Different Women.
Different Needs.

YOUR GUIDE TO MINIMALLY INVASIVE HYSTERECTOMY

1 IN 3 WOMEN WILL HAVE A HYSTERECTOMY BY THE TIME THEY ARE 60 YEARS OF AGE.[1]

If you are considering hysterectomy
you are not alone

of women will consult with their doctor, according to the CDC, because they are experiencing one or more of the following conditions:

- *Fibroids*
- *Menorrhagia*
- *Endometriosis*
- *Uterine Prolapse*
- *Female Reproductive Cancers*

OVER 600,000
WOMEN

in the United States will undergo a hysterectomy this year, according to the CDC.

[1]American College of Obstetricians and Gynecologists, 2011

When to consult a GYN surgeon

If you have been diagnosed with any of these conditions, you may want to consult a gynecology surgeon to determine if hysterectomy is necessary.

Fibroids

Benign (non-cancerous) tissue growths inside or outside of the muscle walls of the uterus that can vary greatly in size and cause pain and abnormal bleeding. Fibroids can grow as a single mass, or there can be multiple fibroids in the uterus. Another medical term for fibroids is “leiomyoma” or just “myoma.” Most fibroids are benign, but there is a small chance they could contain pre-cancerous or cancerous cells. It’s important to speak to your doctor about this risk.

Menorrhagia

Abnormally heavy and prolonged menstrual periods that is commonly caused by fibroids or hormonal changes, but can be caused by disease.

Endometriosis

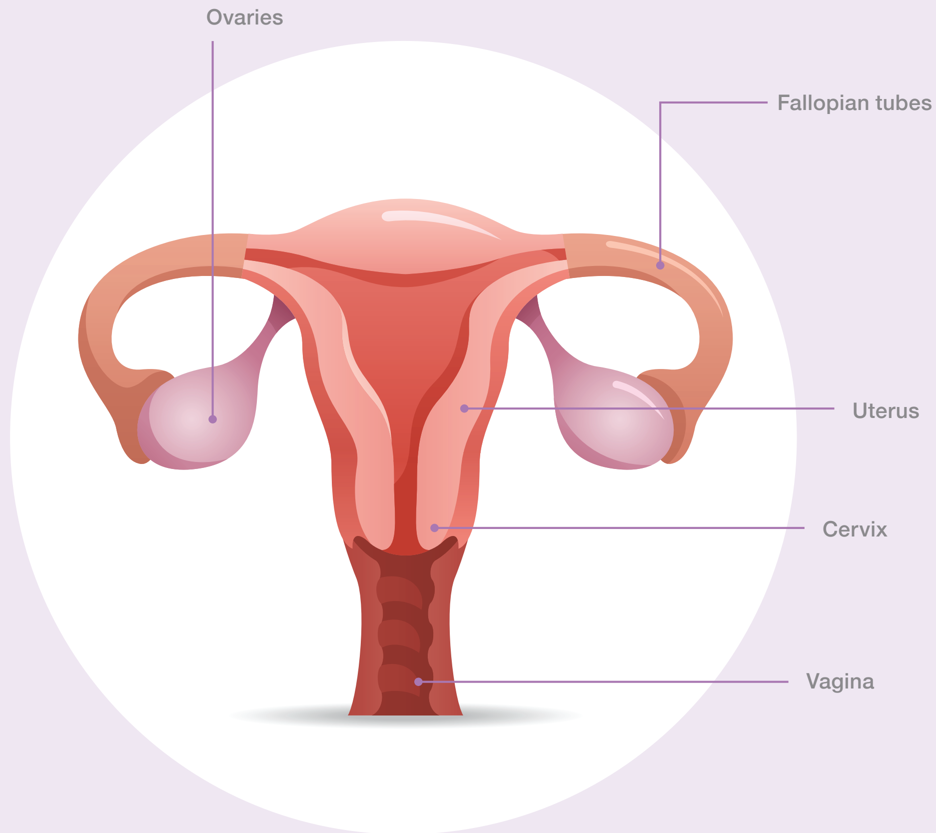
Uterine tissue that has migrated to other parts of the abdomen causing pelvic pain and sometimes infertility.

Uterine Prolapse

A condition where the uterus falls from its normal position and descends uncomfortably into the vagina.

