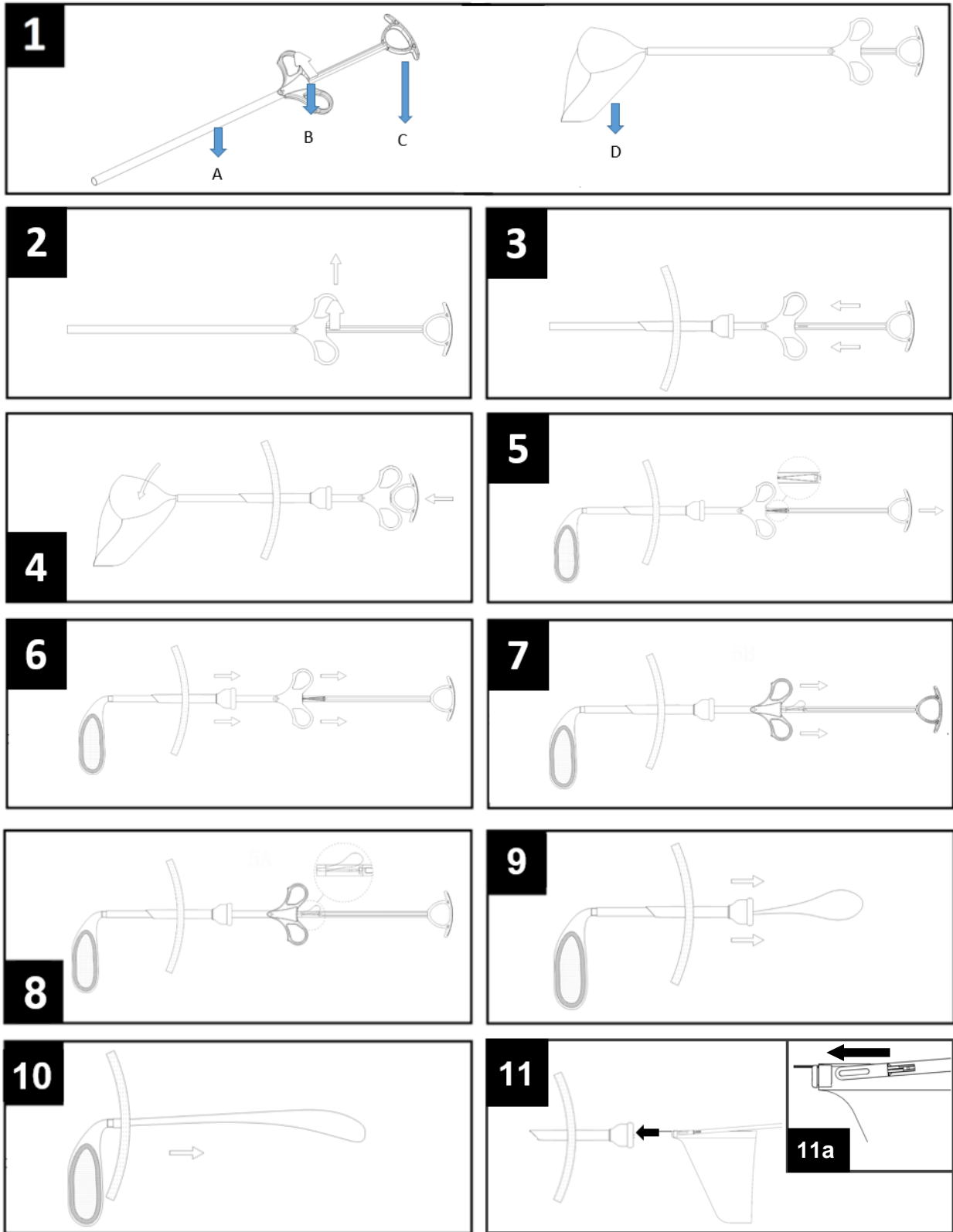


PMI SOLOBAG™ SINGLE USE SPECIMEN RETRIEVAL BAG INSTRUCTIONS FOR USE

Including sterile packaged Single-Use Specimen Retrieval bag and Introducer





BEFORE USING THIS PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

1. This booklet is designed to assist using this product. It is not a reference to surgical techniques.
2. This device was designed, tested and manufactured for single patient use only.
3. Reprocessing and/or re-sterilization of this device may create risk of contamination and patient infection.
4. Do not reprocess or re-sterilize this device for additional use.

