












REFER TO INSTRUCTION MANUAL/ BOOKLET

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CAUTION: Device to be sold on the order of a licensed physician.

Symbols

	Consult Instructions for use
	Do not re-use
	Do not re-sterilize
	Sterilized using irradiation
	Date of Manufacture
	Manufacturer Veol Medical Technologies Pvt. Ltd. A-747, Near Pavan Bus Stop, MIDC Pawane, TTC Industrial Area, Koparkhairane, Navi Mumbai 400705. Maharashtra, India. Ph: +91-882-882-0407 Email: info@veolmedtech.com Website: www.veolmedtech.com
	Medical Device
	Do not use if package is damaged
	Keep away from direct sunlight
	Keep dry
	Caution See instruction for use
	Single sterile barrier system

	Expiry date
	Latex Information: The MorSafe® Tissue Morcellation Bag XG-500 is latex free.
	Phthalate Information: The MorSafe® Tissue Morcellation Bag XG-500 is Phthalate free.
	This device is to be sold by or on the order of a physician only
	Quantity
	Lot Number
	Storage Temperature Range +10°C to +55°C
	EC- Representative Mars Medical, Landhausstrasse 46, 70190 Stuttgart. Germany. Contact: +49 1751938653, Email Id.: info@marsmedical.de EUDAMED SRN No. DE-AR-000006312
	CE mark and identification number of the Notified Body TÜV SÜD. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC. Notified Body: TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany, ID No.0123

Date of Initial Issue: 17-10-2024

Date of Revision: NA

IMPORTANT!

Please read all information carefully.

1 General Information

1.1 Intended Use

MorSafe® Tissue Morcellation Bag is meant for use by surgeons who have been trained in the use of MorSafe® and laparoscopic power morcellator devices such as Versator® Tissue Morcellation System.

MorSafe® Tissue Morcellation Bag is a single-use disposable device intended to be used as a receptacle for laparoscopic removal of benign tissue masses during gynecological procedures such as laparoscopic myomectomy or laparoscopic hysterectomy.

1.2 Indications

MorSafe® Tissue Morcellation Bag is indicated to laparoscopically isolate the benign tissue mass such as myoma and uterus during morcellation procedure using a power morcellator by a trained surgeon.

1.3 Contraindications

MorSafe® Tissue Morcellation Bag should not be used for morcellation or removal of tissue, which is suspected or confirmed to be cancerous.

Do not use the MorSafe Tissue Morcellation Bag where laparoscopic procedures are contraindicated.

1.4 Intended User profile:

The device is intended to be handled by the medical personnel and professionals qualified in the transportation, preparation, sterile processing, and use of surgical devices. This includes scrub technicians, circulating nurses, and sterile processing technicians. This product is intended for use only by medical professionals with adequate training, knowledge and experience in the use of endoscopic / laparoscopic procedures.

1.5 Intended patient population:

The MorSafe Tissue Morcellation Bag is intended to be used in female patients aged 18 years and older and indicated for laparoscopic myomectomy or laparoscopic hysterectomy. The patient should have appropriate medical status to undergo surgery. The indications for surgery may vary from patient to patient.

2 TECHNICAL SPECIFICATIONS

2.1. Technical Specifications of MorSafe® Tissue Morcellation Bag (XG-500)

SL. NO.	SIZE	BIGGER OPENING WIDTH	BIGGER OPENING DIAMETER	SMALLER OPENING DIAMETER	VOLUME (WORKING SPACE)
1.	SMALL	≈ 195 mm	≈125 mm	φ 6 mm	1.6 litres (1600ml)
2.	MEDIUM	≈ 210 mm	≈ 135 mm	φ 6 mm	2.1 litres (2100ml)
3.	LARGE	≈ 225 mm	≈ 145 mm	φ 6 mm	2.6 litres (2600ml)

2.2. Technical Specifications of Introducer Sheath

SL. NO.	DESCRIPTION	SIZE
1.	INTRODUCER, CYLINDRICAL WITH SLIT	13.4 mm OD x 13mm ID

2.3. Classification

Classification	According to Directive 93/42/EEC (MDD)	Class IIa Rule 6
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3 WARNINGS & PRECAUTIONS

3.1 General Precautions

- 3.1.1 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.
- 3.1.2 The clinician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- 3.1.3 The right size of MorSafe® Tissue Morcellation Bag should be selected prior to surgery by referring to table no. 5.1.
- 3.1.4 Do not overfill MorSafe® Tissue Morcellation Bag as it may prevent sufficient insufflation & visualization of the tissue & MorSafe® Bag during the surgical procedure.

- 3.1.5 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.
- 3.1.6 Good surgical practices should be followed for management of contamination or infected wounds.
- 3.1.7 Use of MorSafe® Tissue Morcellation Bag should be considered in patients whom the physician determines are not high-risk surgical candidates.

