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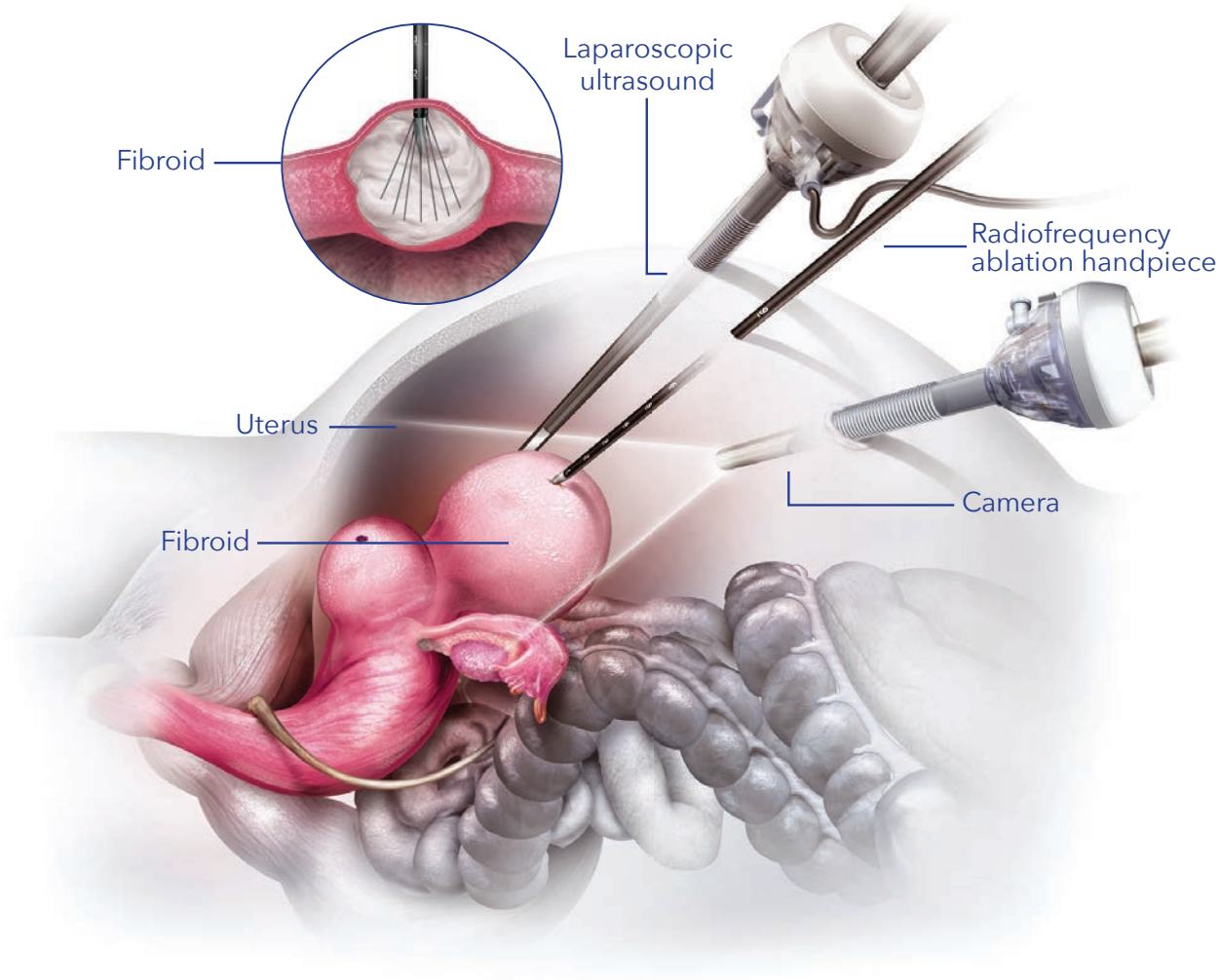
acessa®

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]

