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FIBROIDS & FIBROID TREATMENT OPTIONS

CHANEL, 30
Procedure Date
April 2019

PATRICE, 49
Procedure Date
June 2018

RHONDA, 36
Procedure Date
December 2017

Fibroids 101

Fibroids 101

What are fibroids?

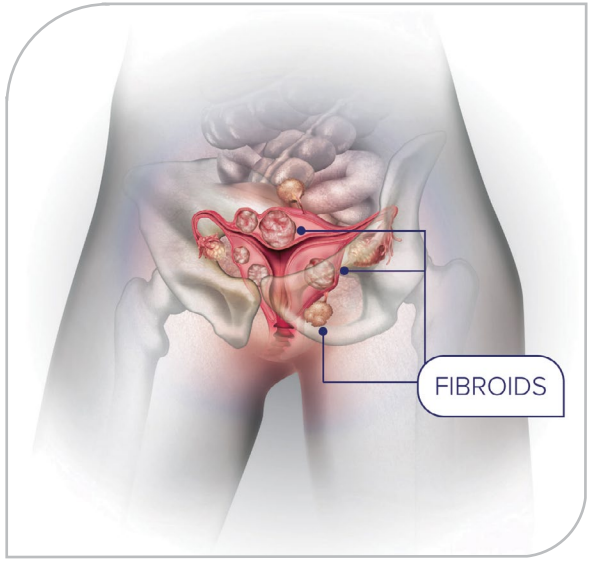
Fibroids are noncancerous tumors that grow in the smooth muscle cells of the uterus.

Where do fibroids come from?[1]

The cause of fibroids isn't well understood. Risk factors include but are not limited to age, race, obesity, and family history of uterine fibroids.

Are fibroids common?[2,3]

Approximately 3 million women are diagnosed with fibroids in the US.



Symptoms[4]

- Heavy and painful or prolonged periods
- Stomach, lower-back and pelvic pain
- Anemia
- Stomach protrusion (causing a woman to look pregnant when she is not)
- G.I. issues like gas and constipation
- Infertility
- Painful sex
- Frequent urination

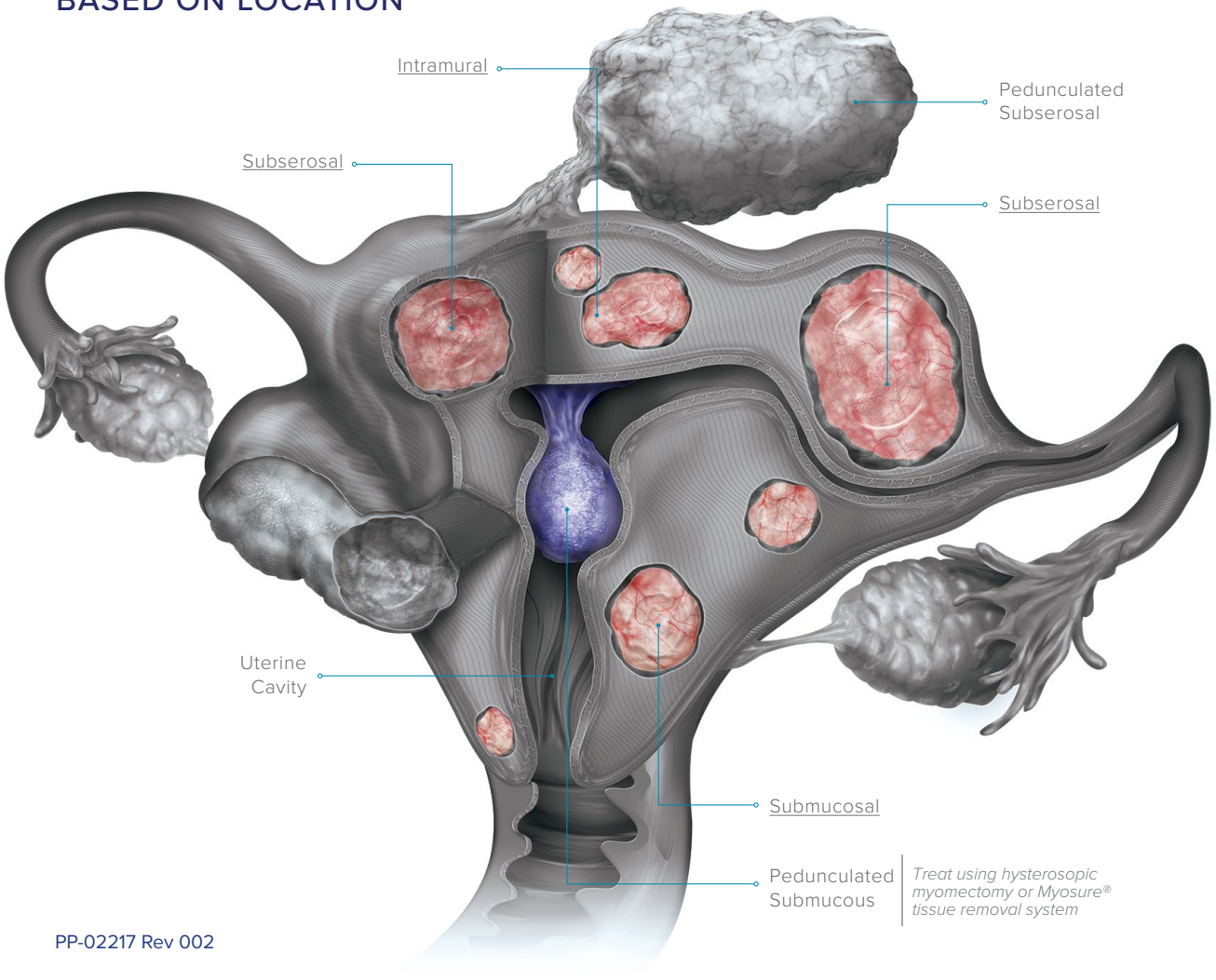
80% **of African American**
women develop fibroids by the age of 50.[5]

3.6 YEARS **Women with fibroids**
waited an average of 3.6 years to seek treatment.[6]

3M **3 million women[2,3]**
3 Million women are diagnosed with symptomatic uterine fibroids in the US.

