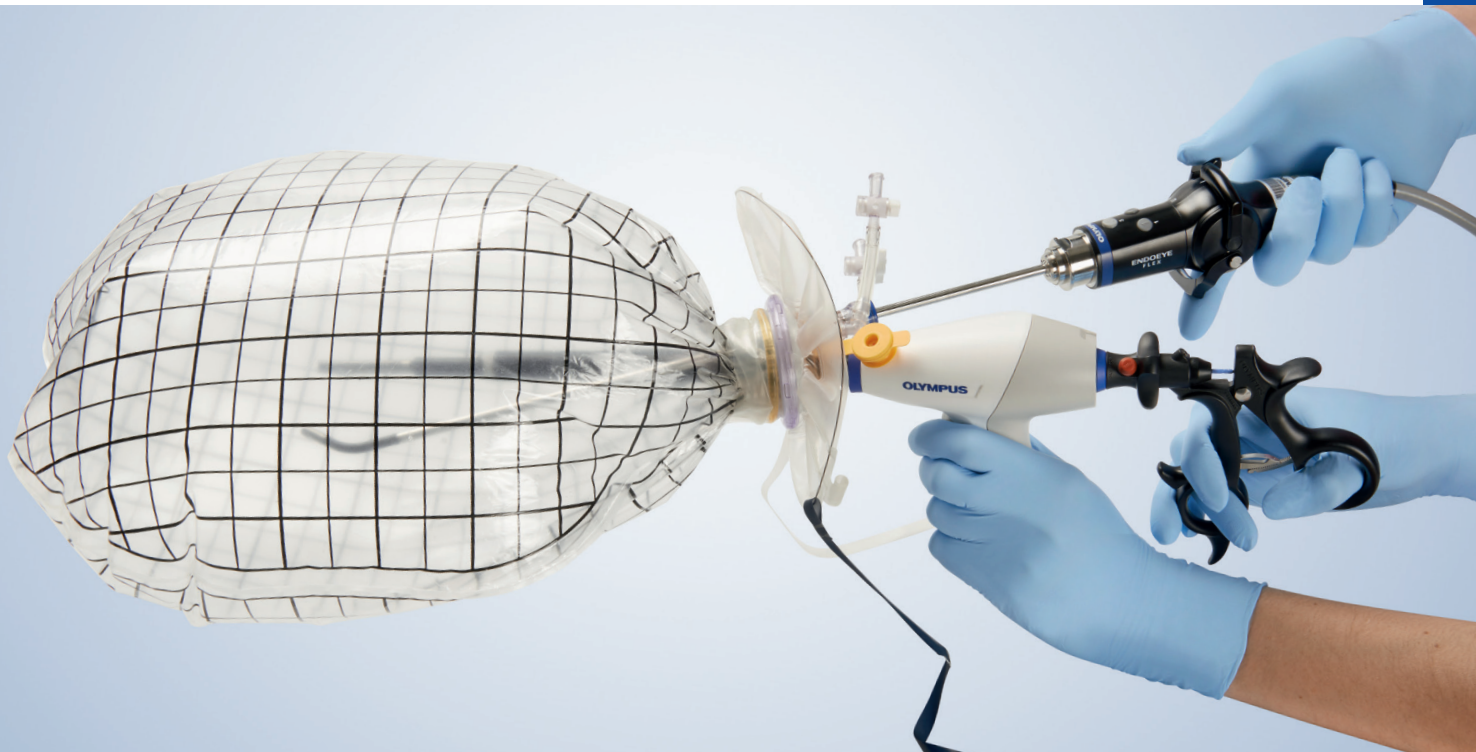


PK[®] Morcellator and PneumoLiner[™]

Bipolar morcellator and containment device





- This is a quick reference guide only.
- For detailed operating instructions, be sure to follow the instructions for use that are included with your devices when purchased.
- Before use, thoroughly read the respective instructions for use of all other products that will be used during the procedure.
- If the required instructions for use are missing, immediately contact an Olympus representative.

PneumoLiner:

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.

CONTRAINDICATIONS: Do not use on tissue that is known or suspected to contain malignancy. Do not use for removal of uterine tissue containing suspected fibroids in patients who are: peri- or post-menopausal; or candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision. Do not use in women with undiagnosed uterine bleeding. Do not use this device on patients with known or suspected allergies to polyurethane. Do not use where the abdominal wall thickness is larger than 10cm. This device should only be used by physicians who have completed the formal validated training program administered by Olympus and/or Advanced Surgical Concepts.

For more information, please read the full PneumoLiner Instructions for Use for indications, additional contraindications, warnings and precautions.

PK® Morcellator:

Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

CONTRAINDICATIONS: The use of the PK Morcellator is contraindicated for surgical procedures in which the tissue to be morcellated is known or suspected to contain malignancy. The PK Morcellator is contraindicated for removal of uterine tissue containing suspected fibroids in the following patient groups:

- Peri- or post-menopausal patients.
- Candidates for en bloc tissue removal. For example, through the vagina or via a mini-laparotomy incision.

The use of the electrosurgical generator ESG-400 is contraindicated when, in the judgment of the physician, bipolar electrosurgical procedures with the PK Morcellator would be contrary to the best interests of the patient or user. For patients with active electronic devices implanted, refer to the instructions for use for those devices before using bipolar electrosurgery.

The PK Morcellator should not be used if the patient is not considered suitable for a laparoscopic hysterectomy procedure or a laparoscopic myomectomy procedure.

