INSTRUCTIONS FOR USE
SPECIMEN RETRIEVAL SYSTEM

IMPORTANT INFORMATION – PLEASE READ BEFORE USE!

Please read all information contained in this insert. The use of an instrument for a task other than that for which it is intended, incorrect handling, improper care, failure to adhere to all warning and precautions and misuse can lead to premature wear and/or have serious clinical consequences to the user or patient, such as injury, contamination, cross-infection, or death. Federal (USA) law restricts this device to sale by or on the order of a physician.

Before using, read the following information thoroughly. This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

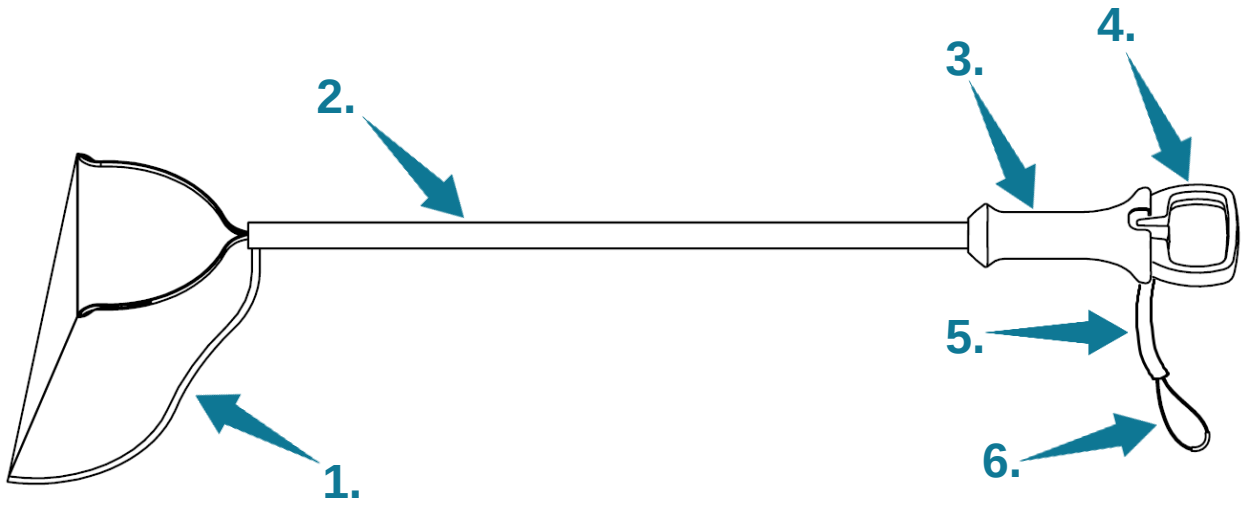
INDICATIONS FOR USE

The PMI Specimen Retrieval System is indicated for use in surgical procedures to capture organs or tissue to be removed from the body cavity during Laparoscopic Surgery via extracorporeal manual morcellation.

The PMI Specimen Retrieval System is contraindicated for laparoscopic power morcellation during gynecologic procedures. The PMI Specimen Retrieval System is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

DESCRIPTION

The PMI Specimen Retrieval System are sterile single patient use devices, which comprise of a flexible plastic bag with and without a deployment mechanism. The bag consists of a large, easily accessible opening and a closure suture that facilitates closure of the specimen bag after the specimen(s) have been collected. The deployment mechanism consists of a push-pull rod and an introducer assembly. The deployment mechanism allows for easy insertion through the cannula and full deployment the bag with the use of the biasing arms.