DESCRIPTION

The **PMI SOLOBAG** Specimen Retrieval Bag is comprised of a flexible plastic bag with a large, easily accessible opening, an actuation rod with thumb ring handle, finger rings, string and closure suture, and an introducer shaft. In the fully deployed condition, the bag opening is maintained in a fully-open position by a metallic rim, and the size of the specimen bag is 4" x 5" with a volume of 280ml. A string with a closure suture facilitates closure of the specimen bag after the specimen had been collected. This device is disposable device packaged and sterilized for single patient use only. Do not reprocess or re-sterilize. Discard after use.

INDICATIONS FOR USE

The **PMI SOLOBAG** Retrieval is indicated for use in laparoscopic procedures to capture organs or tissue to be removed from the body cavity.

CONTRAINDICATIONS

- The use of **PMI** laparoscopic and endoscopic products is contraindicated whenever endoscopic surgical techniques are contraindicated for any reason. Contraindications relevant to individual **PMI** products are noted in the specific sections.

WARNINGS AND PRECAUTIONS

1. Endoscopic surgery should be performed only by physicians who are thoroughly trained in endoscopic techniques and failure modes, precautions, and corrective actions in the event of failure.
2. **PMI SOLOBAG** Specimen Retrieval Bag products are intended for single patient use only – **DO NOT RESTERILIZE REUSE, or REPROCESS.** Rest
3. erilization may alter the structural and/or functional integrity of this device which may result in patient injury, infection, illness or death. Risk of residual contamination and resterilization failure may lead to patient injury, infection, illness or death.
4. Do not use any pre-sterilized products if the packaging sterile barrier is damaged
5. Consult medical literature or country specific regulations for specific techniques, complications, and hazards prior to procedure.
6. Care must be taken when using laparoscopic instrumentation to avoid damage to major vessels and other anatomic structures.
7. Establish and maintain adequate pneumoperitoneum to reduce the risk of injury to internal structures.
8. Properly position the patient and note anatomical landmarks to introduced devices without unintended damage.
9. Do not use morcellator with this device. Safety and efficacy of the use of morcellators with the **PMI SOLOBAG** Specimen Retrieval Bag has not been established.
10. Care should be taken to avoid contact of the **PMI SOLOBAG** Specimen Retrieval Bag with sharp instruments, cutting devices, and electrosurgical and laser instrument.
11. This device is not intended for use with any tissue that will not fit within the confines of the **PMI SOLOBAG** Specimen Retrieval Bag and allow complete closure of the bag.
12. Do not attempt to remove the specimen through the trocar or cannula as this may lead to bag rupture and spillage of contents.
13. Excessive forces should be avoided during bag extraction.
14. If the bag and its contents are too large to be extracted, carefully enlarge the access site to facilitate easy bag removal.
15. Verify that the devices are compatible with other products that will be used in surgery prior to the procedure.
16. Store device safely in a climate-controlled environment
17. The **PMI SOLOBAG** Specimen Retrieval Bag is latex free and sterilized using ETO sterilization, except as noted.
18. Dispose of all used or damaged products using standard hospital practices for biohazard control.
19. Once the bag has been closed, the ratchet system will keep the Actuation Rod in the proximal position. **DO NOT** re-advance the Actuation Rod as this may lead to product failure.
20. If re-introducing bag-only portion into patient, excessive force should be avoided during introduction. Grasping behind the bead and introducing through the cannula with the bead-first is the required method.

POTENTIAL COMPLICATIONS FOR ALL PMI® PRODUCTS

Potential complications associated with the use of laparoscopic devices include but are not limited to organ or vessel damage/perforation, hemorrhage, hematoma, trocar site hernia, and septicemia/infection.

