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, and
- LiVac Connector

  The LiVac Bevel is an optional accessory, not included in all systems

The LiVac Retractor is a soft silicone ring (B) connected to suction tubing (Figure 1, A), and is designed to maintain apposition between substantially planar organs such as 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 (Figure 1, A) must be connected to a sterile suction hose via a suitable connector, which may be the LiVac Connector, supplied with the LiVac Retractor (Figure 2), or a compatible alternative connector (Figure 3). When using the LiVac Connector, 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 also be pulled apart at its join in order to break a seal (Figure 2). The connection device(s) may be used external to the patient or may be used percutaneously, examples are provided in Figures 3a to 3d, as follows:

- The LiVac Connector can lie alongside a 12mm port, within the secondary channel of the LiVac Bevel[1] such as per Hasson technique (Figure 3a)
- The LiVac Connector can lie alongside a 12-15mm port, without the use of the LiVac Bevel[1] (Figure 3b)
- The LiVac Connector can lie within a single incision laparoscopic port device (Figure 3c)
- The LiVac Connector can be separated and just the external part used to join the LiVac tubing to the suction hose (Figure 3d)
- The tubing may also be brought out directly through its own incision

The LiVac Retractor may be lubricated and inserted into the abdominal cavity using an atraumatic grasper.

INDICATIONS FOR USE

The LiVac Retractor is designed as an organ and tissue retractor for use in laparoscopic, robotic and/or open surgical 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.

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. Only atraumatic graspers should be used to insert the LiVac Retractor to avoid damage.
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. A regulator may not be necessary if the suction source pressure does not exceed -600 mmHg. 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 may be used at a suction pressure between the range of -300 to -600 mmHg, with the optimal pressure being -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.

[1] The LiVac Bevel is an optional accessory, not included in all systems.

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; an alternative, longer connector may be used in this situation (Figure 6), or the tubing brought through a separate tract in the abdominal wall, sharing the same skin incision as the port.

13. Any externally supplied tubing or connection devices must be:

    a. Approved for use by the local regulatory agency and used within the approved intended purpose for the device;

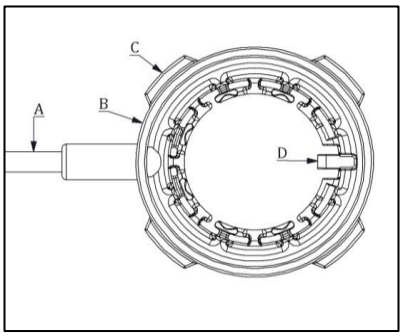
    b. Compatible with the LiVac components, and must not obstruct the surgical procedure;

    c. Of suitable construction to form an air-tight seal with the LiVac tubing to enable the required suction pressure to be maintained (see also Items 7 and 8 above);

    d. Supplied sterile or sterilised prior to use.

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 (supplied with the LiVac Retractor)

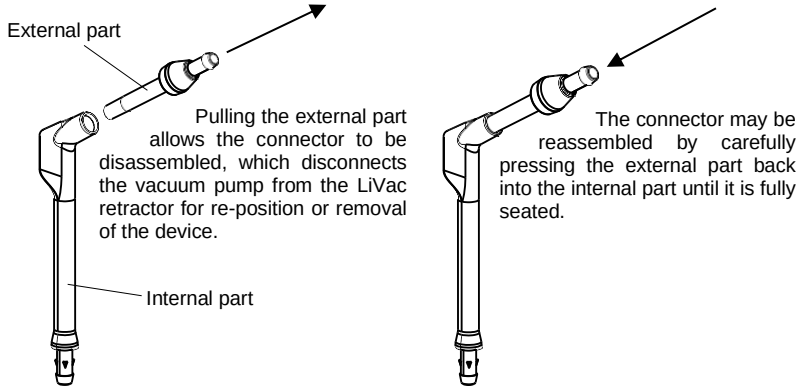


Figure 3a LiVac Connector with Bevel[1]

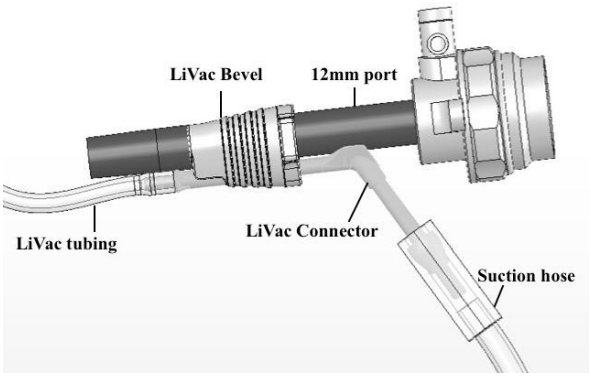


Figure 3b LiVac Connector without bevel[1]