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 & 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 a failure. Consult medical literature and country specific regulations for specific techniques, complications, and hazards prior to the procedure.
2. Single-use products are intended for single patient use only and may not be repaired, modified or re-processed – DO NOT RESTERILIZE.
3. Failure to follow all transport, storage and handling instructions may lead to damage to the device or packaging.
4. Prior to use, carefully examine the packaging and instrument for damage. Do NOT use damaged instruments. Do NOT use the instrument when the sterile package is damaged.
5. Care must be taken when using laparoscopic instrumentation to avoid damage to major vessels and other anatomic structures.
6. Establish and maintain adequate pneumoperitoneum to reduce the risk of injury to internal structures.
7. Verify that the devices are compatible with other products that will be used in surgery prior to the procedure.
8. Safely dispose of all used or damaged products using hospital protocols and local regulations for biohazard materials.
9. This device is not intended for use with any tissue that will not fit within the confines of the specimen bag and allow complete closure of the bag.
10. Do NOT use morcellators with this device.
11. Avoid contact of the bag with sharp, cutting, electrosurgical and laser instruments as this may lead to bag rupture and spillage of contents.
12. Avoid using excessive forces during bag extraction as this may lead to bag rupture and spillage of contents. If the bag and its contents are too large to be extracted, carefully enlarge the access site to facilitate easy bag removal.
13. Do NOT attempt to remove the specimen through the trocar or cannula as this may lead to bag rupture and spillage of contents.

OPERATING INSTRUCTIONS: SUPERBAG (INTRODUCER DEVICES)

Reorder Code	Description
PNI0140	SUPERBAG™ 7mm Nylon Introducer Specimen Retrieval Bag, 140mL
PNI0240	SUPERBAG™ 10mm Nylon Introducer Specimen Retrieval Bag, 240mL
PNI0750	SUPERBAG™ 12mm Nylon Introducer Specimen Retrieval Bag, 750mL
PNI1400	SUPERBAG™ 12mm Nylon Introducer Specimen Retrieval Bag, 1400mL
PNI2000	SUPERBAG™ 15mm Nylon Introducer Specimen Retrieval Bag, 2000mL

1. Inspect the sterile packaging and device for any damage or defects. **DO NOT USE IF THE DEVICE OR PACKAGING IS DAMAGED.**
2. Verify that the sizes of all surgical components selected are compatible.
3. Open the sterile pouch using sterile technique and place instrument on sterile field.
4. Pull back on the Deployment Handle [4] until the Specimen Bag [1] is inside the Introducer Tube [2] and then remove any tip protectors if present.

5. Insert the instrument through the desired correspondingly sized port.
6. Holding the Introducer Handle [3], depress the Deployment Handle [4]. This will advance and deploy the Specimen Bag [1] and open the biasing arms into the body cavity. Ensure that "TOP" on the Deployment Handle [4] is facing up, indicating that the bag will be in the proper position when deployed.
7. Place specimen into the Specimen Bag [1].
8. Follow one of the below procedures to remove the specimen from the patient
   NOTE: If the bag and its contents are too large to be extracted, carefully enlarge the access site to facilitate easy bag removal.
9. Upon completion of the procedure, dispose of this device in accordance with hospital protocols and local regulations for biohazard materials.

TO REMOVE THE INSTRUMENT, SPECIMEN BAG, AND CANNULA TOGETHER:

a. With the bag still attached to the instrument, withdraw the instrument from the cannula until the leading edge of the bag is inside the tip of the cannula.
b. Grasp the instrument and cannula and carefully remove from the access site together.
   NOTE: This method will allow the bag to be redeployed on the same patient. To redeploy the bag, do not pull the closure suture and then repeat steps 4 through 8 above once specimen has been removed from bag.
   NOTE: If the bag and its contents are too large to be extracted, carefully enlarge the access site to facilitate easy bag removal.

TO REMOVE THE SPECIMEN BAG AND CANNULA TOGETHER:

a. To separate the bag from the instrument, release the Tether [5] from the Deployment Handle [4] by pulling back and parallel to the assembly.
b. Once the Tether [5] has been released, withdraw the Deployment Handle [4] from the Introducer Tube [2], leaving the bag within the body cavity and the Tether [5] accessible through the Introducer Tube [3].
c. Pull the Closure Suture [6] until the bag is completely cinched closed.
d. Remove the Introducer Tube [2] from the cannula, thus leaving the Tether [5] exposed though the cannula. Pull up on the Tether [5] until the leading edge of the bag is inside the tip of the cannula. Carefully remove the cannula with the bag and specimen from the access site.
   NOTE: If the bag and its contents are too large to be extracted, carefully enlarge the access site to facilitate easy bag removal.

