

Patient Frequently Asked Questions

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1. I'M INTERESTED IN ACESSA, WHAT'S NEXT?

- 1) Find an Acessa physician <https://www.goodbyefibroids.com/physician-finder/>
- 2) Call the office to schedule an initial consultation (mention Acessa ("Assess-uh") on the phone call)
- 3) During the consultation, discuss Acessa as a fibroid treatment option. Your physician's office will help you determine insurance coverage or discuss self-pay options.

If you have trouble scheduling an appointment, you can also reach us at info@acesahealth.com

2. IS IT COVERED BY INSURANCE?

Is it covered by insurance?

Acessa is covered by many insurance carriers. The first step if you are interested in Acessa is to contact a physician who offers Acessa and schedule an initial consultation. After you have a consultation with a physician and determine if you are a candidate for the procedure, they can help you understand the benefits and coverage for Acessa.

How can I check if Acessa is covered by my insurance carrier?

If you would like to check on your own, you can:

- 1) Call your insurance carrier (phone number on the back of the insurance call).
- 2) Ask if laparoscopic radiofrequency ablation of uterine fibroids is covered under their medical policy. You may need to reference the CPT code 58674.

Note, we have heard from some patients that they have received incorrect information from the insurance call centers. Thus, we suggest scheduling an appointment with an Acessa physician and going through the formal process of prior authorization.

It is covered by my insurance, how much will it cost?

We are unable to provide a quote because every benefit plan is different. Your insurance company and the physician's office are the best resources to provide a price quote. Typically, the out of pocket cost is the same as your deductible.

It is not covered by my insurance, is there an appeals process?

Note, we have heard from some patients that they have received incorrect information from the insurance call centers. Thus, we suggest scheduling an appointment with an Acessa physician and going through the formal process of prior authorization. After the initial consultation, if you are a candidate for the procedure, your physician's office will submit a pre-authorization to your insurance for the procedure.

If your pre-authorization is denied, we have dedicated support to help the appeals process. The only way to initiate the appeals process is after you have a consultation with an Acessa physician. The appeals process takes 2-4 months and does not always result in positive coverage.

Is there a self-pay option? How much does self-pay cost?

Yes, we have physicians who offer cash, self-pay options at ambulatory surgery centers (e.g., less expensive than hospitals). The PDF of the [physician list on our website](#) indicates the physicians who offer the bundled surgery center cash-pay option. Many women travel to these facilities for the bundled rates.

The typical range is \$8,000 - \$15,000. The cost varies by physician, location (hospital or surgery center) and region. As a medical device company, we are unable to provide personal quoted costs due to industry regulations. The best way to get self-pricing information is to call the an Acesa physician's office and request quote information. For some offices, an initial consult is needed before the office can provide a price quote.

Facilities that offer self-pay, cash options at an ambulatory surgery center*:

- Beverly Hills, CA – Dr. Lee 310-237-6043
- Dover, DE – Dr. Hartmann and Dr. Moylan 302-570-3876
- Dallas, TX – Dr. Enggano 972-433-0038
- Portland, OR – Dr. Rosenfield 503-433-3188

*note this list is subject to change

3. WHO IS A CANDIDATE FOR THE PROCEDURE?

Can Acesa treat large fibroids?

It is your doctor's decision to decide if he or she can safely and effectively treat your fibroids. Acesa has studied up to 10cm fibroids and commercially physicians have treated larger. If you have fibroids larger than your doctor feels comfortable treating, he or she may refer you to another Acesa surgeon who has more experience with those cases.

Is there a limit to the number or quantity of fibroids that can be treated?

The physician can treat any number of fibroids present. In fact, many physicians say the ability to treat more fibroids thanks to laparoscopic ultrasound image is an advantage of Acesa compared to myomectomy.

Can Acesa be used to treat any type of fibroid in any location?

Acesa can be used to treat nearly all fibroid types, including subserosal, intramural, transmural, and submucosal. Acesa is not recommended for pedunculated fibroids that have a stalk < 50% of the total diameter of the fibroid. Pedunculated fibroids that have a stalk >50% of the total diameter of the fibroid can be treated with Acesa at the discretion of the surgeon.

How can I figure out what types of fibroids I have?

