INSTRUCTIONS FOR USE (IFU)

LIMAS MORCELLATOR®

THE MOST VERSATILE COMPLETE MORCELLATION SYSTEM

LIMAS MEDICAL DEVICES Pvt. Ltd

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	CONSULT INSTRUCTIONS FOR USE
	ACCOMPANYING DOCUMENTS
	DO NOT REUSE
	STERILE
	NON-STERILE
	STERILISED USING ETHYLENE OXIDE
	PACKAGE IS DAMAGED
	DATE OF MANUFACTURE
	MANUFACTURER
	USE BY DATE
	CATALOG NUMBER
	SERIAL NUMBER

*** LIMAS MORCELLATOR® and SAFETY ISOLATION BAG®- these products are covered under various granted and pending national and international patents and the names are registered Trade Marks belong to LIMAS MEDICAL DEVICES & DIAGNOSTICS Pvt. Ltd.**

LIMAS MORCELLATOR® Tissue Morcellator System
Directions for use

Please read all information carefully

This Instruction for use (IFU) manual is intended to act as technical guideline and not as a training manual. We urge medical practitioners to receive adequate training before carrying out the surgery.

1.0 GENERAL INFORMATION

The following instructions for use are intended for the use of the **LIMAS MORCELLATOR®** Tissue Morcellator. The device is engineered to provide smooth and efficient tissue morcellation. The **LIMAS MORCELLATOR®** Tissue Morcellator can be used for the extraction of tissues during laparoscopic surgery.

2.0 DEVICE DESCRIPTION

The **LIMAS MORCELLATOR®** Tissue Morcellator is a foot-pedal activated device. It consists of the following components:

Type	Sterile/ Non-sterile	Name	Reference figure
Reusable components	Non-sterile, Autoclavable/ETO	Cutter Blades (10/15/18mm) abdominal and vaginal cutter blades	Figure 1
		Morcellator Trocars (10/15/18mm)	Figure 2
	Non-sterile components, sterilize by ETO (Ethylene Tri Oxide)	Rotor Cable, Washers, Handle head Cap, Obturator and Morcellator Handle	Figures 3, 4, 5, 6 and 7,7a
Reusable parts	Not required to be sterile	Motor Drive Unit and Foot pedal	Figures 8, 9 and 10
Disposables	Sterile	SAFETY ISOLATION BAG ®	Fig : 11,12,13

Figures 1-13 show the different components of the **LIMAS MORCELLATOR®** Tissue Morcellator System.

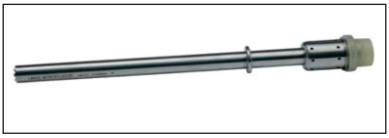
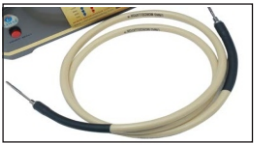


Fig 1

Fig 2



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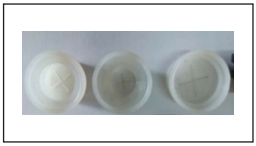


Fig 4

Fig 5

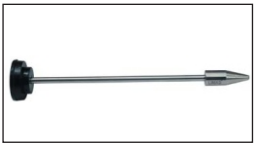


Fig 6

Fig 7

Fig 7a

Fig 8

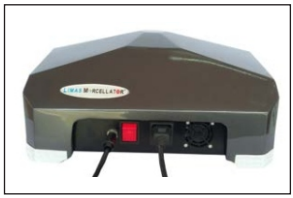


Fig 9

Fig 10

Fig 11

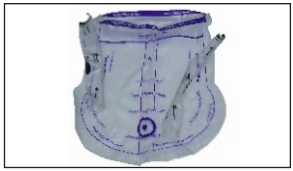


Fig 12

Fig 13

3.0 CONTENTS OF THE LIMAS MORCELLATOR® SYSTEM

The **LIMAS MORCELLATOR®** Tissue Morcellator System consists of non-sterile autoclavable components (1) Reusable Cutter Blades of 10mm, 15mm and 18mm of laparoscopic morcellation or vaginal morcellation and (2) Reusable Morcellator Trocars for Cutter Blades of 10mm, 15mm and 18mm of laparoscopic morcellation or vaginal morcellation (See Figure 1 and 2) These components are autoclavable and or sterilizable with ETO.

Figures 3-7a. Shows Rotor Cable, Washers, Handle head Cap, Obturator and Morcellator Handle respectively and these items are to be sterilized by ETO or by plasma sterilization.