3.2 Procedural Precautions

- 3.2.1 The Sharp blade of morcellators like Versator® Tissue Morcellator should be kept completely covered or in "OFF" configuration during its insertion and removal through Morsafe®.
- 3.2.2 Hot Instrument tips must not touch the morcellation bag.
- 3.2.3 Insertion of MorSafe® Tissue Morcellation Bag through the laparoscopic port, morcellation of benign tissue mass inside MorSafe® and removal of MorSafe® from the abdominal cavity should be performed under direct visualization at all times.
- 3.2.4 MorSafe® is devised to act as containment receptacle during laparoscopic morcellation procedure of a benign tissue, after the tissue has been detached from its stalk.
- 3.2.5 Caution should be exercised when introducing or removing sharp instruments to prevent inadvertent damage to device seals. Special care should be exercised when inserting sharp or angled-edged endoscopic / laparoscopic instruments to prevent tearing of the seals.
- 3.2.6 MorSafe® Tissue Morcellation Bag is not intended for removal of large volume of insufficiently morcellated tissue from the abdomen cavity unless the abdominal incision is accordingly enlarged for its removal. Excessive attempts to pull such tissue through a small incision could lead to damage to MorSafe® bag with resulting spillage of tissue into the peritoneal cavity.

3.3 Device-related Precautions

- 3.3.1 Before opening the sterile pack ensure that the right size of bag is selected. If incorrect size is chosen and product is removed from the protective packaging it must not be re-placed again in the packing.
- 3.3.2 Careful inspection of MorSafe® Tissue Morcellation Bag and all associated equipment prior to use is essential.
- 3.3.3 If the sterile packaging of MorSafe® Tissue Morcellation Bag is damaged or if the seal is opened, please DO NOT attempt to use it as the sterility of the device may have been compromised.
- 3.3.4 MorSafe® Tissue Morcellation Bag and its introducer are single use disposable devices. MorSafe® is intended for one-time use in surgery. DO NOT re-sterilize or re-use.
- 3.3.5 Do not use any part of MorSafe® Tissue Morcellation Bag or introducer beyond the indicated expiration date.
- 3.3.6 MorSafe® Tissue Morcellation Bag should be constantly visually monitored when used for morcellation.
- 3.3.7 In case of damage caused to the bag below the band area on the bigger opening (away from the
- 3.3.8 wire ring) during morcellation, the procedure should be stopped immediately and the use of the MorSafe® Tissue Morcellation Bag should be discontinued to prevent spillage of bag contents within the patient body.
- 3.3.9 Follow aseptic technique, while introducing MorSafe® into the abdominal cavity.
- 3.3.10 It is a must to use blunt instruments so as to prevent damaging integrity of the MorSafe®.
- 3.3.11 Laparoscopic Power Morcellator, such as Versator® Tissue Morcellator, should be introduced inside MorSafe® while in 'off' configuration. Obturator should always be used while introducing a tissue morcellator inside MorSafe®.
- 3.3.12 While using MorSafe® in conjunction with exposed blades or cutting instruments, care should be taken to avoid contact with MorSafe® device as this may rupture the device.
- 3.3.13 MorSafe® should not be used with vacuum-assisted Morcellator.
- 3.3.14 After use, disposal should be done in a safe manner in accordance with the applicable regulations or as per the disposal procedure followed in your healthcare institution.
- 3.3.15 Veol Medical Technologies Pvt. Ltd. explicitly warns against modifying the product. Any modification leads to the exclusion of liabilities by Veol.

4 ADVERSE EVENTS & POTENTIAL COMPLICATIONS

Improper techniques may lead to rupture of the MorSafe® Tissue Morcellation Bag and cause spillage of tissues, blood or fluids in the patient. If this happens, a few tissues may be left in the body and cause infection, pain or tissue growth, including cancerous growths. As with any surgical procedure, there are also risks of damage to surrounding tissues or the need to convert to open surgery.

5 OPERATIONAL INSTRUCTIONS

- 5.1 Open the packaging of the MorSafe® Tissue Morcellation Bag and Introducer Sheath in a sterile Area, remove the separator from the MorSafe® Tissue Morcellation Bag and remove the Introducer Sheath from the separator.



Figure 1: Packaged MorSafe® Tissue Morcellation Bag

- 5.2 Fold the Morcellation Bag and place it in the Introducer Sheath as shown in Figure 1. Ensure that the Morcellation Bag is slightly outside the Introducer Sheath at the end marked as 'INSERT'. This is to enable pulling out of the Morcellation Bag when it has been introduced in the abdomen.



