Consent to Take Part in a Human Research Study

Title of Research Study: Safety and Efficacy of a Contained Electromechanical Power Morcellation System for Laparoscopic Hysterectomy and Myomectomy.

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Why am I being invited to take part in a research study?
We invite you to take part in a research study that is designed to evaluate the safety and efficacy of morcellation in a bag in preventing specimen leakage. You are being asked to participate in this study because you are scheduled for either a laparoscopic myomectomy (removal of fibroids from the uterus) or a laparoscopic hysterectomy (removal of the uterus).

A power morcellator is a surgical instrument used for removal of large masses of tissues during laparoscopic (i.e. minimally invasive) surgery. Due to the small incisions used during laparoscopic surgery, the specimen must be minced up, or morcellated, into smaller pieces inside the abdominal cavity in order to remove them. This is commonly done during a laparoscopic hysterectomy (removal of the uterus) or myomectomy (removal of fibroids from the uterus).

Due to concerns regarding the spread of small amounts of tissue during morcellation, we have been performing this procedure in a contained specimen retrieval bag since May 2014. Our standard of care is to use the Espiner Medical Ltd. EcoSac 230. In order to appropriately visualize the specimen being morcellated, we have needed to create a puncture hole in the side of the bag and use the camera through that hole. We are performing this study to avoid the need for this puncture hole and to demonstrate that there is no risk of leakage outside of the bag.

The bag being used are the Espiner Medical Ltd. EcoSac 400 ECO-T.
The EcoSac 400 ECO-T is an investigational device that is not approved for use in the United States outside of a research protocol. The EcoSac 230, whish is the bag currently used, is a U.S. Food and Drug Administration (FDA) cleared tissue extraction bag; however, the process of insufflating (inflating the bag into a body cavity) the bag is an off-label use of this product, i.e. a use that has not

been FDA approved.

What should I know about a research study?

- Someone will explain this research study to you.
- Participation in the study is voluntary
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, complaints, or think the research has hurt you, talk to the research team at **630-428-2229**.

This research has been reviewed and approved by an Institutional Review Board ("IRB") and will be monitored by the IRB of Advocate Health Care. An IRB is a committee, independent of the investigators, that reviews and oversees research studies to protect the rights and safety of participants. You may talk to them at 630-929-6148 or email IRBMail@advocatehealth.com if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

Uterine fibroids are non-cancerous growths that start from the smooth muscle tissue in the wall of the uterus. Two common treatments for uterine fibroids are hysterectomy and myomectomy.

- A **hysterectomy** is a surgery to remove a woman's uterus (also known as the womb). The uterus is where a baby grows when a woman is pregnant. During the surgery the whole uterus is usually removed. Your doctor may also remove your fallopian tubes and ovaries.
- **Myomectomy** is the surgical removal of fibroids from the uterus. It allows the uterus to be left in place and, for some women, makes pregnancy more likely than before. **Myomectomy** is the preferred fibroid treatment for women who want to become pregnant.
- **Insufflation** is the process of using carbon dioxide gas to inflate your belly and enable appropriate visualization of the organs in the abdomen. This process is used in all laparoscopic surgery in order to see appropriately.

Laparoscopic surgery, also called minimally invasive surgery (MIS), bandaid surgery, or keyhole surgery, is a modern surgical technique in which operations are performed through small incisions (usually 0.5 – 1.5 cm or approximately 0.2 – 0.5 fractions of an inch) using a camera, or laparoscope. It has proven benefits including decreased hospital re-admission, decreased pain, faster recovery, decreased infection rates, decreased overall morbidity (a diseased state, disability, or poor health) and decreased mortality (death) when compared to "open" traditional surgical procedures.

- With any laparoscopic surgery, it may be clinically necessary during the procedure to change to an open incision if there are complications that cannot be safely managed laparoscopically. An open incision can range anywhere from 10 cm (almost 4 inches) to 20 cm (almost 8 inches) and can be transverse ("bikini" incision) or vertical depending on surgical findings and indications.