Figures 8-10 shows the motor drive unit and the foot pedal. These items can be wiped with non-flammable disinfectant solutions as per hospital protocol.

Figures 11 - 13 shows the **SAFETY ISOLATION BAG®** which are supplied sterile

The **LIMAS MORCELLATOR® Motor Drive Unit (**MDU) is classified by Underwriters Laboratories with respect to electrical shock, fire, mechanical and other specified hazards in accordance with the Low Voltage Directive (LVD) 2014/35/EU and Medical Device Directive (MDD) 2007/47/EC

4.0 TECHNICAL SPECIFICATIONS OF THE MDU

4.1 Protection classes

Type of protection against electric shock:	Class I
Degree of protection against electric shock:	BF (defibrillator proof)
Mode of operation of the system:	Continuous running
Degree of protection against flammable anaesthetics:	None provided
Degree of protection against ingress of water; Motor drive unit:	IPX1 (Drip-proof)
Degree of protection against ingress of water; Motor drive unit foot pedal:	IPX8 (Water tight)

4.2 Specifications

Physical	Weight	4.5 kg, 9.9 lbs.
Electrical	Maximum power draw	166.6 VA
Functional	Speed range	100 to 3000 rpm.

5.0 INDICATIONS FOR USE

The **LIMAS MORCELLATOR®** Tissue Morcellator is intended for gynecologic,

urologic and general surgical endoscopic use by individuals who have been professionally trained for the use of such similar devices. The device can be used for the extraction of tissues during laparoscopic general surgery, laparoscopic urologic surgery and laparoscopic gynecologic surgery.

The variable speed of **LIMAS MORCELLATOR®** Motor Drive Unit (MDU) is an integral part of the device since it provides a user selectable speed range at which it drives (rotate) the components of the device.

6.0 CONTRAINDICATIONS

The **LIMAS MORCELLATOR®** Tissue Morcellator is contraindicated for use on vascularized tissues. It is not to be used as a dissecting tool. All target tissues and organs must be devascularized and dissected before morcellation.

7.0 PRECAUTIONS

7.1 General Precautions

- The directions for use manual should be thoroughly studied and make sure you stick to all the instructions given in this user manual must be while using the device.
- This product is intended for use only by clinicians with adequate training, knowledge and experience in the use of endoscopic procedures.
- The clinician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- Failure to carefully follow all applicable instructions may result in significant injury to the patient, surgeon or attendants and may have an adverse effect on procedural outcomes.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Use of the **LIMAS MORCELLATOR®** Tissue Morcellator should be considered for patients whom the physician determines are adequate surgical risks.

7.2 Procedural Precautions

Always use SAFETY ISOLATION BAG® the in-bag mor-cellation device while using LIMAS MORCELLATOR® to avoid spillage of morcellated tissues.

- The **LIMAS MORCELLATOR®** handle is assembled with the trocar of the required size of which the cutter blade will be used. Once the trocar is assembled with the handle, the handle is inserted into the abdominal cavity only with the obturator, at no situation the handle should insert into the abdomen with exposed cutter blade. Once the hand piece with obturator is entered into the abdomen, then remove the obturator and insert the cutter blade. Exercise care when inserting or removing the device from the body. Insertion and removal of the **LIMAS MORCELLATOR®** should be performed under direct visualization at all times.
- To prevent accidental injuries to the abdominal wall or similar other tissues or organs, the tissue to be morcellated should be completely exposed before using the **LIMAS MORCELLATOR®** Tissue Morcellator.
- The **LIMAS MORCELLATOR®** should not be placed in contact with tissue that is not to be morcellated.
- Sometimes it so happens that large masses of tissue move uncontrollably thus coming in contact with the device. This unintended movement of the device can cause significant injury to the patient. Hence a second pair of grasping forceps or a fixation instrument should be used to prevent large pieces of tissue from moving uncontrollably and coming in contact with the device.
- Caution should be exercised when introducing or removing instruments to prevent inadvertent damage to device. Special care should be used when inserting sharp or angled-edged endoscopic instruments to prevent tearing of the **SAFETY ISOLATION BAG®**

- Also the tenaculam or such grasping instruments should be closed well after holding on to the tissue so that the cutter blade will not accidently cause rotating over the metallic instrument and cause over heat and overload and damage to the instrument.

