# Patient Frequently Asked Questions

## Table of Contents


**I'm interested in The Acessa® procedure, what is next?** 3

1. How can I find a physician?
2. There are no physicians in my area who offers the Acessa procedure, what should I do?
3. Is the Acessa procedure offered outside the U.S.?
4. Can my current physician do the Acessa procedure if he or she is not on your list?

**Is the Acessa procedure covered by insurance?** 4

5. Is the Acessa procedure covered by insurance?
6. How can I check if the Acessa procedure is covered by my insurance carrier?
7. If the Acessa procedure is covered by my insurance carrier, how much will it cost?
8. If the Acessa procedure is not covered by my insurance, is there an appeals process?
9. Is there a self-pay option? How much does self-pay cost?

**Who is a candidate for the procedure?** 5

10. What are the indications and contraindications for the procedure?
11. What are the warnings regarding patient candidacy for the procedure?
12. Can the The Acessa procedure system treat large fibroids?
13. Is there a limit to the number or quantity of fibroids that can be treated?
14. Can the Acessa procedure be used to treat any type of fibroid in any location?
15. How can I figure out what types of fibroids I have?
16. Is there an age limit?
17. Is the Acessa procedure recommended for women who want to have future pregnancies?

**What is the procedure?** 7

18. What is the Acessa procedure?
19. What should I expect the day of the Acessa procedure?
20. What makes the Acessa procedure, the Acessa procedure?
21. If the fibroids are not physically removed, how does the Acessa procedure work?
22. What happens to the fibroid? How much do they shrink?
23. What does "laparoscopic" mean?
24. Am I asleep during the Acessa procedure?
25. Can the Acessa procedure be performed in the office?
26. How long does the Acessa procedure take?
27. Is the Acessa procedure painful?

**What information is available about the procedure?** 10

28. How safe is the Acessa procedure? Is it clinically proven?

29. What is the difference between Uterine Artery Embolization (UAE) and the Acessa procedure?

30. What is the difference between laparoscopic myomectomy vs. the Acessa procedure?

**What are the typical results?** 11

31. What are the typical results from the Acessa procedure?

32. When will most patients feel symptom relief after the Acessa procedure?

**Why haven't I heard about the The Acessa procedure before?** 12

33. How long has this option been available? Why has my doctor never heard of it?

34. Are there clinical studies I can join?

# I'm interested in the the Acessa procedure what is next?

1. **How can I find a physician?**
   Find a physician who offers the Acessa procedure at www.acessaprocedure.com, then call the office to schedule an initial consultation (mention the Acessa procedure ("Assess-uh") on the phone call). During your appointment, discuss whether the Acessa procedure is a fibroid treatment option that's right for you. Your physician's office can help you determine insurance coverage or discuss self-pay options.
   If you have trouble scheduling an appointment with an the Acessa procedure trained physician, you can also reach us at INFO@ACESSAHEALTH.COM

2. **There are no physicians in my area who offer the the Acessa procedure, what should I do?**
   Availability of the Acessa procedure is expanding. Meanwhile, some physicians are accustomed to working with women who are traveling for the procedure. You can find a physician trained on the Acessa procedure on our website (**www.acessaprocedure.com)** or via the Acessa procedure patient hotline: 1-800-992-4359.

3. **Is the the Acessa procedure offered outside the U.S.?**
   Minimally invasive gynecologic surgeons across the United States offer the procedure. You can find contact information for surgeons offering the procedure on our website: **www.acessaprocedure.com**

4. **Can my current physician do the Acessa procedure if he or she is not on your list?**
   Most patients choose to see an experienced physician trained in the Acessa procedure for their surgery, and then they return to their original OB/GYN for ongoing care. If your physician's practice is interested in offering the Acessa procedure in your community, specific information is available at info@acessahealth.com

# Is the the Acessa procedure covered by insurance?

### 5. Is the the Acessa procedure covered by insurance?

Many insurance companies and Medicaid carriers cover the procedure.

We understand that some patients have received incorrect information from insurance call centers. We suggest scheduling an appointment with a physician trained in the Acessa procedure to discuss whether the procedure is appropriate for you. If the Acessa procedure is a match for your fibroid treatment, then your physician's office will request insurance approval in advance by submitting a pre-authorization request.

### 6. How can I check if the Acessa procedure is covered by my insurance carrier?

Laparoscopic radiofrequency ablation (Lap-RFA, also known as the "Acessa procedure") is becoming a covered benefit by more insurance companies.
Physician trained on the Acessa procedure can help you determine whether the Acessa procedure is covered by your insurance and provide guidance on your next steps.