Figure 2: Folded MorSafe® in the Introducer Sheath

- 5.3 Insert the Introducer Sheath with the MorSafe® in the patient through the 15 mm incision as shown in Figure 2.

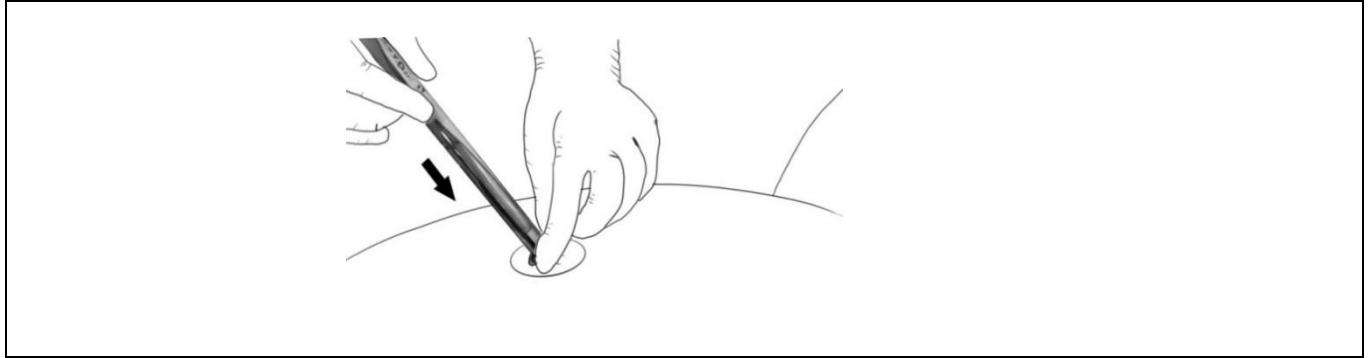


Figure 3: Insertion of Introducer Sheath with MorSafe®

- 5.4 Pull the Introducer Sheath out of the incision while simultaneously pulling the MorSafe® Tissue Morcellation Bag in the abdominal cavity.
- 5.5 Manipulate the big opening of the MorSafe® Tissue Morcellation Bag using blunt grasper till the opening opens up by itself as shown in Figure 4.

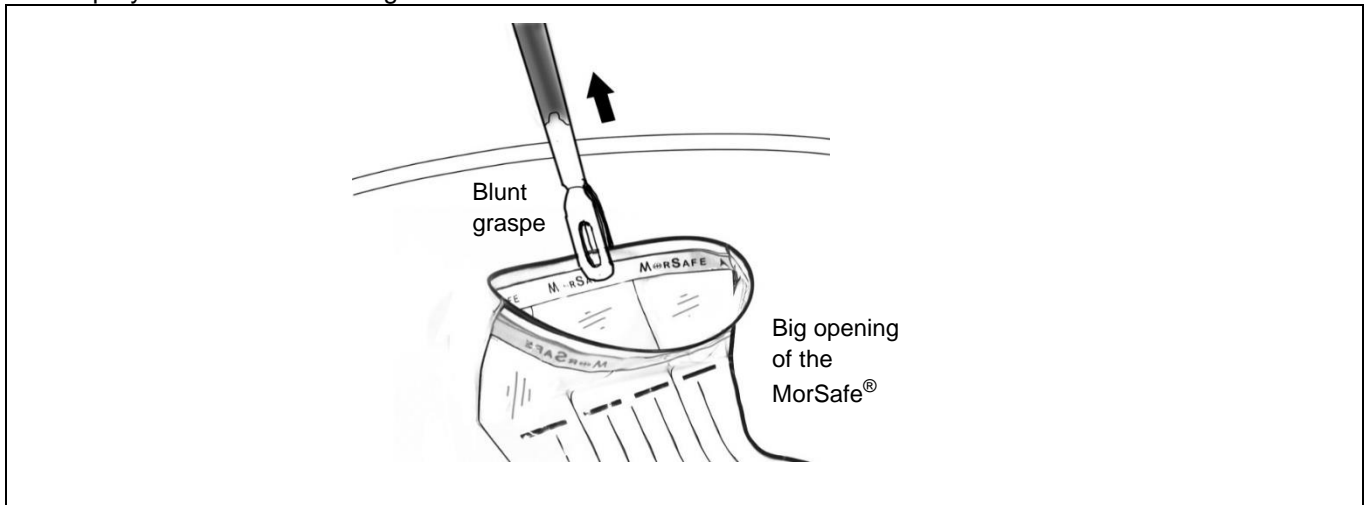


Figure 4: Manipulation of big opening of the MorSafe® Tissue Morcellation Bag

- 5.6 In the Model XG-500 when the text 'MorSafe®' in Black color is seen on the Blue band or when the text "Morsafe®" in Blue color is seen on the Black band just below the opening, it means that this is the inner side of the MorSafe® Tissue Morcellation Bag. Alternatively, the words "Blue Side" and "Black Side" are seen in mirror image and the text 'MorSafe®' on the neck of the opening is not visible when seen from the outside of the Morcellation Bag. This is for the surgeon to distinguish between the inside and outside of the MorSafe® Tissue Morcellation Bag.

