

Instruction for Use

Product: Lap Bag with Auto-Retrieval System

The Following information should be read before using this device.

Indications:

The Lap Bag with Auto-Retrieval system has applications in minimally invasive abdominal procedures for the safe, convenient removal of tissue specimens such as the appendix, gallbladder, gallstones, lymph nodes, an ectopic pregnancy, ovaries, small sections of bowel and other tissue structures.



Contraindications:

The instrument is not intended for use when minimally invasive techniques are contraindicated.

Device Description:

The Lap Bag with Auto-Retrieval system is an elastic pouch that minimizes spillage and intraoperative contamination by isolating and containing tissue specimens. The Lap Bag with Auto-Retrieval system is designed for introduction and use through 10/11 and 12 mm cannula.

REF#	Bag Size	Volume capacity
ALB-AV30	3 x 6 inch	200 ml
ALB-AV50	5 x 7 inch	280 ml
ALB-CUD0	4 x 4 inch	150 ml
ALB-CUE0	5 x 5 inch	300 ml
ALB-CUF0	6 x 6 inch	800 ml
ALB-CUG0	8 x 8 inch	1250 ml

*Note: User shall evaluate the condition and choose the appropriate device.

Direction for Use:

1. Using sterile technique, remove the instrument from the packaging. To avoid damage, do not flip the instrument into the non-sterile field.
2. Take warning label away.
3. Insert the Lap Bag with Auto-Retrieval system into the abdomen and pushing through an appropriately sized trocar cannula. The bag will open automatically.
4. Place the specimen into the pouch.
5. Once the specimen is completely within the confines of the pouch, straight up pull the rear handle away from the flexible cannula (this step will keep the bag closed and take apart from the rigid handle).
6. Take the flexible cannula away through Trocar cannula.

Removing the Pouch and Trocar Cannula.

- The suture with O-ring will keep in outside of abdomen.
- The pouch with specimen can be removed through a 10 mm trocar site, for specimens approximating this diameter.
- Pull back on the O-ring of the suture until the bag complete closed, neck of the pouch reaches the body surface. Visually inspect to see if pouch reaches the body surface, if air is trapped in the pouch, use an atraumatic instrument to enlarge the neck of the pouch to allow air to escape.

- If pouch does not pull through easily, enlarge the incision to accommodate easy removal of the pouch, taking care not to puncture the pouch.

Caution: Do not attempt to pull the pouch device through the trocar cannula when the tissue sample is larger than the cannula diameter. Please mince the tissue to avoid the formation of a pouch with large tissue fragments stuck at the edge of the incision port.

Precautions/Warnings:

- This device is designed for single use only and is not to be re-used or re-sterilized. Do not use if package is opened or damaged.
- Contents sterile unless enclosed package has been opened or damaged. Store at 15°C~25°C.
- Endoscopic procedures should be performed only by physicians with adequate training and knowledge of these procedures. In addition, medical literature should be consulted regarding techniques, hazards, contraindications and complications prior to the performance of these procedures.
- Before endoscopic instruments and accessories from different manufactures are utilized together in a procedure, verify compatibility.
- This device is not intended for use with any tissue that will not fit within the confines of the pouch to allow complete closure.
- Do not remove, or attempt to remove the specimen pouch through the trocar cannula.
- Not for use with Power morcellators! The Lap Bag is not intended for use with sharp surgical instruments. Care should be taken to avoid damaging, puncturing or tearing the Lap Bag.
- Beware of the remaining heat on the surgical instrument might damage the pouch.
- Dispose used product following local state or federal guidelines.



Caution



Sterilized using Ethylene Oxide



Consult instructions for use



Do not use if package is damaged



Batch code



Do not reuse



Keep away from sunlight



Date of manufacture



Keep dry



Catalogue number



Manufacturer



Temperature limitation: 15°C~25°C



Do not re-sterilize



Use by



Single sterile barrier system with protective packaging outside



Medical device



Single sterile barrier system

If further information is required, please contact:



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Instruction for Use

Product: Lap Bag with Introducer

The Following information should be read before using this device.

Description:

The Lap Bag with introducer is a sterile, single-use, disposable specimen container and designed for use in retrieving specimens during endoscopic surgery.



Contraindications:

This device is not intended for use when endoscopic techniques are contraindicated.

Preparation:

1. Remove the sleeve containing the Endo Pocket from the package.
2. Insert the sleeve through the desired 10, 11, or 12mm trocar sheath.
3. To remove the pouch from the sleeve, grasp the exposed pouch at the distal end of the sleeve, and carefully withdraw the pouch from the sleeve.
4. Place the desired specimen in the pouch and tie the pouch with suture if needed.
5. To remove the pouch, use graspers to pull the top of pouch into the distal end of the trocar sheath. While securing the bag with grasper, withdraw the trocar sheath, pouch, and graspers through the incision site until mouth of the pouch can be visualized. Continue removing the pouch from incision under vision by hand.

Cautions/Warnings:

- This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury.
- Contents sterile unless enclosed package has been opened or damaged. Store at 15°C~25°C.
- Reprocessing and/or re-sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device.
- Not for use with Power morcellators! The Lap Bag is not intended for use with sharp surgical instruments. Care should be taken to avoid damaging, puncturing or tearing the Lap Bag.
- Dispose used product following local state or federal guidelines.
- Federal (U.S.A) law restricts this device to sale, distribution, and use by, or on the order of a physician.



Caution



Sterilized using Ethylene Oxide



Consult instructions for use



Do not use if package is damaged



Batch code



Do not reuse



Keep away from sunlight



Date of manufacture



Keep dry



Catalogue number



Manufacturer



Medical device



Do not re-sterilize



Use by



Temperature limitation: 15°C~25°C



Single sterile barrier system



Single sterile barrier system with protective packaging outside

If further information is required, please contact:



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