### 7. If the the Acessa procedure is covered by my insurance carrier, how much will it cost?

Every benefit plan is different. Your insurance company and the physician's office are the best resources to provide a price quote.

### 8. If the Acessa procedure is not covered by my insurance, is there an appeals process?

Yes. Patients whose insurance companies do not yet cover the procedure have options to challenge a negative prior authorization decision. A team of insurance specialists at Hologic can assist you with trying to overturn the denial so you do not have to go through it alone.

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

Yes, there are physicians who offer cash, self-pay options at ambulatory surgery centers (e.g., typically less expensive than hospitals). Our patient hotline can help you identify physicians who offer self-pay options.

Based on data on file, the typical range is $9,000 - $15,000. Cost varies by physician, location (hospital or surgery center) and region. The best way to get self-pay pricing information is to call your physician's office and request a quote. For some offices, an initial consult is needed before the office can provide a price quote.

# Who is a candidate for the Acessa procedure?

## 10. What are the indications and contraindications for the procedure?

The Acessa procedure is FDA cleared and the indications and contraindications are listed in the Acessa ProVu system user manual (Instructions for Use, IFU). For the most recent version of the contraindications, indications and warnings, clinicians can request the IFU from medical affairs via www.acessaprocedure.com

Indications for use: The Acessa ProVu system is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.

Contraindications:

- Patients who are not candidates for laparoscopic surgery (e.g. patients with known or suspected intra-abdominal adhesions that would interfere with safe use of the Handpiece).
- Uterus adherent to pelvic tissue or viscera.
- Non-uterine pelvic mass.
- The Acessa ProVu guidance system is not intended for diagnostic use.
- The The Acessa ProVu guidance system may not be used to guide the tip of the Handpiece once the tip has penetrated the uterine serosa. Ultrasound visualization must be used during fibroid penetration and treatment.

## 11. What are the warnings regarding patient candidacy for the procedure?

Warnings are listed in the Acessa ProVu system User manual (Instructions for Use, IFU) which was approved with the FDA 510k submission. For the most recent version of the contraindications, indications and warnings, clinicians can request the IFU from medical affairs via www.acessaprocedure.com. There are additional warnings in the IFU, the ones listed here are in regard to patient candidacy for the procedure. Please refer to the IFU for full list of warnings.

- Insufficient data exist on which to evaluate the safety and effectiveness of the Acessa procedure in women who plan future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy.
- The safety and effectiveness of the Acessa procedure has not been evaluated in women with uterine size >14 weeks.
- Uterine tissue may contain unsuspected cancer, particularly in patients who are peri- or post-menopausal. Insufficient data exist on which to evaluate the safety and effectiveness of the Acessa procedure for treatment of cancerous uterine tissue. Thoroughly discuss the benefits and risks of all treatments with patients.
- If the patient has a pacemaker, consult the patient's cardiologist prior to this procedure. Using the the Acessa ProVu system
- Treatment with the Acessa procedure ProVu system is not recommended for nursing mothers or pregnant women.
- Electrosurgery is not recommended for patients with metal implants near the ablation site or along the RF return path to Pads.
- Treatment of children is limited due to the physical size and placement of Pads with respect to RF ablation site.

## 12. Can the Acessa procedure treat large fibroids?

It is your doctor's decision to decide if he or she can safely and effectively treat your fibroids. The safety and effectiveness of the The Acessa procedure has not been evaluated in women with uterine size greater than 14 weeks.[11]

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

A physician can treat any number of fibroids present.[3] The number of fibroids that a physician is able to treat in a single procedure may vary. The ability to treat more fibroids thanks to laparoscopic ultrasound imaging can be an advantage of the Acessa procedure compared to myomectomy.[9]

## 14. Can the Acessa procedure be used to treat any type of fibroid in any location?

The Acessa procedure can be used to treat most types of symptomatic uterine fibroids, including subserosal, intramural, transmural, and certain submucosal.[1] The Acessa procedure should not be used on non-uterine masses.

### 15. How can I figure out what types of fibroids I have?

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

### 16. Is there an age limit?

Most women who seek the surgery are pre-menopausal. The Acessa procedure has studied women 25 years and older. The study population included women up to 55 years old.[1] As a reminder, the Acessa procedure is a treatment for benign (non-cancerous) symptomatic fibroids. If patients are at risk for cancer or malignancy, the Acessa procedure is not the appropriate treatment.