INSTRUCTIONS FOR USE

1. Inspect all components carefully for damage during shipment, handling or after maintenance. **Refer to picture 1**
 - A. Introducer Shaft
 - B. Thumb Rings/Grip
 - C. Finger Rings/Actuation Rod with yellow card
 - D. Specimen Bag
2. Inspect sterile packaging and verify that sterile barriers are intact. Do not use if package is compromised.
3. Verify that the sizes of all surgical components selected are compatible.
4. Open package using sterile technique and place instrument on sterile field.
5. Remove and discard the yellow card from the actuation rod. **Refer to picture 2**
6. Insert the **PMI SOLOBAG** Specimen Retrieval Bag through a 10mm or larger trocar cannula. **Refer to picture 3**
7. Ensure that the logo side of the handle is facing up indicating the bag will be in the proper position when deployed in the abdominal cavity.
8. Hold the **PMI SOLOBAG** Specimen Retrieval Bag in a syringe-like fashion, pushing the thumb ring forward to deploy and advance the rim of the bag into the body cavity. The thumb ring must be pushed completely forward until it has reached its advancing endpoint, which is indicated by a stop. **Refer to picture 3**
9. While fully deployed, the open end, or rim, of the bag is maintained in an open position. Unrolling of the bag will be initiated by deployment of the rim element. The bag maybe unrolled further by using the tip of a blunt laparoscopic instrument, such as the grasper.
10. Place specimen into the specimen bag. **Refer to picture 4**
11. Once the specimen is completely within the bag, pull back on the thumb ring, withdrawing the actuation rod proximally, until it reaches a stop. The bag will be closed, exposing the cord loop on the actuation rod. **Refer to picture 5**

NOTE: Once the bag has been closed, the ratchet system will keep the Actuation Rod in the proximal position. **DO NOT RE-ADVANCE THE ACTUATION ROD AS THIS MAY LEAD TO PRODUCT FAILURE.**

REMOVING RETRIEVAL SYSTEM, TROCAR CANNULA, AND SPECIMEN BAG:






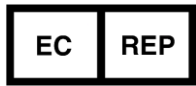






- A-1. When removing the retrieval system, trocar cannula, and the **PMI SOLOBAG** Specimen Retrieval Bag simultaneously, do not detach cord loop from the holding slot.
- A-2. With the bag still attached to the instrument, pull on the retrieval system and trocar cannula to retract the bag through the port side. **Refer to picture 6**
- NOTE:** If the bag and its contents are too large to be extracted, carefully enlarge the port side for ease of bag removal.

REMOVING THE SPECIMEN BAG SEPARATELY FROM INTRODUCER SHEATH AND ROD:

- B-1. To separate the bag from the instrument, detach the cord loop from the holding slot on the actuation rod.
Note: Do not pull on the cord loop once it has been detached from the holding slot. **Refer to picture 7 & 8**
- B-2. Once the cord has been detached, remove the introducer Shaft and rod, leaving the bag within the body cavity and the cord accessible through the trocar cannula.
- B-3. Remove the trocar cannula from the incision. **Refer to picture 9**
- B-4. Remove the specimen by pulling on the cord loop, thus retracting the bag through the port side. **Refer to picture 10**
- NOTE:** If the bag and its contents are too large to be extracted, carefully enlarge the port site for ease of bag removal.
- NOTE: Force should not be applied to the bead during removal. If required, grasp the bag ONLY, to assist with removal.**
- NOTE:** Do not attempt to pull bag through trocar cannula or introducer sheath.
- NOTE:** Do not cut bag cord prior to removal from port site.
- NOTE:** To reopen bag after detachment from actuation rod, hold alignment bead and pull mouth of bag in opposite direction. To reclose bag, hold bead and pull cord until bag is closed.

INTRODUCTION OF THE BAG PORTION ONLY FOR MULTIPLE SPECIMEN RETRACTION:

- C-1. With bag portion emptied and fully opened, use an atraumatic laparoscopic grasper to grab the bag area behind the alignment bead. **Refer to picture 11a**
- C-2. Introduce bag, bead portion first into the cannula with grasper parallel to the mouth of bag, though the desired 10mm or larger port. Applying sterile saline solution to the bag will aid in introduction. **Refer to picture 11**
- C-3. Place specimen into bag. **Refer to picture 4**
- C-4. Once specimen is completely within the bag, pull the closure suture with a second atraumatic laparoscopic grasper until the bag is completely cinched closed.
- C-5. Follow step B-4 above for specimen extraction **Refer to picture 10**

	EN	Manufacturer		EN	Single Patient Use Only
	EN	Not Made with Natural Rubber Latex		EN	Sterilized By Ethylene Oxide/EO/EIO
	EN	Do Not Re-Sterilize		EN	Authorized Representative in EU
	EN	Expiration Date		EN	
	EN	Lot Number		EN	Do not Use if Package is Damaged
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