Female Reproductive Cancers

Surgery is often indicated for treating cancers of the uterus, cervix and/or ovaries.



What is a Hysterectomy?

A hysterectomy is the surgical removal of the uterus. It is a muscular, pear-shaped organ that is part of the female reproductive system.

In some cases, your doctor will also recommend removing the cervix, which connects the uterus to the vagina. Your doctor may also recommend removal of the ovaries where eggs are formed, and the fallopian tubes which the eggs travel through to get to the uterus during a woman's child-bearing years.

Benefits of minimally invasive surgery

A minimally invasive procedure could help you avoid an open surgical procedure. Open surgery is associated with more complications, more pain after surgery, a longer hospital stay, and a longer recovery period.

Hysterectomy is the 2nd most common surgery among women.

22,000,000+ women in the U.S. have had a hysterectomy.

GETTING THE CONVERSATION STARTED

Know your options

Talk to your doctor about the symptoms you are experiencing. They will help you determine what treatment option is best for you.

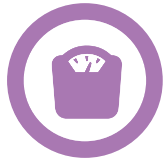
If getting the conversation started once you're there seems hard, try one of these openers:

- "I'd like to ask you a few questions about my symptoms..."
- "I've noticed that ___is different than it used to be..."
- "I've heard that a lot of women are getting treated for ___. Is this something I should consider?"

If you and your doctor determine hysterectomy is the best option for you, ask questions and make an informed choice.

- "Why do I need a hysterectomy, and how soon do I need it?"
- "What type of hysterectomy is appropriate for my symptoms?"
- "Will other parts of my reproductive system (cervix, fallopian tubes, ovaries), in addition to my uterus, need to be removed and how will that affect my health after surgery?"
- "Is there a risk that my fibroids could contain cancer and what is the best way to be treated?

Some factors that your doctor will consider **before surgery are:**



Obesity

History of prior surgery

Underlying medical conditions

Alternative options to hysterectomy

As women, each of our bodies is different, and it can be very difficult to determine what "the right choice" is exactly.

Myomectomy

For women with fibroids who want to preserve their option to have children, myomectomy may be an option. This procedure removes only the fibroids and the uterus remains. You should consult with your doctor to determine if this is an option for you. A myomectomy, depending upon the size and number of fibroids may require an open surgery, but in some cases can be done in a minimally invasive way.

If you determine that you are not ready for surgery, you may have other options, including hormone treatment and endometrial ablation.

Hormone treatment

If you experience heavy menstrual bleeding that lasts for more than 7 days, your doctor may prescribe hormone therapy or a hormone releasing IUD. Hormone treatment options may not work for all women, but it is an option for some.

Endometrial ablation

Another alternative treatment option is endometrial ablation, which can be performed in both the office and the O.R. Endometrial ablation is a medical procedure that removes the uterine lining. After an ablation, the majority of women experience lighter, more normal menstrual cycles and some stop menstruation altogether. Ablation is non-reversible and contraception is either recommended or required after, due to danger of pregnancy post procedure.

You have choices

Today's hysterectomy choices include innovative, minimally-invasive procedures that can be provided by specially-trained gynecologic surgeons to address the treatment and relief of your symptoms. These advanced surgical techniques, which can usually be done on an outpatient basis, result in less pain after surgery, and get you back to your normal routine in 1-3 weeks.

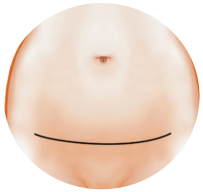
WITH MINIMALLY-INVASIVE SURGERY, MOST PATIENTS RETURN TO NORMAL ACTIVITY WITHIN ONE-THREE WEEKS

“Am I a candidate for minimally invasive surgery?”

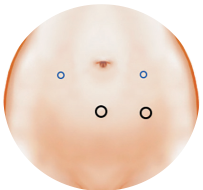
Benefits of Laparoscopic Hysterectomy

Minimally-invasive procedures require less time in the hospital, return to normal activity faster, and only require a few small incisions, which mean less pain and less scarring compared to abdominal hysterectomy.

