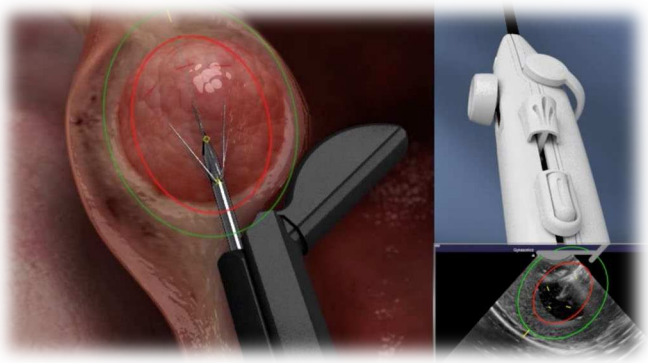
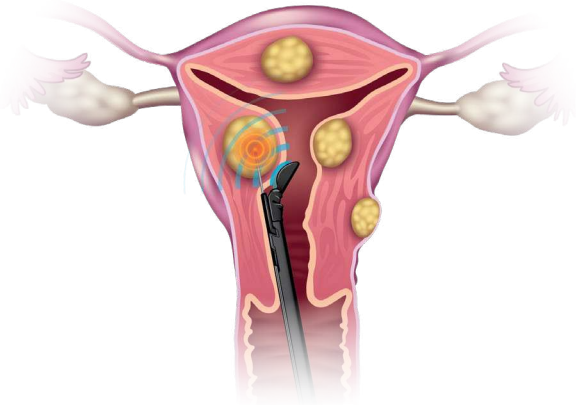




Welcome!

STAN VAN GENT
SENIOR DIRECTOR, GLOBAL MARKETING AT GYNESONICS

Housekeeping

- Webinar defaults to everyone on MUTE at start
- We will turn OFF the mute for everyone at this time
- Please MUTE yourself at your end, so you have control and to avoid background noise and feedback
- At any time, please feel free to unmute and ask a question – we are here for you
- If you are having any troubles with being heard, please use CHAT function to ask a question
- Videos will NOT work on phones, but will be made available after the webinar

Sonata SYSTEM

Introductions

Physician Educators and Gynesonics Faculty

- David Toub, MD, MBA, Medical Director-Gynesonics
- David Levine, MD, Director of MIGS, Mercy-St. Louis
- Shane Raine Sr., Director of Value, Patient Advocacy, Access & Authorization

Sonata SYSTEM

Agenda for Today

Welcome	Stan Van Gent
Dr. Scott Chudnoff: Sonata® Procedure Video	
Sonata System Overview	David Toub, MD MBA
Clinical Trial Results	David Toub, MD MBA
Patient Selection, Expectations, and Experience, Case Discussion	David Levine, MD

Sonata® SYSTEM

Dr. Scott Chudnoff: Sonata® Procedure Video

Sonata Procedure Didactic Training

Sonography-Guided Transcervical Fibroid Ablation

DAVID TOUB, MD, MBA, FACOG
MEDICAL DIRECTOR, GYNESONICS

System Components

SMART Tablet

RF Generator Power Switch Back

System Cart

IUUS Probe (reusable)

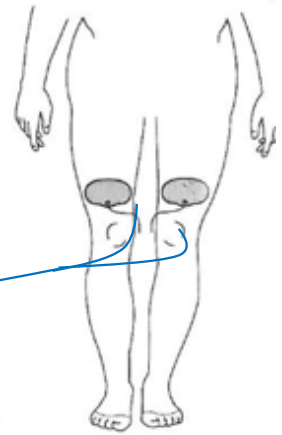
RFA Handpiece (single use)

RFA Handpiece Cable (single use)

Two (2) Dispersive Electrodes (single use)