For more information, please read the full PK Morcellator Instructions for Use for indications, additional contraindications, warnings and precautions.

Instrumentation for PneumoLiner™ containment device



1. PneumoLiner introducer, 2. PneumoLiner, 3. Plunger



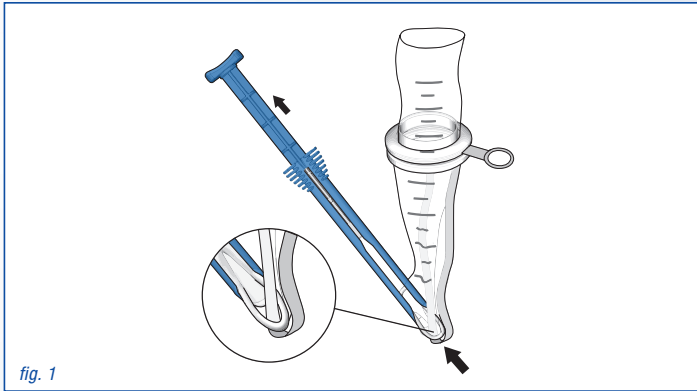
4. Boot, 5. Retractor, 6. Retractor introducer

Product	Technical Data
WA90500US PneumoLiner containment device for laparoscopic morcellation with laparoscopic instrument port	PneumoLiner: Volume.....9 L Collar diameter 160 mm
Boot Retractor Retractor introducer	Boot: Size Large valve for 15-18 mm instruments Small valve for 5 mm instrument

Instrumentation for PK® Morcellator

	Product	Technical Data
	WB91051W Electrosurgical generator "ESG-400"	Dimensions Width 370 mm Height 156 mm Depth 465 mm Weight 12.5 kg Voltage 100 - 120 V 220 – 240 V
	WA90200A PK Morcellator	Outer dimensions Instrument channel diameter 15 mm Working length 170 mm
	Claw forceps or a tenaculum to perform morcellation	Outer dimensions Instrument 10 mm

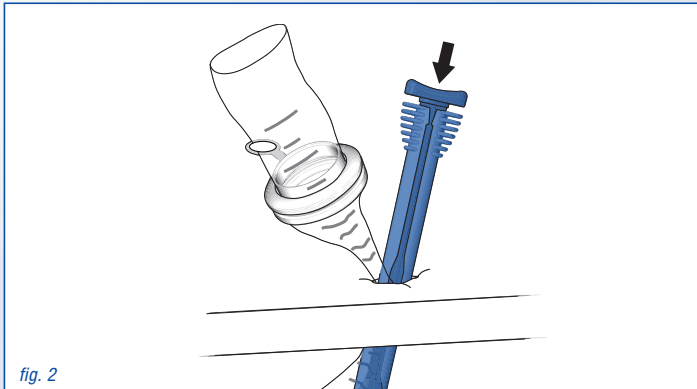
Preparation of PneumoLiner PRIOR To Deployment



- Create an incision with a length of 20 – 25 mm.
- Insert the distal ring into introducer with the removal ribbon at its distal end (fig. 1).

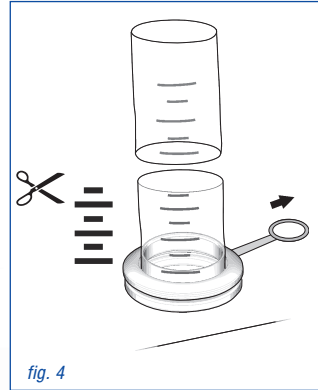
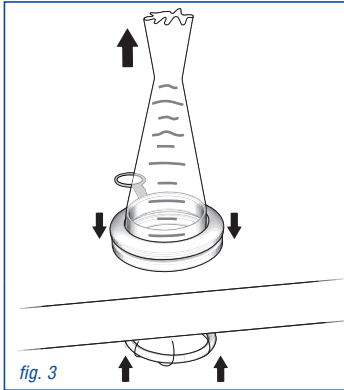
Tip: Avoid bunching of the sleeve.

Tip: Ensure that the removal ribbon is at the distal tip of the introducer.



- Pass the retractor introducer through the incision.
- Fully eject the distal ring into the cavity (fig. 2).
- Remove the retractor introducer.

