

VersaCut™ Tissue Morcellator

Prescriptive Information

Refer to the device user manual for complete instructions on device use.

Intended Use/Indications for Use

The VersaCut Tissue Morcellator System is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparoscopic, percutaneous and open surgical procedures whenever access to the surgical site is limited.

Contraindications

- This instrument is contraindicated for the morcellation of bone and for use in liposuction procedures.
- Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
- Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:
 - Post-menopausal or over 50 years of age, or
 - Candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.

Warnings and Precautions

- This instrument is intended for use in a fluid environment. Do not activate morcellation while the blade set is in air. Doing so may jam and irreparably damage the blade set. If the blade set becomes jammed, discard and replace with a sterile blade set.
- The blade set components (inner & outer blades) are precision-tooled to fit each other. Never attempt to use the inner blade of one set with the outer blade of a different set, or vice-versa.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.
- Verify that the appropriate voltage is displayed in the voltage window before connecting the main power cable to the control unity. If necessary, install the voltage selector, or change the voltage as instructed in the Maintenance section of this manual.
- Do not use tubing other than that provided by Lumenis. Using alternative tubing may jeopardize the safe operation of the instrument.
- Aspiration flows in the direction of the arrow on the pump head. Always verify that the aspiration tube is loaded in the required direction.
- Direct contact of the blade tips with metal instruments can damage the blade set. If contact occurs, stop using the instrument immediately, and examine the blade set carefully for evidence of cracks or fractures. If there is any doubt about the condition of the blade set, discard and replace with a sterile blade set.
- Do not remove the filter from tissue collection container.
- Allow the components to cool for at least 60 minutes before handling. Severe burns may occur if handled before cooling.
- As with any medical instrument, the user should become familiar with this instrument in a nonclinical setting prior to its clinical use. Use extreme caution when first using the instrument in a clinical setting, particularly when operating in proximity to critical anatomical structures.
- This instrument should only be used under direct or endoscopic visualization in a fluid environment.

- Any tissue in contact with the instrument's blade tips when morcellation is activated will be morcellated. Ensure that only target tissue is in contact with the blade tips.
- Unauthorized servicing or modification of this system, not described in this manual, may expose the surgeon/patient to potential electrical hazards.
- 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 VersaCut Tissue Morcellator, including VersaCut Tissue Morcellator cables. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories and cables other than those provided by Lumenis could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The VersaCut Tissue Morcellator is intended for use only in operating rooms within professional healthcare facility environment except for near HF SURGICAL EQUIPMENT, and outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging.
- The VersaCut Tissue Morcellator needs special precautions regarding EMC and needs to be installed according to specific instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life of 7 years.
- This instrument should only be used by physicians who have been instructed in its proper use. Physicians and support staff must be fully familiar with the operation and biological effects of the instrument and the safety precautions associated with its use.
- Handle this instrument with care. If dropped or damaged, return the instrument to Lumenis for evaluation and, if necessary, repair. Refer to your warranty agreement for detailed warranty information.
- 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 for Laparoscopic power morcellators used for gynecologic surgeries:
 - The risk of occult cancer, including uterine sarcoma, increases with age, particularly in women over 50 years of age. This information should be shared with patients when considering surgery with the use of these devices.
 - 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 should only be used with a containment system. The containment system should be compatible with the Laparoscopic power morcellators.

Adverse Events/Complications

Potential complications for this instrument include:

- Unintended morcellation of nontarget tissues
- Post-operative infection

Precautions can be found in the product labeling supplied with each device.

Boston Scientific acquired the global surgical business of Lumenis Ltd.

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