INSTRUCTIONS FOR USE

Device Name: Morcell8OR™

Product code: EMPMOR6

CE 0459

DEVICE DESCRIPTION

The Espiner Morcell8OR is an electrically powered morcellator intended for the controlled cutting, coring, and extraction of devascularised uterine tissue during minimally invasive gynaecologic procedures. The device is specifically designed for use during a laparoscopic hysterectomy and laparoscopic myomectomy procedure. It is to be operated by trained surgeons, competent in minimally invasive gynaecologic surgery within appropriately equipped clinical environments.
The Espiner Morcell8OR contains a rotating cutting tube with a built-in trocar function that also serves to protect the sharp end of the cutting tube. A grasper or a tenaculum forceps must be used to pull the excised tissue through the lumen of the cutting tube. The Espiner Morcell8OR cutting function is controlled by the activation button on the hand piece.

Product code	Content
EMPMOR6	Morcellator with adapter (UK plug) Accessories: EU plug, Obturator, 5mm cap

- Adapter input: 100-240 Vac, 50/60 Hz, 1 A.
- Adapter cable length: 3 meters.

PRINCIPLE OF OPERATION

The Espiner Morcell8OR is a powered electromechanical morcellator designed for minimally invasive gynaecological surgery, such as the removal of fibroids or the uterus. It operates exclusively in a continuous motor-driven rotation mode, with no pulsed or energy-based (e.g., bipolar) functions. The device uses a cylindrical inner blade housed within a protective cannula to perform a combined coring and shaving action, fragmenting devascularised soft tissue into narrow strips typically within a containment system. The Morcell8OR does not grasp, advance, or manipulate tissue autonomously. Tissue handling is performed manually as Surgeons guide the tissue into the cannula opening using 5mm or 10-12mm laparoscopic graspers, maintaining direct visual control throughout the procedure. The Espiner Morcell8OR is introduced into the abdominal cavity using standard laparoscopic trocar insertion techniques with the obturator fully inserted. The device does not incorporate an integrated trocar for blind insertion and must only be introduced and manipulated under direct visual control.

INTENDED USE

The Espiner Morcell8OR is an electrically powered morcellator intended for the controlled cutting, coring, and extraction of devascularised uterine tissue during minimally invasive gynaecologic procedures. The device is specifically designed for use during a laparoscopic hysterectomy and laparoscopic myomectomy procedure. It is to be operated by trained surgeons, competent in minimally invasive gynaecologic surgery within appropriately equipped clinical environments.

INTENDED CLINICAL BENEFIT

When used as intended, the Espiner Morcell8OR provides a means for successful, complete, and effective power morcellation of devascularised uterine tissues in line with the identified indications. Whilst use of the Morcell8OR is not risk free, associated procedural risks and their likelihood of occurrence are reflective of risks commonly associated with power morcellation devices in general.

INDICATIONS FOR USE

The Espiner Morcell8OR is indicated for use in laparoscopic gynaecologic procedures for the controlled morcellation and removal of fully devascularised uterine tissue in the following scenarios:

1. **Laparoscopic Hysterectomy**: For the removal of the uterus in patients with clinical indications for minimally invasive surgery.
2. **Laparoscopic Myomectomy**: For the removal of uterine fibroids in patients undergoing minimally invasive surgery

The device should be used with a containment system specifically designed and approved for use with laparoscopic power morcellators, ensuring safe tissue containment and retrieval.
The device is intended for patients where minimally invasive surgery offers a clinically significant benefit over alternative methods, and where en bloc tissue removal is not feasible.

CONTRAINDICATIONS

The Espiner Morcell8OR is contraindicated in the following scenarios:

Patient-Related Contraindications

1. **Malignant or Suspected Malignant Tissue:**
    - Procedures involving tissue known or strongly suspected to contain malignancy, such as uterine sarcomas or other cancers.

- Patients with undiagnosed uterine masses where malignancy cannot reasonably be excluded preoperatively.

2. **Pregnancy:**
   - Contraindicated for use in pregnant patients.
3. **Patient Ineligibility for Laparoscopic Surgery:**
   - Patients with medical conditions or anatomical factors that contraindicate laparoscopic surgery or morcellation.
   - Pre- and peri-menopausal patients presenting with rapidly enlarging, or highly vascularised uterine masses where malignancy cannot be excluded
   - Patients should be counselled that alternative surgical options (including en bloc removal via vaginal or mini-laparotomy approaches) may be clinically preferable in certain cases and should be discussed pre-operatively.