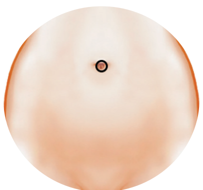
Minimally invasive procedures **require smaller incisions**



Open



Laparoscopic



LESS

Black indicates required incisions. Blue indicates optional or potentially needed for surgical access

Minimally invasive options

Laparoscopic Supracervical Hysterectomy (LSH)

LSH is a minimally-invasive procedure where three to five small incisions are made in the abdomen into which a laparoscope and surgical instruments are inserted. The uterus is removed through these small incisions and the fallopian tubes and/or ovaries may or may not be removed. In this procedure, the cervix is left intact.

Total Laparoscopic Hysterectomy (TLH)

TLH is another minimally invasive option that is similar to the LSH procedure. The main difference is that the cervix is removed with the uterus. The fallopian tubes and/or ovaries may or may not be removed.

Laparoendoscopic Single-Site Surgery (LESS) Hysterectomy

LESS is a new minimally invasive approach for performing a hysterectomy. This approach allows the surgeon to perform the entire procedure through a single incision in the belly button.

Hysterectomy Procedure Comparisons

Hysterectomy Procedures	Typical Recovery Time	Typical Hospital Stay	Abdominal Incision	Minimally Invasive
Laparo-Endoscopic Single-Site (LESS)	1–3 weeks	1 day or less	1 umbilical incision approximately 1 inch	x
Laparoscopic Supracervical (LSH)	1–3 weeks	1 day or less	3–5 incisions ½ inch or less	x
Total Laparoscopic (TLH)	1–3 weeks	1 day or less	3–5 incisions 1/2 inch or less	x
Laparoscopic assisted Vaginal (LAVH)	4 weeks	1–3 days	3–5 abdominal incisions, 1/2 inch or less and vagi-nal incisions	x
Vaginal	4 weeks	1–3 days	Vaginal incisions	x
Abdominal	6 weeks	5–6 days	1 incision approximately 6-8 inches	

FAQs

How long will I need to stay in the hospital?

Minimally-invasive procedures require less time in the hospital compared to abdominal hysterectomy. Most patients can expect to go home the same day as surgery, whereas abdominal hysterectomy requires five to six days in the hospital.

How quickly can I resume my normal activities?

With minimally-invasive surgery, most patients return to normal activity within one to three weeks. Abdominal hysterectomy patients can expect approximately six weeks or more to recover.

Will I experience a lot of pain and scarring?

Minimally invasive procedures also only require a few small incisions, which mean less postoperative pain compared to abdominal hysterectomy. The smaller incisions also result in less scarring on the abdomen.

Are there risks with minimally invasive procedures?

There is a risk that your minimally invasive surgery must be converted to an open surgery. All possible complications should be discussed fully with your doctor.

What is the Contained Tissue Extraction System (CTE) technique?

Women who have determined that laparoscopic hysterectomy or myomectomy is the right option for them may be candidates for contained tissue extraction.

When a doctor performs laparoscopic surgery, there is a chance that very small pieces of tissue can be left behind in the abdomen. These small (sometimes microscopic) tissue fragments are usually not a problem, but there is a small risk of complications that could lead to additional surgery or treatment. For example, if small pieces of a fibroid are left behind, they could actually re-grow.

In addition, if an unexpected cancer was found by the laboratory in the tissue removed, it could result in cancer remaining and spreading in your body if small tissue fragments are left behind.

FDA Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids*

Sarcoma Incidence after benign surgery	2014 Risk Quoted	2017 Risk Quoted	2017 Risk Range
All uterine sarcomas	1 in 352	1 in 360	1 in 225-680 patients
Leiomyosarcoma	1 in 498	1 in 750	1 in 495-1100 patients

*FDA Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December, 2017. Accessed at https://www.fda.gov/Downloads/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/UCM584539.pdf

According to the FDA, there is a 1 in 360 chance of a uterine sarcoma and 1 in 750 chance of a leiomyosarcoma which is an especially aggressive form of uterine cancer.

A new product called the PneumoLiner was recently approved by the FDA to capture tissue fragments, fluids and cells that can be left behind during the process of breaking apart the specimen — necessary in order to remove the tissue through small incisions associated with minimally invasive surgery.

