

## **Power Morcellation**

### **Considerations for Physicians during the Informed Consent Process**

#### **Background**

In a safety communication issued April 17, 2014, the FDA discouraged the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids. Several national professional organizations, including the American College of Obstetricians and Gynecologists (ACOG), the American Urogynecologic Society (AUGS) and the American Association of Gynecologic Laparoscopists (AAGL) have since issued communications stating that they do not discourage the use of power morcellation in all cases. Instead, these organizations emphasize the need for thorough preoperative patient evaluation and informed consent which entails a discussion regarding the risks, benefits and alternatives to power morcellation. This communication provides considerations for obtaining informed consent if a surgeon wishes to proceed in using a laparoscopic power morcellator during hysterectomy or myomectomy for uterine fibroids.

#### **Discussion of the following background information during the preoperative visit:**

- That the surgeon proposes to use a power morcellator during surgery, due to either the size of the uterus, the size of the fibroid(s) or a plan to perform a supracervical hysterectomy.
- Power morcellators are medical devices used to divide tissue into smaller pieces in order to facilitate removing the tissue through small incisions. Power morcellation allows for a minimally invasive approach, as opposed to an open/abdominal procedure.
- The fact that on April 17, 2014, the FDA discouraged the use of power morcellation during hysterectomy or myomectomy for fibroids, but it did not discourage the use of power morcellation for non-fibroid conditions. .

#### **Discussion of the following benefits, risks, and alternatives to power morcellation:**

##### ***Benefits***

- Accomplishment of a minimally invasive surgery with the associated benefits of a lower risk of postoperative complications (e.g., infection, bleeding, venous thromboembolism, wound complications and abdominal wall hernias), less postoperative pain, shorter hospital stays, and quicker return to activities of daily living.

##### ***Potential Risks***

- There is a risk of undiagnosed gynecologic cancer that cannot always be detected preoperatively. .
- If there is undiagnosed cancer use of the power morcellator creates a risk of:
  - Intraoperative dissemination of malignant tissue which may significantly worsen the patient's prognosis.
  - Greater difficulty making a definitive diagnosis and accurate staging of underlying malignancy.
  - Need for additional surgery and/or medical management.
- Dissemination of benign uterine tissue (e.g., leiomyoma, endometriosis, adenomyosis and ovarian remnants) which can result in spread of these tissues beyond where they were originally.
- Injury to adjacent organs when using the morcellator.

### **Alternatives**

- Removal of intact tissue through mini-laparotomy with manual morcellation, laparotomy or colpotomy incisions; total abdominal hysterectomy; vaginal hysterectomy; or laparoscopic hysterectomy with vaginal removal of the specimen. An intraperitoneal bag can also be used to contain the specimen during power morcellation; however, potential disruption of the bag during morcellation and reduced visualization may limit its use and may increase the risk of injury to adjacent organs. Not all of these may be an option for every patient.

An understanding of the risks, benefits and alternatives, as well as the decision to proceed with surgery involving the option of either morcellation within a bag or traditional power morcellation techniques is part of the shared decision-making process. The informed consent process should be fully documented.

### **Additional Resources**

FDA - <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm>

ACOG - [http://www.acog.org/Resources\\_And\\_Publications/Task\\_Force\\_and\\_Work\\_Group\\_Reports/Power\\_Morcellation\\_and\\_Occult\\_Malignancy\\_in\\_Gynecologic\\_Surgery](http://www.acog.org/Resources_And_Publications/Task_Force_and_Work_Group_Reports/Power_Morcellation_and_Occult_Malignancy_in_Gynecologic_Surgery)

AUGS - <http://www.augs.org/p/cm/ld/fid=202>

AAGL - <http://www.aagl.org/aaglnews/new-aagl-tissue-extraction-task-force-report/>

SGO - <https://www.sgo.org/newsroom/position-statements-2/morcellation/>

SGS - [http://www.sgsonline.org/assets/docs/Special\\_Reports/sgs-acog%20support%20statementv2051214.pdf](http://www.sgsonline.org/assets/docs/Special_Reports/sgs-acog%20support%20statementv2051214.pdf)

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