



MEDICAL MUTUAL®

In the News

FDA Recommends New Contraindications for Laparoscopic Uterine Power Morcellators

In 2014, the U.S. Food & Drug Administration (FDA) issued a warning against the use of laparoscopic power morcellators in the majority of women undergoing a hysterectomy or myomectomy to remove uterine fibroids.

The FDA has recommended that laparoscopic power morcellators not be used in menopausal and postmenopausal women as there is a greater risk for uterine sarcoma with increasing age. Furthermore, power morcellators should not be used in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

Laparoscopic hysterectomies and myomectomies are associated with shorter post-operative recovery time, less pain, reduced risk of infection compared to abdominal hysterectomies and myomectomies, and, for hysterectomies, a risk of mortality three times lower than abdominal hysterectomies.

Medical Mutual continues to cover the use of laparoscopic power morcellators according to the member's benefits. However, providers should review current FDA recommendations before advising patients regarding optimal treatment approaches.

Alternative surgical options such as total abdominal hysterectomy (laparotomy), mini-laparotomy, colpotomy incisions, vaginal hysterectomy and laparoscopic assisted vaginal hysterectomy should be considered, as appropriate. The risks and benefits of all treatments should be discussed with your patients.

While there is currently no reliable way to predict before surgery whether a woman with fibroids may have an occult uterine sarcoma, the American College of Obstetrics and Gynecology recommends thorough patient evaluation prior to choosing a surgical option. Considerations include:

- Current cervical cytology, potentially along with pelvic imaging and endometrial assessment
- Patient's age, as the incidence of uterine cancer increases with age
- Menopausal status, as menopausal or postmenopausal women have an increased risk of occult malignancy
- The size and rate of growth of uterine fibroids
- Hereditary conditions and select treatments, like tamoxifen or pelvic radiation



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The FDA has asked manufacturers of laparoscopic power morcellators to issue a box warning for the device. Ethicon, a division of Johnson & Johnson has since [withdrawn its morcellation devices](#) from the market and several hospitals across the nation have [elected to stop using the device](#).

The FDA recommendations are available by visiting FDA.gov and selecting Medical Devices, Medical Device Safety, Safety Communications, [UPDATED Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication \(11/24/14\)](#).

These recommendations are informational only. They are not intended to require a specific course of treatment or take the place of professional medical advice, diagnosis or treatment. Members should make decisions about care with their healthcare providers. Recommended treatment or services may not be covered. Eligibility and coverage depend on the member's specific benefit plan.