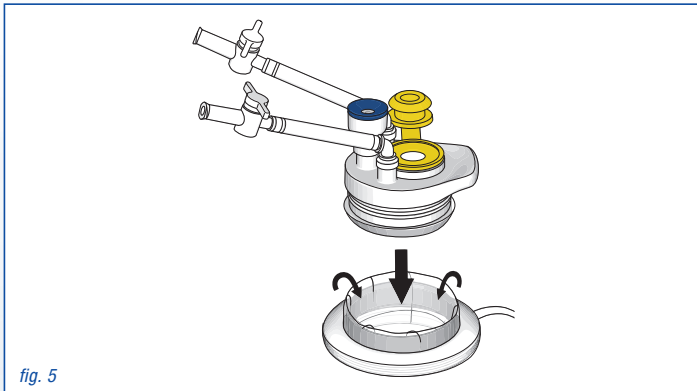
Deployment of PneumoLiner



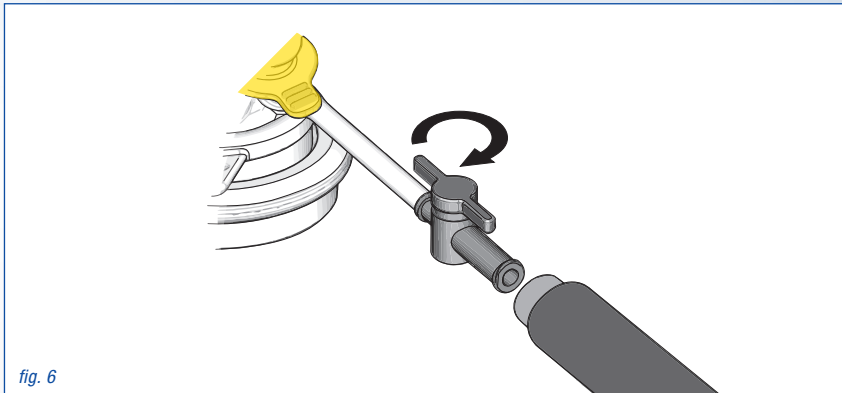
- While pulling upwards on the retracting sleeve, push down on the outer proximal ring to slide it towards the abdomen. Continue until the incision is retracted (fig. 3).

Tip: Check for viscera/adhesions under the distal ring prior to full retraction.

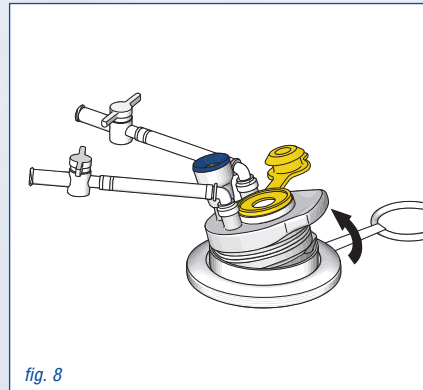
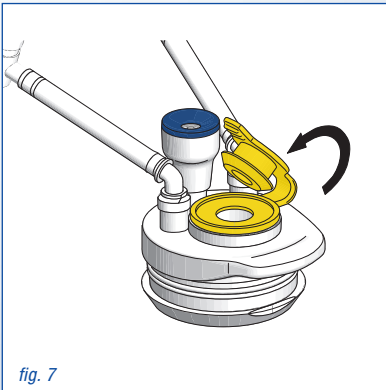
- Gently pull on the removal ribbon to remove excess inside the incision. Trim the retracting sleeve six gradations above the inner proximal ring (fig. 4).



- Fold the Retracting Sleeve inside the Inner Proximal Ring and press the Boot into position (fig. 5).

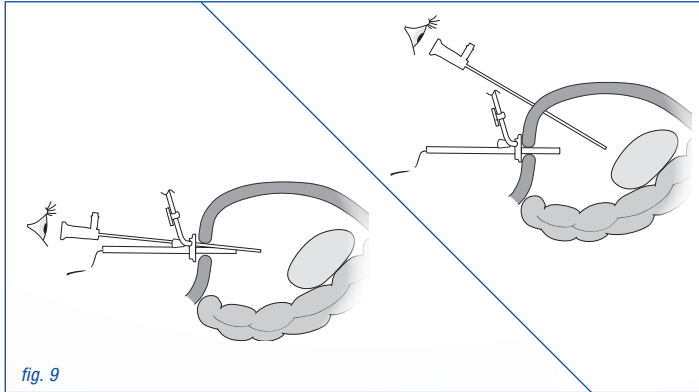


- Insufflate abdomen through either of the insufflation/venting ports (fig. 6).
- Smoke can be vented through the unused insufflation/venting port.



- A 5 mm instrument can be inserted through the yellow valve using the reducer (fig. 7).
- The Boot can be removed using the removal tab, and re-attached (fig. 8).

Deployment of PneumoLiner

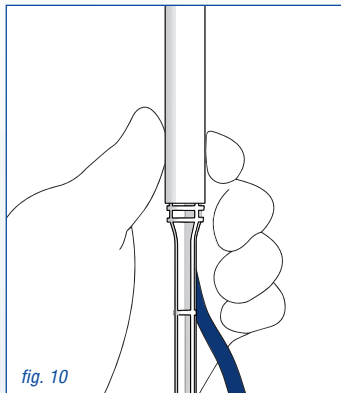


- Insert a 5 mm laparoscope with minimum 30° lens angle or deflectable tip either through the blue valve or through a separate trocar.

Tip: Before deployment of the PneumoLiner bring the target tissue into a position which enables easy encapsulation.

- Insert PneumoLiner introducer shaft (fig. 9), white distal tab first, through the yellow valve.

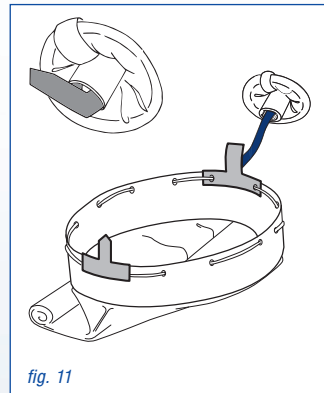
Tip: Ensure that the distal tab is the leading end and is pointing up.