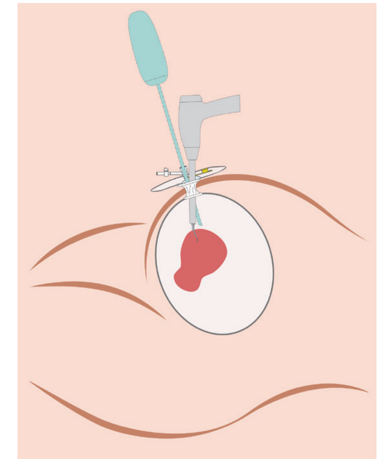
Only surgeons trained in the use of PneumoLiner can offer this advantage and added layer of protection.

This system is not for everyone. It is approved for use in women who are at a low risk of having an unexpected cancer and are under 50 years of age.

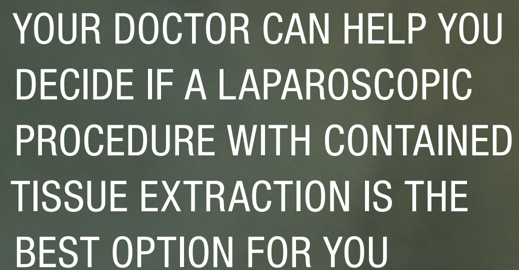
When used as directed, the PneumoLiner will reduce the risk of any cells, fluids or tissue fragments left behind during surgery.

Please see the back of this brochure for indications and contraindications for use.

Contained Tissue Extraction System (CTE) technique



The PneumoLiner is specially designed for use in gynecology procedures that require tissue to be removed through small incisions. It affords tissue to be broken apart and removed in a bag that prevents tissue pieces falling into the abdomen at the end of the procedure.



Talk to your doctor

Your doctor can help you decide if a contained tissue extraction is possible based upon his/her training. If so, it could help you avoid an open surgical procedure with a longer hospital stay, a longer recovery time, and a large scar.

Please let the doctor know the following:

- If you know or if cancer is suspected based on discussions with your gynecologist or primary care doctor
- If it is known or suspected that you have fibroids and you are either perimenopausal or post menopausal
- If you are allergic to polyurethane

What are the risks of Contained Tissue Extraction?

There is a chance that the containment system could be punctured or torn during the procedure. Doctors are specially trained to minimize this risk before using this product.

To find out more about the Contained Tissue Extraction procedure:

- Talk to your doctor
- Visit ContainedTissueExtraction.com

PneumoLiner

WARNING: Information regarding the potential risks of a procedure with this device should be shared with patients. Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk.

CONTRAINDICATIONS:
Do not use on tissue that is known or suspected to contain malignancy. Do not use for removal of uterine tissue containing suspected fibroids in patients who are: post-menopausal or over 50 years of age; or candidates for en bloc tissue removal, through the vagina or via a mini-laparotomy incision. Do not use in women with undiagnosed uterine bleeding. Do not use this device on patients with known or suspected allergies to polyurethane. Do not use where the abdominal wall thickness is larger than 10cm. This device should only be used by physicians who have completed the formal validated required training program administered by Olympus and/or Advanced Surgical Concepts.

PK Morcellator

WARNING: 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.

CONTRAINDICATIONS:
The use of the PK Morcellator is contraindicated for surgical procedures in which the tissue to be morcellated is known or suspected to contain malignancy. The PK Morcellator is contraindicated for removal of uterine tissue containing suspected fibroids in the following patient groups:

- Peri- or post-menopausal patients.
- Candidates for en bloc tissue removal. For example, through the vagina or via a mini-laparotomy incision.

The use of the electrosurgical generator ESG-400 is contraindicated when, in the judgment of the physician, bipolar electrosurgical procedures with the PK Morcellator would be contrary to the best interests of the patient or user. For patients with active electronic devices implanted, refer to the instructions for use for those devices before using bipolar electrosurgery.

The PK Morcellator should not be used if the patient is not considered suitable for a laparoscopic hysterectomy procedure or a laparoscopic myomectomy procedure.

Information provided on this brochure is for informational purposes only. Olympus does not endorse, suggest or advise on medical procedures.

Talk to your doctor about the best procedural approach that is right for you.

Olympus America Inc. OAIGYN0620BRO35991