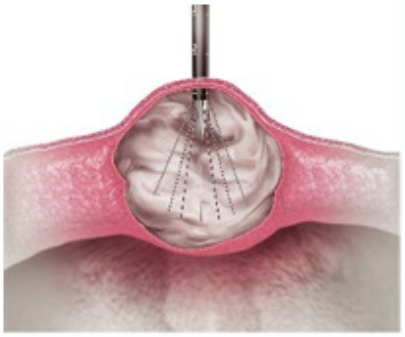
### 17. Is the Acessa procedure recommended for women who want to have future pregnancies?

Insufficient data exists to evaluate the safety and efficacy of the Acessa procedure for women seeking future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy.[3]

## What is the procedure?

### 18. What is the Acessa procedure?

The Acessa procedure, also known as laparoscopic radiofrequency ablation (Lap. 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 symptomatic uterine fibroids. It is a minimally invasive alternative to hysterectomy, myomectomy and uterine artery embolization (UAE) for uterine fibroids.[7] The Acessa procedure utilizes radiofrequency ablation (heat) under laparoscopic ultrasound guidance to shrink the fibroid, without disrupting normal uterine tissue.[8,12] See "How does the Acessa procedure work?" for more information.



### 19. What can I expect on the day of the Acessa procedure?

**Prep and Access -** You are prepped and brought into the operating room for anesthesia. Your physician makes small incisions, typically three – one in your belly button, one below your bikini line, and the third is where the Acessa handpieces is inserted. He or she inserts a tiny camera through one incision, and an ultrasound into the other. Note: each woman is different, and the procedure may require additional incisions or incisions in different locations depending on the location and size of the fibroids. Using the instruments previously discussed, the surgeon treats each fibroid

individually with radiofrequency energy (heat) that is specifically controlled to shrink the fibroid tissue with the goal of leaving the surrounding tissue unharmed.

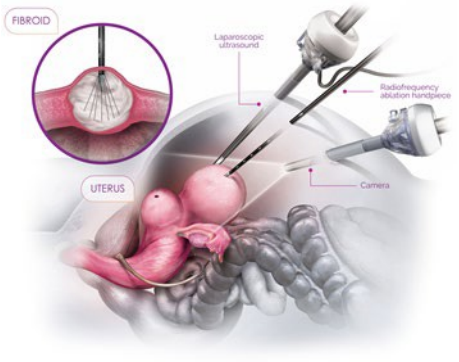
**Visualize -** Your physician precisely locates each fibroid with the ultrasound probe and guidance mapping, allowing a full view of your uterus.

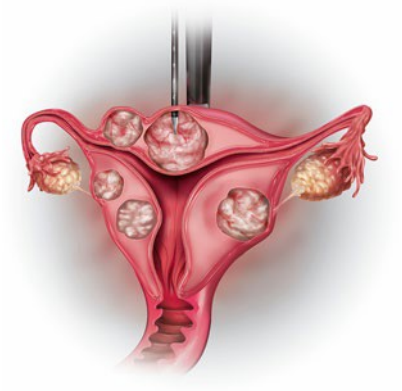
**Deploy -** Next, your physician deploys the tip of the Acessa handpiece into the fibroid while preserving healthy uterine tissue. [8,12]

**Treat -** The physician deploys controlled heat through the Acessa handpiece to destroy the fibroid tissue. The physician repeats this process until every targeted fibroid is fully treated.

**Finish -** Once the procedure is complete, your physician stitches the small incisions on the skin. Ta da!

**Recover -** You will wake up in the recovery room. Most patients get cleared to go home within two hours. Women typically feel ready to return to work and after 4-5 days.[1] In terms of when you will see symptom relief - it depends on size of your fibroid and which symptoms you've experienced. Your physician will discuss a symptom relief timeline with you in more detail.



## 20. What makes the Acessa procedure, the Acessa procedure?

Our technology allows for a more thorough and less invasive method of treating your fibroids when compared to other common treatment options like hysterectomy or myomectomy. Let's dig into what makes the Acessa procedure different. The latest version of the technology (The Acessa ProVu) is a fully integrated system with:

- **Ultrasound Probe -** This allows physicians to locate almost all fibroids you may have.[1] Imagine X-ray vision for your uterus.
- **The Acessa Handpiece -** This deploys controlled radiofrequency energy (heat) that shrinks fibroid tissue without destroying healthy uterine lining.[8] Imagine a light saber for fibroids.
- **Guidance Mapping -** This provides visual cues for physicians. Imagine GPS for your car.