Types of Fibroids

BASED ON LOCATION



Fibroids are classified by their location in the uterus:

Subserosal*

Outer wall of the uterus and typically cause bulk or pressure symptoms.

Intramural*

Within the muscular walls of the uterus and typically can cause heavy bleeding or pressure symptoms.

Submucosal*

Either inside or abutting the uterine cavity and typically cause heavy bleeding (least common type).

Pedunculated

Fibroids on a thin stalk (less common)

*Fibroid types that can be treated with the **Acessa procedure** (also underlined on graphic).

Fibroid Size

APPROXIMATE FIBROID SIZE COMPARISON CHART

Fibroids may range in size from a pea to a melon.[7] Typically patients are provided two measurements.

Fibroid size – Often expressed as centimeters (cm) by diameter.

Uterus size – Often expressed as the number of weeks pregnant the woman would be if the uterus + fibroids was the size of the uterus + fetus. This chart does not take into account the presence of multiple fibroids. Multiple fibroids can cause the uterus size to be larger than in the case of a single fibroid.

Symptoms and severity depend on both the location and size of the fibroid(s)[8]

Sweet Pea/Apple Seed
UTERUS SIZE: 6 weeks
DIAMETER: 0.5 cm

Blueberry
UTERUS SIZE: 7 weeks
DIAMETER: 1 cm

Raspberry/Cranberry
UTERUS SIZE: 8 weeks
DIAMETER: 2 cm

Strawberry
UTERUS SIZE: 10 weeks
DIAMETER: 3 cm

Lime
UTERUS SIZE: 11 weeks
DIAMETER: 5 cm

Peach
UTERUS SIZE: 13 weeks
DIAMETER: 8 cm

Lemon
UTERUS SIZE: 14 weeks
DIAMETER: 9 cm

Mango
UTERUS SIZE: 19 weeks
DIAMETER: 15 cm

Spaghetti Squash
UTERUS SIZE: 21 weeks
DIAMETER: 27 cm

Lettuce
UTERUS SIZE: 27 weeks
DIAMETER: 35 cm

Honeydew
UTERUS SIZE: 32 weeks
DIAMETER: 42 cm

Watermelon
UTERUS SIZE: 36 weeks
DIAMETER: 50 cm

This table is used to illustrate approximate sizes and diameters of a single fibroid based on average fruit sizes. It does not reflect clinical data. Source: Physician Working Group. The safety and effectiveness of the Acessa procedure has not been evaluated in women with uterine size > 14 weeks.

Other Conditions

THAT ARE COMMONLY FOUND WITH FIBROIDS

Endometriosis[9]

A condition resulting from the appearance of endometrial tissue in sites outside the uterine cavity, such as the ovaries or pelvic wall.

Adenomyosis[10]

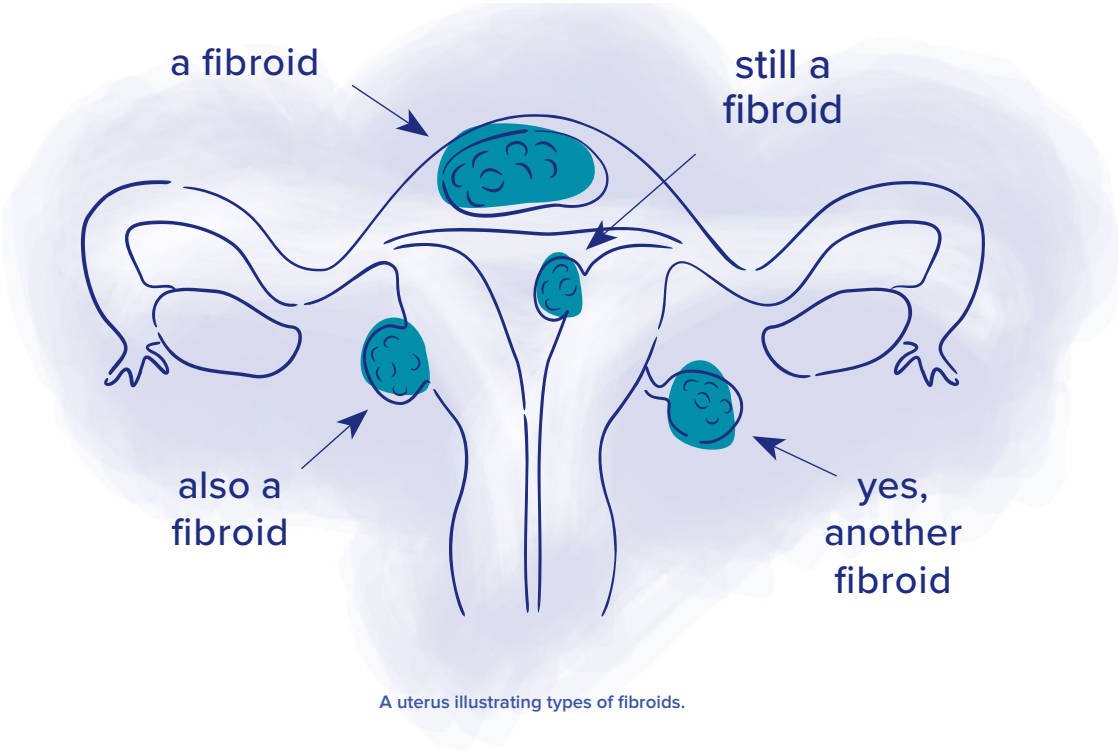
A type of endometriosis. Presence of endometrial tissue inside the muscle layers of the uterus. May be focal or diffuse. Focal creates focal adenomyomas; often softer than a fibroid with a poorly defined border. Diffuse results in a uniformly enlarged uterus.

Polyps[11]

A benign overgrowth of endometrial tissue from the uterine lining. They attach to the uterine lining by a large base or thin stalk.

Cysts

A closed, sac-like structure, typically filled with liquid, semisolid or gaseous material. May be benign or malignant and typically forms on the ovaries.

