Laparoscopic Power Morcellators

Laparoscopic power morcellators are Class II medical devices used during laparoscopic (minimally invasive) surgeries to cut tissue into smaller pieces so the tissue can be removed through a small incision site (typically 2 cm long or less).

These devices are commonly used in gallbladder, kidney, liver, and spleen removal surgery. They are also used in hysterectomy (surgical procedure to remove a women's uterus) and myomectomy (surgical procedure to remove uterine fibroids which are noncancerous growths in the lining of a women's uterus).

Laparoscopic surgeries are associated with shorter post-operative recovery time and a reduced risk of infection compared to hysterectomy or myomectomy done through an abdominal incision.

What Women and their Health Care Providers Need to Know about Using Laparoscopic Power Morcellators to Treat Uterine Fibroids

Uterine sarcoma (a type of cancer) is more common in women undergoing surgery for uterine fibroids (noncancerous growths in the lining of a women's uterus) than previously thought, and it can be hard to distinguish between a uterine sarcoma and a uterine fibroid prior to surgery with available tests. When laparoscopic power morcellators are used for myomectomy or hysterectomy in women with presumed uterine fibroids that are actually uterine sarcomas, the surgical procedure poses a risk of spreading cancerous tissue beyond the uterus, worsening their chances of long-term survival without cancer.

The FDA currently estimates that a hidden uterine sarcoma may be present in approximately 1 in 225 to 1 in 580 women undergoing surgery for uterine fibroids based on recent publications. The FDA also estimates that a leiomyosarcoma (a specific type of uterine sarcoma) may be present in approximately 1 in 495 to 1 in 1100 women undergoing surgery for uterine fibroids based on recent studies. Prior to 2014, the clinical community estimated uterine sarcomas to be present much less frequently, in as few as 1 in 10,000 women undergoing surgery for uterine fibroids.

Several studies show that using a laparoscopic power morcellator during gynecologic surgery in women with hidden uterine sarcomas is associated with lowering their chances of long-term survival without cancer. While these studies have limitations, women who have had fibroid surgery with a laparoscopic power morcellator later found to have a hidden uterine sarcoma, have lower disease-free survival (less time without any sign or symptom of cancer after surgery), when compared to women who were treated with manual morcellation or without morcellation.

Uterine sarcomas and uterine fibroids have similar signs and symptoms. There are no imaging tests proven completely accurate or reliable laboratory markers to distinguish between uterine sarcomas and uterine fibroids. Pre-procedure or pre-operative tests, including endometrial biopsies (tissue sampling), cannot reliably predict the presence of a hidden uterine sarcoma.

The FDA recommends health care providers share this information with patients, and warns against using laparoscopic power morcellators in gynecologic surgeries to treat patients with suspected or confirmed cancer, and in the majority of women undergoing myomectomy or hysterectomy for uterine fibroids.

Health care providers and informed patients can work together to choose the best treatment approach based on known risk factors for uterine sarcoma (e.g., age, exposure to pelvic radiation therapy, prior use of the drug Tamoxifin, and race). For some patients, the benefits of minimally invasive surgery with a laparoscopic power morcellator may outweigh the risks. These patients may include some younger women who wish to maintain their fertility.

Considerations for Manufacturers of Laparoscopic Power Morcellators

The FDA recommends that manufacturers of laparoscopic power morcellators with a general indication or a specific gynecologic indication include more information in their device's labeling to inform health care providers and patients about the risk of cancer spread when these devices are used to treat uterine fibroids.

Manufacturers have added the information below to the labeling on their devices:

- Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy;
- Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or post-menopausal, or candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision; and,
- A specific boxed warning that states 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.

Using Real-World Data to Compare Treatments for Uterine Fibroids on Patient Outcomes

The FDA is collaborating with Duke Clinical Research Institute, patients and patient advocacy groups, health care providers, professional associations, and other federal agencies on the COMPARE-UF registry to gather real-world data from women having any treatment for uterine fibroids. Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.

The registry will collect information about clinical outcomes, quality of life, need for additional procedures, and issues related to pregnancy for women aged 18-54 through three years post-fibroid treatment.

The FDA believes that this information will be used to help future patients, clinicians, and others make the most informed decisions about the best type of treatment for each patient's situation.

To learn more about this registry, or learn how to participate, see the "Participate" section of the COMPARE-UF registry website.

Making Surgeries with Laparoscopic Power Morcellators Safer through Containment Systems

In 2016, the FDA allowed the first tissue containment system on the market for use with certain laparoscopic power morcellators to isolate uterine tissue not suspected to contain cancer. This containment system is a first step in FDA-regulated device innovations to help mitigate potential risks of tissue spread.

The containment system has not been proven to reduce the risk of spreading cancer during these procedures, and is intended to be used only in a limited patient population, including women without uterine fibroids undergoing hysterectomy and some pre-menopausal women with fibroids who want to maintain their fertility.

Reporting Problems Related to Laparoscopic Power Morcellators to the FDA

The FDA calls for patients, health care providers, and manufacturers to continue to report events associated with laparoscopic morcellators to the Agency; such information is critical in helping us learn as much as possible about the adverse events associated with these devices.

If you suspect a problem resulting from the use of a laparoscopic power morcellator, we encourage you to file a voluntary report through MedWatch, the FDA Safety

Information and Adverse Event Reporting program.

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

Device manufacturers must comply with the Medical Device Reporting (MDR) regulations.

Contact Us:

If you have questions about this issue, please contact the Center for Devices and Radiological Health's Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV**, 800-638-2041 or 301-796-7100.

Resources on FDA Actions Related to Using Laparoscopic Power Morcellators to Treat Uterine Fibroids

- 2014 Safety Communication
- 2014 Meeting Materials of the Obstetrics and Gynecology Devices Panel
- 2014 Review

More in Surgery Devices

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