Recommended Labeling Statements


As a result of the new information and discussions during the public Advisory Committee meeting, FDA recommends that manufacturers of LPMs with a general indication or a specific gynecologic indication prominently include the following Contraindications and Boxed Warning in their product labeling:

**CONTRAINDICATION:** Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

**CONTRAINDICATION:** Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:

- peri- or post-menopausal, or
- candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.

**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.