U.S. Food and Drug Administration

Recommended Labeling Statements

Excerpted from: *Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators: Guidance for Industry and Food and Drug Administration Staff*

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.**

Center for Devices and Radiological Health
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