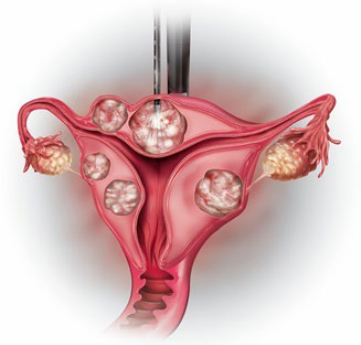
## 21. If the fibroids are not physically removed, how does the Acessa procedure work?

Studies show that fibroids do not have to be completely removed to resolve symptoms.[1] Treating the fibroid cells so they shrink and stop putting pressure on the uterus may help to resolve symptoms. The data in the IDE clinical study showed even a 45.1% average shrinkage in fibroid volume can result in significant improvement in heavy periods, pelvic pain and bulk.[1]
As a reminder, the Acessa procedure is a treatment for benign (non-cancerous) symptomatic fibroids. If patients are at risk for cancer or malignancy, The Acessa procedure is not the appropriate treatment.

To summarize, the Acessa procedure works by heating the fibroid cells from the inside out, not by removing the fibroid. Cell tissues die when they reach a certain temperature. The Acessa procedure is designed to heat the fibroid tissue to the point that the tissue dies. The dead fibroid tissue shrinks and shrivels over time. The dead fibroid tissue is not harmful. It gets absorbed by the body, just like any dead tissue cell.[3]

## 22. What happens to the fibroid? How much do they shrink?

Once the fibroid is treated, the destroyed fibroid tissue cell shrinks over time. Total volume shrinkage is dependent on fibroid size and location. From the pivotal trial across 137 patients, there was an average of 44% decrease in fibroid volume at 12 months after the procedure.[1] Fibroids may continue to shrink after 12 months; however, results vary.[1]



Fibroids before the Acessa procedure

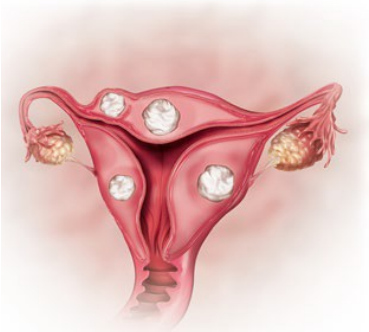


Illustration of fibroids after the Acessa

## 23. 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 makes a longer incisions.

## 24. Am I asleep during the The Acessa procedure?

Yes, the procedure is performed under general anesthesia. Patients are not awake during the procedure. The procedure cannot be performed under local anesthesia.[3]

### 25. Can the The Acessa 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. The Acessa procedure can be performed at an ambulatory surgery center or a hospital.

### 26. How long does the The Acessa 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 1-2 hours.[6] It may take longer for more fibroids or complications. Results may vary.

### 27. Is the The Acessa procedure painful?

Patients may experience cramping or pelvic pain following the procedure. Typically, patients go home on Tylenol or an NSAID such as ibuprofen. Patients often return to work in 4-5 days.[1] Results may vary. Patients should discuss the Acessa procedure, including its risks and benefits, with their physician.

## What information is available about the procedure?

### 28. How safe is the The Acessa procedure procedure? Is it clinically proven?

Radiofrequency ablation has been used for decades. The idea for laparoscopic radiofrequency ablation (Lap RFA) to treat fibroids, or the the Acessa procedure, was first conceived by Bruce Lee, MD in 1999.[2] The original the Acessa procedure was FDA cleared in November 2012. Since 2012, physicians have performed over 4000 procedures with over 49 peer reviewed publications.[4] The newest, most advanced technology, the Acessa ProVu system, was FDA cleared in 2018.

**"Our analysis indicates that Lap RFA is associated with low complication rates, minimal EBL, and low reintervention rates. In addition, patients reported major improvement in their HRQL and symptom severity scores compared to reports of more traditional interventions, such as hysterectomy, myomectomy, and UAE.[6]"**
– Havryliuk Meta Analysis JSLS 2017

### 29. What is the difference between Uterine Artery Embolization (UAE) and The Acessa procedure?

UAE involves ischemic necrosis which consists of the tissue slowly dying due to lack of blood supply and typically involves an overnight stay for pain management.[10] The Acessa procedure uses coagulative necrosis which destroys the fibroid cells and nerve endings with heat and results in the reduction of the fibroid volume over time.[1,8] The Acessa procedure patients typically return home same day.

