U.S. Food and Drug Administration
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FDA News Release

FDA warns against using laparoscopic power morcellators to treat uterine fibroids

Agency recommends adding important safety information to product labels

For Immediate Release

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Release

Today, the U.S. Food and Drug Administration is taking immediate steps to help reduce the risk of spreading unsuspected cancer in women being treated for uterine fibroids. In an updated safety communication, originally issued in April 2014, the FDA warns against using laparoscopic power morcellators in the removal of the uterus (hysterectomy) or fibroids (myomectomy) in the vast majority of women.

In an Immediately in Effect (IIE) guidance, the FDA is also recommending that manufacturers of laparoscopic power morcellators include in their product labeling specific safety statements in the form of a boxed warning and two contraindications. The IIE guidance allows the FDA to issue its recommendations expeditiously to help address a significant public health issue.

“The FDA’s primary concern is the safety and well-being of patients and taking these steps will help the agency’s safety recommendations to be implemented as quickly as possible,” said William Maisel, M.D., M.P.H., deputy director for science and chief scientist at the FDA’s Center for Devices and Radiological Health. “Updating the device label with a boxed warning and contraindications will provide clinicians and patients with critical information about the risk of spreading cancerous tissue when these procedures are performed.”

The boxed warning informs health care providers and patients 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.

The two contraindications advise of the following:

- Laparoscopic power morcellators are contraindicated (should not be used) for removal of uterine tissue containing suspected fibroids in patients who are: peri- or post-menopausal, or candidates for *en bloc* tissue removal (removing tissue intact) through the vagina or mini-laparotomy incision. (These groups of women represent the majority of women with fibroids who undergo hysterectomy and myomectomy.)
- Laparoscopic power morcellators are contraindicated (should not be used) in gynecologic surgery in which the tissue to be morcellated is known or suspected to be cancerous.

The IIE guidance applies to currently marketed and new laparoscopic power morcellators for general and specific gynecological indications.

Based on a quantitative analysis of currently available data, the FDA estimated that approximately 1 in 350 women who are undergoing hysterectomy or myomectomy for fibroids is found to have an unsuspected uterine sarcoma. If laparoscopic power morcellation is performed in these women, 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.

The two contraindications help to clarify the narrow population of patients in which laparoscopic power morcellation may be an appropriate therapeutic option. For example, some younger women who are interested in maintaining their ability to have children or wish to keep their uterus intact after being informed of the risks may be candidates for this procedure.

"The FDA strongly encourages doctors to inform their patients of the risk of spreading unsuspected cancer from the use of these devices in fibroid surgery and discuss the benefits and risks associated with all treatment options," said Dr. Maisel.

There are other surgical treatment options available for women with symptomatic uterine fibroids, such as traditional surgical hysterectomy (performed either vaginally or abdominally) and myomectomy, laparoscopic hysterectomy and myomectomy without morcellation, and laparotomy using a smaller incision (minilaparotomy).

loads/MedicalDevices/Safety/AlertsandNotices/UCM393589.pdf), in July 2014 the FDA

oryCommittee/ObstetricsandGynecologyDevices/ucm404143.htm) to discuss patient populations in which laparoscopic power morcellators should not be used, specifically mentioning 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. The panel indicated that it is critical that doctors discuss the risks and benefits of all options with their patients.

In addition to the updated safety communication and IIE guidance, the FDA is considering other ways to further help reduce the risk of unsuspected cancer spread by laparoscopic power morcellation, such as encouraging innovative ways to better detect uterine cancer and contain potentially cancerous tissue.

The agency will continue to review adverse event reports, peer-reviewed scientific literature and information from patients, health care professionals, gynecologic and surgical professional societies and medical device manufacturers and may take further action in the future, if necessary.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

Jennifer Rodriguez (mailto:jennifer.rodriguez@fda.hhs.gov)
301-796-8232

Consumers

DICE@fda.hhs.gov (mailto:dice@fda.hhs.gov)
888-INFO-FDA

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Related Information

- **Updated FDA Safety Communication: Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy, November 2014 (/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm)**
- **Recommended Labeling Statements for Laparoscopic Power Morcellators (PDF - 151KB) (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM424444.pdf)**
- **National Institutes of Health: Uterine Fibroids Fact Sheet, March 2013 (http://report.nih.gov/nihfactsheets/viewfactsheet.aspx?csid=50)**