7.3 Device-related Precautions

- Careful inspection of the **LIMAS MORCELLATOR®** Tissue Morcellator and all associated equipment prior to use is extremely essential.
- The blade of the device should not be sharpened or modified. Bent or distorted blades can injure the patient, surgeon or the attending staff and also damage the device.
- Non-functional instruments should not be used and should be returned to the supplier.
- If any component or accessory of the device appears to be damaged, please DO NOT attempt to use it.
- Do not use the **LIMAS MORCELLATOR®** Tissue Morcellator, if any part of the device is found damaged, or if the sterility is found compromised.
- Do not use any part of the **LIMAS MORCELLATOR®** Tissue Morcellator beyond the indicated expiration date after sterilization.
- Store the **LIMAS MORCELLATOR®** in a clean, dry area away from the direct sunlight and at room temperature.
- After use, or when it is to be discarded, dispose the product and packaging in accordance with hospital, administrative and/or local government policy.
- **LIMAS MORCELLATOR®** Drive Unit is a precision instrument that must be handled with care by well trained and knowledgeable professionals. Carefully inspect the device and all associated equipment, instrumentation and cabling for wear or damage prior to use. DO NOT attempt to operate this device if any damage is observed. Contact limasmedicals@gmail.com or mail@limasindia.com for replacement of damaged devices or for service.
- Perform the specified operational inspections and tests as recommended in this instruction manual (section on Inspection and Test) prior to performing each procedure. Failure to adequately inspect and test the instrument to assure adequate performance may result in injury to the patient and /or medical personnel and may have an adverse effect on the procedures performed.
- Use only non-flammable materials when cleaning or disinfecting the MDU.
- Use ONLY the **LIMAS MORCELLATOR®** MDU and Rotor Cable to connect the **LIMAS MORCELLATOR®** products. Use of any other drive mechanisms may result in failure of the **LIMAS MORCELLATOR®** products. Use of any other drive mechanisms may result in failure of the **LIMAS MORCELLATOR®** devices to perform as intended.
- The **LIMAS MORCELLATOR®** Motor Drive Unit contains no user-serviceable components. Repairs and maintenance must be made directly by Limas Medical Devices and Diagnostics Pvt ltd only. If it is opened by any other person, company will not hold any responsibility.
- If signs of excess wear or damage are evident for assistance regarding repair or replacement.
- Medical electrical equipment needs special precautions regarding EMC and the MDU needs to be installed and put into service according to the EMC information provided below:

o The MDU has been tested and found to comply with the EMC limits for medical devices listed in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful electromagnetic interference in a typical medical installation. The **LIMAS MORCELLATOR®** MDU generates and can radiate radio frequency energy. If not installed and used in accordance with the instructions, the system may cause harmful

interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices (which can be determined by switching the equipment OFF and ON and operating the motor), the user is encouraged to attempt correction of the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the interfering equipment to outlets on different circuits.
- Consult the manufacturer or field service technician for help.
- Portable and mobile RF communications equipment can interfere with the MDU operation.
- Stacking or placing the MDU adjacent to other devices is not recommended. Where such configurations are necessary, all equipment should be carefully monitored to ensure that EMI does not degrade performance.

The use of cables, cords, and accessories other than those specified by Limas Medical Devices and Diagnostics Pvt ltd may result in increased emissions or decreased immunity of the **LIMAS MORCELLATOR®** MDU

8.0 ADVERSE EVENTS

- Accidental injury to other organs due to the device coming in contact with other tissues or organs eg. Bowel injury.
- Caution should be exercised because most of the above complications have been reported to be caused due to remnants of the morcellated tissue in the patient. Small missed specimen can get re-vascularized and grow to form another mass of tissue thus leading to complications like pain, dysmenorrhea, adenoma, parasitic fibroids or secondary fibroids etc. Hence it is very important to use **SAFETY ISOLATION BAG® in-bag morcellation device in every case where LIMAS MORCELLATOR® is used.**

9.0 OPERATIONAL INSTRUCTIONS

9.1 Overview

The **LIMAS MORCELLATOR®** Tissue Morcellator is a single hand operated device engineered to provide smooth and efficient tissue morcellation. The **LIMAS MORCELLATOR®** Motor Drive Unit is used in conjunction with the **LIMAS MORCELLATOR®** Tissue Morcellator Handle and other accessories.

Note: Failure to carefully follow all applicable instructions may result in significant injury to the patient, physician or attendants and have an adverse effect on the outcome of procedures performed.

9.2 Unpacking and General Instructions

- All the shipping containers have to be thoroughly checked for any signs of damage. In case any damage is found, contact the shipping company as soon as possible.
- Remove all components carefully from the shipping cartons and check all components to ensure they have not been damaged in shipment.