SYSTEM

Radiofrequency Ablation



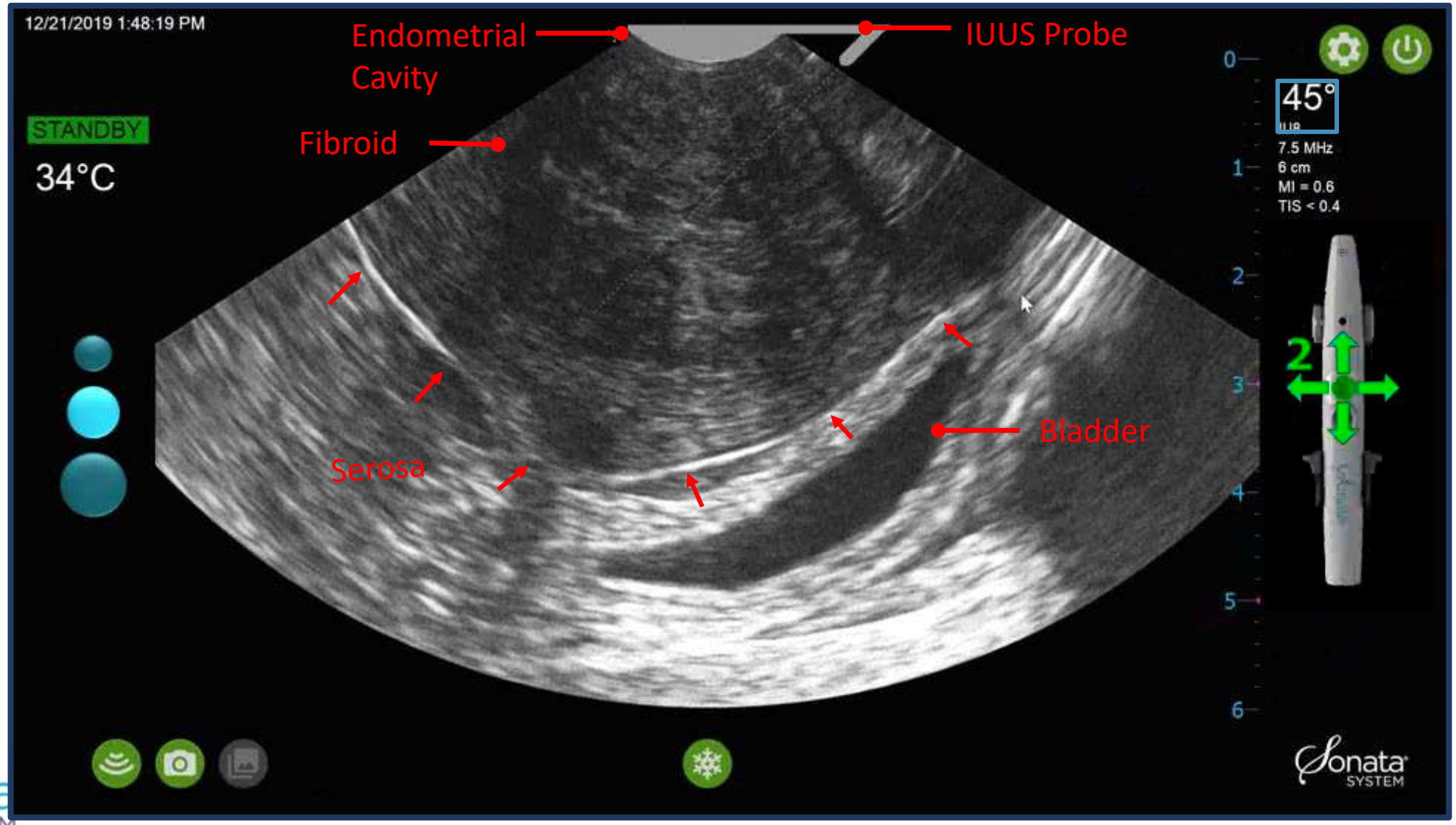
RF Generator

- Energy delivered through RFA Handpiece
- Dispersive electrodes complete circuit