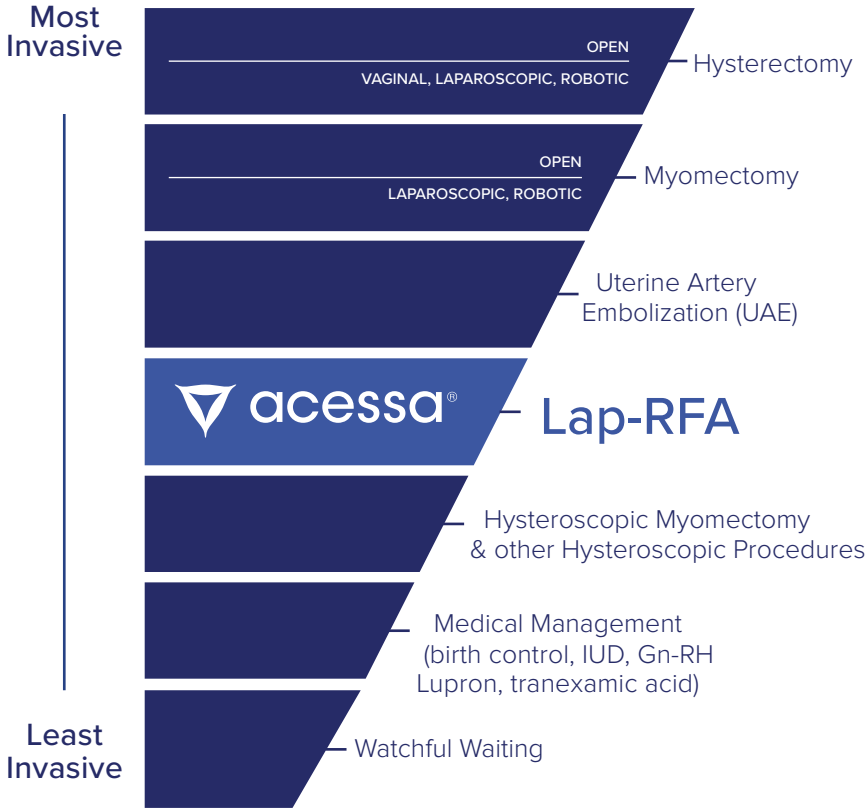


A uterus illustrating types of fibroids.

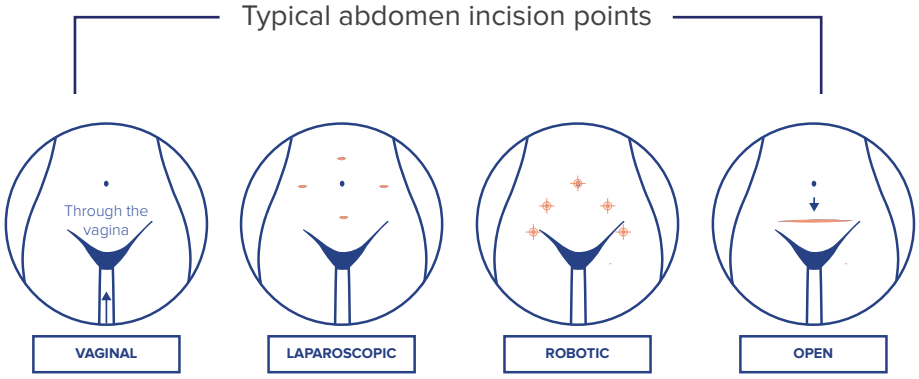
The Acessa Procedure is indicated for the treatment of symptomatic uterine fibroids. It should not be used to treat any of the conditions listed above. Talk to your doctor to determine the right treatment option(s) for you.

Fibroid Treatment Options

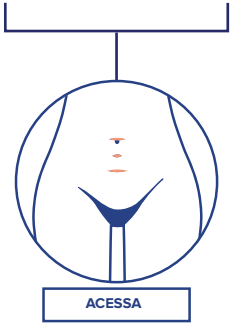
Fibroid Treatment Options



Hysterectomy and Myomectomy can be performed using different approaches

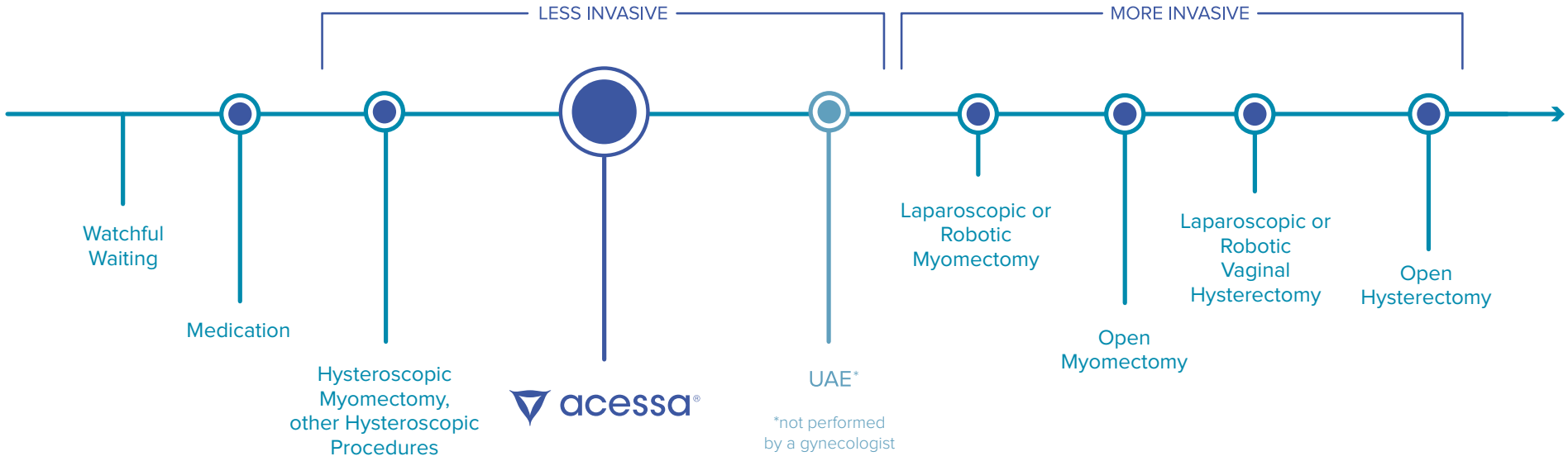


The Acessa procedure incision points



This chart is representative only, to be used in shared decision making between patients and physicians. It is based on physician and patient input. The invasiveness and time to return to daily life of different procedures is dependent on numerous factors. This chart is not intended to be a representation of a single study or clinical data.