- In order to remove a large specimen such as an enlarged uterus (commonly caused by uterine fibroids) or large fibroids laparoscopically, power morcellation is often utilized. Power morcellators are medical devices used during different types of laparoscopic surgeries, including hysterectomy and myomectomy, to cut tissue into pieces small enough that they can be easily removed through the small incisions. Power morcellation can inadvertently cause the tissue to be spread throughout the belly. This may result in small pieces attaching to the bowel, pelvic walls and organs that may result in further fibroid growth, pelvic pain, bowel obstruction and the need further surgical procedures. In addition, the FDA has determined that approximately 1 in 350 women who are undergoing hysterectomy or myomectomy for fibroids may have an unsuspected type of uterine cancer called a leiomyosarcoma. If this tissue is morcellated and spread throughout the abdomen, it may affect the patient's long term survival by distributing the cancerous cells more widely.

- This research study is being done in response to the statement released by the FDA discouraging the use of power morcellation in patients undergoing laparoscopic hysterectomy. Some doctors are advocating the use of a specimen bag during power morcellation for containment of the specimen. We would recommend performing morcellation in a bag during your procedure whether or not you participate in the study.

- The purpose of the research study is to evaluate whether there is any leakage from the bag after contained power morcellation. This research may therefore benefit patients undergoing similar procedures in the future.

How long will the research last?
The study is expected to last approximately one year. We expect that you will be in this research study from the time of your operation through the time it takes for you to complete the postoperative pain assessments during follow up visits or phone calls, approximately 4 – 6 weeks total.

How many people will be studied?
We expect that up to 60 people will be in this research study.

What happens if I say yes, I want to be in this research?
- You will undergo your scheduled procedure as stated on your regular hospital procedure consent form.
- We will use the **EcoSac 400 ECO-T:**
- If your uterus or fibroids need to be removed by power morcellation, we will perform this in the bag.
- The bag will be insufflated during morcellation to allow the surgeons to visualize the procedure being done.
- We will perform a "washing" of the inside of the bag that pathology will evaluate for any retained fibroid pieces or cells.
- After performing the morcellation and removing the bag, we will place an albumin solution with blue dye inside of the bag to assess for any areas of leakage. This will occur outside of and away from your body in a separate room.
- We will confidentially record information about your surgery and your post operative period.

Follow up will occur as outlined in the schedule of study activities below:

Table 1: Study Activities

Study Activities	Screening, Enrollment, and Baseline Evaluation (Visit 1 – in the Office)	Pre-operative Care (Visit 2 – in the Hospital)	Surgery (Visit 3 – in the Hospital)	Immediate Post-operative Follow-Up (Visit 4 – in the Hospital)	Post Op Follow-Up (Visit 5-7 Phone calls week 1 and 2* then in the Office week 4-6)
Medical History/ Clinical Status	X				
Secure Informed Consent	X				
Morcellation			X		
Bag Testing			X		
Adverse Event Assessment			X	X	X
Pain Assessment				X	X

*Note: Phone calls week 1 and 2 are the only items in this schedule that are outside routine care

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for undergoing your already planned procedure and permitting data pertaining to your case to be included in the study analyses.

What happens if I do not want to be in this research?
You can leave the research at any time and it will not be held against you.

Instead of being in this research study, your choices include:

- Undergoing power morcellation in a bag without participating in the study;
- Undergoing power morcellation without a bag;
- A larger incision (40 - 100 mm or 1.6 – 4 inches) can be made to remove the specimen intact and without morcellation.

The important risks and possible benefits of these alternatives include:

- Risk of power morcellation without a bag increases your risk of tissue spreading throughout your abdomen
- Risks of a larger incision include longer recovery time, increased infection rate, higher pain scores, higher hospital admission rate, increased morbidity and mortality

A benefit of making a larger incision and removing the tissue intact is that it may improve the ability of the pathologist to analyze the tissue and determine whether disease is present. A larger incision also avoids the risk of spreading cancer cells, should any be present, due to power morcellation.

As this is an investigational procedure, either because of the unapproved bag used or due to the insufflation of the approved bag, there may be other risks that are not anticipated.

What happens if I say yes, but I change my mind later?
You can leave the research at any time it will not be held against you.

If you wish to withdraw from the study after your procedure is complete, we will not record any further information for research purposes. However, all data collected prior to your withdrawal will remain in the study and will not be removed.