5.7 Grasp the tissue to be morcellated and place it inside the Bag as shown in Figure 5.

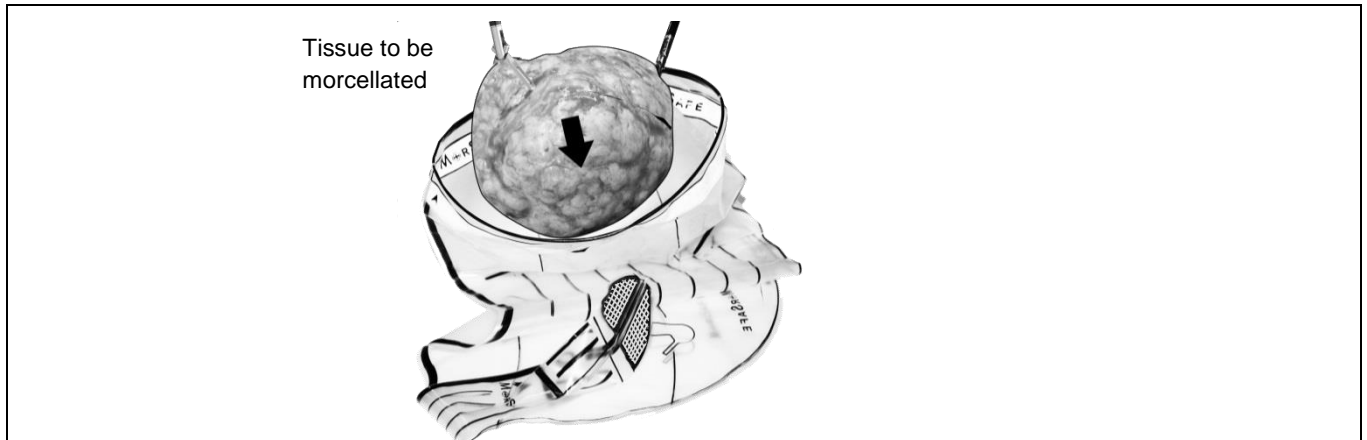


Figure 5: Placement of tissue in the MorSafe® Tissue Morcellation Bag

5.8 Using blunt graspers, grasp the big opening near the arrow mark as shown in Figure 6.

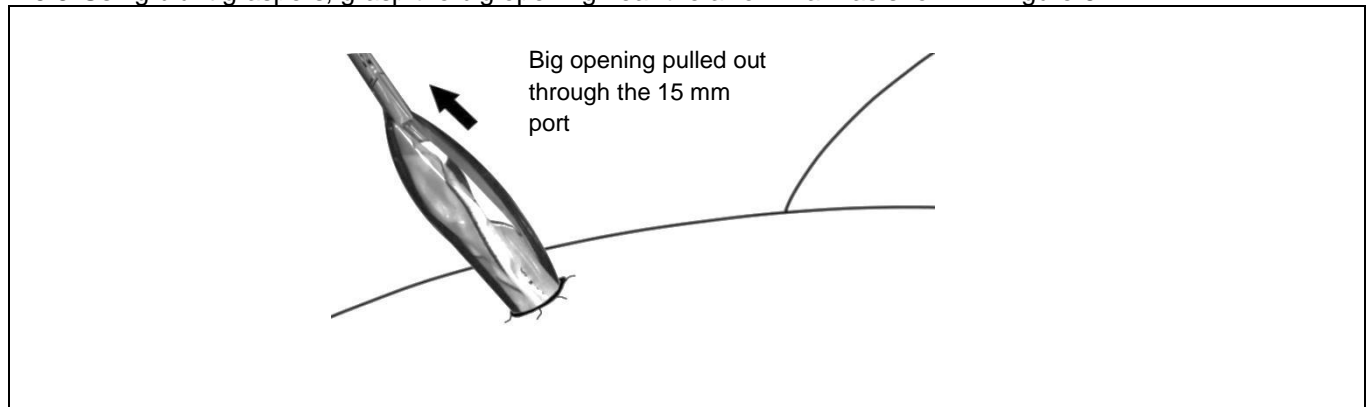


Figure 6: Pulling out the MorSafe® Tissue Morcellation Bag

5.9 Pull out the MorSafe® Tissue Morcellation Bag XG-500 through the 15 mm port till the bold line is completely outside the body as shown in Figure 7. This will make the big opening come out of the body (Figure 7).