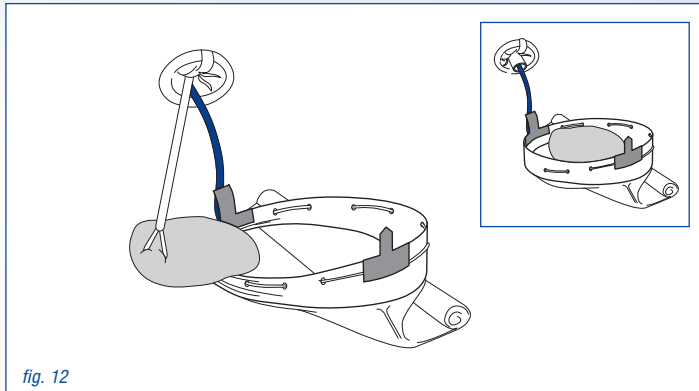


- Insert PneumoLiner introducer plunger into shaft. Push plunger to deploy PneumoLiner. Remove PneumoLiner introducer (fig. 10 and fig. 11).

- The distal tab should point upwards to indicate correct orientation of the PneumoLiner.
- Ensure free end of the tether remains external throughout procedure.

Tip: Remove plunger and introducer shaft simultaneously to avoid losing pneumoperitoneum.





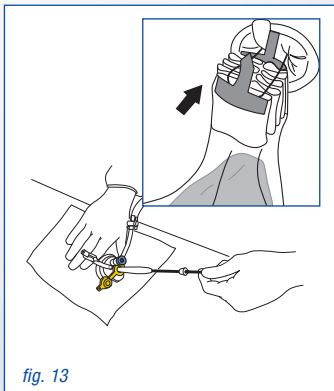
- Manipulate the target tissue into the PneumoLiner, ensuring it is contained within the collar (fig. 12).

NOTE:

To manipulate the PneumoLiner only use an atraumatic grasper to manipulate PneumoLiner.

Tip: Grasp collar to move the PneumoLiner and ensure encapsulation.

Tip: Pull the distal tap upward and slightly forward over the tissue to ensure complete containment of the tissue within the collar.

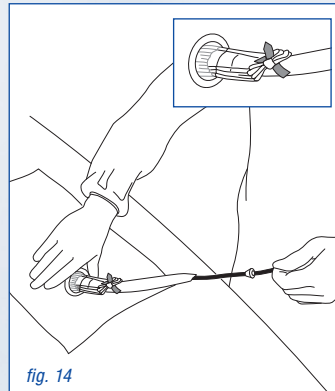


- Using the tether, pull the opening ring partially through the yellow valve until PneumoLiner is closed (fig. 13).

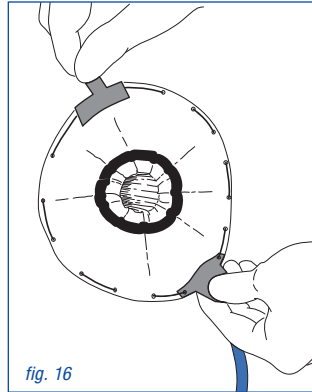
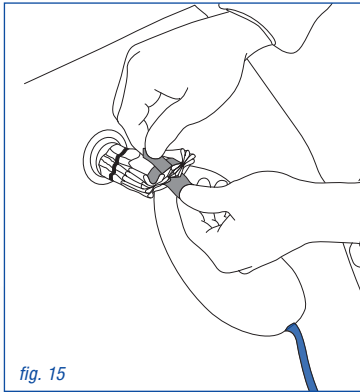
- Remove all trocars and detach Boot, deflating abdomen. Remove the Boot from tether.

Tip: Ensure that the Boot remains in the sterile field at all times.

- Pull the tether until the printed line is visible (fig. 14).

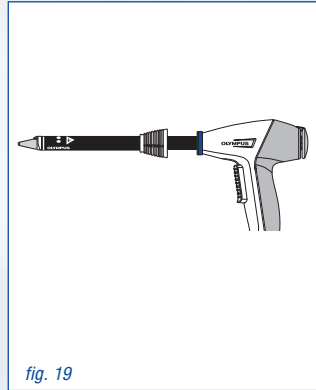
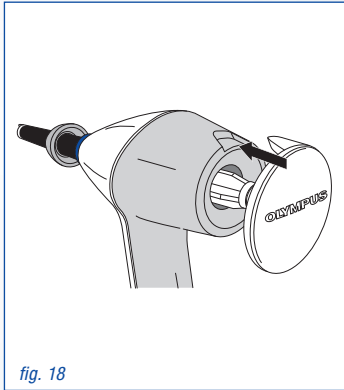


Deployment of PneumoLiner

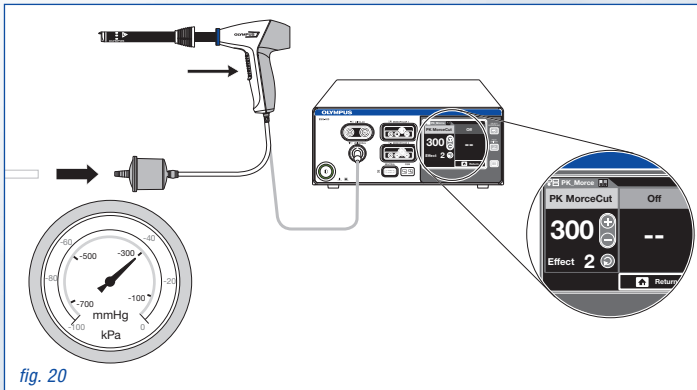


- Pull the tabs apart to open PneumoLiner (fig. 15 and fig. 16).
Tip: Check that opening ring is in correct orientation.
Tip: Check that the PneumoLiner is not twisted.
- Re-attach Boot in desired orientation (fig. 17).
NOTE: Do not twist Boot while it is attached.
- Prior to insertion of the instruments, insufflate PneumoLiner using the insufflation port (12-15 mmHg). 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.

