Acessa Procedure: Laparoscopic Radiofrequency Ablation (Lap-RFA) for Uterine Fibroids

A clinically proven alternative to hysterectomy and myomectomy that addresses nearly any type of fibroid, including intramural.¹
Lap-RFA

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Acessa ProVu® System Benefits

- First and only fully integrated system utilizing laparoscopic ultrasound, guidance mapping and radiofrequency ablation
- Originally designed by a gynecologist, specifically for uterine fibroids
- Identifies 1.5-2.0x more fibroids than preoperative TVUS and MRI
- Most complete view of fibroids allowing surgeons to identify more fibroids than any other uterine sparing, minimally invasive procedure
- Lap, specific category 1 CPT code, 58674 with favorable reimbursement
- 11% cumulative 3-yr reintervention rate

Alternative to Hysterectomy and Myomectomy

- Proven on highly symptomatic patients
- Treats nearly all types of fibroids
- Uterine sparing
- No suturing of uterine tissue
- Outpatient, quick 4-5 day recovery
- Addresses symptoms including heavy bleeding and bulk
- Lower intraoperative blood loss compared to myomectomy and hysterectomy

Lap-RFA

Lap-RFA uses an ultrasound probe to locate the fibroids, guidance mapping that provides visual cues, and a percutaneous handpiece that deploys radiofrequency energy to destroy fibroid tissue through coagulative necrosis.

PROCEDURE STEPS

1. Prep & Access
2. Visualize
3. Deploy
4. Treat

Lap-RFA uses radiofrequency energy under laparoscopic ultrasound guidance to cause coagulative necrosis of the fibroid tissue, while preserving healthy uterine tissue. Coagulative necrosis is not ischemic necrosis (UAE) – unlike UAE, Acessa is designed to destroy the fibroid cells during the procedure vs. a gradual degeneration process from starving the uterus of blood supply.

Coagulative Necrosis

The consistency of the fibroid changes. To explain it to patients, use an analogy: from being hard like a baseball to soft like a marshmallow.

Clinically proven symptom relief - even on highly symptomatic patients

Symptom Relief - Significant improvement in Health Related Quality of Life and Symptom Severity Scores by 3 months and continued out to 3 years.

Heavy Menstrual Bleeding Relief - Significant improvement in HMB; avg. of 103 mL decrease in blood loss per cycle by 12 months after baseline (~20 tampons), measured objectively by alkaline-hematin method.

Fibroid & Uterine Size Reduction - Average 45% volumetric reduction of fibroid size, 24% volumetric reduction of uterine size by 12 months.

Studied Highly Symptomatic Patients - Baseline menstrual blood loss ranging up to 500 mL per cycle (~100 tampons per cycle) and included symptoms: bulk, pain, back pain, etc.
is limited data regarding pregnancy following the Acessa procedure; if you become pregnant following the Acessa procedure, you should contact your doctor immediately. Please consult with your doctor to understand the risks and benefits of surgery.

Energy, mild intraoperative bleeding, transient urinary retention or urinary tract infection, adhesion formation, post ... (cramping, pelvic pain), and transient amenorrhea, infection, injury to adjacent structures, vaginal bleeding and temporary anemia, blood loss requiring transfusion or hysterectomy, pneumothorax, wound dehiscence, deep vein thrombosis and pulmonary embolus, treatment failure, and complications related to laparoscopy and/or general anesthesia including death. Insufficient data exists 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. There is limited data regarding pregnancy following the Acessa procedure; if you become pregnant following the Acessa procedure, you should contact your doctor immediately. Please consult with your doctor to understand the risks and benefits of surgery and find out if Acessa may be right for you. Rx Only.

Acessa Procedure 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. Although many patients may benefit from the Acessa Procedure, this treatment is not for everyone and results may vary. You should talk to your doctor about the potential benefits and risks and whether this treatment is right for you. Information contained in this brochure is not to be used as a substitute for talking to your doctor. You should always talk to your doctor about diagnosis and treatment information. The Acessa ProVu system is cleared by the FDA for the treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The Acessa procedure is generally safe but complications may occur and can be serious. Risks and complications associated with the Acessa procedure include, but are not limited to: skin burns from the dispersion of radiofrequency energy, mild intraoperative bleeding, transient urinary retention or urinary tract infection, adhesion formation, post-procedural discomfort (vaginal, pelvic pain), and transient ammenorrhea, infection, injury to adjacent structures, vaginal bleeding and temporary anemia, blood loss requiring transfusion or hysterectomy, pneumothorax, wound dehiscence, deep vein thrombosis and pulmonary embolus, treatment failure, and complications related to anesthesia and/or general anesthesia including death. Insufficient data exists 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. There is limited data regarding pregnancy following the Acessa procedure; if you become pregnant following the Acessa procedure, you should contact your doctor immediately. Please consult with your doctor to understand the risks and benefits of surgery and find out if Acessa may be right for you. Rx Only.

Acessa Procedure

The Acessa Procedure is a uterine fibroid treatment that uses radiofrequency energy to destroy fibroid tissue. The procedure is performed under laparoscopic ultrasound guidance, allowing for precise targeting of fibroids while minimizing damage to surrounding tissue. Acessa procedures are typically performed on an outpatient basis, allowing patients to return home the same day.

Acessa Health

Acessa Health is a medical device company that specializes in the development and commercialization of minimally invasive technologies for the treatment of uterine fibroids. The company is committed to providing patients with safe and effective treatment options for uterine fibroids, and is dedicated to advancing the field of minimally invasive gynecology.


51% of women surveyed with fibroids indicated they wanted to keep their uterus.8

"Many fibroid patients do not seek treatment because they fear hysterectomy is their only option. By offering all the options, including Acessa, I can break the barrier of fear and develop a personalized surgical approach to each patient’s unique fibroids, symptoms, and goals."

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