IMPORTANT: Sterilize all accessories before use as per the hospital protocol and as mentioned in the user guide.

9.3 Preparation of the device for use

1. Place the sterilized reusable handle, trocar, cutter blade, washers; handle head cap and rotor cable (sterilized at the hospital by autoclaving, ETO or plasma) in the operating area.
2. Assemble the reusable handle and trocar and this makes the hand-piece and insert the obturator into the hand-piece and lock it to the lock on the handle head. The rotor cable

is inserted into the handle as shown in the figure 20, Once the hand-piece is inserted into the abdominal cavity using the obturator, the obturator is removed and carefully insert the cutter blade with its washer placed on it, advance it to the first lock and lock it at the locking pinholes of the cutter blade with the handle. And once the pneumoperitoneum is well created, the cutter blade is advanced further so that the cutter blade is in exposed position. Also during the procedure, as and when needed the cutter blade can be withdrawn and kept in the non-exposed position. Once the cutter blade is ready for morcellation, assemble the handle head cap on to the handle before performing the procedure. Fig. 16 shows the different size if trocars, obturators and cutter blades interchangeable on to the same handle.

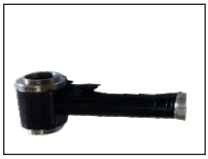


Fig 14

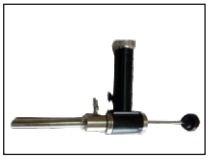


Fig 15


Fig 16

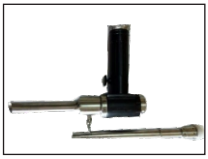


Fig 17


Fig 18


Fig 19


Fig 20

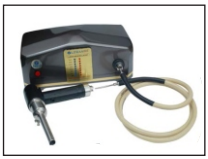


Fig 21

3. The rotor Cable is inserted on to the handle by pressing the knob on the handle and an audible click is heard which indicates that the rotor cable has been locked into the handle.
4. Check whether the rotor cable has been securely locked in the handle.
5. The Rotor Cable has both the ends similar (Fig.3), either of the end can be connected to the handle or to the MDU

9.4 Assembly of the MDU

Please note that the MDU and other accessories are shipped non sterile.

The MDU system components should be assembled as follows:

- Attach the power cord to the back of the **LIMAS MORCELLATOR® MDU**.
- Connect the power cord of the **LIMAS MORCELLATOR® MDU** to a 110/230 VAC grounded receptacle.
- Attach the foot pedal connector to the **LIMAS MORCELLATOR® MDU**.
- Connect the Rotor Cable cord to the **LIMAS MORCELLATOR® MDU**.
- The rotor cable receptacle is located on the front of the **LIMAS MORCELLATOR® MDU** Press down on the metal tab until it locks in place.
- Carefully insert the squared end of the rotor cable into the receptacle. Rotate the metallic handle head until it engages with the adaptor.

IMPORTANT: Do not attempt to sharply bend the motor drive rotor cable to a diameter of less than 8 inches (20 centimeters). Sharply bent or kinked Motor Drive rotor cable can cause the **LIMAS MORCELLATOR® MDU** to overheat and stop momentarily. During a procedure, a minimum of 1.5 metres distance should be maintained between the MDU and the patient such that the rotor cable is as straight as possible to allow the rotor cable to the surgeon's hand is in a large arc with no bends or loops.

9.5 Connecting the rotor cable to the LIMAS MORCELLATOR® MDU

6. Connect the rotor cable to the motor drive unit (See Figure 22),

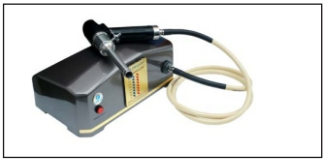


Fig 22

Fig 23

7. Switch ON the main power switch.
8. The MDU is powered on by pressing the switch located at the front of the MDU which glows when the Power is switched ON and the speed can be adjusted by pressing the blue buttons on the control panel and the rpm ranging 100 to 3000. The ideal speed for most of the cases would be 400 or 800rpm. .

9.6 Insertion of the device in the body

9. Insert the sterilized obturator (re-sterilized by autoclaving/ ETO if it has already been used before) through the proximal end of the hand-piece and lock into the handle head pin.