Is there any way being in this study could be bad for me?
There is a small potential risk of the bag tearing during morcellation leading to use of a foreign body without benefit of tissue containment. Were this to happen, a new bag would immediately be used and the abdomen and pelvis completely irrigated.

There is also a potential for decreased visualization of surrounding organs while the bag is insufflated. However, there should not be a risk of trauma to these surrounding structures because we will only be operating inside the bag and will be able to visualize everything inside the bag.

The use of the bag may prolong the surgery slightly due to the time spent inserting and removing the bag.

Finally, as this is an investigational procedure, there may be other risks that are not anticipated.

Will there be any costs to me if I participate?
You and/or your insurance carrier will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance carrier to see what services will be covered and what you will be responsible to pay. Study staff can assist you with this.

Espiner Inc., the manufacturer of the morcellation bags, will provide these free of charge for the study. Neither you nor your insurance carrier will be charged.

Will being in this study help me in any way?
Although at this time it has not been scientifically demonstrated, we believe that contained power morcellation in a bag inherently decreases the spread of the morcellated tissue. For this reason, we recommend using this morcellation technique whether or not you agree to participate in this research. If you do participate in this research, we will be able to systematically evaluate power morcellation in a bag.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB, FDA and other representatives of this organization.

Federal law provides additional protections for your medical records and related health information. That law is the Health Insurance Portability and Accountability Act (HIPAA). This study's HIPAA statement is provided at the end of this consent form, before the signature page. You are providing your authorization if you sign this consent form to participate in the study.

What happens if I am injured because I took part in the study?
We do not anticipate any increase in injury risk by participation in this study. In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury.

No funds have been set aside by Advocate Health Care as reimbursement for injury or associated costs. You are not giving up any legal rights to seek to obtain compensation for injury.

Can I be removed from the research without my OK?
The principal investigator in charge of this research can remove you from this study without your approval. Possible reasons for removal may include an intraoperative decision to not proceed with morcellation, any suspicion of malignancy, or the ability to remove the fibroids without power morcellation. We will tell you about any new information that may affect your choice to stay in the research.

What else do I need to know?
Espiner Inc. will supply the bags free of charge for the study. The company has no other financial relationship with the research or the investigative team.

There is no compensation for your participation in this study.

How will my information be kept confidential?
Your identity will be protected as required by law and according to any policies described in privacy and confidentiality sections above. You should be aware that your study records (which may include your medical records, your signed consent form and other identifiable information) will be shared as needed for the purposes of the study. If this is a sponsored study, researchers may share your information with representatives of the sponsor for the purposes of managing and overseeing the study. Usually the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Additionally, governmental oversight authorities [e.g. the U.S. Food and Drug Administration (FDA) or the Department of Health and Human Services Office for Human Research Protections (OHRP)] may have access to your information. Representatives of the Institutional Review Board overseeing this study may have access to your data.

Please note that the study investigator or study staff may also share personal information about you if required by law (for example, if the study investigator or study staff suspects that you are going to harm someone or yourself). If you have questions about this, please ask the study investigator.

How will my information be used and shared for this study?
This section explains who will use and share your health information if you agree to be in this study. You must authorize this use and sharing of your information by signing this form or you cannot be in the study.

The study principal investigator and study staff will collect, use, and share identifiable health information about you, including any information needed to conduct the study. Information used and shared may include:

- information from your medical records related to the research;
- information collected about you during the research and any follow-up concerning study visits, tests, procedures, outcomes, etc.

Your information may be used and shared for some or all of the following purposes:

- to conduct this research;
- to review the study, and to check the safety and results of the study;
- to seek government approval of an investigational study drug, vaccine, device or product if such was involved in the trial;
- to facilitate a public health authority that is authorized by law to collect or receive such information for the purpose ofpreventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

After your information is shared with the organizations listed above, the law may not require them to protect the privacy of your information. To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

You can cancel your authorization to use and share your information at any time by writing a letter to the study investigator. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

If you cancel your authorization, the study investigator and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study. No new information will be collected without your permission. This authorization to use and share your information has no expiration date. If study information is used for scientific publications or educational purposes, all identifying information will be removed.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

[A witness signature is required only if the subject is illiterate or does not speak English.]

Witness statement: My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	