Morcellation Setup

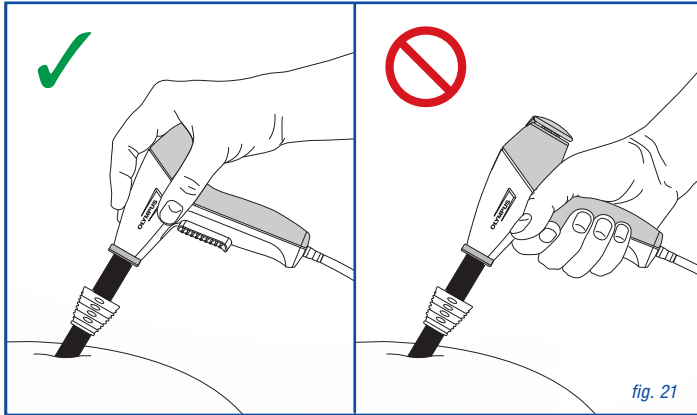


- Insert the obturator into the instrument channel.
- Make sure that the locator of the obturator head is located in the slot at the back (fig. 18) of the main body.
- Make sure that the obturator is fully inserted in the channel. (fig. 19).



- Connect the in-line filter to the suction system by using tubing from the operating room.
- Plug the PK Morcellator into the ESG-400.
- The PK Morcellator is recognized and <PK_Morce> is displayed on the touchscreen of the ESG-400 (fig. 20).

Inserting the Instrument Channel

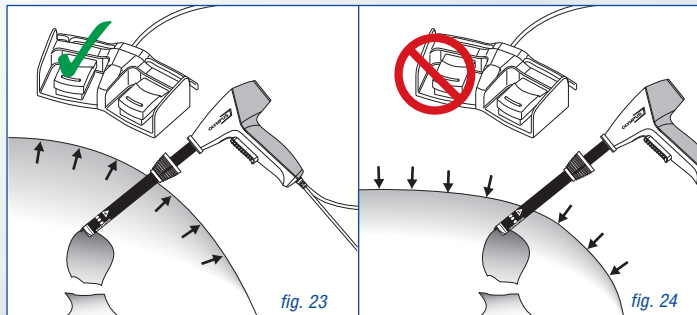
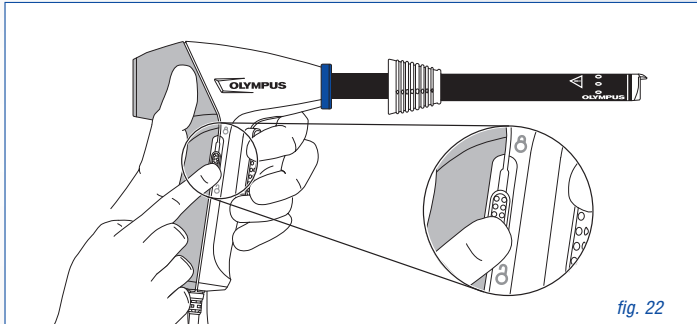


- Insert morcellator with obturator in place, through the yellow valve.
Tip: The laparoscope should always be inserted prior to insertion of the Morcellator. If the laparoscope needs to be cleaned, both instruments must be removed. After cleaning the laparoscope must be reinserted first followed by the morcellator with obturator in place.

Insert the PK Morcellator through the abdominal wall by applying continuous but controlled pressure with a deliberate rotating motion of approximately 180°. For safe and effective insertion, do not apply force to the handle but to the back of the main body as shown in the figure above.

- When using the PK Morcellator with a trocar, remove the depth stop.
- Make sure that the obturator is inserted. Insert the PK Morcellator through the abdominal wall by applying continuous but controlled pressure with a deliberate rotating motion of approximately 180°. For safe and effective insertion, do not apply force to the handle but to the back of the main body as shown in the figure above. (fig. 21)
- Remove the obturator.

Prior to Morcellation



Insufflation test for smoke evacuation mode

To perform the test proceed as follows:

1. Set the insufflator flow to maximum output.
2. Once the abdomen (or the containment device) is fully insufflated, press the trigger or the containment device for smoke evacuation and keep it depressed.
3. Set the suction system to a vacuum pressure of -300 mmHg (≈ -40 kPa).
4. Monitor the pneumoperitoneum for 10 seconds.

4a.) If adequate pneumoperitoneum is maintained:

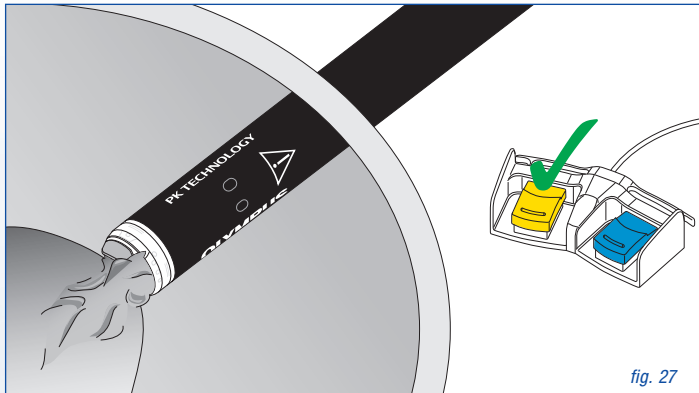
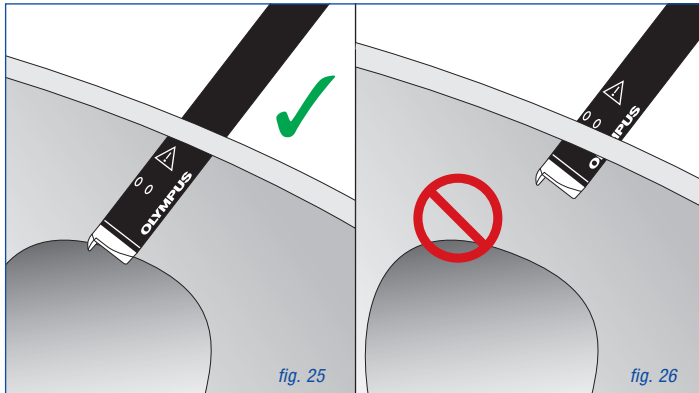
It is possible to use the constant smoke evacuation mode, i.e. the trigger for smoke evacuation can be locked with the sliding lock (fig. 22).

4b.) If adequate pneumoperitoneum is not maintained:

Do not lock the trigger for smoke evacuation with the sliding lock. The intermittent smoke evacuation mode must be used.

- Make sure that the pneumoperitoneum is not compromised by smoke evacuation (fig. 23 and fig. 24).
- Monitor the pressure in the abdominal cavity during the whole morcellation procedure.

Morcellation

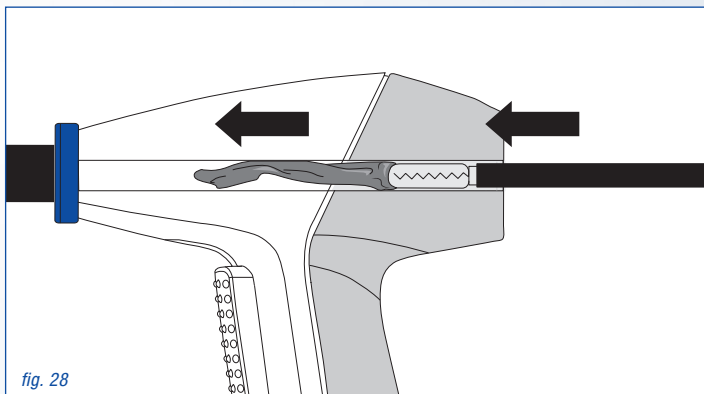


- Make sure that the minimum insertion depth is maintained, i.e. the warning triangle is visible within the abdominal cavity (fig. 25).
- Grasp and retract the target tissue, making contact with the tip.
- Bring the morcellator's tip and the target tissue in optimal position.
- Activate the PK Morcellator by pressing the yellow pedal on the foot switch. The tissue that comes into contact with the cutting part of the tip (active electrode) is cut (fig. 27, refer page 16).
- Make sure that the guide beak (return electrode) remains on the surface of the tissue mass.
- When morcellating, hold the PK Morcellator steady and bring the tissue to the tip for morcellation. If resistance is felt as the grasping forceps enter the instrument channel, the jaws may be opened too wide to pass through. Release and regrasp the tissue to promote better closure.
- Morcellate and remove tissue taking care not to damage the PneumoLiner with instruments.

Tip: Keep tenaculum in view at all times. Do not touch bag with open instruments.

NOTE:

Stop morcellation once gross tissue mass has been reduced to pieces, each smaller than 4 printed grid squares.

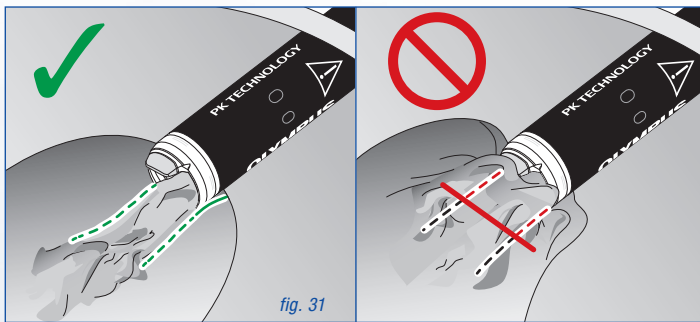
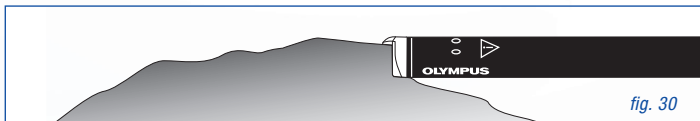


- Do not open the grasping forceps and do not try to regrasp the tissue section within the instrument channel as this could damage the product.

In the event that a tissue section tears apart or loosens from the grip of the grasping forceps inside the instrument channel, proceed as follows:

1. Keep the jaws of the grasping forceps closed.
 - 2a.) If the tissue is visible at the tip:
Use assisting grasping forceps to pull the tissue from the tip of the product.
 - 2b.) If the tissue is completely inside product:
With the jaws of the grasping forceps closed, apply a single, controlled stroke to push the tissue fragments to the distal end out of the instrument channel.