Fig 24

Fig 25

Fig 26

Fig 27

10. Now insert the hand-piece assembly with obturator through the keyhole into the abdomen.
11. Once the hand piece is in place in the abdomen, the Obturator can be released by pressing the button on the handle and removed from the handle (Fig. 24).

9.7 Tissue morcellation with the LIMAS MORCELLATOR®

12. To expose the cutter blade, the cutter blade is inserted fully into the hand-piece and locked at the second pinhole slot with handle. And the handle head cap is assembled on to the handle head.

Fig 28

Fig 29

13. Through the opening of the handle head cap a laparoscopic grasping instrument (tenaculam) is inserted through the lumen to grasp the tissue for morcellation.
14. The tissue is grasped with the grasping instrument, held in place and morcellated by switching ON the **LIMAS MORCELLATOR®** and activating the foot pedal.
15. The morcellated tissue can be drawn proximally through the lumen of the **LIMAS MORCELLATOR® hand-piece.**
16. A pneumoperitoneum valve – a double decker washer has been provided to prevent loss of insufflation gas which is placed on the head of the cutter blade, when no instrument traverses the lumen (Fig. 4).
17. Every time to enable the cutting of the tissue, the foot pedal is activated by the operating surgeon after holding the tissue with the tissue grasping instrument. It is very important to keep the grasper closed tightly while morcellating.

9.8 Removal of the device

18. After morcellation is completed, the MDU can be switched OFF and also by lifting the foot from the pedal switch each time the working of the MDU can be stopped.
19. After the cutter blade rotation has stopped, the handle head cap is dis assembled and the cutter blade is kept in the deactivated position and then only the morcellator hand-piece is removed from the abdomen. Each part is dismantled, in such a way that the last assembled part is dismantled first.

20 **Important:** The cutter blade must be completely covered while withdrawing from the patient's body or it could cause serious injury to the surrounding organs and tissues.

9. 9 immediate post-operative steps

1. Pressing the button provided at the lower end of the handle will unlock the rotor cable from the handle
2. The reusable hand-piece assembly is dismantled and each component is kept in a container for thorough cleaning. Please ensure that after proper disinfection and cleaning thoroughly with water, the handle is dried well and made completely water free by blowing with air/ hot air and stored on the handle rest (Fig.23) to drain off any trace of water before sent for sterilization procedures followed at your hospital.
3. Clean the rotor cable assembly thoroughly by wiping it with a dry cloth. It should be stored in a clean, dry place away from direct sunlight.
4. Please note that each reusable item should be re-sterilized by ETO/ plasma before using it again.
5. Please ensure to rotate the morcellator handle at least weekly once by connecting to the motor drive unit with rotor cable, if it is not used regularly.

10.0 POTENTIAL COMPLICATIONS

The following complications have been reported as consequences that may occur in association with a morcellator:

- Laparoscopic port site pain
- Scar dehiscence
- Scar rupture
- Excessive blood loss
- Pelvic pain
- Dyspareunia
- Dysmenorrhea
- Abdominal pain
- Adhesions.
- Bowel distension
- Hematoma
- Pelvic abscess
- Tachycardia
- Fever

11.0 WARNING

- Do not use if sterility is compromised. If any damage is found any/parts of the **LIMAS MORCELLATOR®** system and its components, call the representative who supplied the product to your institution.
- Do not use any other power cable except the one supplied along with **LIMAS MORCELLATOR®**
- After use or intended number of usage, disposal should be done in a safe manner in accordance with the sharp product disposal procedure followed in your institution or as per applicable regulations.

12.0 MDU-SPECIFIC INSTRUCTIONS

12.1 Transport, storage, care and maintenance

The **LIMAS MORCELLATOR®** Motor Drive Unit should be transported\stored and used at temperatures between -18ºC and 55ºC, 30 to 75% relative humidity, and -0.5 to +1.5 atmospheric pressure (507 to 1520 hPa). Do not drop or immerse the MDU in liquid.

12.2 Cleaning/ Reuse

The MDU can be reused many times. It should be wiped clean using a damp cloth or sponge and soapy water. Do not use a wet cloth or sponge.

Important: Disconnect the **LIMAS MORCELLATOR®** MDU from the power supply before cleaning.

13.0 WARRANTY AND CUSTOMER SERVICE

The **LIMAS MORCELLATOR®** is manufactured for use only by qualified medical practitioners who have been trained in their use.

