

AUGS Position Statement: Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy FDA Safety Communication and ACOG Special Report

The U.S. Food and Drug Administration discouraged the use of laparoscopic power morcellation, also known as electromechanical morcellation, in hysterectomy or myomectomy for the treatment of women with uterine fibroids. In a safety communication notice issued April 17, 2014, the FDA concluded that power morcellation poses a risk of intraperitoneal dissemination of malignant tissue, notably uterine sarcomas. This announcement refers to the use of power morcellation for treatment of uterine fibroids and not for other conditions associated with hysterectomy, such as pelvic organ prolapse. The FDA safety communication was updated in December 2017, to include the prevalence of leiomyosarcomas and the differences in patient outcomes between those who had surgery with and without use of power morcellation. Thus, the FDA continues to caution against the use of power morcellation during hysterectomy or myomectomy for the treatment of fibroids.

https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLife Support/UCM584539.pdf

In response, the American College of Obstetricians and Gynecologists (ACOG) issued a special report (May 9, 2014) and statement (November 24, 2014) on the use of power morcellation:

https://www.acog.org/Clinical-Guidance-and-Publications/Task-Force-and-Work-Group-Reports/Power-Morcellation-and-Occult-Malignancy-in-Gynecologic-Surgery

https://www.acog.org/About-ACOG/News-Room/Statements/2014/ACOG-Statement-on-Power-Morcellation

AUGS endorses the ACOG Special Report. AUGS also supports the FDA safety communication recommendation against the use of power morcellation for women with suspected or known uterine cancer. In cases of unsuspected malignancies (uterine sarcomas and carcinomas), dissemination from power morcellation may also reduce survival rates for these patients. When used correctly in appropriately selected patients, power morcellation facilitates the completion of minimally invasive hysterectomy. Minimally invasive surgery is associated with reduction in postoperative morbidity due to reduced time under anesthesia, reduction in infection and pain and a quicker return to activities of daily living compared to open laparotomy.

Separate considerations may apply for patients undergoing hysterectomy for the primary indication of pelvic organ prolapse. After appropriate pre-operative evaluation, supracervical hysterectomy facilitated by power morcellation during mesh sacrocolpopexy is a reasonable procedure. Shared decision making between a patient and her surgeon to perform power morcellation during a supracervical hysterectomy for a minimally invasive mesh sacrocolpopexy should include the risks and benefits during the informed consent process.

AUGS supports the utilization of a registry to audit occult malignancy with hysterectomy for benign gynecologic conditions.