LiVac™ Retractor System
Instructions for Use

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device is provided sterile and is designed, tested and manufactured for single patient use only. Discard after use, do not resterilise as re-use may be harmful to patients.

DESCRIPTION

The LiVac Retractor System comprises:

- LiVac Retractor,
- LiVac Connector, and
- LiVac Bevel.

The LiVac Retractor is a soft silicone ring (B) connected to suction tubing (A) (Figure 1), and is designed to maintain apposition between the diaphragm and either right or left lobes of liver or spleen, thereby exposing the underlying organs or hila. Different sizes are available as denoted by the outer diameter of the ring of the retractor. The suction tubing (A) must be connected to a sterile suction hose via the LiVac Connector (Figure 2), which is positioned partially within the abdominal wall. The longer end of the connector joins to the LiVac Retractor tubing, and the shorter end connects to the suction hose. The LiVac Connector can lie alongside a 12-15mm port, within the secondary channel of the LiVac Bevel such as per Hasson technique (Figure 3), or within a single incision laparoscopic port device (Figure 4). The LiVac connector can be pulled apart at its join in order to break a seal (Figure 2). The LiVac Retractor may be lubricated and inserted into the abdominal cavity using a laparoscopic grasper.

INDICATIONS FOR USE

The LiVac Retractor is designed as an organ and tissue retractor for use in laparoscopic procedures to elevate organs and tissue to provide improved access and visualisation of surgical sites.

CONTRAINDICATIONS

The LiVac Retractor should not be used in patients in whom laparoscopic access is contraindicated.

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WARNINGS AND PRECAUTIONS

1. Laparoscopic procedures should be performed only by physicians with adequate training and familiarity with laparoscopic techniques.

2. A general laparoscopic inspection of the peritoneal cavity and liver/target organ is recommended prior to insertion of the LiVac Retractor to assess suitability and size of the LiVac Retractor. There must also be a clear space into which the LiVac Retractor is inserted.

3. Abnormal livers may not be suitable for use of the LiVac Retractor. In particular, cirrhotic livers may not achieve a seal against the device and may be too stiff to retract. Livers and/or diaphragms that have a highly rounded or irregular contour may not be able to achieve a seal, as the best seal is achieved between substantially planar surfaces. Fatty livers and patients with coagulation or platelet disorders may be at increased risk of injury with any type of liver retractor. Care should be taken when using the LiVac Retractor in these patients.

4. There must be enough surface area over the liver/organ for the LiVac Retractor to achieve a seal. An unusually small left lobe of liver may therefore be unsuitable for the LiVac Retractor.

5. Any part of the LiVac Retractor System may be lubricated with a sterile water-soluble lubricant (including N. Saline) prior to insertion. Adequate amounts should be applied to the outer surfaces of the retractor to reduce the resistance of insertion. Excessive lubricant, particularly around the inner perimeter of the ring, may clog the suction inlets.

6. Sharp-edged graspers which may cause damage should not be used on the LiVac Retractor.

7. Either wall suction, or a portable medical suction pump, with a high vacuum regulator that encompasses the 0 to -600 mmHg (0 to -80 kPa) range should be used with the LiVac Retractor (Figure 5). A fixed pressure regulator in the order of -350mmHg to -500mmHg can also be used. The suction should be separate from any other suction device used for irrigation or removal of bodily fluids, to ensure that there is no interference with the suction forces applied to the LiVac Retractor during use.

8. The LiVac Retractor is typically used at a suction pressure range around -400 to -500 mmHg. Once a seal is attained, the pressure cannot be readily dropped from a higher to lower level of suction, hence it is recommended that the main suction tubing is clamped and the regulator adjusted to about -500 mmHg (-67 kPa) at the outset. This also serves to check that there are no leaks along any of the component connections, such as the suction canisters. Once the LiVac Retractor has been positioned and LiVac suction tubing attached to the main suction tubing, the clamp can be released and pressure re-checked. If the seal is lost, increase the pressure by small increments. Do not exceed -600 mmHg pressure.

9. The LiVac Retractor has been safely used for procedures lasting over 180 minutes duration. It is possible to re-position the retractor, assessing the original suction site, and start a new period of suction on the second site.

10. The liver will show an embossed imprint of the LiVac Retractor following use, which should flatten within minutes. Histological assessment of liver barotrauma in animal studies confirmed that any changes were limited to 2mm thickness. Prolonged operations and/or high suction pressures may increase barotrauma.

11. The best seal is attained between two smooth, firm surfaces. In some patients, the peritoneum over the diaphragm can be loose and fatty anteriorly. In these patients, the LiVac should be positioned further back over the tendinous portion of the diaphragm. Desufflating the pneumoperitoneum with the LiVac in place, then activating the vacuum, may also achieve a better seal as the liver and diaphragm will align in their normal anatomical relationship. Do not attempt to seal the LiVac Retractor against the falciform ligament, which is membranous, but rather against the true diaphragm.

