



LapSac™ Surgical Tissue Pouch



Instructions for Use

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

DEVICE DESCRIPTION

The LapSac™ Surgical Tissue Pouch is a reinforced pouch with inner liner and drawstring closure. It is available in 4 sizes, see below table.

Product Codes		Description	Size
RPN	GPN		
J-LS-050201	G16493	LapSac™ Surgical Tissue Pouch	2"x5"
J-LS-060401	G16495	LapSac™ Surgical Tissue Pouch	4"x6"
J-LS-080500	G16496	LapSac™ Surgical Tissue Pouch	5"x8"
J-LS-081000	G16497	LapSac™ Surgical Tissue Pouch	8"x10"

PERFORMANCE CHARACTERISTICS

- LapSac Surgical Tissue Pouches aiding in the isolation of various volumes of tissue during or prior to surgical removal procedures.
- A drawstring to allow for tissue containment and transferral.

CLINICAL BENEFITS AND EXPECTED CLINICAL OUTCOMES

To aid in the effective isolation of tissue during surgical procedures, allowing for removal of identified tissue before or during surgery.

INTENDED USE

The LapSac Surgical Tissue Pouch is intended to isolate tissue during or prior to surgical removal.

INDICATIONS FOR USE

The LapSac Surgical Tissue Pouch is indicated for surgical procedures in which there is a need to isolate excised tissue during or prior to removal.

INTENDED USERS

The LapSac Surgical Tissue Pouches are intended for use by physicians trained and experienced in diagnostic and interventional techniques.

PATIENT POPULATION

There is no limited patient population for use of this product. It can be used with any patient who, at the discretion of the healthcare provider, meets the indications for use.

CONTRAINDICATIONS

Not for use with power morcellators.

WARNINGS

- Use caution when removing potentially malignant or harmful tissues, to isolate contamination from surrounding tissue.
- Single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

PRECAUTIONS

Use caution if using sharp surgical instruments which could puncture, tear, or otherwise damage the LapSac Surgical Tissue Pouch.

REPORTING OF SERIOUS INCIDENTS

PLEASE NOTE: If a serious incident is suspected from using the LapSac Surgical Tissue Pouch, report the details of the incident to CooperSurgical via the online complaint form <https://www.coopersurgical.com/support/customer-complaint-form/>, by email at ProductSurveillance@coopersurgical.com, or by phone number +1 203-601-5200 Ext. 3100 and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

INSTRUCTIONS FOR USE

1. Following aseptic technique, introduce the LapSac Surgical Tissue Pouch into the abdominal cavity.
2. Place tissue to be removed from the body into the pouch.
3. Using the drawstring, carefully close the LapSac Surgical Tissue Pouch. Please note that if excess force is used, the drawstring may break or tear the LapSac.
4. Remove the LapSac Surgical Tissue Pouch from the body, taking care not to spill contents of the bag.

HOW SUPPLIED






















Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

DEVICE DISPOSAL

After the procedure, this device may be contaminated with potentially infectious substances of human origin and should be disposed of in accordance with institutional guidelines.

GLOSSARY OF SYMBOLS

Source: ISO 15223-1 and ISO 7000

Symbol	Title	Symbol	Title
	Packaging unit		Single sterile barrier system
	Catalogue number		Caution
	Batch code		Consult instructions for use or consult electronic instructions for use
	Country of manufacture ("CC" shall be replaced by either the two letter or the three letter country code)		Do not use if package is damaged and consult instructions for use
	Date of manufacture		Keep dry
	Manufacturer		Keep away from sunlight
	Use-by date	Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Medical Device		Product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations
	Do not re-use		The product conforms to the UK Device Medical Regulation 2002, as amended. The product can be freely marketed in Great Britain (England, Wales and Scotland)
	Do not re-sterilize		Importer
	Sterilized using ethylene oxide		Authorized representative in the European Community

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