Procedure-Related Contraindications

4. **Non-Devascularised or Undissected Tissue:**
   - The device must not be used on vascularised or non-dissected tissue. Target tissues must be fully devascularised and excised before morcellation.
5. **Alternative Tissue Removal Options:**
   - Where en bloc tissue removal via mini-laparotomy or vaginal routes is feasible and clinically appropriate, morcellation should not be used.

General Contraindications

6. Inadequate Clinical Environment:
   - Use outside of fully equipped surgical facilities capable of laparoscopic surgery and emergency interventions.
7. Untrained Operators:
   - Use by individuals lacking advanced training in laparoscopic gynaecologic surgery.

Patient Counselling Requirement

Patients must be informed of the following risks before surgery:

- The possibility that uterine tissue may contain undiagnosed malignancy.
- The potential for tissue dissemination of benign or malignant tissue, including the associated clinical implications, which could impact long-term outcomes.
- The risks associated with morcellation, including the need for additional procedures in the event of complications or dissemination.
- Patients should be counselled that alternative surgical options (including en bloc removal via vaginal or mini-laparotomy approaches) may be clinically preferable in certain cases and should be discussed pre-operatively.

COMPLICATIONS/SIDE EFFECTS

The risk of occult cancer, including uterine sarcoma, increases with age, particularly in women over 50 years of age. This information, which reflects non-binding recommendations in current guidance, should be communicated to patients when discussing surgery involving the use of these devices.

The following complications and side-effects remain as residual risks of device use. They are identified qualitatively (which complications/ side-effects) and sorted by reported occurrence for quantification to inform risk assessment. Note that these include device-related as well as procedure-related risks.

Serious long-term risks associated with power morcellation include the dissemination of benign or malignant tissue, which may significantly impact patient outcomes and may require additional surgical intervention. These risks should be carefully considered and discussed with the patient prior to the procedure.

Reported Complication / Side-Effect Occurrence Brackets	Reported Complications / Side-Effects Quality
Reported to **occur often** (occurring in > 25 % of power morcellator uses)	Recurrence
Reported to be **likely to occur** (occurring in 10 % < x ≤ 25% of power morcellator uses)	Dissemination of malignant tissue (e.g., by uterine sarcoma morcellation)
	Residual myoma
	Adhesion formation
Reported to be unlikely to occur (occurring in ≤ 10 % of power morcellator uses)	Infection
	Injury of surrounding viscera and internal structures, including - Bowel injury - Liver injury or damage - Adjacent organ injury Visceral or vascular injury
	blood loss

	Herniation
	Dysmenorrhea
	Fistula formation
	Bag rupture or spillage
	Abdominal hernia
	Dissemination of benign tissue
Not reported at quantifiable rates, hypothetical complications / side-effects associated with power morcellator uses	Thromboembolism
	Injury of patient or user by blades
	Skin reaction
	Death

PATIENT GROUP

The Espiner Morcell8OR is designed for adult (as defined by local jurisdiction) patients undergoing minimally invasive gynaecologic surgery procedures, where there is a requirement to remove a large devascularised uterine tissue mass through a small trocar port incision identified as hysterectomies, or myomectomies.

INTENDED USER

The device is intended to be used by trained surgeons, competent in minimally invasive gynaecologic surgery within appropriately equipped clinical environments.

Warning: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

WARNINGS & PRECAUTIONS

- Uncontained power morcellation has been associated with the spread of benign uterine tissue, i.e., parasitic myomas and disseminated peritoneal leiomyomatosis, potentially requiring additional surgeries.
- Laparoscopic power morcellators must be used in line with local clinical practice and regulatory recommendations, including with a containment system where required.
- Laparoscopic surgery should only be performed by physicians who are thoroughly trained in laparoscopic techniques, precautions and corrective actions in the event of a failure.
- The Espiner Morcell8OR is provided sterile. Carefully inspect the packaging for any damage prior to use. Do not attempt to use the device if the sterile barrier is damaged.
- For single-use only. Do not reuse, reprocess or resterilise the Espiner Morcell8OR. Any reprocessing may impede the functions of this device. Reusing single-use devices may also increase the risk of cross contamination. Attempts to clean the device can result in increased risk of device malfunction and/or erroneous pathology specimen collection due to residual tissue in the Espiner Morcell8OR, causing significant gas leakage through the morcellator.
- Do not use after the expiration date shown on the label.
- Any abdominal incision introduces a risk of abdominal hernia.
- To reduce the risk of injuries to surrounding viscera, exercise caution while manipulating the Espiner Morcell8OR, insert the Espiner Morcell8OR under direct vision. Do not place the cutting tip nearby or in contact with tissue which is not intended to be morcellated.
- Take care when inserting or removing the device. Ensure that the cutting blade is retracted by rotating the trocar to the “Safety mode” position during insertion, removal and whenever the cutting blade is not in active use. Insertion and removal of the Espiner Morcell8OR should always be performed under direct visual control. Keep the rotating blade visible during the entire morcellation procedure.
- Maintain adequate insufflation throughout the morcellation procedure to reduce the risk of injury to internal structures.
- Be aware that the cutting tip of the Espiner Morcell8OR is not in contact with other instruments. Contact with other instruments must be avoided to prevent unintended mechanical damage.
- Do not activate the Espiner Morcell8OR if it is not possible to visualise the cutting tip to reduce the risk of injury to internal structures.
- Do not attempt to sharpen or modify the cutting tube. Modified or distorted cutting tube can result in patient, physician or equipment damage.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Be aware of sharp edges.
- Failure to carefully follow all applicable instructions may result in significant injury to the patient, physician or attendants and may have an adverse effect on the outcome of procedures performed.