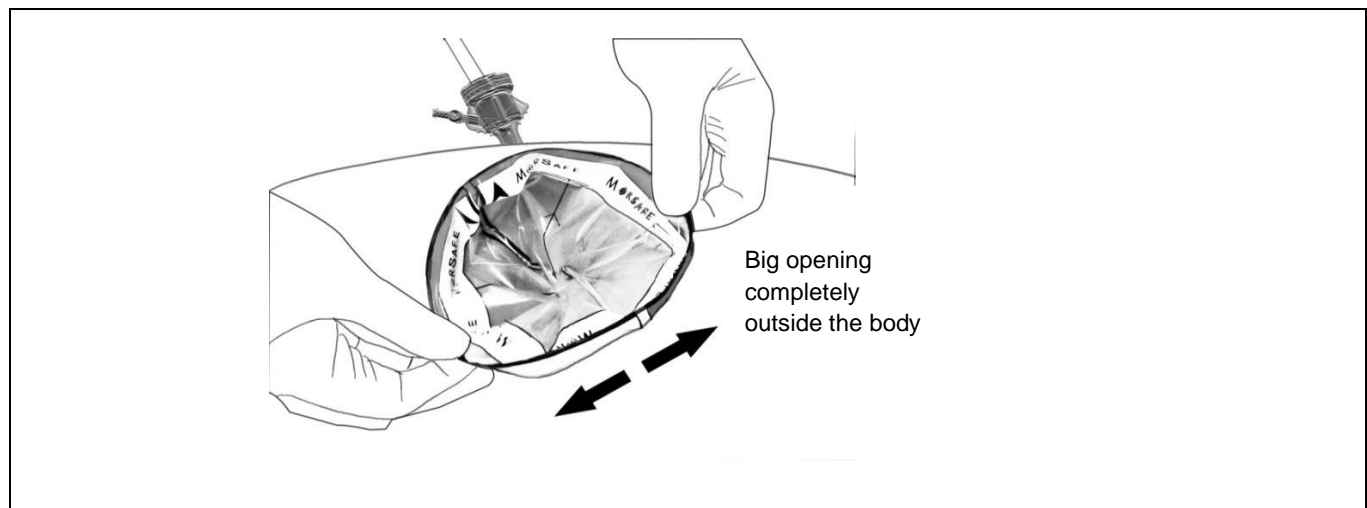


Figure 7: Big Opening of the MorSafe® Tissue Morcellation Bag outside the body

5.10 Now remove the Telescope from the umbilical port and insert it through the side port (Figure 8).

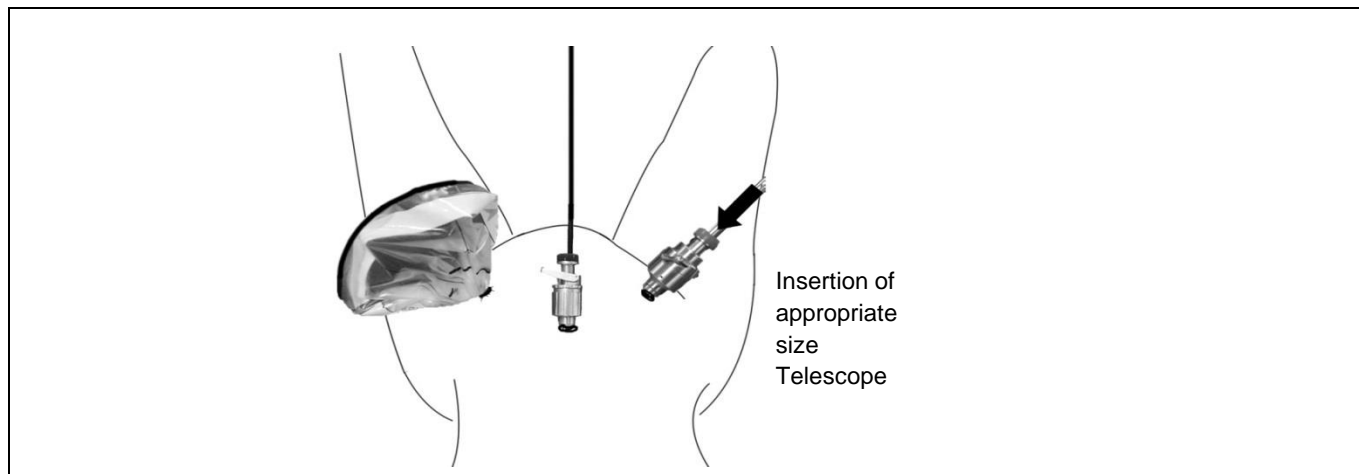


Figure 8: Insertion of Telescope through the side port

- 5.11 Insert the grasper into the abdominal cavity through the umbilical port.
- 5.12 Locate the tail end of the MorSafe® Morcellation Bag with the help of the distinctive Blue and Black color checkered pattern provided on the tail.
- 5.13 With the help of the grasper that has been passed through the umbilical port, pull the tail end out through the umbilical port (Figure 9).
- 5.14 Remove the trocar from the umbilical port.

