

## 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.


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 <b>Caution</b>	 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	 Authorised representative in the European community
 Do not re-sterilize	 Use by	 Temperature limitation: 15°C ~25°C
 Notified body: DNV GL NEMKO Presafe AS, with CE2460		

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**If further information is required, please contact:**

Manufacturer by:

 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

**EC REP**

Lotus Global Co., Ltd.  
1 Four Season Terrace, West Drayton,  
Middlesex.London, UB7 9GG. U.K.  
Tel : 44-20-75868010 Fax: 44-20-79006187

## Instruction for Use

### **Product: Lap Bag with Fabric Pouch**

The Following information should be read before using this device.

#### **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 10/11 and 12mm cannula.

The Lap bag fabric pouch 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.

#### **Preparation:**

1. Remove the lap bag pouch from the packaging.
2. Open the folded paper; take the Lap bag fabric pouch away from the paper.
3. Use a grasper forceps instrument to hold up the pouch and insert through 10/11 and 12 mm cannula.
4. Place the specimen into the pouch.

#### **Removing the Pouch and Trocar Cannula:**

1. Pull the pouch top using the grasping forceps and withdrawn into the cannula.
2. Please remove the pouch whilst holding the bag in the cannula partially. While the cannula is removed, the pouch can then be removed through the 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.
- 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.



**Advanced Medical Design CO., LTD.**  
4F~5F, No29, Wuquan 5th Rd., Wugu Dist., New Taipei city, 248 Taiwan  
TEL: 886-2-22902627 FAX: 886-2-22988501

- 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



Authorised representative in the European community



Do not re-sterilize



Use by



Temperature limitation: 15°C~25°C



Notified body: DNV Product Assurance AS, with CE2460

**If further information is required, please contact:**



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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



OBELIS S.A  
Bd. Général Wahis, 53, 1030 Brussels, Belgium  
TEL: +3227325954  
FAX: +3227326003  
E-mail: mail@obelis.net