

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

The following information updates our April 17, 2014 communication.

Date Issued: Nov. 24, 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, Obstetrics/Gynecological Surgery; General Surgery

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. The FDA is warning against using laparoscopic power morcellators in the majority of women undergoing hysterectomy or myomectomy for uterine fibroids. Health care providers and patients should carefully consider

available alternative treatment options for the removal of symptomatic 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 symptoms¹. 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 myomectomy². Many of these laparoscopic procedures are performed using a power morcellator.

Based on an FDA analysis of currently available data, we estimate that approximately 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. At this time, there is no reliable method for predicting or testing whether a woman with fibroids may have a uterine sarcoma.

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 long-term survival. While the specific estimate of this risk may not be known with certainty, the FDA believes that the risk is higher than previously understood.

Because of this risk and the availability of alternative surgical options for most women, **the FDA is warning against the use of laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids.**

Limiting the patients for whom laparoscopic morcellators are indicated, the strong warning on the risk of spreading unsuspected cancer, and the recommendation that doctors share this information directly with their patients, are part of FDA guidance to manufacturers of morcellators. The guidance strongly urges these manufacturers to include this new information in their product labels.

Recommendations for Health Care Providers:

- Be aware of the following new contraindications recommended by the FDA;
 1. Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or post-menopausal, or are candidates for en bloc tissue removal, for example through the vagina or mini-laparotomy incision. (Note: These groups of women represent the majority of women with fibroids who undergo hysterectomy and myomectomy.)
 2. Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
- Be aware of the following new boxed warning recommended by the FDA:

The FDA warns that 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.
- Carefully consider all the available treatment options for women with uterine fibroids.
- Thoroughly discuss the benefits and risks of all treatments with patients. Be certain to inform the small group of patients for whom laparoscopic power morcellation may be an acceptable therapeutic option that their fibroid(s) may contain unexpected cancerous tissue and that laparoscopic power morcellation may

spread the cancer, significantly worsening their prognosis. This population might include some younger women who want to maintain their fertility or women not yet peri-menopausal who wish to keep their uterus after being informed of the risks.

Recommendations for Women:

- Ask your health care provider to discuss all the options available to treat your condition. There are risks and benefits associated with all medical devices and procedures and you should be aware of them.
- If your doctor recommends laparoscopic hysterectomy or myomectomy, ask him/her if power morcellation will be performed during your procedure, and to explain why he or she believes it is an appropriate 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.
- A number of additional surgical 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, and laparotomy using a smaller incision (minilaparotomy). All treatments carry risk, and you should discuss them thoroughly with your health care provider.

FDA Actions:

The FDA has taken the following actions in light of scientific information that suggests that the use of laparoscopic power morcellators may contribute to the spread and upstaging of unsuspected uterine cancer in women undergoing hysterectomy and myomectomy for fibroids:

- The FDA conducted a review of published and unpublished scientific literature, including patients operated on from 1980 to

2011 to estimate the prevalence of unsuspected uterine sarcoma and uterine leiomyosarcoma in patients undergoing hysterectomy or myomectomy for presumed benign fibroids (leiomyoma). This analysis led us to believe that the prevalence of unsuspected uterine sarcoma in patients undergoing hysterectomy or myomectomy for presumed benign leiomyoma is 1 in 352 and the prevalence of unsuspected uterine leiomyosarcoma is 1 in 498. Both of these estimates are higher than the clinical community previously understood.

- Convened a meeting of the Obstetrics and Gynecological Medical Device Advisory Panel in July 2014. The panel discussed patient populations in which laparoscopic power morcellators should not be used, mentioning specifically patients with known or suspected malignancy. The panel also discussed mitigation strategies such as labeling, and suggested that a boxed warning related to the risk of disseminating unsuspected malignancy would be useful.
- Issued an Immediately In Effect (IIE) guidance that asks manufacturers of new and existing laparoscopic power morcellators to include two contraindications and a boxed warning in their product labeling. This information warns against using laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy and recommends doctors share this information with their patients.
- Published safety information related to these devices and alternative treatment options for the treatment of fibroids available on its website to help people better understand the risks of laparoscopic power morcellators.

In addition to the most recent contraindications and boxed warning, the FDA continues to consider other steps that may further reduce such risk—such as encouraging innovative ways to better detect uterine cancer and containment systems designed specifically for gynecological surgery.

The FDA 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.

Health care professionals employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Federal law requires hospitals to report some adverse events related to medical devices. Specifically, federal regulations require user facilities to report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must also report a medical device-related serious injury to the manufacturer or to the FDA if the medical device manufacturer is unknown.

With regard to the spread of unsuspected cancer when using laparoscopic power morcellation for hysterectomy or myomectomy in women with symptomatic uterine fibroids, the FDA considers this to be reportable as a serious injury.

Other Resources:

- FDA News Release: FDA warns against using laparoscopic power morcellators to treat uterine fibroids
- Recommended Labeling Statements for Laparoscopic Power Morcellators (PDF - 151KB)
- Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators - Guidance for Industry and Food and Drug Administration Staff
- FDA Obstetrics and Gynecology Panel Meeting Materials-July 10 and 11, 2014

- Society of Gynecologic Oncology (SGO)'s position statement on morcellation published in December 2013
- American Congress of Obstetricians and Gynecologists (ACOG)'s Statement on Choosing the Route of Hysterectomy for Benign Disease November 2009 (Reaffirmed 2011)
- *American Association of Gynecologic Laparoscopists (AAGL)'s AAGL Member Update: Disseminated Leiomyosarcoma With Power Morcellation 2014*

References:

1. NIH Fact Sheet on Uterine Fibroids. March 2013. Available at <http://report.nih.gov/nihfactsheets/viewfactsheet.aspx?csid=50>
2. Nieboer TE, Johnson N, Lethaby A, et al. Surgical approach to hysterectomy for benign gynecological disease. Cochrane Database Syst Rev. 2009;(3):CD003677.
3. Ibid.

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

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