Jennifer L. Keel - FDA MedWatch - Laparoscopic Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication - Use Discouraged Due to Increased Risk in Women With Uterine Fibroids

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Subject: FDA MedWatch - Laparoscopic Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication - Use Discouraged Due to Increased Risk in Women With Uterine Fibroids

The FDA Safety Information and Adverse Event Reporting Program

Laparoscopic Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication - Use Discouraged Due to Increased Risk in Women With Uterine Fibroids

AUDIENCE: Internal Medicine, Nursing, OB/GYN, Oncology

ISSUE: FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.

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.

BACKGROUND: 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.

RECOMMENDATION: Health care providers and patients should carefully consider available alternative treatment options for symptomatic uterine fibroids. Do not use laparoscopic uterine power morcellation in women with suspected or known uterine cancer.

See the FDA Safety Communication for a complete list of recommendations for health care providers and patients.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including links to the FDA safety communication and data summary, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm393809.htm

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