Positioning of grasping forceps and guide beak

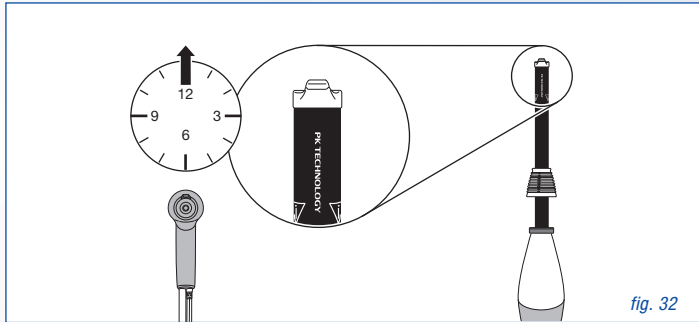


NOTE:

If the grasping forceps or the morcellator's tip are engaged centrally into the tissue mass, the **non-cutting** guide beak impedes the cut after only 5 to 10 mm. Optimal positioning on the surface of the target tissue minimizes the morcellation forces and ensures long cutting lengths.

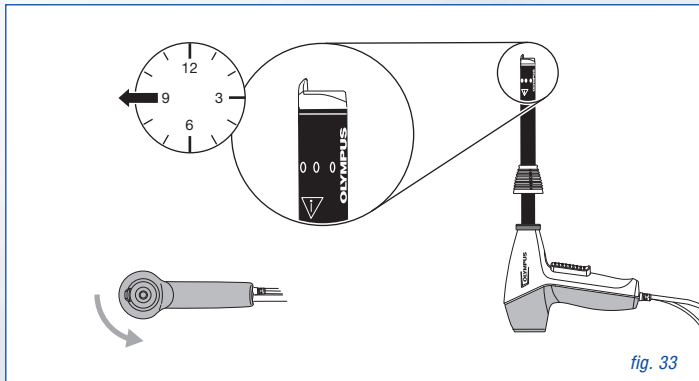
- Grasp the tissue at the edge of the tissue mass (fig. 29).
- Retract the grasping forceps.
- Apply the morcellator's tip so that the guide beak is on the surface of the tissue mass, as the guide beak is not able to cut (fig. 30).
- During morcellation, make sure that the guide beak remains on the surface of the tissue mass (fig. 31).

Orientation aid for guide beak position



Guide beak in 12 o'clock position

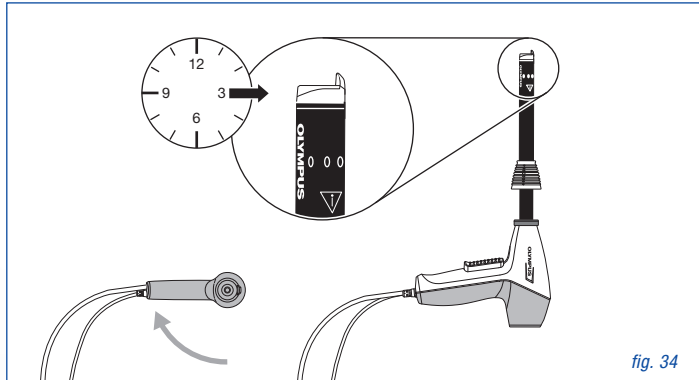
- The guide beak of the PK Morcellator is in 12 o'clock position if:
 - the handle of the PK Morcellator points downwards.
 - the PK Technology logo can be seen on top of the instrument channel.



Guide beak in 9 o'clock position

- The guide beak of the PK Morcellator is in 9 o'clock position if:
 - the handle of the PK Morcellator is turned to the right by 90°.
 - the warning triangle can be seen on top of the instrument channel.

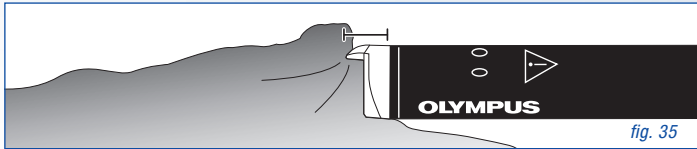
Orientation aid for guide beak position



Guide beak in 3 o'clock position

- The guide beak of the PK Morcellator is in 3 o'clock position if:
 - the handle of the PK Morcellator is turned to the left by 90°
 - the warning triangle can be seen on top of the instrument channel.

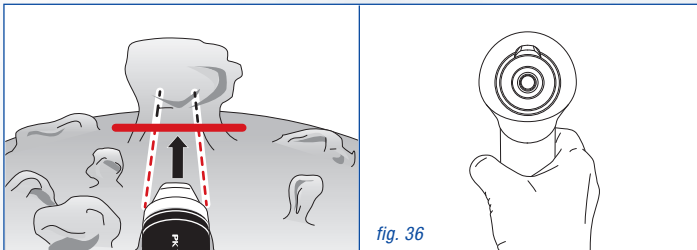
Obstacles by non-uniform tissue



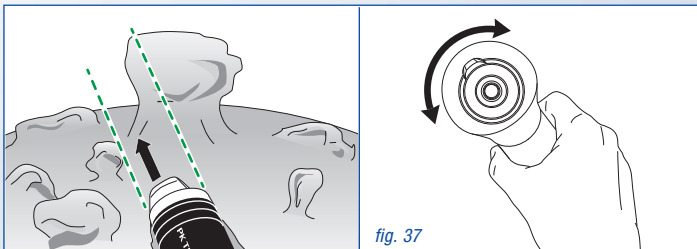
Non-uniform tissue shapes, like tough collagenous tissue or fibroids, can present an obstacle and can impede the cutting progress if the PK Morcellator is not reoriented accordingly.