Typically, patients and physicians determine the type of fibroids and locations using an MRI or transvaginal ultrasound (TVUS), when determining diagnosis and treatment plan. If you have already received an MRI or ultrasound, but do not know what type of fibroids or the location of your fibroids, we encourage you to ask your doctor for a written list of types and locations of the fibroids.

Is there an age limit?

No, most women who seek the surgery are pre-menopausal. Acessa studied women 25 years and older. The study population included women up to 55 years old. As a reminder, Acessa is a treatment for benign (non cancerous) symptomatic fibroids. If patients are at risk for cancer, or malignancy, Acessa is not the appropriate treatment.

Is Acessa recommended for women who want to have future pregnancies?

Insufficient data exists to evaluate the safety and efficacy of the Acessa Procedure for women who are seeking future pregnancy. Therefore, the Acessa Procedure is not recommended for women who are planning future pregnancy.

Have women have gotten pregnant after using Acessa?

Yes, there are publications on this topic. Patients should discuss the safety of all available treatment options to treat their fibroids with their physician.

4. WHAT IS THE PROCEDURE?

What is the Acessa Procedure?

The Acessa Procedure, also known as laparoscopic radiofrequency ablation (RFA), is an outpatient procedure (i.e., go home from the surgery the same-day) performed under general anesthesia (i.e., patients are asleep during surgery) to treat uterine fibroids. It is a minimally invasive alternative to hysterectomy, myomectomy and uterine artery embolization (UAE) for uterine fibroids. Acessa utilizes radiofrequency ablation (heat) under laparoscopic ultrasound guidance to shrink or eliminate the fibroid, without harming healthy uterine tissue. The Acessa Procedure allows the physician to treat almost all fibroids regardless of size and location. See “How does the Acessa procedure work?” for more information on how the procedure works.

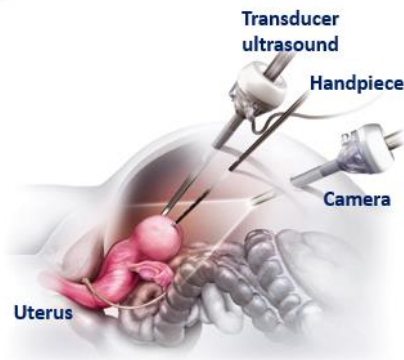
Radiofrequency ablation is a technique used in other procedures to destroy tumor tissue, including liver ablation.



What should I expect the day of surgery?

- After arriving at the hospital or surgery center, the nurses will prep the patient for surgery and be brought to the operating room.
- In the operating room, an anesthesiologist will give the patient medicine to fall asleep – general anesthesia.
- The surgery team will prepare the patient and the instruments for surgery and begin the procedure.

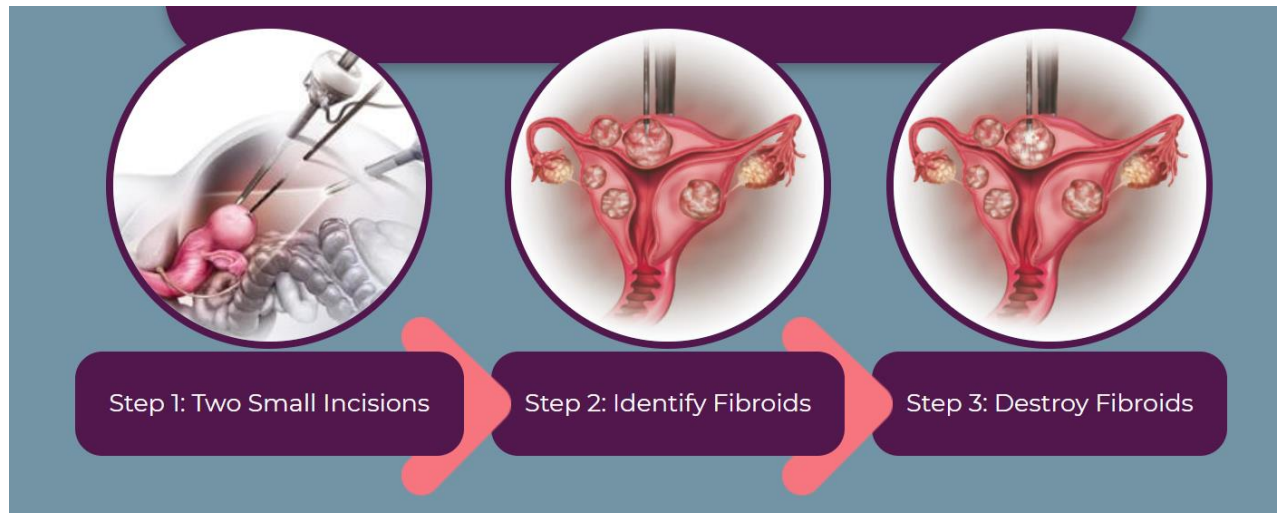
- The procedure starts with two small incisions in the abdomen. One in the belly button, then a second at the bikini line. The incisions are typically less than 1/4 of an inch in diameter. These are the ports the surgeon will use for his or her instruments. Again, the patient will be asleep for all of this.
- The surgeon will primarily use three sterilized instruments:
 - Laparoscopic camera – a camera with a light that is used to see inside the body. Many procedures use a laparoscopic camera.
 - Acesa Transducer probe – an ultrasound probe that is used to see inside the uterus to find fibroids. The Acesa transducer probe is integrated in the Acesa system and designed specifically for this procedure.
 - Acesa Handpiece – a needle inserted through the skin, used for treating the fibroid focally with heat.