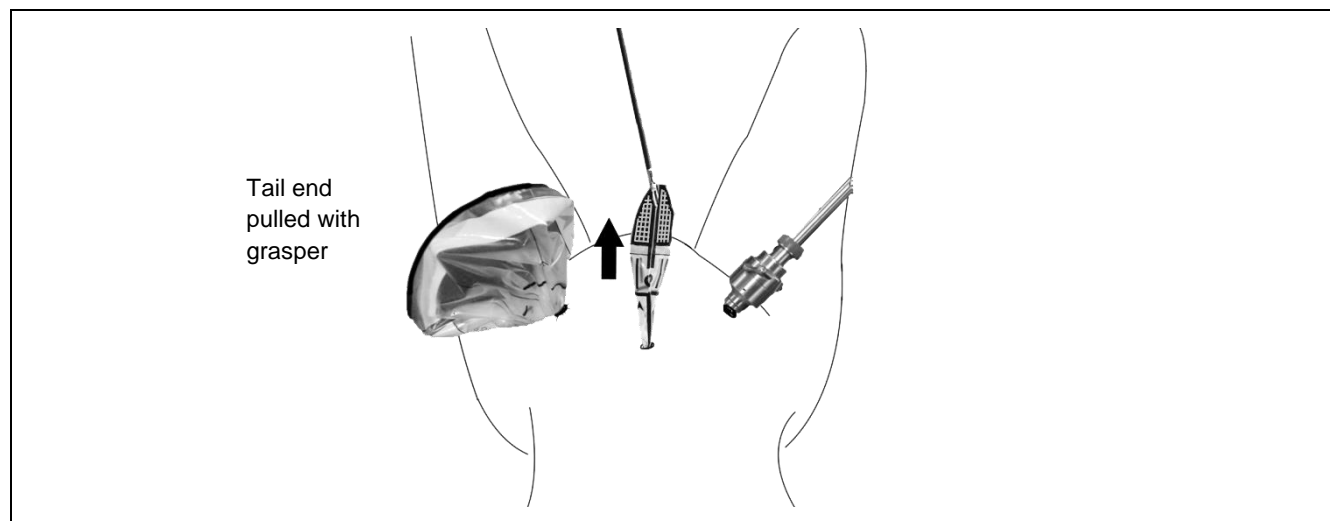


Figure 9: Pulling out trocar from the umbilical port

- 5.15 Make sure that the thick lining on the sealed edge is inside. This will help prevent twisting of the MorSafe® Tissue Morcellation Bag.
- 5.16 The Blue color markings on the body of the bag should be kept on one side of the patient to avoid twisting of the bag.
- 5.17 Pass a blunt tip trocar through the hole present on the tail end of the Morcellation Bag and insufflate the abdomen (Figure 9). While passing the trocar, care should be taken to see that the trocar tip does not puncture the MorSafe® Tissue Morcellation Bag.
- 5.18 Pass a Telescope through this trocar and insufflate the MorSafe® Tissue Morcellation Bag.

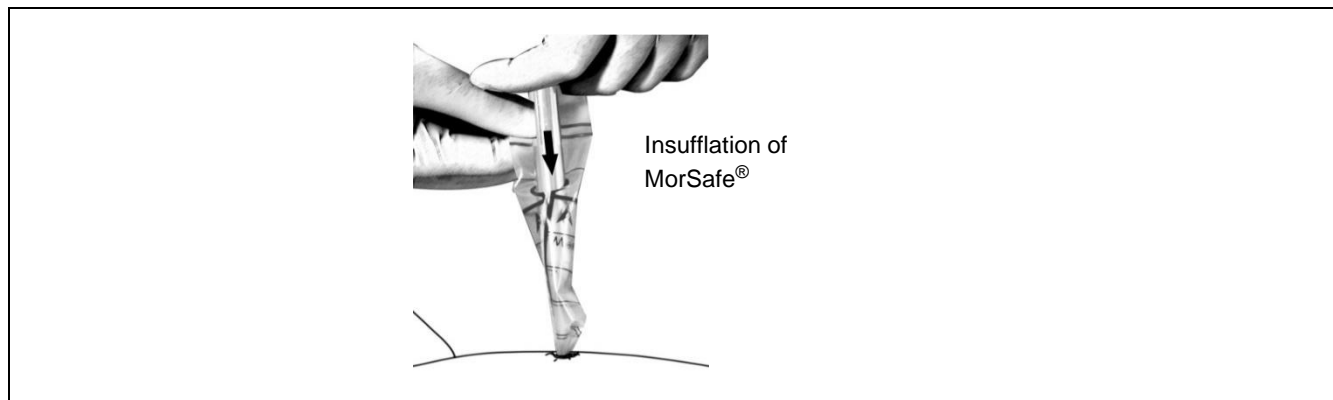


Figure 10: Passing a trocar from the tail end of the MorSafe® Tissue Morcellation Bag and Insufflation