UAE is performed by interventional radiologists. The Acessa procedure is performed by minimally invasive gynecologic surgeons.[10]

### 30. What is the difference between Myomectomy vs. The Acessa procedure?

Myomectomy cuts fibroids and surgically removes fibroid tissues from the uterus. The Acessa procedure, by comparison, does not require cutting or suturing within the uterus.[3] Myomectomy may be considered a minimally invasive surgery because incisions into the abdomen can be small. The Acessa procedure may be a less invasive option because there are zero incisions on the uterine surface (serosa) that require suturing, and only 3 small incisions on the skin (myomectomy typically requires 4 to 6 incisions in the skin).

## What are the typical results?

### 31. What are the typical results from the The Acessa procedure?

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 the effectiveness of the treatment, at least 94% of the subjects responded that the treatment had been somewhat, moderately, or very effective in eliminating their symptoms.[1]

Most patients report they have significantly lighter periods and alleviated pelvic pain and pressure. Often patients who experience "bulking" (looking pregnant with a distended abdomen) from the fibroids report reduced or eliminated bulk symptoms.[1] However, results may vary. To hear directly from patients, search "The Acessa procedure" on YouTube. Or explore the video section on www.acessaprocedure.com

### 32. When will patients feel symptom relief after the The Acessa procedure?

The Acessa procedure is able to resolve many of common fibroid symptoms including: extreme periods, stomach swelling and bloating, leg and back pain, stomach and pelvic pain, digestive issues, anemia, pain during sex, frequent urination.[1]

Based on clinical data, the average reduction in menstrual blood loss among evaluable subjects was 87 mL less blood than baseline periods after 3 months and reduced even further to 103.6 mL less by 6 months.[1] According to HealthLine, 103.6 mL of period blood is equivalent to reducing a period by approximately 20 regular tampons.[13]

Most patients see the greatest effects 3—6 months after the Acessa procedure.[1,5] However, results may vary. To hear directly from patients, search "The Acessa procedure" on YouTube. Or explore the video section on www.acessaprocedure.com

# Why haven't I heard about the Acessa procedure before?

### 33. How long has this option been available, why has my doctor never heard of the Acessa procedure?

Radiofrequency ablation has been used for decades. The idea for laparoscopic radiofrequency ablation (Lap RFA) to treat fibroids, or the The Acessa procedure procedure, was first conceived by Dr. Bruce Lee in 1999.2 The original The Acessa procedure was FDA cleared in November 2012. Since 2012, physicians have performed over 4000 procedures and generated 49 peer reviewed publications.4 The newest, most advanced technology, the Acessa ProVu system, was cleared by FDA in 2018.

Hologic is on a mission to give women more options. More physicians learn about the Acessa procedure each day.

### 34. Are there clinical studies I can join?

The Acessa procedure is already FDA cleared for commercial use in the United States.

Additional studies using the Acessa ProVu technology are described here

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

You should discuss whether you may be eligible for enrollment with your physician.

## IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION The Acessa ProVu system is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The Acessa ProVu system is contraindicated for patients who are not candidates for laparoscopic surgery and/or patients with a uterus adherent to pelvic tissue or viscera. The Acessa ProVu system's guidance system is not intended for diagnostic use. Please read all instructions for use of the Acessa ProVu system prior to its use. Safe and effective electrosurgery is dependent not only on equipment design but also on factors under control of the operator. Rare but serious risks include, but are not limited to, skin burns, mild inter-operative bleeding, post-procedural discomfort (cramping, pelvic pain), infection, vaginal bleeding, blood loss and complications related to laparoscopy and or general anesthesia. If you or someone you know has possibly experienced a side effect when using our product please contact your physician. Insufficient data exists on which to evaluate the safety and effectiveness of the Acessa ProVu system in women who plan future pregnancy, therefore the Acessa ProVu system is not recommended for women who are planning future pregnancy.

## REIMBURSEMENT DISCLAIMER:

Reimbursement information is provided for convenience only and is not legal advice or official guidance from payers. It is not intended to increase or maximize reimbursement by any payor. Hospitals and physicians are solely responsible for being in compliance with Medicare and other payor rules and requirements for the information submitted with all claims and appeals. The Acessa procedure Health, Inc. does not warrant or guarantee that the use of this information will result in coverage or payment. Before any claims or appeals are submitted, hospitals and physicians should review official payor instructions and requirements, should confirm the accuracy of their coding or billing practices with these payors and should use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient. CPT five-digit numeric codes, descriptions, and numeric modifiers are © 2020 AMA. All rights reserved.

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