

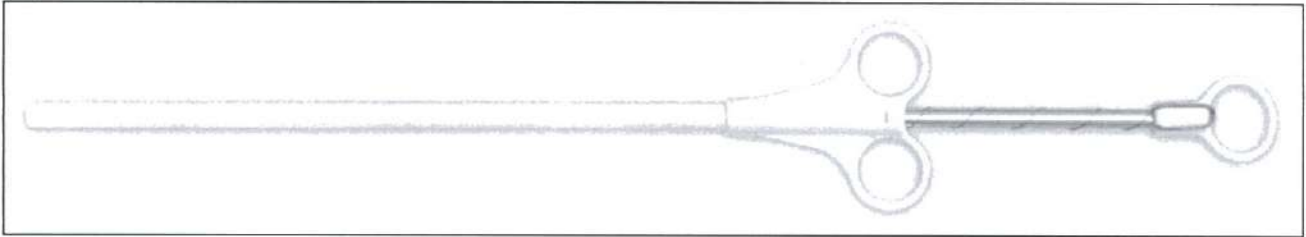
Instruction for Use

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.

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:



Advanced Medical Design Co., Ltd.
 4F~5F, No29, Wuquan 5th Rd., Wugu Dist.,
 New Taipei City, 24888 Taiwan R.O.C.
 TEL: 886-2-22902627
 FAX: 886-2-22988501
<https://www.amdintl.com.tw/>
 Email: sales@amdintl.com.tw



Instruction for Use

Product: Lap Bag with Fabric Pouch

The Following information should be read before using this device.

Indications for Use:

The Lap Bag with Fabric Pouch is applied in minimally invasive abdominal procedures for the safe and convenient removal of the tissue, organ or specimen during surgery. **The product is intended for prescription use only.**

Description:

The Lap bag with fabric pouch is a coated nylon fabric pouch that minimizes spillage and intraoperative contamination by isolating and containing tissue specimens. The Lap bag with fabric pouch system is designed for introduction and use through 11/12/15 mm cannula.

REF#	Contents	Thickness of the bag	Volume capacity	Suggest to use with
ALB-LAA0	9*19 cm Nylon Bag with drawstring	0.14 mm	100 ml	11 mm Trocar
ALB-YAA0	9*19 cm Nylon Bag	0.14 mm	100 ml	11 mm Trocar
ALB-YAB0	12*30 cm Nylon Bag	0.14 mm	800 ml	12 mm Trocar
ALB-YAC0	20*35 cm Nylon Bag	0.14 mm	2800 ml	15 mm Trocar

Contraindications:

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

Instruction for Use – ALB-LAA0

1. Take the Lap Bag out of the sterile packaging.
2. Use a grasper to grasp the bottom of the Lap Bag and deploy the Lap Bag through a 11 mm trocar.
3. Open the Lap Bag with a second grasper by grasping the edge of the Lap Bag mouth.
4. Place the specimen inside the Lap Bag.
5. Once the specimen is securely within the Lap Bag, pull the drawstring using graspers to close the Lap Bag mouth.
6. Grasp the drawstring and pull it through the trocar until the Lap Bag is out of the abdomen wall.
7. Remove the trocar.
8. Remove the Lap Bag.

Instruction for Use – ALB-YAA0

1. Take the Lap Bag out of the sterile packaging.
2. Use a grasper to grasp the bottom of the Lap Bag and deploy the Lap Bag through a 11 mm trocar.
3. Open the Lap Bag with a second grasper by grasping the edge of the Lap Bag mouth.
4. Place the specimen inside the Lap Bag.
5. Once the specimen is securely within the Lap Bag, grasp the tip of the Lap Bag mouth and pull it through the trocar until the Lap Bag is out of the abdomen wall.
6. Remove the trocar.
7. Remove the Lap Bag.

Instruction for Use – ALB-YAB0

1. Take the Lap Bag out of the sterile packaging.
2. Fold the Lap Bag into a shape that can fit a 12 mm trocar.
3. Use a grasper to grasp the bottom of the Lap Bag and deploy the Lap Bag through a 12 mm trocar.
4. Open the Lap Bag with a second grasper by grasping the edge of the Lap Bag mouth.
5. Place the specimen inside the Lap Bag.
6. Once the specimen is securely within the Lap Bag, grasp the tip of the Lap Bag mouth and pull it through the trocar until the Lap Bag is out of the abdomen wall.
7. Remove the trocar.
8. Remove the Lap Bag.

Instruction for Use – ALB-YAC0

1. Take the Lap Bag out of the sterile packaging.
2. Fold the Lap Bag into a shape that can fit a 15 mm trocar.
3. Use a grasper to grasp the bottom of the Lap Bag and deploy the Lap Bag through a 15 mm trocar.
4. Open the Lap Bag with a second grasper by grasping the edge of the Lap Bag mouth.
5. Place the specimen inside the Lap Bag.
6. Once the specimen is securely within the Lap Bag, grasp the tip of the Lap Bag mouth and pull it through the trocar until the Lap Bag is out of the abdomen wall.
7. Remove the trocar.



8. Remove the Lap Bag.

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.
- The contents are sterile unless enclosed package has been opened or damaged.
- Endoscopic procedures should be performed only by physicians with adequate training and knowledge of these procedures.
- Before endoscopic instruments and accessories from different manufacturers 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.
- 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.



Glossary of symbols

Symbol	Title or Description of Symbol	Reference Number (ISO 15223-1)
	Manufacturer, indicating the medical devices manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Date of manufacture, indicating the date when the medical device was manufactured.	5.1.3
	Use-by date, indicating the date after which the device is not to be used.	5.1.4
	Batch code, indicating the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Catalogue number, indicating the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Sterilized using ethylene oxide, indicating a medical device that has been sterilized using ethylene oxide.	5.2.3
	Do not re-sterilize, indicating a medical device that is not to be re-sterilized.	5.2.6
	Do not use if package is damaged, indicating a medical device that should not be used if the package has been damaged or opened.	5.2.8
	Keep away from sunlight, indicating a medical device that needs protection from light sources.	5.3.2
	Keep dry, indicating a medical device that needs to be protected from moisture.	5.3.4
	Temperature limit, indicating the temperature limits to which the medical device can be safely exposed.	5.3.7
	Do not re-use, indicating a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use, indicating the need for the user to consult the instructions for use.	5.4.3
	Caution, indicating the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4

If further information is required, please contact:



Advanced Medical Design Co., Ltd.
4F~5F, No29, Wuquan 5th Rd., Wugu Dist.,
New Taipei City, 24888 Taiwan R.O.C.
TEL: 886-2-22902627 FAX: 886-2-22988501
Email: sales@amdintl.com.tw

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:



Advanced Medical Design Co., Ltd.
4F~5F, No.29, Wuquan 5th Rd., Wugu Dist.,
New Taipei City, 24888 Taiwan R.O.C.
TEL: 886-2-22902627
FAX: 886-2-22988501
<https://www.amdintl.com.tw/>
Email: sales@amdintl.com.tw