- After the surgery, the surgeon will close the small incisions using stiches. Patients will still be asleep under general anesthesia.
- After waking up, patients typically do not feel post-operative pain. Most patients stay at the hospital or surgery center for a 1-2 hours before returning home and are sent home on a Tylenol.
- The surgeon will speak with the patient about the surgery and discuss next steps.
- Most patients are back to normal activity in 3-5 days.

What steps are involved in the actual Acesa procedure?

Using the three instruments previously discussed, the surgeon treats each fibroid individually with radiofrequency energy (heat) that is specifically controlled to destroy the fibroid and leave the surrounding tissue unharmed.



The Acessa Procedure involves three basic steps:

(1) Two small incisions

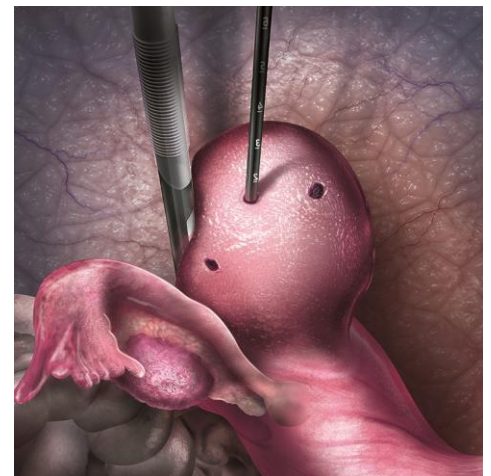
- a. Two tiny incisions are made in the abdomen, typically less than ¼” in diameter in the belly button, then a second at the bikini line.

(2) Identify fibroids

- a. A laparoscopic camera is inserted.
- b. A laparoscopic ultrasound probe is used to determine the location and size of all fibroids present.

(3) Destroy fibroids

- a. The Acessa handpiece needle is advanced into the fibroid using ultrasound guidance.
- b. The electrode array on the tip of the handpiece is deployed into the fibroid.
- c. Energy is applied based on the size and location of the fibroid, destroying the fibroid. No incisions are made in the uterus and no tissue is removed.
- d. The surgeon alternates between scanning the uterus with the transducer and heating tissue with the handpiece needle until all fibroids have been treated.
- e. Before finishing the procedure, the surgeon will scan your uterus with the ultrasound probe to ensure he or she has treated all the fibroids.



If the fibroids are not physically removed, how does Acessa work?