TO REMOVE THE SPECIMEN BAG SEPARATELY FROM THE INSTRUMENT AND CANNULA:

a. To separate the bag from the instrument, release the Tether [5] from the Deployment Handle [4] by pulling back and parallel to the assembly.
b. Once the Tether [5] has been released, withdraw the Deployment Handle [4] from the Introducer Tube [2], leaving the bag within the body cavity and the Tether [5] accessible through the Introducer Tube [3].
c. Pull the Closure Suture [6] until the bag is completely cinched closed.
d. Remove the Introducer Tube [2] and cannula from the access site, thus leaving the Tether [5] exposed though the access site. Pull up on the Tether [5] until the top of the closed bag reaches the body surface or access site. Carefully remove the bag from the access site.
   NOTE: If the bag and its contents are too large to be extracted, carefully enlarge the access site to facilitate easy bag removal.

OPERATING INFORMATION – SIMPLEBAG (BAG ONLY)

1. Inspect the sterile packaging and device for any damage or defects. **DO NOT USE IF THE DEVICE OR PACKAGING IS DAMAGED.**
2. Verify that the sizes of all surgical components selected are compatible.
3. Open the sterile pouch using sterile technique and place instrument on sterile field.
4. Refer to the table below for introduction techniques depending on the size of the bag. Applying sterile saline solution to the bag will aid in introduction.

Reorder Code	Cannula Diameter	Introduction Technique
PNS0050	10mm	Grasp the tab with an atraumatic laparoscopic grasper and insert the bag completely through the desired port.
PNS0150	10mm	
PNS0240	10mm	
PNS0750	12mm	Grasp the tab with an atraumatic laparoscopic grasper and roll the short side of the bag along the shaft of the grasper. Insert the rolled bag into the appropriate size port.
PNS1600	15mm	
PNS3000	15mm	

5. Place specimen into the bag.
6. Once the specimen is completely within the bag, pull the closure suture with a second atraumatic laparoscopic grasper until the bag is completely cinched closed.
7. Once extraction is desired, prepare by pulling the specimen bag with an atraumatic laparoscopic grasper until the leading edge of the bag and closure suture is inside the tip of the cannula.
8. While maintaining the grip on the closure suture, pull the cannula and instrument out of the port site together until the top of the closed bag reaches the body surface or access site. Carefully remove the bag from the access site.
   NOTE: Do not attempt to pull the specimen through the cannula.
   NOTE: If the bag and its contents are too large to be extracted, carefully enlarge the access site to facilitate easy bag removal.
9. After removal, the bag may be opened to remove the specimen and following the above steps re-introduced to remove additional specimens from the same patient.
10. Upon completion of the procedure, dispose of this device in accordance with hospital protocols and local regulations for biohazard materials.

INSPECTION & FUNCTIONAL CHECK

It is very important to examine carefully each surgical instrument for breaks, cracks or malfunctions before use. It is especially essential to check all movable parts. **DO NOT USE DAMAGED INSTRUMENTS. DO NOT USE THE INSTRUMENT WHEN THE PACKAGE IS DAMAGED.** Never attempt to make repairs yourself. Any repairs made by the customer may void the warranty.

TRANSPORTATION & STORAGE

During transportation, avoid shaking, striking or dropping the devices or packaging or getting them wet.

Devices must be stored in a clean, dry, moisture free environment, without direct sunlight or corrosive gases. The instruments should be stored individually in their shelf box or in a protective tray with partitions.

SYMBOLS

	MR Unsafe		Manufacture Date
	Caution		Expiration Date
	Single Patient Use Only		Do Not Re-Sterilize
	Do Not Use if Package is Damaged		Consult Instructions for Use
	Catalog Number		Lot Number
	Sterilized by Ethylene Oxide (EO)		Authorized for sale or use by physician only