Fibroid Treatment Options



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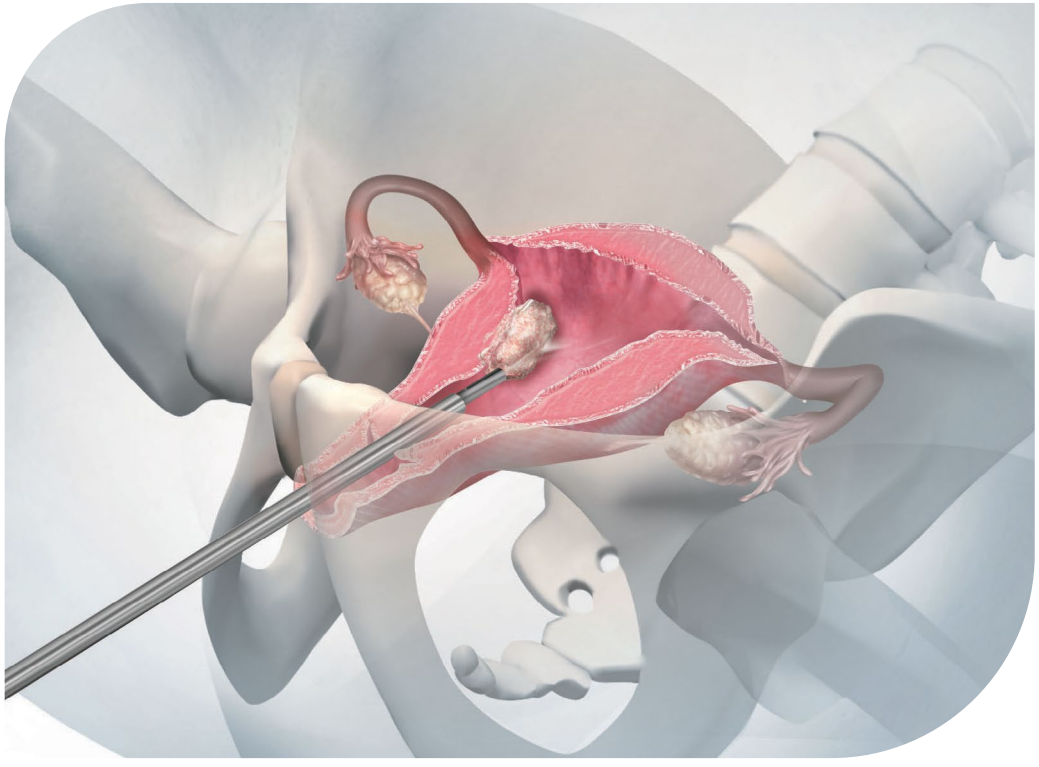
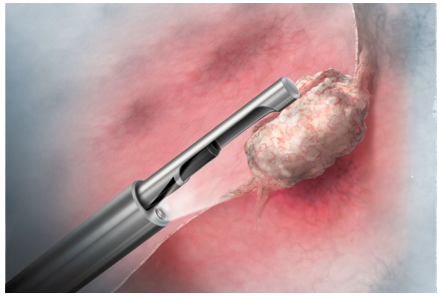
Hysteroscopic Procedures

Hysteroscopic Myomectomy[12]

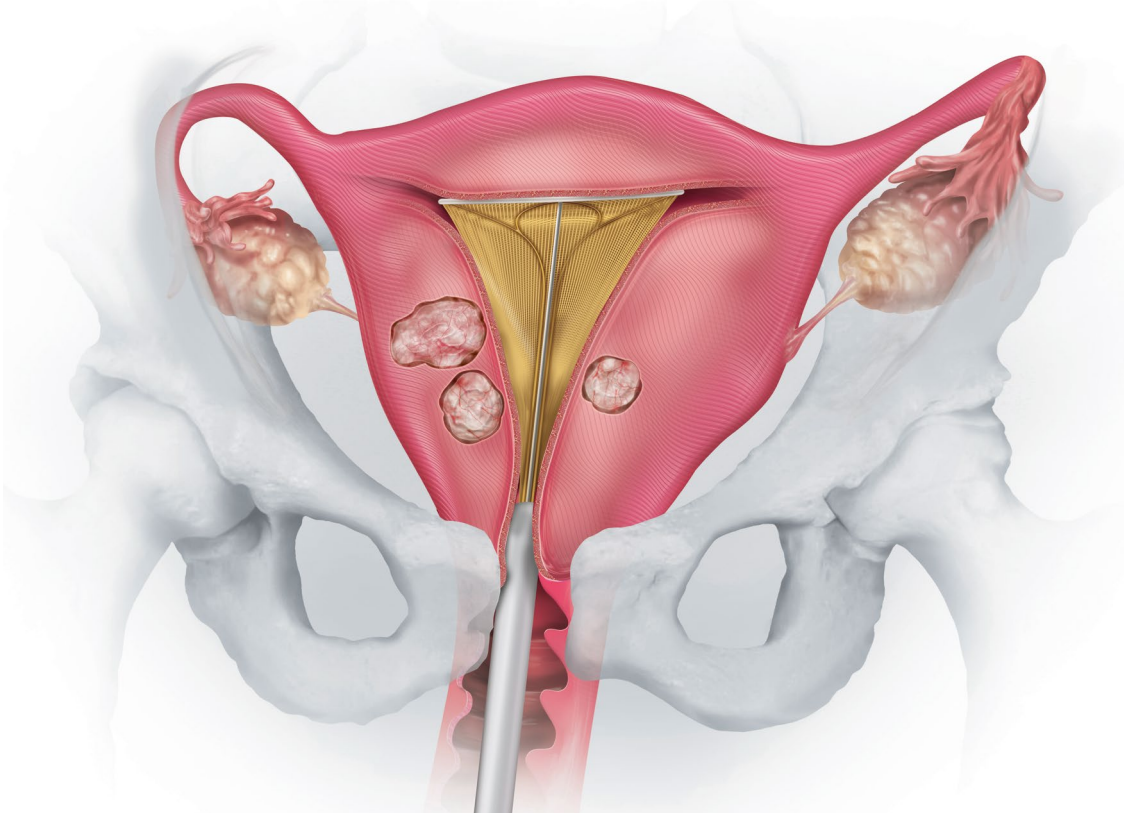


- Removal of fibroids from uterus through the vagina using a scope (camera) to visualize the fibroid and a tool to remove the fibroid.
- Also known as hysteroscopy or hysteroscopic resection.
- Addresses fibroids that are in the uterine cavity; these fibroids typically cause heavy bleeding.
- Typically a short recovery time.