- Any damages which might arise or be caused, whether by the customer or by any of the users of the products, as a result of;
- Misuse, mishandling, and/or improper operation.
- Repairs or modification performed other than by a Limas Medical Devices and Diagnostics Pvt ltd authorized repair facility.
- Use in any manner or medical procedure, other than those for which it is designed.
- Any special, indirect and/or consequential damages of any kind and however caused arising from the sale or use of the products. THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED, AND/OR STATUATORY, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS AND/OR SUITABILITY FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON Limas Medical Devices and Diagnostics Pvt ltd.

Caution: Federal Law restricts this device to sale by or on the order of a physician.

14. SAFETY ISOLATION BAG®

THE PNEUMOPERITONEUM DEVICE FOR POWER MORCELLATION

PLEASE READ ALL INFORMATIONS CAREFULLY: This Instruction for Use (IFU) manual is intended to act as technical guideline and not as a training manual. We urge medical practitioners to receive adequate training before using the device. The physician should read this entire manual with particular attention to the Warnings and Precautions and be thoroughly familiar with the use of the device prior to performing any clinical procedure.

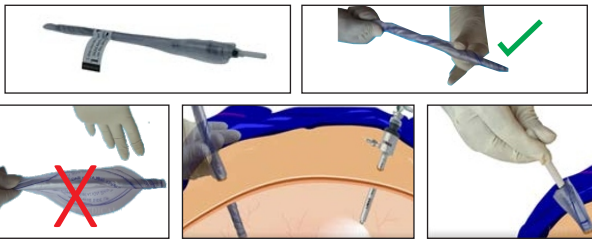
14. 1. GENERAL INFORMATION The following Instructions for Use are intended for the use of **SAFETY ISOLATION BAG®** and its introducer.

14. 2. INTENDED USE: SAFETY ISOLATION BAG® is meant for use by surgeons who have been professionally trained in the use of laparoscopic power morcellator devices and laparoscopic procedures. **SAFETY ISOLATION BAG®** is a single-use disposable device intended to be used as a receptacle for laparoscopic removal of tissue masses during endoscopic procedures such as, ovarian cyst, laparoscopic myomectomy or laparoscopic hysterectomy etc. **SAFETY ISOLATION BAG®** is indicated to laparoscopically isolate the benign tissue mass such as myoma and uterus during morcellation procedure using a power morcellator by trained surgeons.

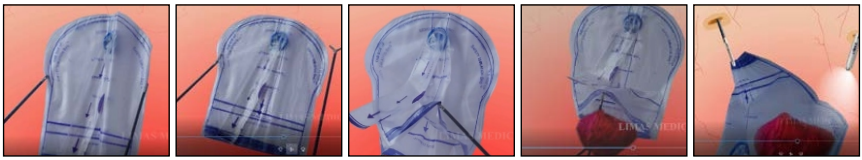
14. 3. PROCEDURE STEPS:

14. 3a. Once ready for power morcellation, widen the morcellation port incision enough considering the size of the morcellator and the morcellation bag. Slide-out the paper tag from the device as shown on the tag by holding just below the paper tag. Insert the ready to insert **SAFETY ISOLATION BAG®** into the abdominal cavity directly through the incision through which the morcellation will be performed, Once the device is pushed maximum into the

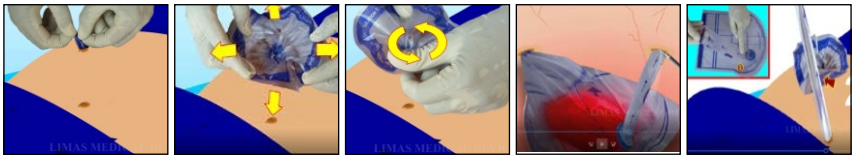
abdominal cavity. Pull out the flexible introducer from the **SAFETY ISOLATION BAG®** by pulling with an anti-clockwise rotation on the introducer**.** And the **SAFETY ISOLATION BAG®** is fully pulled into the abdominal cavity using a non-traumatic grasper.



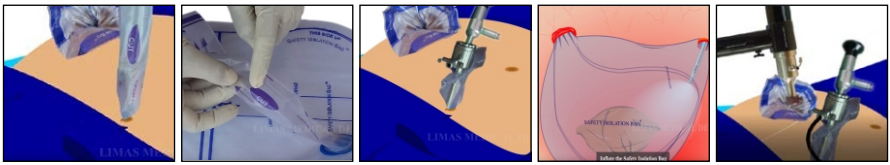
14. 3b. Open the **SAFETY ISOLATION BAG®** by holding at the flaps of the device using non-traumatic graspers ensuring the tubular guides are seen upside. Make sure that the body of the device is fully opened before trying to place the tumour inside the device. Place the tissue specimens to be removed inside the **SAFETY ISOLATION BAG®** and push it to the bottom of the bag**.**



14. 3c. Once the specimens are placed inside, **-** pull out the mouth of the **Safety Isolation Bag®** edge- by- edge till the marking, through the morcellation port using a non-traumatic grasper, keeping the maximum body of the device inside the abdominal cavity. Clamp the mouth of the device with an artery forceps. Then pull out the **tubular guide** through the primary port either by rail roading or by using a 5 mm telescope. Pull the tubular guide till all the three arrow marks on the tubular guides are brought out.

