The U.S. Food and Drug Administration (FDA) issued a Safety Communication on April 17, 2014, warning about the use of laparoscopic power morcellation for removal of the uterus or uterine fibroids.\(^1\) Morcellator devices, first approved for use by the FDA in the 1990s, are used to cut tissue into smaller pieces that can be removed through the incisions made during minimally invasive surgery.\(^2\)

Based on an analysis of currently available data, the FDA has determined that approximately 1 in 350 women who are undergoing hysterectomy or myomectomy for fibroids has an unsuspected uterine sarcoma.\(^3\) "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."\(^4\) The risk of spreading cancer during power morcellation has been known since the devices were first used, but the magnitude of the risk appears to be higher than previously appreciated.\(^5\)

The FDA has made the following recommendations for healthcare 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.\(^6\)

In light of the FDA warning, some hospitals have suspended use of the device. Dr. Isaac Schiff, chief of the Department of Obstetrics & Gynecology at Massachusetts General Hospital, has been quoted as saying, "I have asked our doctors to stop the procedure immediately until we have more information."\(^7\) Dr. Robert Barbieri, chairman of obstetrics and gynecology at the Brigham and Women's Hospital, advised surgeons that "we are immediately suspending use of this device in all cases until further notice."\(^8\) Both of these Boston hospitals are among a group of medical centers in the United States that had put safety restrictions on the procedure this year.\(^9\) Additionally, the Cleveland Clinic and the University of Pennsylvania Health System have stopped using power morcellation pending further review.\(^10\)

Johnson and Johnson (J&J), the largest maker of the devices, has announced that it has suspended sales, distribution and promotion of the tools, although it is not permanently pulling them from the market at this time.\(^11\) J&J has been quoted as stating:
We believe that suspending the commercialization of these products until their role is better understood and redefined by the medical community is the appropriate course of action at this time. … This decision was not made lightly because we are well aware of the significant benefits that these products can offer many women … Since 1998, Ethicon’s morcellation devices have enabled thousands of patients to have minimally-invasive surgical hysterectomy and myomectomy procedures, instead of more-invasive surgical procedures.12

Two organizations which represent physicians who perform the procedure, ACOG (American College of Obstetricians and Gynecologists) and AAGL (American Association of Gynecologic Laparoscopists), are presently conducting reviews of the scientific literature regarding power morcellation and alternative treatment options for uterine fibroids.13, 14 Further, the FDA plans to hold a meeting of its obstetrics and gynecological medical devices panel this summer to discuss the matter and determine whether further measures, including warnings posted by manufacturers of the equipment, are necessary.15

Although the FDA does not directly regulate the practice of medicine, its warnings and advisories do carry weight and could potentially be used against a physician and/or a hospital in professional liability litigation.

If a decision is made to continue performing morcellation, patient education and a thorough informed consent process with detailed supporting documentation is critical.16, 17 As with any invasive procedure, healthcare providers and patients should consider all available treatments and thoroughly discuss the risks and benefits of each. It is imperative for physicians to communicate fully with patients about the alternatives, risks and benefits of the procedure, including informing patients that their fibroids may contain unexpected cancerous tissue and that laparoscopic power morcellation may spread the cancer, significantly worsening patients’ prognosis, so that patients are able to make informed and voluntary decisions about their care.18, 19, 20

With respect to alternative treatments, the FDA notes:

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.21

Given the fact that failure to diagnose cancer claims are among the most frequent and costly claims in the professional liability industry, Coverys supports the FDA advisory which discourages the use of laparoscopic morcellation for removal of uterine fibroids. Should a healthcare provider make the decision to use this procedure, Coverys strongly recommends use of a thorough and comprehensive informed consent process, including:

- Discussion with the patient and documentation of the risks of performing the procedure, including those outlined previously
- Discussion with the patient and documentation of the alternatives to morcellation, including those outlined previously
- Documentation in the medical record of the physician’s medical decision-making regarding why morcellation is the appropriate procedure for the patient’s condition
- Documentation of the patient’s comprehension of the informed consent discussion – documenting “patient verbalized understanding” is not sufficient. The use of teach-back and documentation of the patient’s response or the adequacy of the response is recommended.

Coverys will continue to keep its insured physicians and hospitals apprised of future developments. For more information please contact your Coverys risk management consultant or visit the FDA website at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm
References

4. Ibid.
5. Dennis Thompson.
6. U.S. Food and Drug Administration (FDA).
8. Ibid.
12. Ibid.
15. Liz Kowalczyk.
18. The American College of Obstetricians and Gynecologists (ACOG).
19. Tracy Hampton.
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