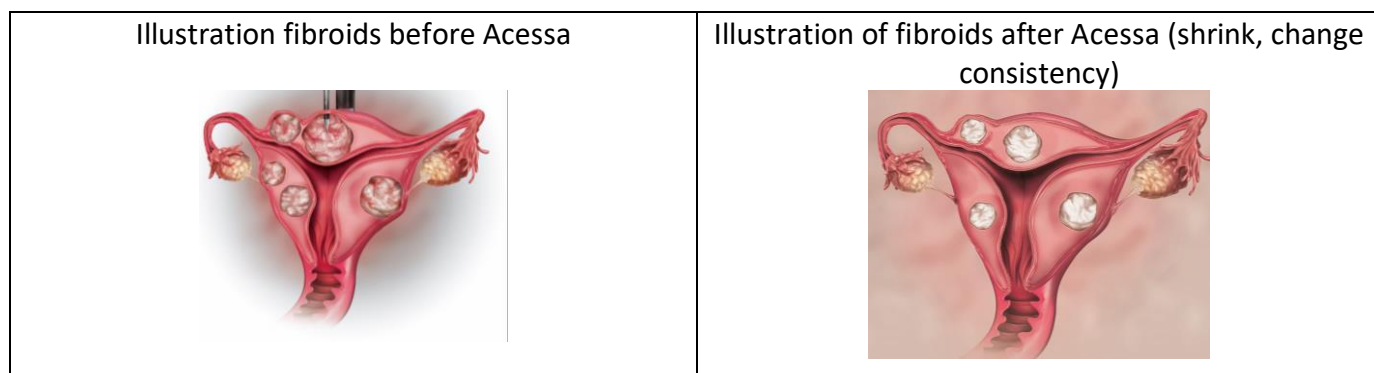
As a reminder, Acessa is a treatment for benign (non cancerous) symptomatic fibroids. If patients are at risk for cancer, or malignancy, Acessa is not the appropriate treatment.

Studies show that fibroids do not have to be completely removed to solve symptoms. Killing the fibroid cells so they shrink and stop putting pressure on the uterus can solve symptoms. It has been proven that even a 10% reduction in fibroid volume can result in significant improvement in heavy periods, pelvic pain and bulk.

To summarize, Acesa works by heating the fibroid cells from the inside out, not by removing the fibroid. Cell tissues die when they reach a certain temperature. Acesa heats the fibroid tissue to the point that it dies. The dead fibroid tissue shrinks and shrivels. The dead tissue is not harmful. It gets absorbed by the body, just like any dead tissue cell.

What happens to the fibroid? How much do they shrink?

Once the fibroid is treated, the destroyed fibroid tissue shrinks. Depending on the size and location of the fibroid, some fibroids may completely go away, where the others will not have any associated symptoms. Total volume shrinkage is dependent on fibroid size and location. From our clinical studies, there was an average of 45% decrease in fibroid volume at 12 months after the procedure. Fibroids continue to shrink after 12 months.



Do the fibroids come back after the procedure?

After the fibroid is treated with Acesa, typically that particular fibroid will not return. However, it is possible to grow new fibroids after the procedure is performed.

What does laparoscopic mean?

Laparoscopic surgery is a minimally invasive surgical technique where surgical tools are operated through small keyholes in the body and a camera (laparoscope) is used to see inside the body. Laparoscopic means there are only small incisions compared to an open procedure where the surgeon cuts a longer incisions.

Am I asleep during the procedure?

Yes, the procedure is performed under general anesthesia. Patients are not awake during the procedure. The procedure cannot be performed under local anesthesia.

Can the procedure be performed in the office?

No, the procedure cannot be performed under local anesthesia nor in an office setting. Most office procedures do not have the ability to visualize and treat a wide variety of size, location and number of fibroids. Acessa can be performed at an Ambulatory Surgery Center or a hospital.

How long does the procedure take?

Each procedure varies in length based on the number and size of fibroids. Typically, the entire procedure from anesthesia to waking up lasts 45 minutes to 1.5 hours.

Is the Acessa Procedure painful?

Most patients do not experience post-operative pain following the procedure. Typically, patients go home on a NSAIDs such as Tylenol 3, and are back to normal activity in 3-5 days.

5. WHAT ARE THE TYPICAL RESULTS?

What are typical results?

Most patients report they have significantly lighter periods, alleviated pelvic pain and pressure. Often patients who experience “bulking” – looking pregnant/ distended abdomen from the fibroids, report reduced or eliminated bulk symptoms. Women often report back that they “love Acessa!”. To hear directly from patients, search “Acessa” on YouTube.

The results of the Overall Treatment Effect Survey of the Pivotal study of 124 patients showed that 94% of the subjects responded that they were very satisfied, moderately satisfied, or somewhat satisfied with the treatment. At 12-months post treatment, 98% of the subjects reported that they would probably or definitely recommend the procedure to their friends with the same health problem. When asked about effectiveness of the treatment, at least 94% of the subjects responded that the treatment had been somewhat, moderately, and very effective in eliminating their symptoms.

