When attorneys advertise on TV that they are putting together a class action lawsuit addressing a rising number of patient injuries or deaths, it is usually an indicator of an arising risk management issue. In the most recent series of such ads, attorneys are looking for individuals who have developed cancer following the use of power morcellators—primarily during gynecologic surgical procedures. A number of law firms have responded to this issue, exposing several substantial concerns. These matters have given rise to new regulatory concerns and warnings, in addition to causing changes in both the sales and distribution of these devices. Morcellators have provided significant benefits for many individuals, including shorter lengths of stay, shorter surgical recovery times, and fewer wound problems—such as lesser likelihood of infection. Considering these benefits as well as recent concerns, patient safety and risk managers have been prompted to rethink how, if at all, these devices should continue to be used.

What are Power Morcellators?

Gynecologists utilize power morcellators in procedures like hysterectomies and myomectomies. These instruments, also called electric morcellators, execute much of the cutting involved in laparoscopic and robotic surgeries. The morcellators are tiny devices with rotating blades that break large tissue masses into small fragments. Broken down tissues are then vacuumed out of the body through the laparoscope.

The use of power morcellators provides many advantages to both surgeons and patients. “The technique allows surgeons to make incisions of less than 2 centimeters in size, and remove fibroids and other tissue. These smaller entry points to the body mean doctors do not have to make large incisions through core stomach muscles. The transition to the smaller incisions has led to quicker patient recoveries, less post-operative pain and fewer wound complications.”

Power morcellators may also be used in laparoscopic renal (nephrectomy) or spleen (splenectomy) surgery. In these cases, benign or cancerous tissue may also
spread to the abdomen in both women and men, potentially producing severe complications.

**Type of Morcellators**

Surgeons typically perform surgery using two morcellation techniques: laparoscopic and hysteroscopic. The majority of morcellators fall into the laparoscopic category. In laparoscopic morcellation, surgeons insert the drill-like device through a small incision in the abdomen from which they are able to shred and remove the tissue. However, because the shredding occurs in an open environment, bits of tissue – including cancerous cells – can spray into the abdominal and pelvic cavity.

The second type of morcellation is called hysteroscopic morcellation. Hysteroscopic morcellators are designed with tissue traps or collection pouches, so when surgeons grind up tissue, it is safely contained in a pouch for testing. These devices also use mechanical versus electrical energy to both cut and collect the tissue. Studies thus far have shown that this newer technique is not linked to increased cases of cancer.

The FDA has stated that “when used in accordance with current indications and instructions for use, hysteroscopic morcellators do not pose the same risk as the devices addressed in this guidance because any sarcomatous tissue present does not enter the peritoneal cavity.”

**Risk of Potential Harm from Power Morcellator Use**

Power Morcellators are small devices that can be used during a hysterectomy or myomectomy to cut tissue through a small incision. Current reports indicate that 1 in 350 women having surgery to remove fibroids also have an undetected uterine sarcoma, a cancer of the uterus muscle and tissues. The morcellator uses spinning blades that can facilitate the spread of these, as well as other, cancerous cells to other organs in the body during the procedure. As a result of these reports, the FDA has issued recommendations that physicians discontinue all use of Power Morcellators devices. Some hospitals have taken these recommendations so far as to completely ban the usage of all Power Morcellators in their practice.

**Recommendations for Health Care Providers**

On November 24, 2014, the FDA issued an updated statement directed at power morcellator providing manufacturers, providers and patients, declaring that the FDA now believes the risks associated with the use of power morcellators may be higher than previously estimated. Due to the re-estimated severity of this risk as well as 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.

**Recommendations for Health Care Providers and Patients**

Risk managers should make certain that all providers using laparoscopic power morcellators be made 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 of the available treatment options for women with uterine fibroids.

Physicians should also be advised of the need to thoroughly discuss the benefits and risks of all treatments with patients. They should 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.

In the same FDA Guidance, recommendations for patients include:

- Ask your health care provider to discuss all the options available to treat your condition. You should be aware of the risks and benefits associated with all medical devices and procedures.

- 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. These include 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 multiple actions in light of scientific information that suggest 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: vii

- The FDA has 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 them to believe 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.

- The FDA 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.

- The FDA issued an Immediately In Effect (IIE) guidance asking 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.

In addition to the most recent contraindications and boxed warning, the FDA continues to consider other risk mitigation steps — 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.

**Response by the Device Manufacturers**

Ethicon, Inc., a subsidiary of Johnson & Johnson, has recently halted sales of their power morcellators following the issuance of usage warnings from federal health regulators. A report from the Food & Drug Administration (FDA) indicates that the morcellators can spread undetected cancer cells while patients undergo a hysterectomy or myomectomy for fibroids, and lead to the development of uterine sarcoma (cancer of the muscle and supporting tissues around the uterus). Johnson & Johnson has also stopped sales and distribution as a result of the alerts issued by the FDA. However, it is important to note that Johnson & Johnson has failed to issue a recall of the morcellators, so the devices continue to be used by physicians.
Reporting Patient Injuries to the FDA

It is the responsibility of risk managers to report any device-related claims to the device manufacturer, as well as the FDA. Promptly reporting adverse events can help the FDA identify and better understand the risks associated with medical devices like power morcellators. 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.

The View of the Professional Society

Following the more stringent warning from the FDA, the American College of Obstetricians and Gynecologists (ACOG), through their executive Vice President and Chief Executive Officer, Dr. Hal Lawrence, explained what the industry needed to do to make the procedure safer. In an interview reported on Medscape, dated January 15th 2015, he highlighted three specific issues that practitioners should consider before making the decision to use a morcellator. The first, and most imperative, is that physicians ensure they know which patients are not candidates for morcellation. Second, it is also essential to understand there may be some patients who are good, or reasonable, candidates for morcellation based on their situation, their diagnosis or their co-diagnoses. Finally, Dr. Lawrence stated it is crucial for physicians who believe they have identified a patient who will benefit from morcellation, that helpful and thorough informed consent is provided.

Additional Risk Management Considerations

Even though guidance is primarily directed at gynecologists or surgeons performing hysterectomy or myomectomy procedures, all surgeons using a power morcellator in conjunction with a laparoscopic procedure should be made aware of the risk, and be advised of the need to use a morcellator only when the tissue traps or collecting pouches are used to capture all of the tissue which is being morcellated.

v. Ibid (accessed 1/5/15)
vi. Ibid (accessed 1/5/15)
vii. Ibid (accessed 1/5/15)
ix. Ibid (accessed 1/18/15)
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