- 5.19 Visualize the tissue inside the MorSafe® Tissue Morcellation Bag.
- 5.20 Insert a morcellator through the big opening of the MorSafe® Tissue Morcellation Bag (Figure 10). Exercise caution while passing the morcellator. Care should be taken to ensure that cutter blades of the morcellator are not in exposed position.
- 5.21 Now pass a grasper through the morcellator to hold the tissue and carry out morcellation.

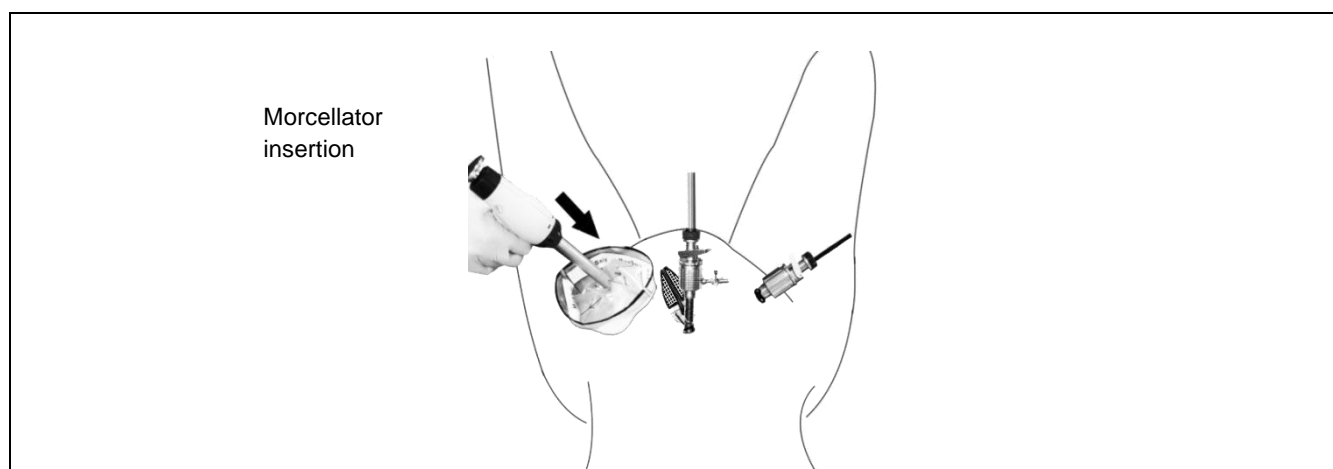


Figure 11: Inserting a morcellator through the big opening of the MorSafe® Tissue Morcellation Bag

- 5.22 After the tissue is sufficiently morcellated to enable the bag to be pulled out along with its content without much resistance through the incision made, remove the grasper from the morcellator. At this point, the size of the non-morcellated tissue may be compared with the size indicator for making the judgement if the tissue requires further morcellation or the tissue can be pulled out along with the bag without further morcellation.
- 5.23 Withdraw the morcellator from the abdominal cavity. Keep the cutter blades in unexposed position while removing the morcellator from the body.
- 5.24 Desufflate the MorSafe® Tissue Morcellation Bag.
- 5.25 Tie a knot to the tail end of the the MorSafe® bag as per the below instructions:
- 5.26 Tie a secure knot at the tail end of the MorSafe® bag. This knot should be tied below the thick, horizontal line present at the tail end (Figure 12) so that the small opening on the tail end is isolated (made inaccessible) from the internal contents of the bag.