Endometrial Ablation[13]

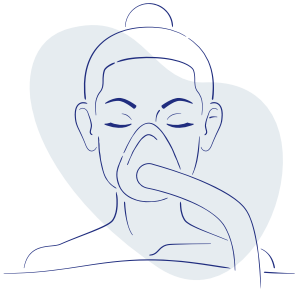
DESIGNED FOR ABNORMAL UTERINE BLEEDING



- Designed to address abnormal uterine bleeding.
- Destroys the uterine lining (endometrium) using heated fluids, microwave energy, extreme cold, or high-energy radiofrequencies.
- Also known as GEA (global endometrial ablation).
- Can be effective for multiple causes of abnormal uterine bleeding.

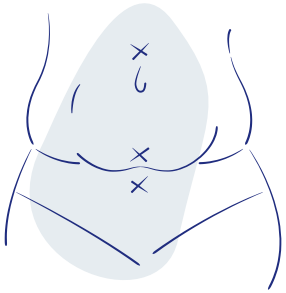
The Acessa Procedure

Lap-RFA[14,15,16]



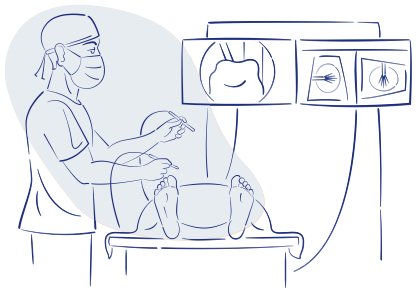
Prep

You'll be brought into the operating room for anesthesia



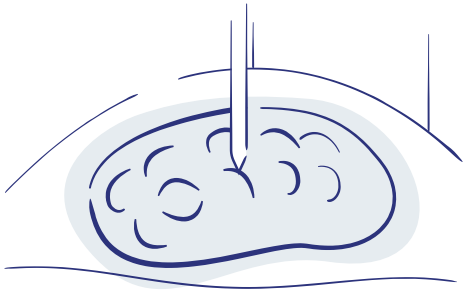
Access

After you're asleep, your physician will make a minimum of three small incisions for a camera, ultrasound, and Acessa handpiece.



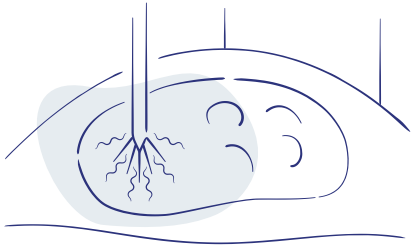
Visualize

Your physician uses a special ultrasound directly on the uterus that allows them to find and ultimately treat more fibroids than other standard imaging methods.



Deploy

Next your physician deploys the tip of the Acessa handpiece into the fibroid and only the fibroid.



Treat

Controlled heat will destroy fibroid tissue. The heat shrinks the tissue mass into a fibroid into a soft mass that is absorbed by the body over time. Your physician will repeat this process until every targeted fibroid is treated.

Recover

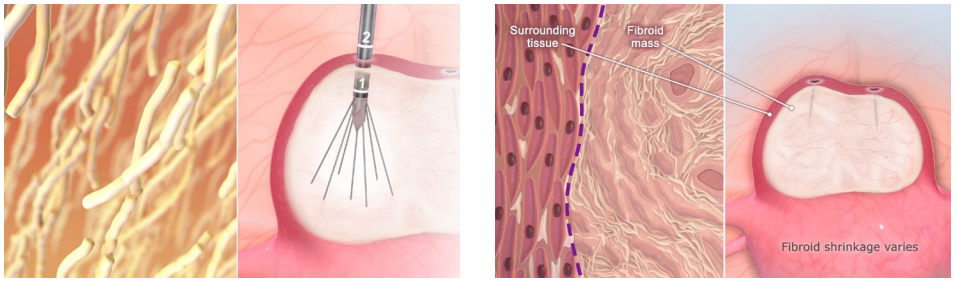
After surgery, most patients get cleared to go home in two hours, and return to work in 4-5 days. Most women experience relief in the first 3 months, and continual improvement for 12 months.