LI-07-0167 A | PB-00861-001 Rev 001

Lap-RFA

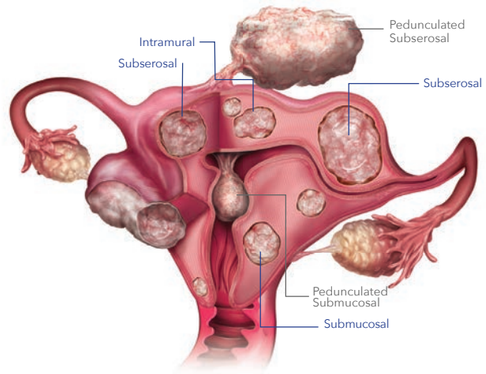
ADDRESSES NEARLY ALL TYPES OF FIBROIDS, INCLUDING INTRAMURAL

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[3]
- Most complete view of fibroids allowing surgeons to identify more fibroids than any other uterine sparing, minimally invasive procedure[3]
- Lap. specific category 1 CPT code, 58674 with favorable reimbursement
- 11% cumulative 3-yr reintervention rate[7]

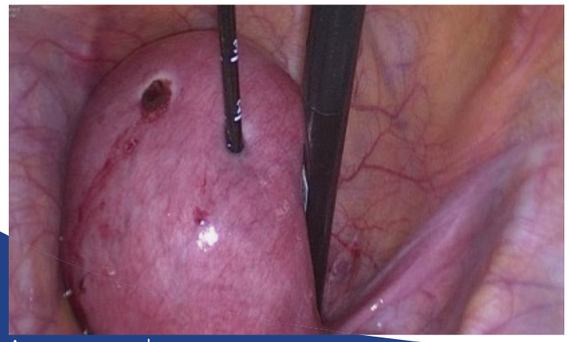
Alternative to Hysterectomy and Myomectomy[1]

- Proven on highly symptomatic patients[2]
- Treats nearly all types of fibroids[2]
- Uterine sparing
- No suturing of uterine tissue
- Outpatient, quick 4-5 day recovery[2]
- Addresses symptoms including heavy bleeding and bulk[2]
- Lower intraoperative blood loss compared to myomectomy and hysterectomy[1]

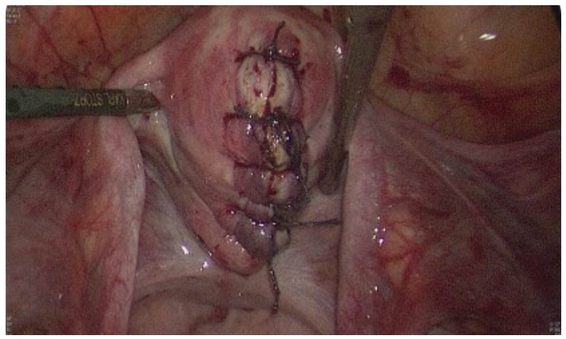


"Our analysis indicates that Lap-RFA is associated with low complication rates, minimal EBL, and low reintervention rates. In addition, patients reported major improvement in their HRQL and symptom severity scores compared to reports of more traditional interventions, such as hysterectomy, myomectomy, and UAE."

Havryliuk Meta Analysis JSLS 2017[1]



Acessa procedure



Myomectomy

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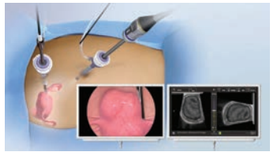
Lap-RFA

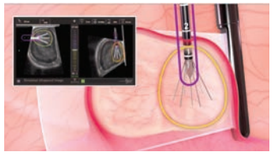
Lap-RFA uses an ultrasound probe to locate the fibroids, guidance mapping that provides visual cues, and a percutaneous handpiece that deploys radiofrequency energy to destroy fibroid tissue through coagulative necrosis.

PROCEDURE STEPS

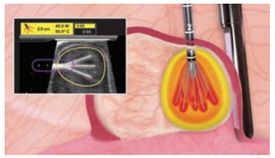
1. Prep & Access



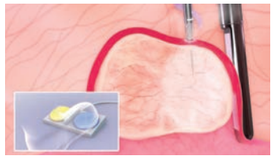
2. Visualize



3. Deploy

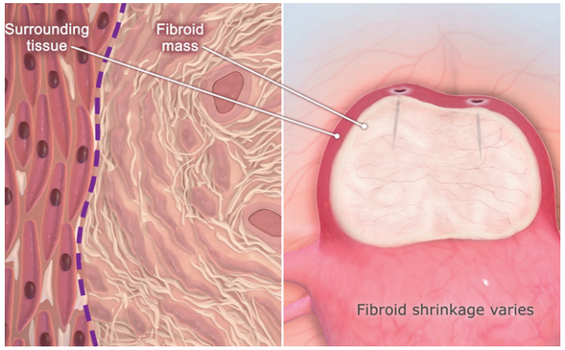


4. Treat

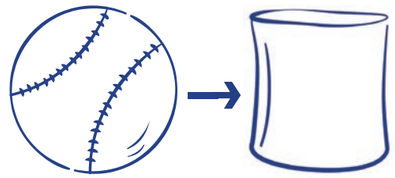


Coagulative Necrosis

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.



