As a patient, you have the right to receive information about the risks, benefits, limitations and alternatives to any proposed treatment or procedure in order to give informed consent or to refuse a specific type of treatment. Informed consent respects your rights as a person. It respects your right to body integrity, to self-determination, and supports your freedom to make informed decisions. Communication is essential for informed consent. It is important for you and your surgeon to communicate fully about the risks and benefits of all procedures, including surgical options so that you are able to make an informed and voluntary decision about the care you receive. You have the right to a second opinion at anytime.

You are scheduled to have an operation utilizing Minimally Invasive Surgery which means one or more small incisions. Sometimes the tissue specimen is too large to remove through a less than 1 inch incision and the tissue needs to be divided (or morcellated) to remove it through the small incision. Surgeons may choose to divide the tissue or morcellate to avoid a larger incision in the vagina or abdomen. Alternatives to morcellation include removal of tissue through a larger incision in the abdomen or vagina, or a hysterectomy (removal of the entire uterus) without dividing the tissue through an incision in the abdomen or vagina.

You and your surgeon have decided to proceed with a surgery which will include tissue morcellation, or cutting the tissue into smaller pieces. This can be performed manually using a scalpel, or by using a power morcellator. A power morcellator is a surgical device that divides tissue inside your abdominal cavity during minimally invasive procedures to allow your surgeon to remove fibroids or a uterus through very small incisions in your abdominal wall (laparoscopy).

On April 17, 2014, the U.S. Food and Drug Administration (FDA) issued a safety communication discouraging the use of laparoscopic uterine power morcellation in hysterectomy and myomectomy to avoid the risk of spreading an undetected cancer. The statement can be accessed at:


The FDA released an updated communication on November 24, 2014 restating the importance of a comprehensive discussion with your surgeon about the risks, benefits, and possible alternative treatment options. This statement can be accessed at:

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm

The Society of Gynecologic Oncology, The American Association of Gynecologic Laparoscopists and The American College of Obstetricians and Gynecologists researched and published special reports on power morcellation of tissue. These organizations state that there are benefits and risks of tissue power morcellation. These statements can be accessed at:

http://www.acog.org/Resources_And_Publications/Task_Force_and_Work_Group_Reports/Power_Morcellation_and_Occult_Malignancy_in_Gynecologic_Surgery


Without power morcellation, some patients would not be able to have minimally invasive surgery. A larger incision may have more complications such as infection, bleeding, blood clots, and injury to the nerves and other organs. A patient who has an abdominal hysterectomy has three times the risk of death compared to a patient who has a laparoscopic (small incision) hysterectomy. In addition, smaller incisions generally result in less postoperative pain, shorter hospital stays, and quicker recoveries.

Every patient undergoing surgery has a risk of a hidden cancer. The risk estimate of a uterine sarcoma (a type of uterine cancer) in women having a myomectomy or hysterectomy for fibroids is 2:1000. If a hidden cancer is present, the procedure of power morcellation may increase the risk of spreading the cancer, increase the need for further treatment, and potentially worsen the outcome for the patient. Furthermore, these rare fibroid cancers have an extremely poor prognosis even when specimens are removed intact. There have been reports that power morcellation may also spread benign tissue to other areas of the abdomen, which may require
additional surgery.

Alternatives to power morcellation include removal of tissue by manually cutting the tissue into smaller pieces, remove tissue through a larger incision in the abdomen or vagina, or a hysterectomy (removal of the entire uterus) without dividing the tissue through an incision in the abdomen or vagina. You are encouraged to discuss all options with your physician to ensure you understand the risks, benefits, and alternatives of all treatment options.

References:
• UPDATED Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication, 11.24.14
• FDA Safety Communication on Laparoscopic Uterine Power Morcellation, 04.27.14
• ACOG Committee Opinion on Informed Consent, number 439 (2009, reaffirmed 2012)
• AAGL Member Update: FDA Issues Safety Communication on Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy, 04.22.14
• ACOG Statement: FDA Issues Safety Communication on Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy, as of 04.27.14
• SGO Statement on Morcellation, December 2013
• American College of Obstetricians and Gynecologists. Power Morcellation and Occult Malignancy in Gynecologic Surgery. May 2014
• AAGL. Morcellation During Uterine Tissue Extraction. May 2014
INFORMED CONSENT:
By designating your choice below, you verify that you understand the information provided in the patient education document titled, PATIENT EDUCATION FOR TISSUE EXTRACTION BY POWER MORCELLATION, and that your surgeon has provided thorough counseling and answered all questions you have regarding the use of tissue morcellation during your procedure. There may be additional risks and benefits due to your specific medical condition(s). You have discussed this with your surgeon and have had all questions answered to your satisfaction. The potential risks, benefits, alternatives and limitations to power morcellation are clear to you and you are willing to document your preference in writing.

Please initial one choice:

I consent to the use of power morcellation inside my body during surgery and accept the potential risks associated with the possible spread of an undetected gynecologic cancer.

I consent to the use of power morcellation (by power morcellation or alternative morcellation techniques) inside my body during surgery CONTAINED in a bag and accept the potential risks associated with the possible spread of an undetected gynecologic cancer.

I decline the use of power morcellation inside my body during surgery and have discussed the alternatives with my surgeon to my satisfaction.

Other__________________________________________________

Print Patient Name Patient Signature Date

SURGEON DOCUMENTATION OF INFORMED CONSENT FOR USE OF POWER MORCELLATION

I am the primary surgeon for the proposed procedure. The risks and benefits of tissue morcellation by the power morcellator or alternative morcellation techniques have been discussed with my patient. All of my patient’s questions have been answered.

Print Surgeon Name Surgeon Signature Date