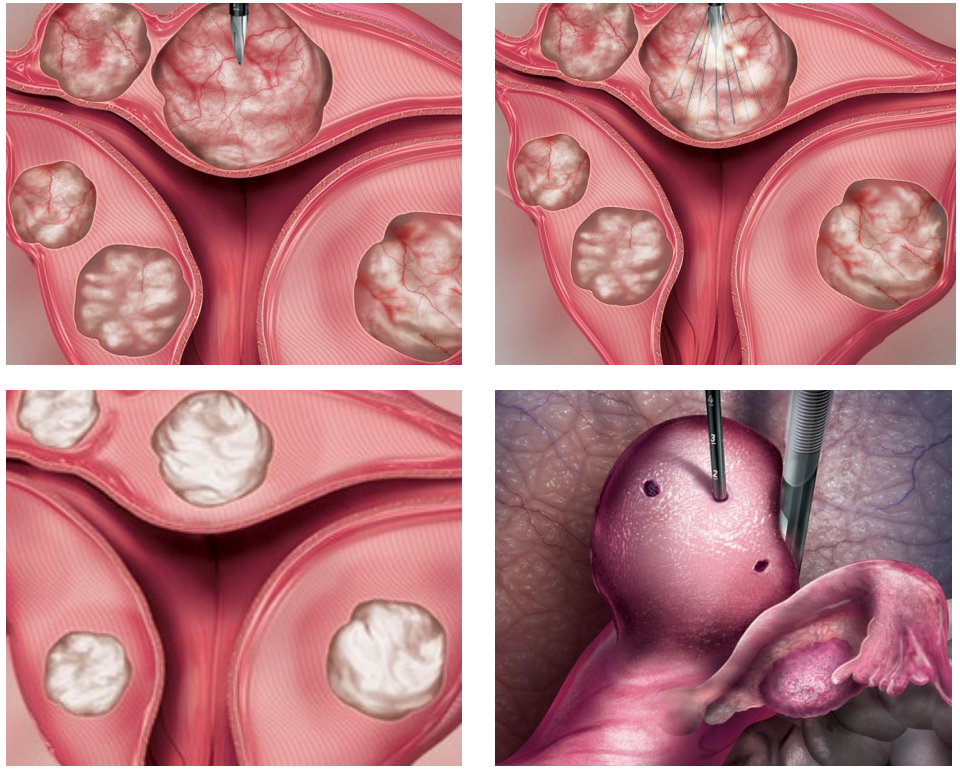
How Acessa Works

The Acessa procedure is performed laparoscopically through small incisions in the abdomen. The procedure has an ultrasound probe and allows for the use of a camera, which helps physicians visualize fibroids.

The heat causes fibroid tissue to shrink overtime, resulting in symptom improvement. Women typically see the most improvement within 3-6 months with continued improvement throughout the first year.[15] Different symptoms resolve at different rates; some may resolve faster or slower than others.[15]

Coagulative Necrosis → Destroys Fibroid Tissue





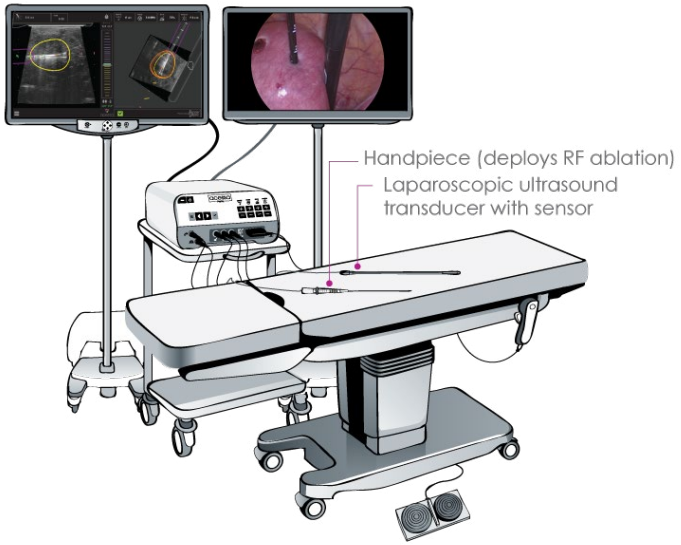
White colored fibroids are representative of treated fibroid tissue

Lap-RFA

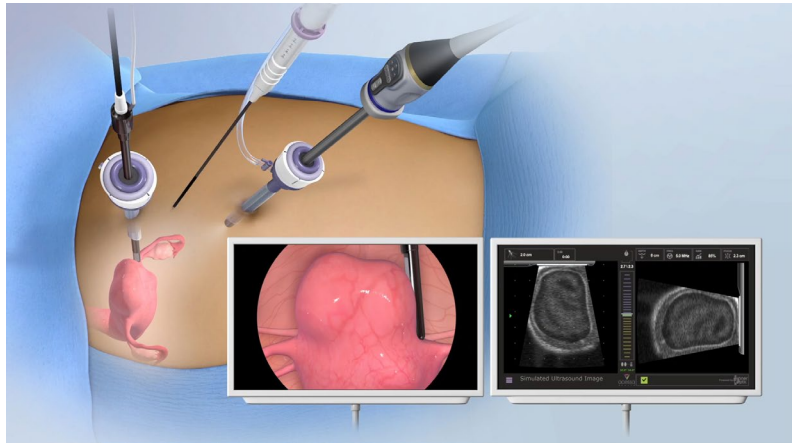
Radiofrequency ablation (RFA) is not new

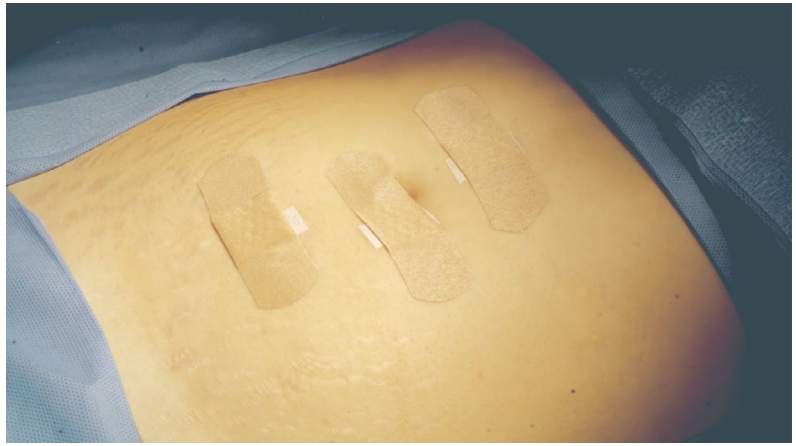
Other procedures that treat conditions in the liver, bone and prostate use the same technology, but the Acessa procedure is the first of its kind to use **Lap-RFA** on uterine fibroids. Although the risk is minimal, there is still a chance of skin burns.

Other rare but serious risks of the Acessa procedure include, but are not limited to, infection, internal injury, blood loss and complications related to laparoscopic surgery and/or general anesthesia.



Acessa Procedure equipment setup in the Operating Room





Results may vary.

VOLUMETRIC SHRINKAGE EXAMPLE

Acessa is designed to shrink the volume of a fibroid.

Even a seemingly small decrease in diameter yields a large decrease in volume.