If the initial path of the cut is maintained, as shown in the figure 35, the non-cutting guide beak will press against the obstacle and the cut is impeded after only 5 to 10 mm.

Reorient the device to navigate through the outside edge of the obstruction as follows:

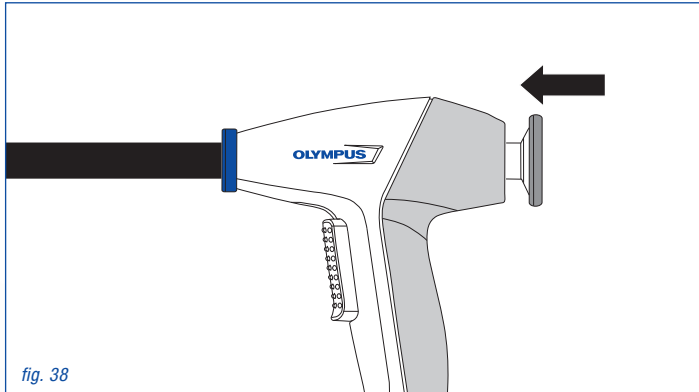


- Pause the current cut by releasing the foot switch.
- Lower the force that retracts the target tissue. Keep the jaws of the grasping forceps closed.

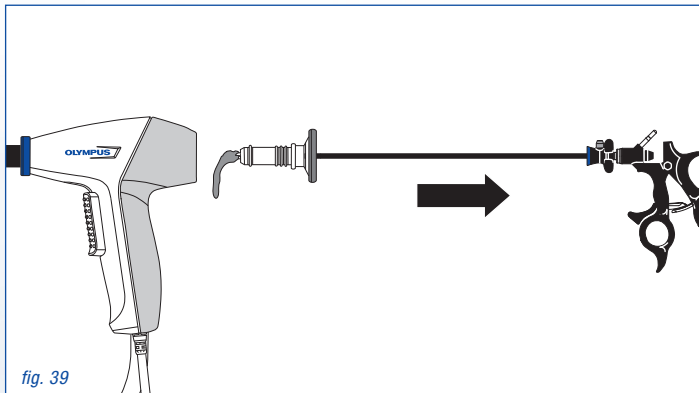


- Rotate the handle so that the non-cutting beak is oriented to ensure that it remains on the outer surface of the non-uniform tissue.
- With the grasping forceps, retract the target tissue again.
- Reactivate the PK Morcellator by depressing the yellow footswitch and proceed with the cut.

Use with 5 mm grasping forceps

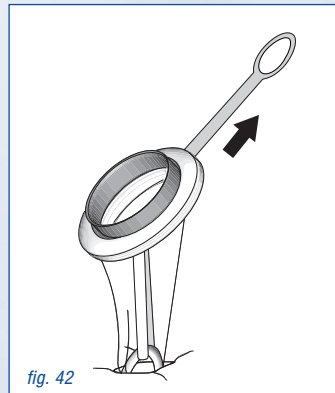
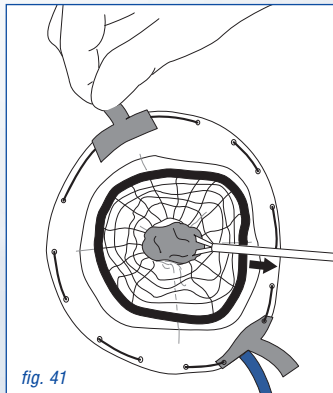
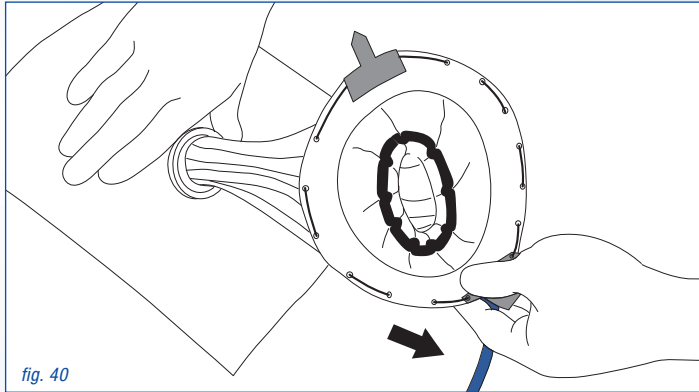


- Insert the 5 mm adapter into the back of the main body until a resistance is felt. A gap remains between the adapter and the back of the main body (fig. 38).



- If larger tissue fragments are removed during post morcellation clean-up, then the 5 mm adapter is intended to detach when withdrawing the 5 mm instrument (fig. 39).

After Morcellation



- Remove all instruments.
- Detach Boot allowing the PneumoLiner to deflate.
- Gently remove PneumoLiner (fig. 40).

NOTE: Ensure that the PneumoLiner neck remains open to allow gas to escape.

- If the PneumoLiner is not easily removed, tissue pieces can be extracted using an atraumatic grasper at the incision (fig. 41).
- Disconnect the PK Morcellator from the ESG-400.
- Disconnect the in-line filter from the suction system.
- Dispose of the PK Morcellator. Follow all applicable national and local laws and guidelines.
- Remove the retractor by pulling on the removal ribbon (fig. 42).
- Dispose of the Boot and do not use it again!

NOTE: In case final inspection is needed, use one of the additional trocars used in the early stage of the procedure and a second clean scope.

Notes

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