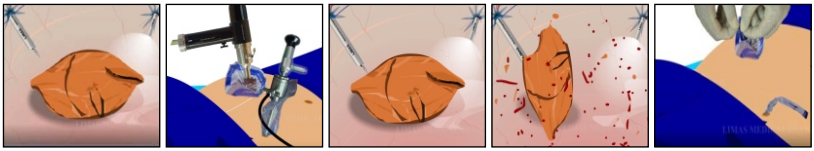


14.3d. Make a small opening to pass the telescope and trocar cannula through the tubular guide. Along **with gas flow,** advance the telescope first through the tubular guide till it passes through the valve's opening under vision and once the telescope entered the body of the device, then push the trocar fully into the body of the device. Inflate the device with gas. Once the trocar is well entered, tie outside the tubular guide, with one of the thread provided along with the device.



14.3e. Once the **SAFETY ISOLATION BAG®** is completely filled up, untwist the mouth opening of the device and under vision introduce the **LIMAS MORCELLATOR®** hand piece through the mouth opening of the **SAFETY ISOLATION BAG®.** Put a Tie outside the mouth of the device and the morcellator hand piece with another thread. Once the morcellation is complete

and the tissues are extracted, remove the telescope and the morcellator hand piece after untying the threads. **Put a tight knot just below the opening made on the tubular guide**. and pull out the **SAFETY ISOLATION BAG®** through the morcellation port holding at the mouth of the device.



14.4. PRODUCT SUMMARY : SAFETY ISOLATION BAG® the Single-use Pneumoperitoneum Device comprises of a medical grade flexible bag with a wide mouth opening which is made up of single or multi layer construction with tubular guides (single or double) for insertion of telescope and or other hand instruments. **SAFETY ISOLATION BAG®** is rolled over to the flexible introducer having a blunt tip for easy insertion of **SAFETY ISOLATION BAG®** through the laparoscopic port/ incision. The **SAFETY ISOLATION BAG®** Pneumoperitoneum Device and introducer (flexible obturator) are disposable components and are supplied sterile for one time use only. Once the device is inserted into the abdominal cavity unfold the device such that the tubular guide is kept upside. The mouth end is utilised for insertion of the pelvic masses into the device which are to be morcellated or extracted using an electromechanical morcellator. The tubular guides help the surgeons to perform the morcellation with telescope and or hand instruments through the existing incisions.

14. 5.AVAILABLE SIZES:

Available with single or double tubular guides (multiple instruments channel) having capacity of **SMALL(S) -1800ml, LARGE(L) - 2500ml, DOUBLE LARGE (LL) -3200ml, EXTRA LARGE SMALL (XLS) -4200 & EXTRA LARGE (XL) – 5000ml**

with Single Tubular Guide | with Double Tubular Guide

14.6. CONTRAINDICATIONS

SAFETY ISOLATION BAG® should not be used for morcellation or removal of tissue which is suspected or confirmed to be cancerous.

14.7 WARNINGS & PRECAUTIONS

14.7a. General Precautions

The Instructions for Use - manual should be thoroughly studied and ensured that all the instructions given in this user manual are followed while using the device. This product is intended for use only by clinicians with adequate training, knowledge and experience in the use of laparoscopic endoscopic procedures. The clinician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

Failure to carefully follow all applicable instructions may result in significant injury to the patient, surgeon or attendants and may have an adverse effect on procedural outcomes.

Good surgical practices should be followed for management of contaminated or infected wounds.

Use of **SAFETY ISOLATION BAG®** should be considered in patients whom the physician determines are not high-risk surgical candidates.