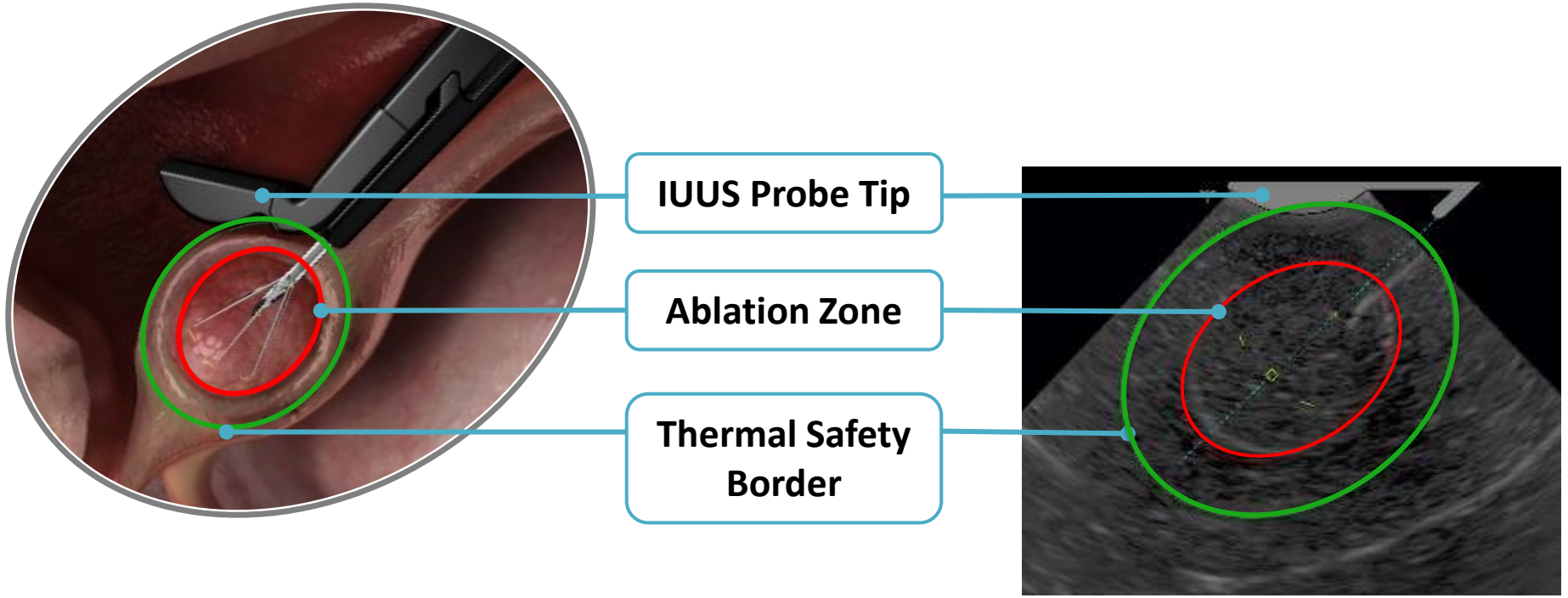
Volumetric Ablation

- Energy is dispersed through Needle Electrodes for predictable sizes
- Ablation temperature is 221°F (105°C)
- Heat is dispersed for tissue treatment in Ablation Zone
- Ablation size depends on:
  - Amount of needle electrode deployed
  - Amount of time in ablation