- Clinical data showed an average **45% reduction** in fibroid volume over 12 months, although results may vary.[15]
- Volume = 4/3 π r3
- Acessa destroys fibroid tissue and causes shrinkage over time, which helps relieve symptoms such as heavy periods, pelvic pressure, urinary frequency, etc.[15]

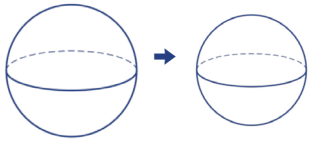
Results may vary and patients may still experience symptoms associated with their fibroids despite a reduction in volume.

Other volumetric shrinkage examples.

This image shows the relationship between diameter reduction size and volume reduction size for an initial fibroid diameter of 5 cm.

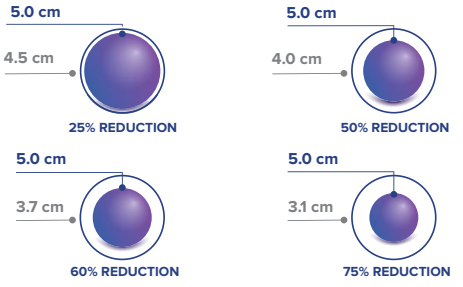
SHRINKS IN VOLUME...

~45%
VOLUMETRIC REDUCTION³



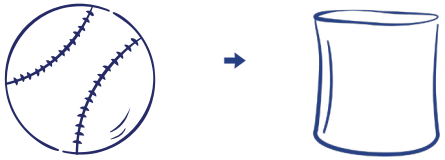
Diameter:	**5.4 cm**	**4.4 cm**
Volume:	**80 cm³**	**44 cm³**

Avg. by 12 months



...AND CHANGES CONSISTENCY[1,2]

Baseball **Marshmallow**



Baseball to marshmallow is to represent consistency, not size.

Typical baseballs ~7cm, jumbo marshmallow 3cm which would = 92% volumetric reduction.

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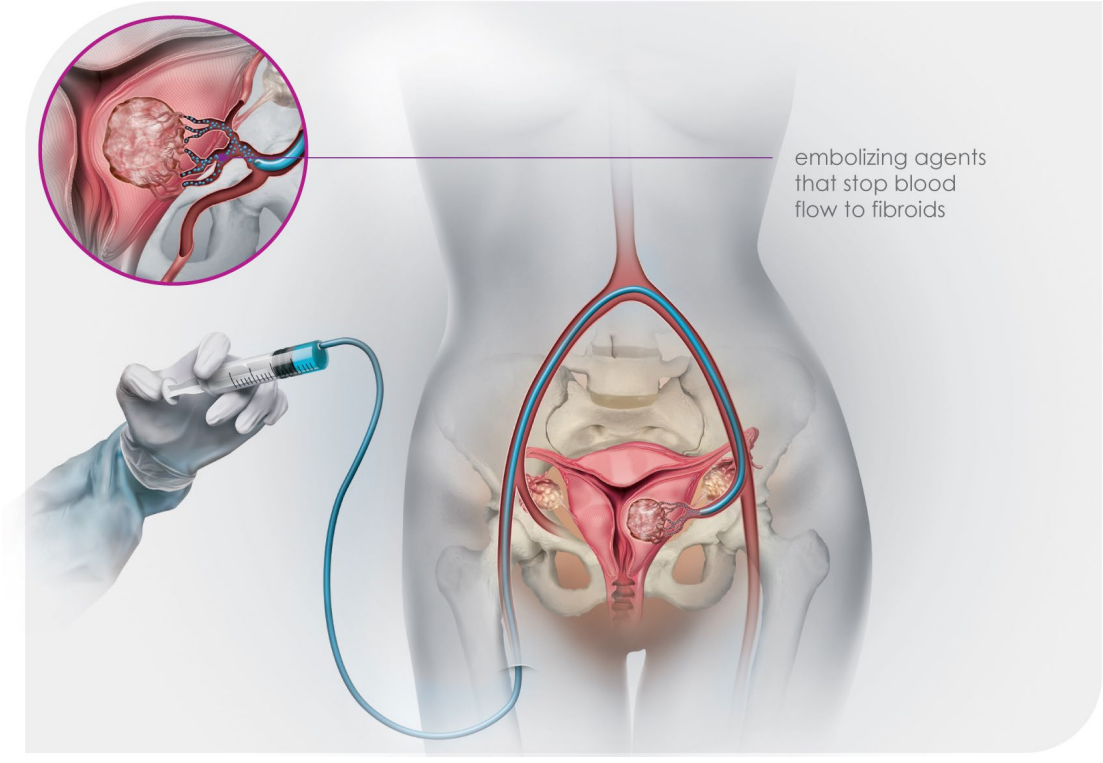
UAE

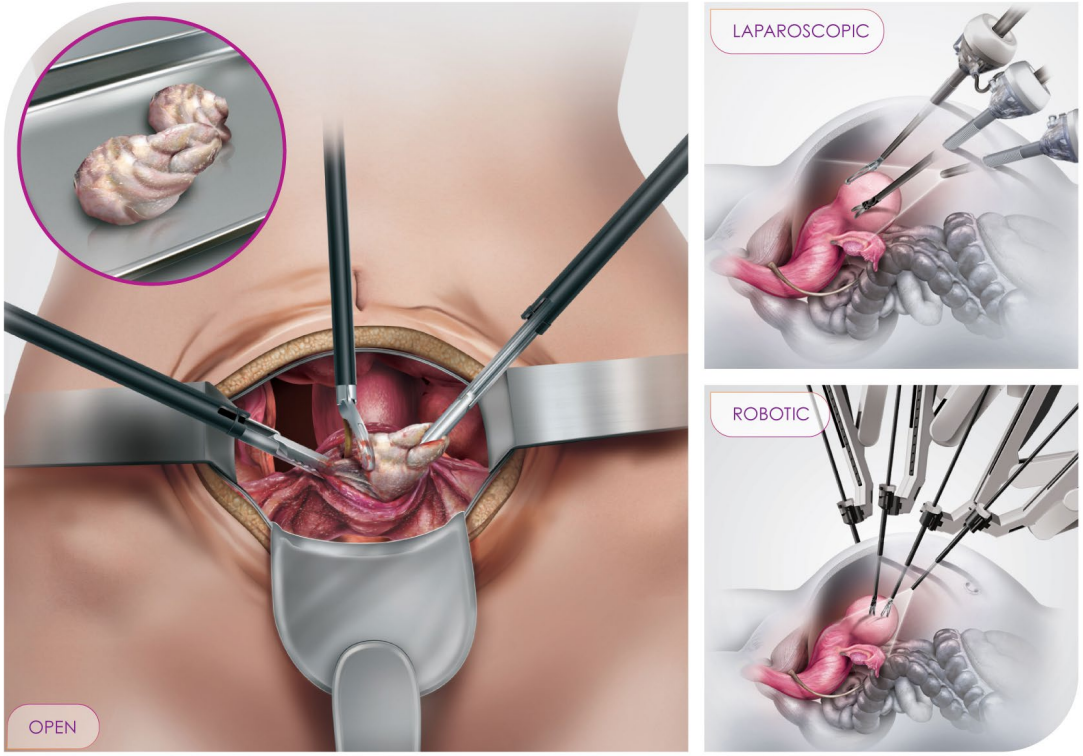
Uterine Artery Embolization (UAE)



