



Control Her
Treatment...
End Her Pain
and Suffering

- Outpatient fibroid therapy
- High patient satisfaction
- Low re-intervention rate

Acessa
system

Acessa

Treat all the fibroids – just the fibroids.

She will prefer this option:

- No Referral
- Limit Rejection of Treatment

She will be happy with the results:

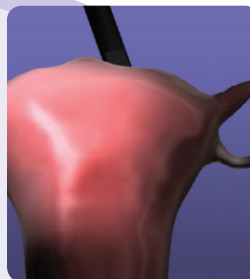
- 94%** Patients were satisfied with the treatment
- 98%** Patients would recommend to a friend
- 94%** Patients responded that the treatment had been effective in eliminating their symptoms

Physicians identify and treat significantly more fibroids:

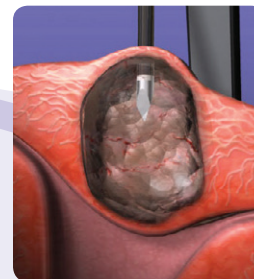
- Intra-abdominal ultrasound identified 46% more fibroids than MRI and 107% more fibroids than transvaginal ultrasound
- Treated an average of 5 fibroids in each patient

The Acessa Procedure

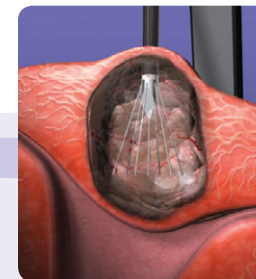
The Acessa procedure is a new minimally-invasive, same-day (outpatient) therapy for fibroids. It uses a technology called radiofrequency ablation. Each fibroid is destroyed by applying energy through a small needle array. The surrounding normal uterine tissue is not affected. The destroyed tissue may then be completely reabsorbed.



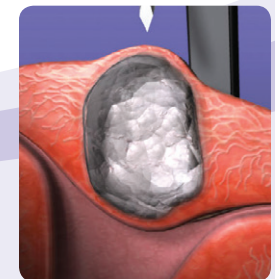
Uterus mapped for fibroids



Acessa Handpiece introduced into fibroid



Deployment of Acessa Handpiece electrodes



Ablation of the fibroid

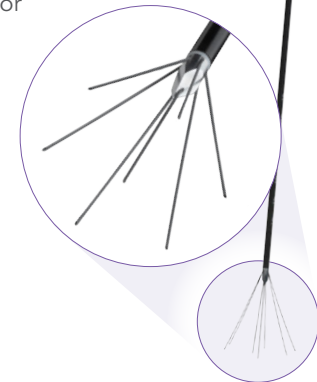


Acessa Generator

The Generator works seamlessly with the Handpiece to provide radiofrequency energy for ablation and traditional electrocautery to control the bleeding common in the treatment of myomas. It provides the surgeon continuous monitoring and real-time temperature control.

Acessa Handpiece and Electrode Array

The Handpiece includes the control feature for generator interface and the Electrode Array. The deployable electrode array allows the treatment of fibroids of varying size. Once the Handpiece is inserted into the myoma, the electrode array is deployed under ultrasound guidance. The duration of the ablation is defined by a treatment algorithm based on the amount of deployment.



Summary of Clinical Results

- **Subject Inclusion Criteria**
137 women, 25 years of age or older, with clinical menorrhagia, ≤ 6 treatable fibroids, none exceeding 7 cm in diameter, and total uterine fibroid volume not exceeding 300 cc
- **Device-Related Safety**
The rate of complications for the Acessa System was $< 4\%$
- **Efficacy**
81% of subjects experienced a reduction of bleeding at 12 months
- **Surgical Reintervention Rate**
 $< 5\%$ /year
- **Change in Uterine Volume**
 -25% at 12 months
- **Change in Uterine Fibroid Volume**
 -44% at 12 months
- **Improvement in HRQL Scores**
At Baseline: 37; at 24 months: 80
- **Improvement in Symptom Severity Scores**
At Baseline: 61; at 24 months: 24

Please reference product Instructions for Use for more information regarding indications, warnings, precautions, contraindications and adverse events.

Description	Model #	Description	Model #
Acessa Generator	1000	Power Cord	4110
Acessa Handpiece	2000	Handpiece Cable	4200
Acessa Pads	3000	Pad Cable	4300
Foot Pedal	4100		

Customer Service

+1-877-412-3828 or customerservice@haltmedical.com

References

Levine DJ, Harris M, Berman JM et al. Leiomyoma assessment by Intra-abdominal ultrasound compared to preoperative ultrasound and preoperative magnetic resonance imaging. J Minim Invasive Gynecol 2011;18 (6 Suppl):S1.
Halt Fibroid Study, NCT00874029, September 07, 2012 provided by Innovative Analytics, Kalamazoo, MI.

Halt Medical, Inc.

131 Sand Creek Rd., Ste. B, Brentwood, CA 94513
tel: 925-634-7943 fax: 925-634-7841

www.haltmedical.com

LI-00-0007-C