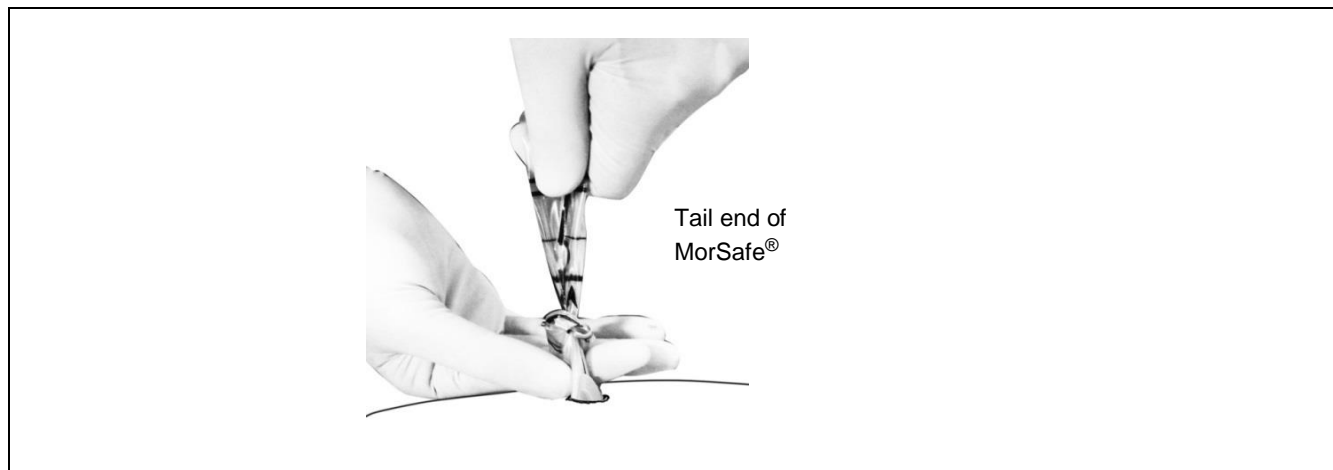


Figure 12: Knot tying at the tail end of the MorSafe® Tissue Morcellation Bag

5.27 Hold the big opening of the MorSafe® Tissue Morcellation Bag and pull it in the outward direction (Figure 13).

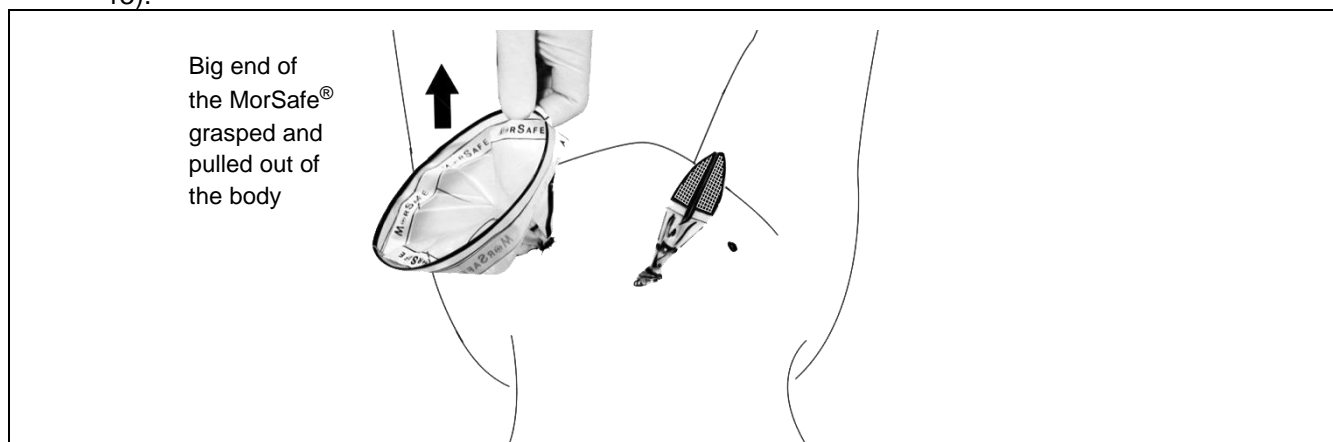


Figure 13: Pulling out MorSafe® Tissue Morcellation Bag from the body

5.28 During the procedure the surgical instruments which are inserted into the Morsafe® Tissue Morcellation Bag, might get stained with blood and tissue. Hence the surgical instruments should be thoroughly cleaned (or new sterile surgical instruments must be used) before re-inserting directly into the body orifice without Morsafe® Bag.

Operational Condition:

The whole procedure using the MorSafe should be carried out in ambient atmospheric condition in a hospital environment or ambulatory surgery centers.

6 Transport, Storage And Care

The MorSafe® Tissue Morcellation Bag should be transported and stored in a clean and dry area away from the direct sunlight, as per the below temperature and humidity conditions.

- **Storage:** +10°C to + 55°C
- **Transportation:** -10°C to + 60°C

After use, dispose MorSafe® and its packaging in accordance with hospital, administrative and/or local government policy.

MorSafe® Tissue Morcellation Bag is packaged as a STERILE device. MorSafe® Tissue Morcellation Bag is intended for one-time surgical use only. Do not reprocess, re-use or re-sterilize MorSafe® Tissue Morcellation Bag.

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

Any serious incident that has occurred in relation to the device should be reported to Veol Medical Technologies Pvt Ltd and Veol's authorized representative in respective country in which the user and/or patient is established.