

**U.S. Food and Drug Administration**  
Protecting and Promoting *Your* Health

# Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication

**Date Issued:** April 17, 2014

**Audience:**

- Health Care Providers
- Medical Professional Associations
- Cancer Advocacy Organizations
- Health Care Facilities/Hospitals
- Women with Symptomatic Uterine Fibroids who are Considering Surgical Options
- Manufacturers of Devices used for Minimally Invasive Surgeries

**Medical Specialties:** Pathology, Internal Medicine, Nursing, Obstetrics/Gynecology, Oncology

**Product:**

Laparoscopic power morcellators are medical devices used during different types of laparoscopic (minimally invasive) surgeries. These can include certain procedures to treat uterine fibroids, such as removing the uterus (hysterectomy) or removing the uterine fibroids (myomectomy). Morcellation refers to the division of tissue into smaller pieces or fragments and is often used during laparoscopic surgeries to facilitate the removal of tissue through small incision sites.

**Purpose:**

When used for hysterectomy or myomectomy in women with uterine fibroids, laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus. Health care providers and patients should carefully consider available alternative treatment options for symptomatic uterine fibroids. Based on currently available information, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.

**Summary of Problem and Scope:**

Uterine fibroids are noncancerous growths that develop from the muscular tissue of the uterus. Most women will develop uterine fibroids (also called leiomyomas) at some point in their lives, although most cause no symptoms<sup>1</sup>. In some cases, however, fibroids can cause symptoms, including heavy or prolonged menstrual bleeding, pelvic pressure or pain, and/or frequent urination, requiring medical or surgical therapy.

Many women choose to undergo laparoscopic hysterectomy or myomectomy because these procedures are associated with benefits such as a shorter post-operative recovery time and a reduced risk of infection compared to abdominal hysterectomy and myomectomy<sup>2</sup>. Many of these laparoscopic procedures are performed using a power morcellator.

A number of additional treatment options are available for women with symptomatic uterine fibroids including traditional surgical hysterectomy (performed either vaginally or abdominally) and myomectomy, laparoscopic hysterectomy and myomectomy without morcellation, laparotomy using a smaller incision (minilaparotomy), deliberate blocking of the uterine artery (catheter-based uterine artery embolization), high-intensity focused ultrasound, and drug therapy. Evidence demonstrates that, when feasible, vaginal hysterectomy is associated with comparable or better results and fewer complications than laparoscopic or abdominal hysterectomy<sup>3</sup>.

Importantly, based on an FDA analysis of currently available data, it is estimated that 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma. **If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.**

#### **Recommendations for Health Care Providers:**

- Be aware that based on currently available information, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids.
- Do not use laparoscopic uterine power morcellation in women with suspected or known uterine cancer.
- Carefully consider all the available treatment options for women with symptomatic uterine fibroids.
- Thoroughly discuss the benefits and risks of all treatments with patients.
- For individual patients for whom, after a careful benefit-risk evaluation, laparoscopic power morcellation is considered the best therapeutic option:
  - Inform patients that their fibroid(s) may contain unexpected cancerous tissue and that laparoscopic power morcellation may spread the cancer, significantly worsening their prognosis.
  - Be aware that some clinicians and medical institutions now advocate using a specimen “bag” during morcellation in an attempt to contain the uterine tissue and minimize the risk of spread in the abdomen and pelvis.

#### **Recommendations for Women:**

- Ask your health care provider to discuss all the options available to treat your condition and discuss the risks and benefits of each.
- If laparoscopic hysterectomy or myomectomy is recommended, ask your health care provider if power morcellation will be performed during your procedure, and to explain why he or she believes it is the best treatment option for you.

- If you have already undergone a hysterectomy or myomectomy for fibroids, tissue removed during the procedure is typically tested for the presence of cancer. If you were informed these tests were normal and you have no symptoms, routine follow-up with your physician is recommended. Patients with persistent or recurrent symptoms or questions should consult their health care provider.

## **FDA Actions:**

The FDA is concerned about women undergoing laparoscopic power morcellation for the treatment of uterine fibroids and the risk of inadvertent spread of unsuspected cancer to the abdominal and pelvic cavities. In an effort to enhance understanding of the problem and provide information on the appropriate use of laparoscopic power morcellators, the FDA:

- Instructed manufacturers of power morcellators used during laparoscopic hysterectomy and myomectomy to review their current product labeling for accurate risk information for patients and providers;
- Will convene a public meeting of the Obstetrics and Gynecological Medical Device Advisory Committee to discuss: 1) the clinical role of laparoscopic power morcellation in the treatment of uterine fibroids, 2) whether surgical techniques and/or use of accessories, such as morcellation/specimen bags, can enhance the safe and effective use of these devices, and 3) whether a “boxed warning” related to the risk of cancer spread should be required for laparoscopic power morcellators;
- Will continue to review adverse event reports, peer-reviewed scientific literature, and information from patients, health care providers, gynecologic and surgical professional societies, and medical device manufacturers.

## **Reporting Problems to the FDA:**

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect that a morcellator and/or specimen bag has malfunctioned or contributed to a serious injury or adverse outcome, the FDA encourages you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**.

Health care professionals employed by facilities that are subject to the **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEve** should follow the reporting procedures established by their facilities.

## **Other Resources:**

- **Society of Gynecologic Oncology (SGO)'s position statement on morcellation published in December 2013 (https://www.sgo.org/newsroom/position-statements-2/morcellation/)** 
- **American College of Obstetricians and Gynecologists (ACOG)'s Statement on Choosing the Route of Hysterectomy for Benign Disease November 2009 (Reaffirmed 2011) (https://www.acog.org/Resources And Publications/Committee Opinions/Committee on Gyn**
- **American Association of Gynecologic Laparoscopists (AAGL)'s AAGL Member Update: Disseminated Leiomyosarcoma With Power Morcellation 2014 (http://www.aagl.org/aaglnews/aagl-member-update-disseminated-leiomyosarcoma-with-power-morcellation/)**   
**(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

**References:**

<sup>1</sup> NIH Fact Sheet on Uterine Fibroids. March 2013. Available at

<http://report.nih.gov/nihfactsheets/viewfactsheet.aspx?csid=50>  
[\(http://report.nih.gov/nihfactsheets/viewfactsheet.aspx?csid=50\)](http://report.nih.gov/nihfactsheets/viewfactsheet.aspx?csid=50)

<sup>2</sup> Nieboer TE, Johnson N, Lethaby A, et al. Surgical approach to hysterectomy for benign gynecological disease. Cochrane Database Syst Rev. 2009;(3):CD003677.

<sup>3</sup> Ibid.

**Contact Information:**

If you have questions about this communication, please contact the Center for Devices and Radiological Health's Division of Industry and Consumer Education (DICE) at [DICE@FDA.HHS.GOV](mailto:DICE@FDA.HHS.GOV) (<mailto:DICE@FDA.HHS.GOV>), 800-638-2041 or 301-796-7100.

**Additional Information**

- [Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids - Summary and Key Findings \(PDF - 253KB\)](#)  
[\(/downloads/MedicalDevices/Safety/AlertsandNotices/UCM393589.pdf\)](#)