Intrauterine Ultrasound Imaging and Anatomy



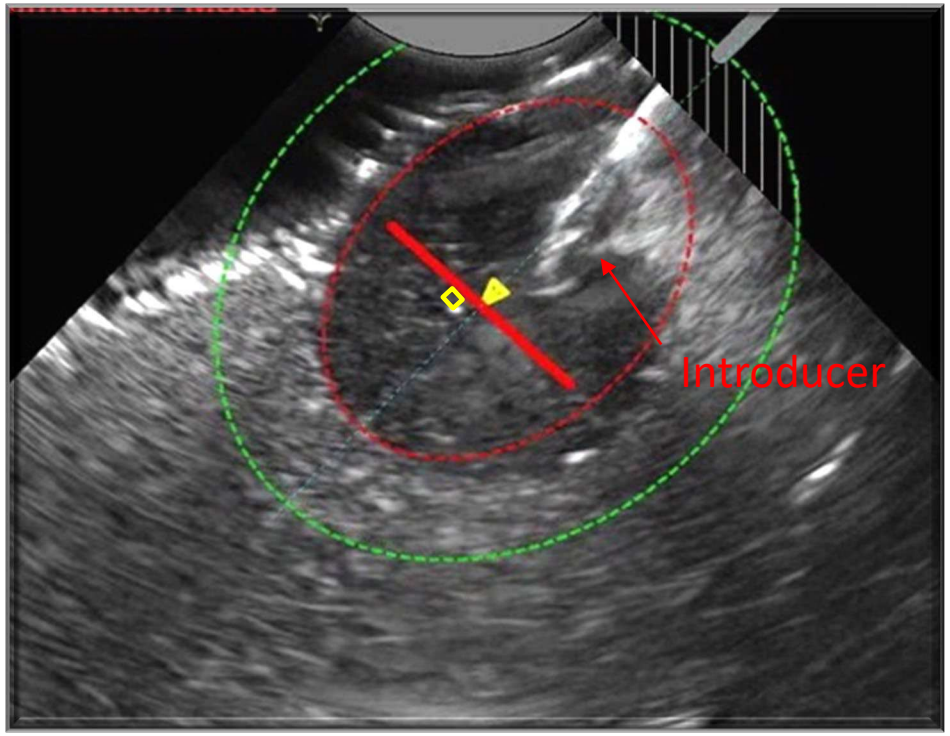
SMART Guide: Graphical Overlays on Live Ultrasound Image

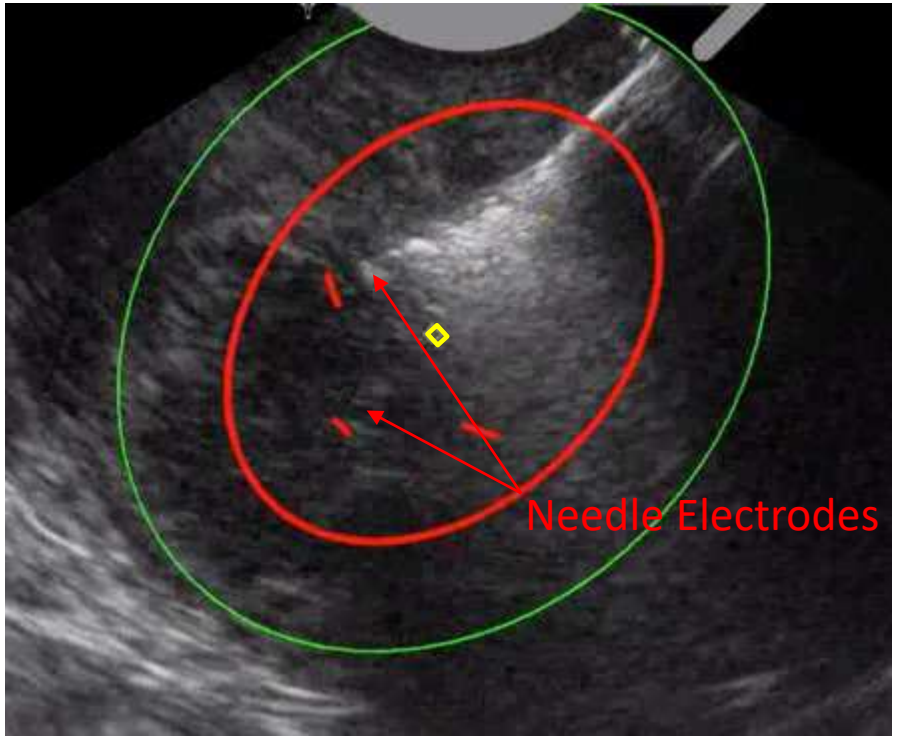


Ablation Zone: (red inner ellipse)
A graphical representation of the average region of tissue ablation

