

EndoGuidance Specimen Retrieval Bags Instruction for Use

The following information should be read before using this device.

INTENDED USE

The EndoGuidance Specimen Retrieval Bags is used for removal of tissue specimens during a suitable laparoscopic procedure.

INTENDED PATIENT

The EndoGuidance Specimen Retrieval Bags is intended for Adults, teenagers on laparoscopic procedure. It is not intended for infants or aged higher than 70 years old, and any patient have negative medical indication against laparoscopic/endoscopic.

CONTRAINDICATIONS:

This device is not intended for use except as indicated. In addition, it is not intended for use when Laparoscopic surgery is contraindicated.

PERFORMANCE CLAIM:

1. The Device shall be able to withstand 20N pull force.
2. The Pouch body shall be able to withstand 1kg weight without damage.
3. The Drawstring shall be able to withstand 20N pull force.

DIRECTIONS FOR USE:

The instrument has specific indications for use as detailed above. In that context the surgeon is best advised to use a method which his/her own practice and discretion dictates to be best for the patient. The following instructions are a guide to recommended safe and proper function of the Auto Retrieval Pouch. Any other tissue retrieval system modes of operation not described herein are therefore performed at the discretion of the surgeon.

1. Open the primary packaging and pass to the scrub nurse (following general O.R. sterile protocol).
2. Line up the arrow on the devices handle with the logo adjacent to the finger slots further down the shaft. (Thus allowing deployment of the specimen bag with its opening uppermost).
3. Insert the black shaft of the retrieval system into an appropriately sized cannula and into the abdomen.
4. Deploy the specimen bag by pushing the handle forward i.e. moving the arrow towards logo until the top frame of the specimen bag is completely open.
5. Use an appropriate laparoscopic instrument to place the specimen into the retrieval bag. Care should be taken that sharp instruments do not come into contact with the bag.
6. Pull back the handle until the top frame of the bag is completely closed and has just returned into the shaft.
7. Pull back the cannula through which the tissue retrieval system was inserted and pull the bag from the abdomen. Cut the bag from the shaft of the device freeing the cannula for further use.

8. Should it be necessary to reduce the size of the specimen prior to removal of the bag from the abdomen, place an atraumatic clip on the bag and cut the bag away from the shaft just below the top frame. The specimen can now be reduced to an appropriate size (careful to use appropriate instruments not to compromise the integrity of the bag) for ease of removal from the abdomen.
9. When the endoscopic procedure is complete, dispose of this device in accordance with local regulations.

CAUTIONS/ WARNINGS:

1. This device is single-use and can't be re-used or re-sterilized. Do not use if package is opened or damaged.
2. Only physicians with adequate training and knowledge of these procedures should perform endoscopic procedures. In addition, medical literature should be consulted regarding techniques, hazards, contraindications, and complications prior to the performance of these procedures.
3. Before endoscopic instruments and accessories from different manufacturers are utilized together in a procedure, verify compatibility and ensure that electrical isolation or grounding is not compromised.
4. A thorough understanding of techniques and principles involved in electrosurgical procedures is necessary to avoid burn or shock hazard to patient and/or operator.
5. 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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Symbol	Definition	Symbol	Definition
	No Latex		Expiry Date
	EO Sterilized		unique device identifier
	Do Not Reuse		Indicates the medical device manufacturer
	Do not use if package is damaged.		DEHP Free
	Do not reuse		Indicates a medical device is non-pyrogenic
	Consult Instruction for Use		Indicates the item is a medical device
	Model Number		This device is prescription only
	Lot Number		Indicates a single sterile barrier.
	Manufacture Date		Single sterile barrier system with protective packaging outside