REPORTING

- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state.

COMPATIBILITY WITH OTHER DEVICES

The Espiner Morcell8OR is compatible with standard laparoscopic tissue grasping forceps with a working length of >250mm. Instruments between 10mm - 12 mm in diameter may be used via the native instrument channel, or 5mm when used in accordance with the reducer cap (5 mm). Compatibility is mechanical only and relates to shaft diameter, jaw profile and working length. No electrical or functional interfacing exists between the Morcell8OR and the grasping instrument.

The Espiner Morcell8OR is suitable for use with commercially available laparoscopic tissue-retrieval containment systems that are intended and validated for contained power morcellation. Compatibility is based on the use of containment bags that provide: (i) adequate internal volume for the size of the specimen, (ii) a trocar access route allowing direct visualisation and insertion of the morcell8OR device, and (iii) a material and design that permit safe morcellation without compromising bag integrity. Containment bags in common clinical use (e.g., 1000 ml, 2000 ml, 4000 ml) may be used provided they meet these characteristics.

The manufacturer does not claim compatibility with any specific third-party brand or model of containment bag or instrument. Users must verify that the selected containment system or grasper is intended for laparoscopic use and suitable for contained power morcellation in accordance with its own Instructions for Use.

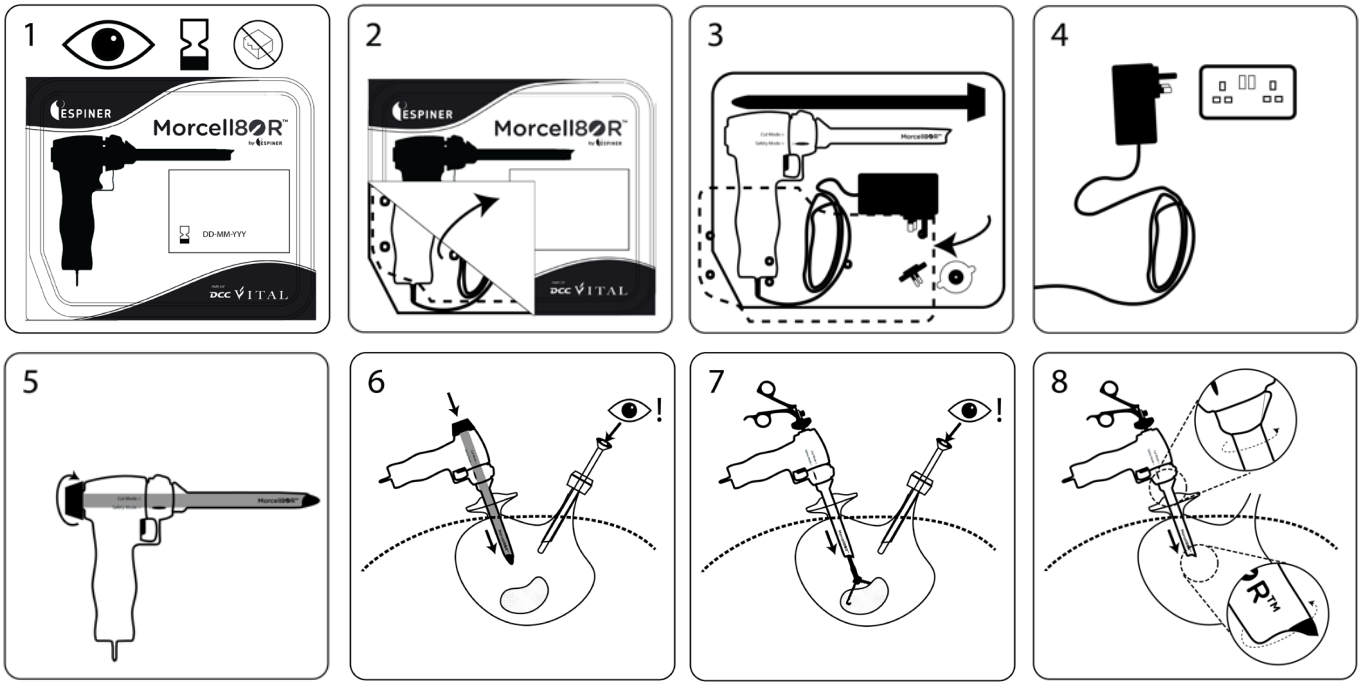
PRECISE IDENTIFICATION OF ORGANS, TISSUES OR BODILY FLUIDS IN CONTACT WITH THE DEVICES AND THE ACCESSORIES