14.7b. Procedural Precautions

The sharp blade of the Morcellator should be kept completely covered or in "OFF" configuration during its insertion and removal through the **SAFETY ISOLATION BAG®** Insertion of **SAFETY ISOLATION BAG®** through the laparoscopic port, morcellation of tissue masses inside **SAFETY ISOLATION BAG®** and removal of **SAFETY ISOLATION BAG®** from the abdominal cavity should be performed under direct visualization at all times. **SAFETY ISOLATION BAG®** is devised to act as a Pneumoperitoneum Device**,** a containment receptacle during endoscopic morcellation or tissue extraction procedures of a benign pelvic tissue masses after the tissues have been detached from its stalk.

Caution should be exercised when introducing or removing sharp instruments to prevent inadvertent damage to the device. Special care should be exercised when inserting sharp or angled-edged endoscopic /laparoscopic instruments to prevent tearing of the device.

14.7c. Device-related Precautions

Careful inspection of the **SAFETY ISOLATION BAG®** and all associated equipments prior to use is extremely essential. If the sterile packaging of **SAFETY ISOLATION BAG®** appears to be damaged or if the seal is opened, please DO NOT attempt to use it as the sterility of the device may have been compromised.

SAFETY ISOLATION BAG® and its introducer are single use disposable devices. DO NOT re-sterilize or re-use.

Do not use any part of **SAFETY ISOLATION BAG®** or introducer beyond the indicated expiration date. **SAFETY ISOLATION BAG®** is intended for only one-time use in surgery. **SAFETY ISOLATION BAG®** should be constantly monitored by video when used for morcellation or tissue extraction.

Follow aseptic techniques, while introducing the **SAFETY ISOLATION BAG®** into the abdominal cavity. It is recommended to use blunt instruments for holding or pulling out the device so as to prevent damaging integrity of the product. Laparoscopic Power Morcellator should be introduced inside the **SAFETY ISOLATION BAG®** while in "OFF" configuration and with a clockwise spiral movement. Blunt obturator of the morcellator should always be used for while introducing a tissue morcellator into **SAFETY ISOLATION BAG®**

While using **SAFETY ISOLATION BAG®** in conjunction with exposed blades or cutting instruments, care should be taken to avoid contact with **SAFETY ISOLATION BAG®** as this may rupture the device. **SAFETY ISOLATION BAG®** should not be used with vacuum-assisted Morcellator. After use, disposal should be done in the safe manner in accordance with the applicable regulations or as per the disposal procedure followed in your healthcare institution.

14.8. ADVERSE EVENTS & POTENTIAL COMPLICATIONS

SAFETY ISOLATION BAG® system may get ruptured during surgery and may cause spillage of tissues, blood or fluids in the patient. If this happens, the tissue could get left in the body and cause an infection, pain, or tissue growth, including cancerous growths. As with any surgical procedure, there are also risks of damage to surrounding tissues or having to convert to an open surgery (with bigger incisions).

14.9. HOW SUPPLIED

SAFETY ISOLATION BAG® Pneumoperitoneum Device rolled on to its Introducer is packaged in peel-open Tyvek pouches. The product is supplied and is intended for one-time use.

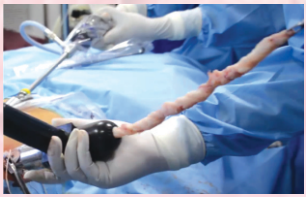
Do not use if the packaging of the product is damaged or unsterile. Store the **SAFETY ISOLATION BAG®** in a dark, dry and cool place. Avoid extended exposure to light. Upon removal from package in an aseptic area, inspect the product to ensure no damage has occurred.

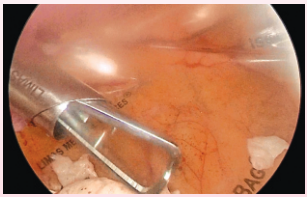
14.10. TRANSPORT, STORAGE, CARE AND MAINTENANCE

SAFETY ISOLATION BAG® should be transported, stored and used at temperatures between15°C and 60° C, and 30 to 75% relative humidity, and 0.5 to + 1.5 atmospheric pressure (507 to 1520 hpa). Store the **SAFETY ISOLATION BAG®** in a clean, dry area away from the direct sunlight and at room temperature.

After use, dispose **SAFETY ISOLATION BAG®** and its packaging in accordance with hospital, administrative and/or local government policy. **SAFETY ISOLATION BAG®** is normally packaged as a STERILE device. **SAFETY ISOLATION BAG®** is intended for one-time surgical use only. Do not reprocess, re-use or re-sterilize **SAFETY ISOLATION BAG®**.

14.11. Caution: Federal Law restricts this device to be sold by or on the order of a physician.





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