12. If the thickness of the abdominal wall exceeds the length of the connector, then the retractor tubing within the abdominal wall may be at some risk of compression.

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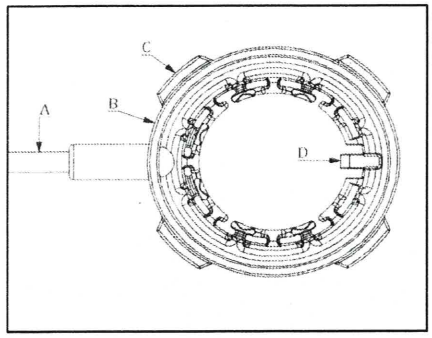
SCHEMATIC VIEW

Figure 1 LiVac Retractor



A Silicone suction tubing
B LiVac ring
C Outer handling tabs
D Slot for attachment of inserter or laparoscopic grasper

Figure 2 LiVac Connector

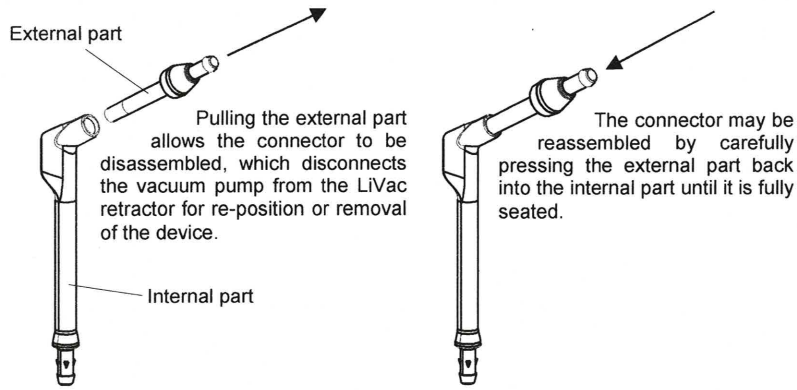


Figure 3 LiVac Connector with Bevel

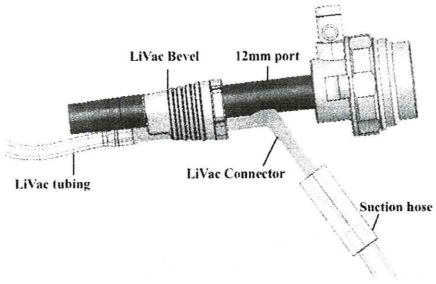


Figure 4 LiVac Connector with a Single port

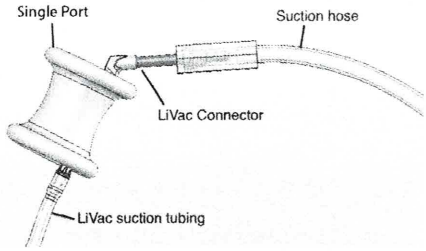
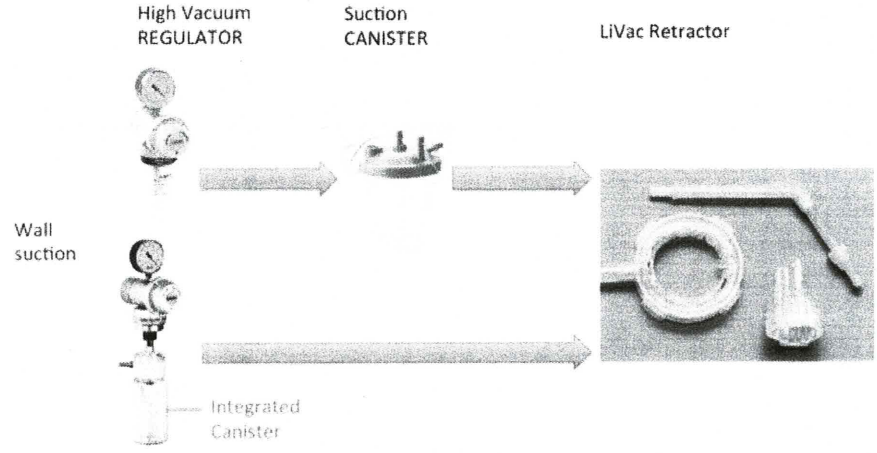


Figure 5 Suction Equipment



USE OF THE LIVAC RETRACTOR SYSTEM

Caution should be exercised during insertion, suction and removal of the LiVac Retractor to avoid damage to internal organs. The liver is used in these examples, as the most common target organ for retraction, Organs such as the spleen have also been successfully retracted.

The suction hose should be clamped at the patient end from the outset and the vacuum pressure set at the regulator. The liver should be inspected first to assess its suitability for the LiVac Retractor, and choice of LiVac Retractor size. Additional ports are inserted at this point, unless it is a single port procedure, and carbon dioxide insufflation transferred to one of those ports so as to maintain the pneumo-peritoneal space.