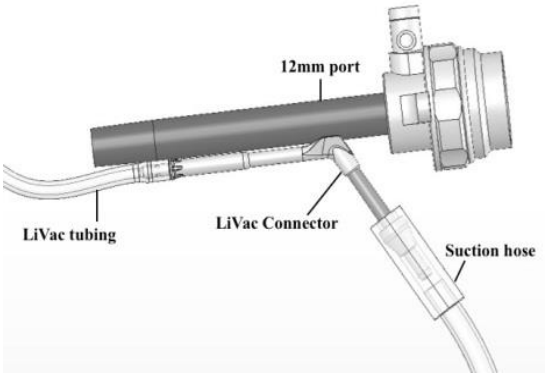


Figure 3c LiVac Connector with a Single port

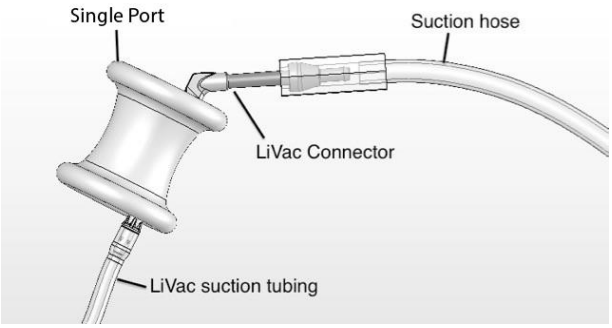
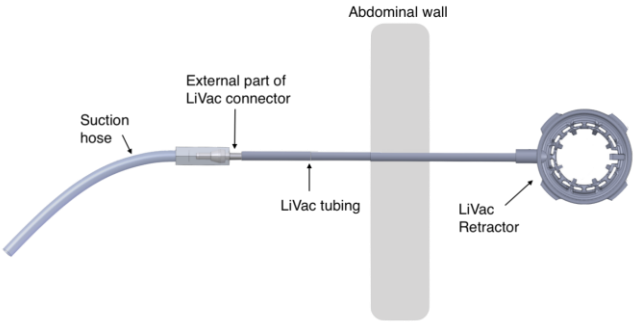


Figure 3d Percutaneous tubing and LiVac Connector (External part only)



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. Whilst 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 LiVac Retractor System may be used in conjunction with any suitable commercially available percutaneous devices to reduce incision sizes within the abdomen if desired. Use with such devices will not compromise the function of the LiVac Retraction System.

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 to maintain the pneumo-peritoneal space. The LiVac Retractor tubing should be stretched out to reduce coiling and may be shortened according to the length needed.

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 a retractor (such as an S Retractor) into the peritoneal space. Insert enough length that the tubing can be draped out of the way of the instruments. Once the LiVac Retractor has been inserted, the tubing of the retractor can be attached to the LiVac Connector if not already connected. 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 (Figure 3b). Using a LiVac Bevel[1] with a 12mm port will further prevent any gas leak (Figure 3a).
2. 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 3c). The tubing can also be drawn though the gel membrane for external attachment to the LiVac Connector.
3. LiVac Connector used externally: the LiVac connector can remain external to the patient, with the tubing passing through the abdominal wall (Figure 3d). Alternatively, any suitable commercially available percutaneous devices can be used to bridge the abdominal wall, to reduce incision sizes.

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.

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. Alternatively, the LiVac seal can be disrupted directly by a laparoscopic instrument after clamping the external hose. The LiVac Retractor is removed by pulling on the tubing through a 12mm or larger incision site. 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 source of suction should be used with a suction regulator (0 to -600 mmHg). A sterile suction hose, such as for Yankuer sucker, is then attached to the external connection of the LiVac Connector. A smaller suction canister is preferable, as it will achieve the target vacuum pressure faster than a larger canister as there is less air to evacuate.

PACKAGING

The LiVac Retractor, Connector and optional Bevel[1] 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 carton.

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.

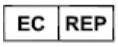
REPORTING

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

	MANUFACTURER
	EUROPEAN REPRESENTATIVE
	DATE OF MANUFACTURE
	USE BY DATE
	REFERENCE NUMBER
	LOT NUMBER
	STERILISED USING ETHYLENE OXIDE
	SINGLE *STERILE* BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE
	DO NOT RESTERILISE
	DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTIONS FOR USE
	KEEP AWAY FROM SUNLIGHT
	KEEP DRY
	STORE THE DEVICE IN A TEMPERATURE RANGE OF 5°C to 30°C
	FOR SINGLE USE ONLY
	CONSULT INSTRUCTIONS FOR USE
	ATTENTION! SEE INSTRUCTURES FOR USE
	MEDICAL DEVICE
	UNIQUE DEVICE IDENTIFIER
CE 0297	MANUFACTURER'S DECLARATION THAT THE PRODUCT CONFORMS WITH THE APPLICABLE EUROPEAN DIRECTIVES

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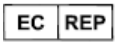

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Patent Protected

IFU-LIV002-03 Instructions for use, LiVac Retractor System. Date of issuance of IFU: 2023-06-23.

Symbols as per ISO 15223-1:2021, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements. FDA FR recognition number 5-134.