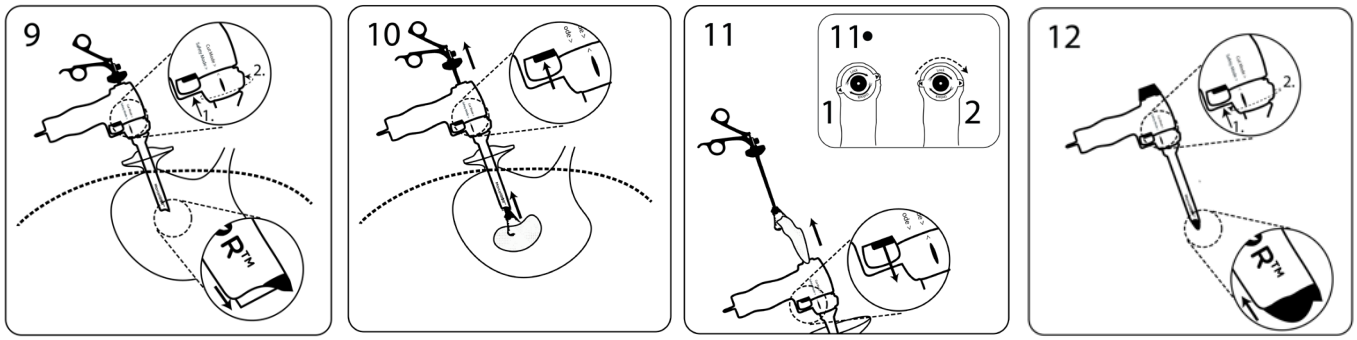
The Espiner Morcell8OR is intended to morcellate fully devascularised uterine tissue. When used without a containment system, the device may contact abdominal organs, tissues, and bodily fluids during insertion and manipulation. This incidental contact can include, but is not limited to, structures such as the stomach, small and large intestines, spleen, pancreas, liver, and gallbladder. Any such contact is incidental to insertion and manipulation of the device. These tissues are not morcellated. To reduce the risk of injury to surrounding viscera, the Espiner Morcell8OR must be inserted and manipulated under direct visualisation. Avoid placing the cutting tip near or in contact with tissue that is not intended to be morcellated.

Direct visualisation must be maintained at all times during insertion, manipulation, and morcellation to minimise incidental contact with non-target tissues and reduce the risk of unintended injury.

INSTRUCTION FOR USE

The following instructions should be read before using the device. This IFU is designed to assist using this product. It is not a reference for surgical techniques.