- Interventional Radiologist uses embolizing agent to stop blood flow to fibroids.
- Can be performed under conscious sedation (while awake).
- Common side effects may include: post-embolization syndrome, amenorrhea, pain, discharge, angiography-related complications, vaginal discharge of fibroid material, hot flashes, endometritis/myometritis, deep leg vein thrombosis/pulmonary embolus.[17]
- Works via ischemic necrosis versus coagulative necrosis (LAP RFA).

Myomectomy

Myomectomy



- Opening of the uterus to remove fibroids by excising them from the uterus.
- Depending on the size, location, and number of fibroids, can be performed:
  - Open (abdominal incision)
  - Laparoscopic (Robotic or straight stick)*
- Typically a 2-4 week recovery for laparoscopic and abdominal hysterectomy.[18]

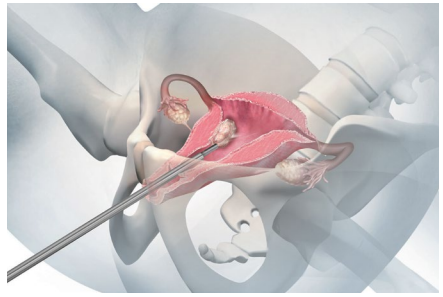
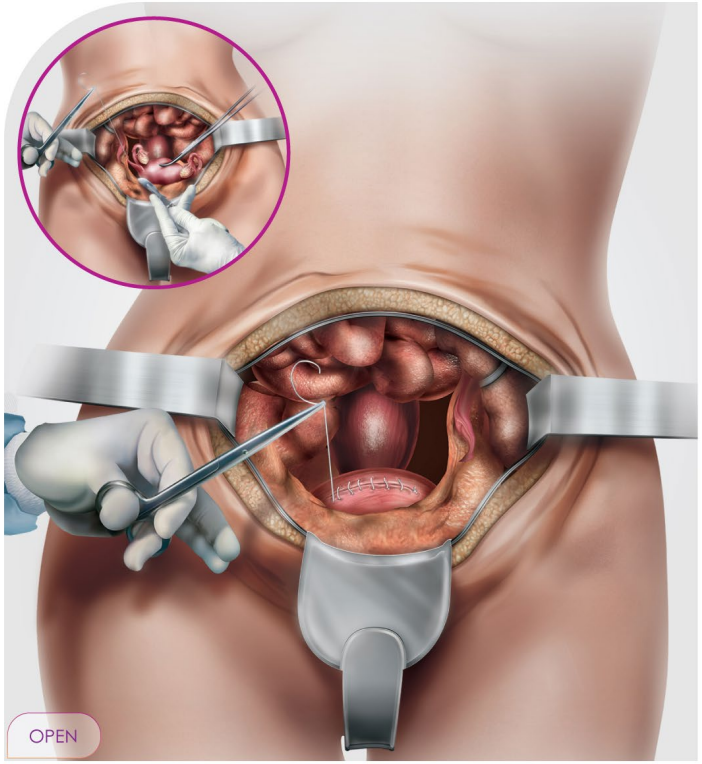
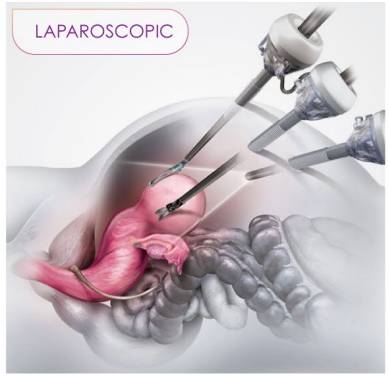


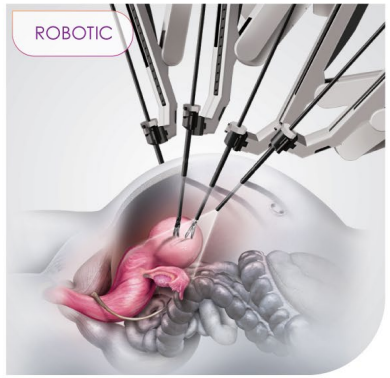
Illustration of hysteroscopic myomectomy.
Refer to page 11

Hysterectomy

Hysterectomy







- Removal of the uterus.
- Depending on the size, location, and number of fibroids, can be performed:
  - Open (abdominal incision)
  - Laparoscopic (Robotic or straight stick)*
  - Vaginal*

  *Often these options will be referred to as a “minimally invasive” hysterectomy
- Typically a 3-6 week recovery.[19]

Disclaimer

This booklet has described several different options for the treatment of symptomatic fibroids. Not every procedure may be right for you. You should discuss your treatment options, as well as the risks and benefits associated with each treatment option, with your physician.

Only you and your physician can determine the right course of treatment for you.

Important Safety Information The Acessa ProVu system is intended to identify and shrink symptomatic uterine fibroids. The Acessa ProVu system is used by trained physicians during laparoscopic surgery under general anesthesia. Rare but serious risks of this procedure include, but are not limited to, infection, internal injury, blood loss and complications related to laparoscopic surgery and/or general anesthesia. This procedure is not recommended for women who are planning future pregnancy. This information is not medical advice. Please discuss the risks and benefits with your doctor to find out if the Acessa procedure may be right for you.

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