When will patients feel symptom relief?

Most patients feel symptom relief right away. Most patients see the greatest effects 3-6 months after Acessa. Some patients report a heavier period their first two periods after the surgery, then bleeding returns to baseline around the 3-month mark. To hear directly from patients, search “Acessa” on YouTube.

Based on our clinical data, the average reduction in menstrual blood loss was 87ml less blood than baseline periods after 3 months and reduced even further to 110 ml less by 6 months.

6. WHAT INFORMATION IS AVAILABLE ABOUT THE PROCEDURE?

How safe is the Acessa Procedure? Is it clinically proven?

Laparoscopic RFA was first performed on fibroids in 1999 by Dr. Bruce Lee. After many successful studies, the original Acessa System was FDA cleared in November 2012. Since 2012, physicians have performed over 3,000 procedures to date. The newest, most advanced technology, the Acessa ProVu system, was cleared in 2018.

The Acessa Procedure is clinically proven. There are over 29 peer reviewed studies that show Acessa as a clinically proven, safe and effective for the treatment of uterine fibroids. In fact, in three separate clinical studies leading up to FDA clearance, the complication rates were extremely low (<4%). Your physician can explain the potential complications of the Acessa Procedure, as well as those of other available fibroid therapies.

What is the difference between Uterine Artery Embolization (UAE) vs Acessa?

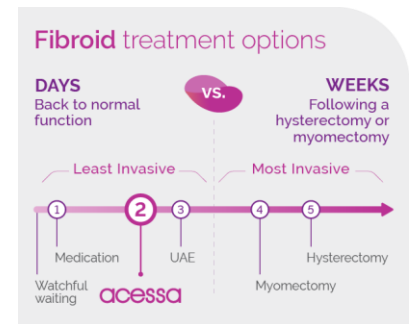
UAE involves ischemic necrosis which consists of the tissue slowly dying due to lack of blood supply (like tying a rubber band around your finger and waiting for it to fall off), and typically involves an overnight stay for pain management. Acessa uses coagulative necrosis which destroys the fibroid cells and nerve endings with heat

right away, thus minimal pain is associated with the Acessa Procedure compared to UAE. Acessa patients may return home the same day.

UAE is performed by interventional radiologists. The Acessa procedure is performed by minimally invasive gynecologic surgeons.

What is the difference between Myomectomy vs Acessa?

Myomectomy involves cutting fibroids and removing the fibroid tissues from the uterus. Acessa, by comparison, does not require cutting or suturing within the uterus. Myomectomy is often considered a minimally invasive surgery because the incisions into the abdomen are small. Most physicians who offer Acessa and myomectomy, consider Acessa as a less invasive option because there are zero incisions on the uterine surface (serosa), and only 2 small incision on the skin (myomectomy has 4 to 6 incisions in the skin).



Can Acessa be combined with other procedures?

Yes, it is also known as concomitant or combination procedures. Acessa can be used as another tool for treating fibroids. For example, your physician may recommend a myomectomy + Acessa – removing some fibroids using the myomectomy technique and destroying others with the Acessa procedure. Acessa may also be performed after hysteroscopic procedures.

7. WHY HAVEN'T I HEARD ABOUT ACESSEA BEFORE? And WHERE CAN I GET THE PROCEDURE?

How long has this option been available, and why has my doctor never heard of it?

Laparoscopic RFA was first performed on fibroids in 1999 by Dr. Bruce Lee. After many successful studies, the original Acessa System was FDA cleared in November 2012. Since 2012, physicians have performed over 3,000 procedures to date. The newest, most advanced technology, the Acessa ProVu system, was cleared in 2018.

One of the reasons patients may have not heard about Acessa, is because some insurance companies do not cover the procedure. We are working on changing that. As we receive more coverage we will expand to new areas. For comparison, uterine artery embolization is still considered a 'newer technology' and it was approved 10 years before the Acessa Procedure for fibroids in 2002.

We are on a mission to give women more options. Thankfully, more and more physicians are learning about Acessa, and we are growing daily.

Where is the procedure offered in the US?

Acessa is growing and expanding daily. Check back to see where Acessa grows!