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.[5,6]



Baseball **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.[7]

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.[2]

Fibroid & Uterine Size Reduction - Average 45% *volumetric* reduction of fibroid size, 24% volumetric reduction of uterine size by 12 months.[2]

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.[2]

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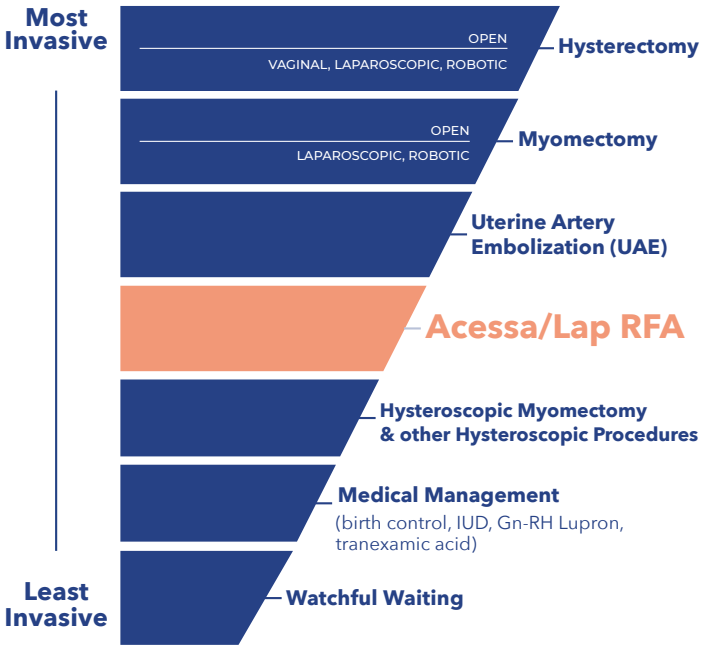
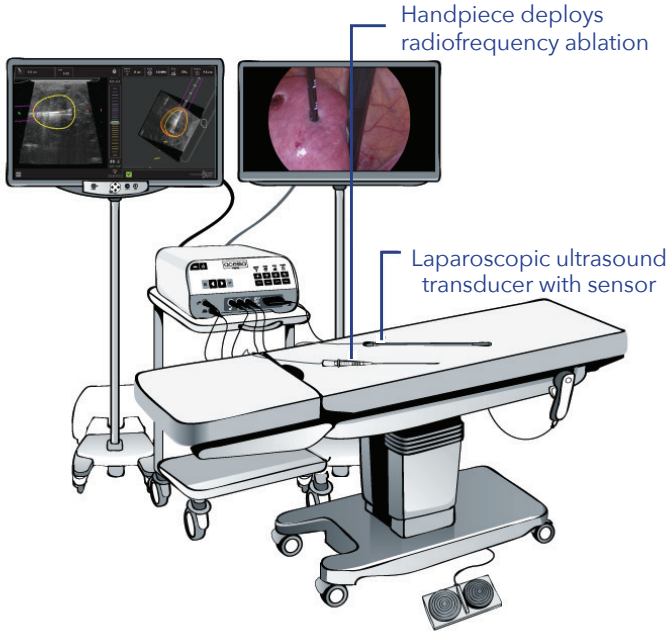
Join the growing number of Acessa trained physicians who are elevating the standard of care for women suffering from uterine fibroids.

For information about the Acessa procedure and physician training opportunities visit **www.acessaprocedure.com** or email **clinical@acessahealth.com**

Women Want Uterine Sparing Options

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."

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 (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 fi nd out if Acessa may be right for you. Rx Only.

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8. Borah, Bijan J. et al. The impact of uterine leiomyomas: a national survey of affected women. American Journal of Obstetrics & Gynecology, October 2013, Volume 209, Issue 4, 319. e1—319.e20

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