Insertion

1. 12-15 mm port: the LiVac Retractor can be inserted through the wound created by the port. An atraumatic laparoscopic grasper is used to grasp the tab (Figure 1, D) on the inside of the ring opposite to the suction tube inlet and the tubing pulled to elongate the ring. The outside of the ring may be lubricated with water-soluble lubricant. The LiVac Retractor is then inserted alongside an S Retractor into the peritoneal space. Insert enough length that the tubing can be draped out of the way of the instruments. Shorten the tubing if required. Once the LiVac Retractor has been inserted, the tubing of the retractor can be attached to the LiVac Connector. Join the tubing to the LiVac Connector, insert the connector into the wound such that the bend is just above skin level, and re-insert the port alongside the connector, with the curved wings of the connector sitting flush against it. Using a LiVac Bevel with a 12mm port will further prevent any gas leak.

2. Hasson technique: insert the LiVac Connector through the second channel of the LiVac Bevel and laparoscopic port through the central channel, then join the retractor tubing to the connector and insert the assembly through the wound. Stay sutures should be wound around the wings of the bevel and the ends clamped with an artery forcep (Figure 3).

3. Single port: the LiVac Connector should occupy one of the channels or be pushed through a gel membrane, with LiVac tubing attached to the internal end (Figure 4).

Procedure following insertion of the LiVac Retractor into the abdominal cavity

Once the LiVac Retractor has been inserted, position it over the right or left lobe of liver where maximum retraction is sought, but not against the falciform ligament. Another grasper should then be used to gently lift up the gallbladder or liver lobe towards the diaphragm until the LiVac ring is secured between liver and diaphragm without a gap. Release the clamp on the external suction hose when the LiVac is in position to activate the seal. An alternative approach for a larger lobe is to desufflate the abdomen as the suction is applied to the LiVac Retractor, by ceasing insufflation or even releasing carbon dioxide. This brings the liver and diaphragm together without needing to lift a large liver with instruments and in its natural alignment. The left triangular ligament may be divided to reduce tension with retraction of the left lobe of liver. A temporary suture placed between the right crus and falciform ligament can enhance exposure of the hiatus in some patients.

Removal of the LiVac Retractor

When liver retraction is no longer required, the external suction hose should be clamped, then the external part of the LiVac Connector disconnected from the internal part, causing the seal to be lost. It should then be reconnected to prevent further escape of carbon dioxide. The port is then removed followed by the LiVac Connector. The LiVac Retractor is removed by pulling on the tubing. Care should be taken to ensure that no omentum, small bowel or other viscera is caught up as it is removed.

Suction sources

A high vacuum suction regulator (0 to -600 mmHg) attached to wall suction will be the usual source of suction. A suction canister is either attached directly to the regulator, or through a suction hose (Figure 5). A sterile suction hose, such as for Yankuer sucker, is then attached to the canister from the operating table, and the other end attached to the external connection of the LiVac Connector. A smaller canister is preferable, as it will achieve the target vacuum pressure faster than a larger canister given that there is less air to evacuate. An alternative source of suction may be a portable medical grade high suction pump with regulator (0 to -600 mmHg). A fixed pressure regulator in the range of -350 mmHg to -500 mmHg should also provide satisfactory retraction.

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PACKAGING

The LiVac Retractor, Bevel and Connector are packaged together in a double bag which is terminally sterilised. The bags are shipped within a carton. One set of Instructions for Use is packaged per device.

DISPOSAL

When the LiVac devices have been removed from the patient at the end of the operation, all should be disposed of in the hospital's contaminated waste facilities.

REPORTING

Customers should use the following telephone number for reporting adverse reactions or complications involving this device: +61 413 227 332.

CAUTION

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

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEFINITIONS

	FOR SINGLE USE ONLY
	STERILIZED BY ETHYLENE OXIDE (not all products are sterilized by ethylene oxide)
	STERILIZED BY GAMMA IRRADIATION (not all products are sterilized by gamma irradiation)
	REFERENCE NUMBER
	LOT NUMBER
	USE BY DATE
	ATTENTION! SEE INSTRUCTION FOR USE
	CONSULT INSTRUCTION FOR USE
	PRODUCT SHOULD BE KEPT DRY
	STORE THE DEVICE IN A TEMPERATURE RANGE OF 5°C-30°C
	MANUFACTURER
	KEEP AWAY FROM SUNLIGHT
	EUROPEAN REPRESENTATIVE
	DO NOT RESTERILIZE
	DO NOT USE IF PACKAGE IS DAMAGED
	MANUFACTURER'S DECLARATION THAT THE PRODUCT CONFORMS WITH THE APPLICABLE EUROPEAN DIRECTIVES (not all products will be CE marked)

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LiVac Patent Protected

IMA-N-04149-08 User Manual, LiVac Retractor System, Type II
Symbols as per ISO 15223-1, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements. FDA recognition number 5-90.
This user manual was last revised in June 2018