Minimally invasive gynecologic surgeons across the United States offer the procedure. We encourage you to call their offices, mention you found them through the Acesa website and make an appointment. See the list of surgeons who offer Acesa here <https://www.goodbyefibroids.com/physician-finder/>

Currently we have physicians in the following cities who offer the Acesa procedure:

- South
 - o Dallas, TX
 - o Austin, TX
 - o Fort Worth, TX
 - o San Antonio, TX
- Southwest
 - o El Paso, TX
 - o Albuquerque, NM
- Southeast
 - o Atlanta, GA
 - o Columbia, SC
- West
 - o Los Angeles, CA
 - o San Francisco, CA
- Midwest
 - o Chicago, IL
 - o Detroit, MI
- Northeast
 - o Dover, DE
 - o New York, NY

Is it offered outside the US?

There is a clinical study ongoing in Germany. Find out more at clinicaltrials.gov

<https://clinicaltrials.gov/ct2/show/NCT03028610>

Many patients travel internationally to the US to physicians who offer cash-based bundles for Acesa. If you are interested, please reach out to the physician offices for quotes and more information.

I'm from Canada, is there a waitlist I can get added to?

The Acesa Procedure for fibroids is not offered in Canada at this time.

Dr. Thiel at University of Saskatchewan will begin offering the Acesa Procedure again as soon as the new technology is approved by Health Canada. We are aiming for 2020. In the meantime, he is taking consults and has a waiting list for the procedure. You can contact him at: drjthiel@aol.com. He is the only physician in Canada taking consults and creating a waiting list at this time.

Are there clinical studies I can join?

The studies that continue to enroll using Acessa Technology are:

- United States - <https://clinicaltrials.gov/ct2/show/NCT02100904>
- Germany - <https://clinicaltrials.gov/ct2/show/NCT03028610>

There are no physicians in my area who offer the procedure, what should I do?

Many women travel for the procedure.

Some physicians are accustomed to working with patients who are traveling. If you are interested in traveling for the procedure, we recommend reaching out to any Acessa physician office to learn more about their policies and your insurance coverage in that city.

Can my current physician do the Acessa Procedure even if he or she is not on your list?

Most patients choose to see another physician who offers Acessa for their surgery, then they return to their original OBGYN for ongoing care. If your doctor has never heard of the Acessa Procedure for fibroids, we encourage you to tell them about the procedure. We would be happy to train your physician if they have proper training in minimally invasive surgery. However, please note that not all OBGYN physicians are trained in minimally invasive surgery. Thus, not all OBGYN's will be able to offer the Acessa procedure. If your physician is interested in being trained on the procedure, please have him or her reach out to Acessa Health at info@accessahealth.com.

LEGAL DISCLAIMER: Acessa Health encourages patients to seek medical attention for typical and atypical symptoms associated with fibroids to help achieve and maintain good health with as high a quality of life as possible. Acessa Health offers this "Find a Doctor" directory as a resource to help patients find an Acessa-trained physician that uses the Acessa procedure in a specific geographical area. Please be advised: any communication outside this web site is not covered by our privacy policy or terms of use. Not all Acessa-trained physicians are displayed. Acessa-trained physicians have the option of not being listed on this locator. Acessa Health does not warrant, whether expressed or implied, the accuracy, completeness, or feasibility of the information contained in the "Find a Doctor" directory. In no event shall Acessa Health be liable to you or anyone else for any actions taken by you in reliance on the information contained in the "Find a Doctor" directory. Acessa Health does not make any recommendations, referrals, or endorsements regarding specific physicians with whom patients may seek treatment, nor does this site serve as a tool for verification of a specific surgeon's credentials, qualifications, or abilities. Only a trained physician is qualified to recommend treatments and/or make diagnoses. You assume full responsibility for your communications and interactions made with any physician you choose to contact from the use of this "Find a Doctor" directory. By using the search field, you agree to and accept the above terms.

RISK STATEMENT: Acessa is cleared by the FDA for the treatment of symptomatic uterine fibroids. There are risks associated with all minimally invasive surgical procedures, including serious complications such as infection, bowel injury, and postoperative bleeding. Insufficient data exist on which to evaluate the safety and effectiveness of Acessa procedure in women who plan future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy. Please consult with an Acessa-trained gynecologist to understand the risks of surgery and find out if Acessa may be right for you.