

# Current labeling for laparoscopic power morcellators with gynecologic indications

August 1, 2014

SOURCE: US Food and Drug Administration

Device	Manufacturer/ distributor	Summary of safety information in labeling	Comments
Gynecare Morcellex Tissue Morcellator	Ethicon (Somerville, New Jersey)	<p>Contraindicated for use in vascularized tissue and as a dissecting tool.</p> <p>Warning: To prevent accidental injuries to the abdominal wall or similar structure, the tissue to be morcellated should be completely exposed before applying the device. In addition, it is recommended that a second pair of grasping forceps or a fixation instrument be used to prevent large pieces of tissue from uncontrollably moving. Unintended movement of the device can cause significant injury.</p> <p>CAUTION: A tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue that the physician considers to be potentially harmful when disseminated in a body cavity.</p> <p>Exercise care when inserting or removing the instrument. Insertion and removal of the instrument should be performed under direct visualization at all times.</p>	Worldwide sales of this device were suspended indefinitely by the manufacturer on April 30, 2014, after a safety communication from the US Food and Drug Administration (FDA) about their use in women with suspected malignancy.
Sawahle Rotocut G1	Karl Storz (Tuttlingen, Germany)	<p>Contraindicated for use on vascularized tissue and as a dissecting tool.</p> <p>Direct use for electromechanical morcellation, resection, or tissue ablation is contraindicated in the case of malignant tumors and vascularized tissue.</p> <p>Warning: Risk of injury! Sharp-edged cutting tube. Can cause injury to tissue even in unactivated state. For this reason, insert or remove the cutting tube only under optical control.</p> <p>Note: A tissue extraction bag is advised for the morcellation of tumors or tissue suspected of being malignant and for tissue that the surgeon may consider to be harmful if disseminated in a body cavity.</p>	
Morce Power Plus	Richard Wolf (Vernon Hills, Illinois)	<p>Contraindicated for treatment of malignant tumors, treatment of vascularized tissue, and preparation of tissue.</p> <p>Cautions: To prevent accidental injuries to the abdominal wall or similar structure, the tissue to be morcellated should be completely exposed before applying the device. In addition, it is recommended</p>	

		<p>that a second pair of grasping forceps or a fixation instrument be used to prevent large pieces of tissue from uncontrollably moving. Slippage of the cutting tube can cause significant injury.</p> <p>Exercise care when inserting or removing the instrument. Use the blade guard to prevent lateral injury to tissue from the sharp-edged cutting tube. Insertion and removal should be performed under direct visual control at all times.</p> <p>The use of a tissue extraction bag is recommended for the morcellation of tissue suspected of being malignant and for tissue the surgeon may consider to be potentially harmful when disseminated in the body cavity.</p>	
LiNA Xcise	LiNA (Norcross, Georgia)	<p>Contraindicated for use on vascularized tissue (ovaries, fallopian tubes, myomas, and other structures); must be devascularized before morcellation.</p> <p>The LiNA Xcise should not be used in patients who have been diagnosed with a malignant condition.</p> <p>Warning: Do NOT activate the LiNA Xcise if it is not possible to visualize the cutting tip.</p> <p>Precaution: Use of LiNA Xcise requires adequate training and experience in performing laparoscopic myomectomy and hysterectomy.</p> <p>Be careful when inserting or removing the device. Make sure that the cutting blade is retracted by putting the trocar in the "Safe Guard" position during insertion and removal and whenever the cutting blade is not in active use. Insertion and removal of the LiNA Xcise should always be performed under direct visual control. Keep the rotating blade visible during the entire morcellation procedure.</p>	
Trokamed Morcellator	Trokamed (Geisingen, Germany)	<p>Contraindicated for use in treatment of malignant tumors or for vascularized tissue. It also may not be used to prepare tissue.</p>	
PlasmaSord	Gyrus (Southborough, Massachusetts)	<p>Contraindicated when, in the best judgment of the physician, bipolar electrosurgical procedures would be contrary to the best interests of the patient.</p> <p>Warnings: Inappropriate use of electrosurgery instruments can cause damage to tissue, both electrically and thermally. This instrument should not be used in close proximity to tissue structures (including the bladder, bowel, or abdominal wall) susceptible to damage unless it is the intention to resect the tissue.</p> <p>Only open the PKS PlasmaSord grasper jaws in good visibility and when in close proximity to the target tissue.</p>	This device carries an advisory not to use in with tissue-removal bags.

Keep the instrument tip in sight during use. Inadvertent activation or movement of the instrument outside the field of vision may result in patient injury. To prevent accidental injuries to the abdominal wall, bladder, bowel, or other structures or nerve stimulation, the tissue to be morcellated should be completely exposed and fixed to prevent large pieces of tissue from moving before applying the device. Depress the foot pedal to activate the device only when the distal tip is in the field of view.

If visualization of the treatment site or device is lost during the procedure, stop immediately. Do not proceed until visibility is restored.

Do not use this device with tissue-removal bags.

SOURCE: US Food and Drug Administration. FDA Executive Summary. Laparoscopic Power Morcellation during Uterine Surgery for Fibroids. Appendix E: Labeling for Uterine Laparoscopic Power Morcellators.  
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM404148.pdf>.