1. Carefully inspect the packaging for any damage prior to use. Do not attempt to use the device if sterile barrier is damaged.
2. Peel back Tyvek pouch.
3. Remove plastic insert.
4. Plug the adaptor into a 110-240V mains power source to provide power.
5. Prior to the insertion of the Espiner Morcell8OR, insert the obturator fully into the device. The obturator has a twist-lock function that can fix the obturator in the morcellator. Be sure that the trocar is placed in the “Safety mode” position. If not, place the trocar in the “Safety mode” position by pressing the trigger guard and turning the trocar.
6. The Espiner Morcell8OR with obturator should be placed into the abdomen using standard technique for laparoscopic trocar placement. It is recommended to insert the Espiner Morcell8OR with obturator through a 12-15 mm incision under direct visualisation.
7. To remove excised tissue, remove the obturator and proceed to use 10-12 mm forceps or similar instrument, inserted through the lumen of the Espiner Morcell8OR, under direct visualisation to grasp the tissue. To prevent injury to the abdominal wall and surrounding tissues, the target tissue must be fully dissected and devascularised before extraction through the morcellator.
8. The core guard can be adjusted, if needed, by rotating the core guard trocar.
9. To activate the cutting blade and begin morcellating, 1. press the trigger guard and 2. turn the trocar to select ‘cut mode’.
10. **Under direct visualisation**, press the activation button on the hand piece whilst pulling pieces of excised tissue through the cutting tube. **ONLY PLACE YOUR FINGER ON THE ACTIVATION BUTTON WHEN YOU ARE READY TO MORCELLATE.**
11. Release the activation button as soon as the strip of tissue is extracted from the Espiner Morcell8OR.
    - Note: If using the morcellator with 5 mm instruments: You can mount the 5mm reducer cap onto the back of the morcellator using the twist-lock.
12. After morcellation is completed, turn the trocar to “Safety mode”, remove the reducer cap (if used) and re-insert the obturator. Then, remove the Morcell8OR from the abdominal cavity. The morcellator may now be disposed in accordance with local governing ordinances and recycling plans.

OPERATIONAL, STORAGE AND TRANSPORTATION CONDITIONS

- Operational temperature and humidity: 15°C to 25°C; 10%~75% RH; 700~1060hPa; altitude <2000m.
- Storage temperature: 15°C to 25°C; 10%~75% RH; 700~1060hPa.
- Transportation temperature: 5°C to 60°C.; 10%~75% RH; 700~1060hPa.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

1. **WARNING**: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
2. **WARNING**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Espiner Morcell8O, including cables specified by the manufacturer. Otherwise, performance degradation may occur.

Manufacturer’s declaration – Electromagnetic Emissions		
The Morcell8OR™ is intended for use in the electromagnetic environment specified below. The customer or the user should assure that the device is used in such an environment.		
Emission test	Compliance level	Electromagnetic environment-guidance
Radiated Emissions EN 55011 Group 1	Class A	The Morcell8OR™ uses RF energy only for its internal function. The RF emissions are low and unlikely to cause interference in nearby electronic equipment.
Conducted Emissions EN 55011 Group 1	Class A	The Morcell8OR™ is suitable for use in all medical establishments, including domestic establishments that are directly connected to the public low voltage power supply network.
Voltage fluctuations and flicker emissions EN 6100033	Complied	

Manufacturer's declaration – Electromagnetic Immunity			
The Morcell8OR™ is intended for use in the electromagnetic environment specified below. The customer or the user should assure that the device is used in such an environment.			
Immunity test	Immunity test levels	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge EN 6100042	±8 kV Contact Discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV Air Discharge	±8 kV Contact Discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV Air Discharge	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material (carpet), the relative humidity should be at least 30%.
Radiated RF EM fields EN 6100043	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	-
Electrical fast transient EN 6100044	±2 kV	±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 6100045	0.5 kV, 1 kV	0.5 kV, 1 kV	-
Conducted susceptibility EN 6100046	3 Vrms 0.15 MHz – 80 MHz 6 Vrms in ISM and bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0.15 MHz – 80 MHz 6 Vrms in ISM and bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	-
Power Frequency Magnetic Field EN 6100048	30 A/m 50 Hz	30 A/m 50 Hz	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips EN 61000411	0% residual voltage for 0.5 cycle 0% residual voltage for 1 cycle 70% residual voltage for 25 cycles	0% residual voltage for 0.5 cycle 0% residual voltage for 1 cycle 70% residual voltage for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during main power interruptions, it is recommended that the Morcell8OR™ be powered from an uninterruptible supply.
Voltage interruptions EN 61000411	0% residual voltage for 250 cycles	0% residual voltage for 250 cycles	
Proximity magnetic fields EN 61000439	65 A/m, 7.5 A/m	65 A/m, 7.5 A/m	-

GLOSSARY OF SYMBOLS

	Manufacturer		Consult instructions for use
	Date of manufacture		Caution
	Authorised representative in the European Community		Federal law restricts this device to sale by or on the order of a physician
	Use-by date		Type BF applied part

LOT	Batch code	QTY	Quantity
REF	Catalogue number	UDI	Unique device identifier
STERILE EO	Sterilised using ethylene oxide	MD	Medical Device
	Do not resterilise		Single sterile barrier system
	Do not use if package is damaged		Single sterile barrier system inside protective packaging
	Keep dry	CE 0459	CE Mark: Notified Body Number 0459. In accordance with MDR 2017/745, Article 20.
	Do not re-use		Electrical and Electronic Equipment.
	Refer to Instruction manual/booklet		

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