Thermal Safety Border: (green outer ellipse)
The distance at which tissue is safe from potential of thermal damage

SMART Guide Graphics





- Red Ablation Zone marks region of tissue treatment
  - Optimize over fibroid tissue
  - Min: 2.0 x 1.3 cm
  - Max: 4.9 x 4.2 cm
- Green Safety Border to be kept inside serosa
- Plan Lines show user how far to deploy

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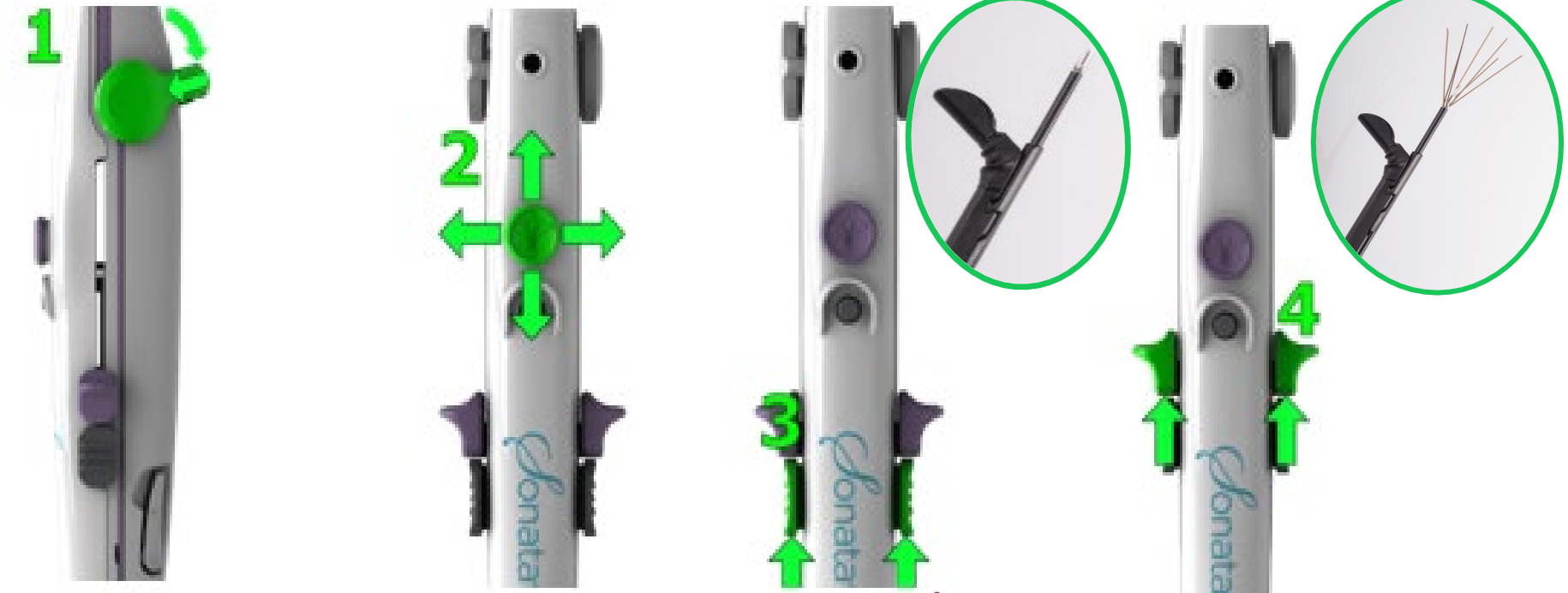
Control Sequence

Deploy



Articulate

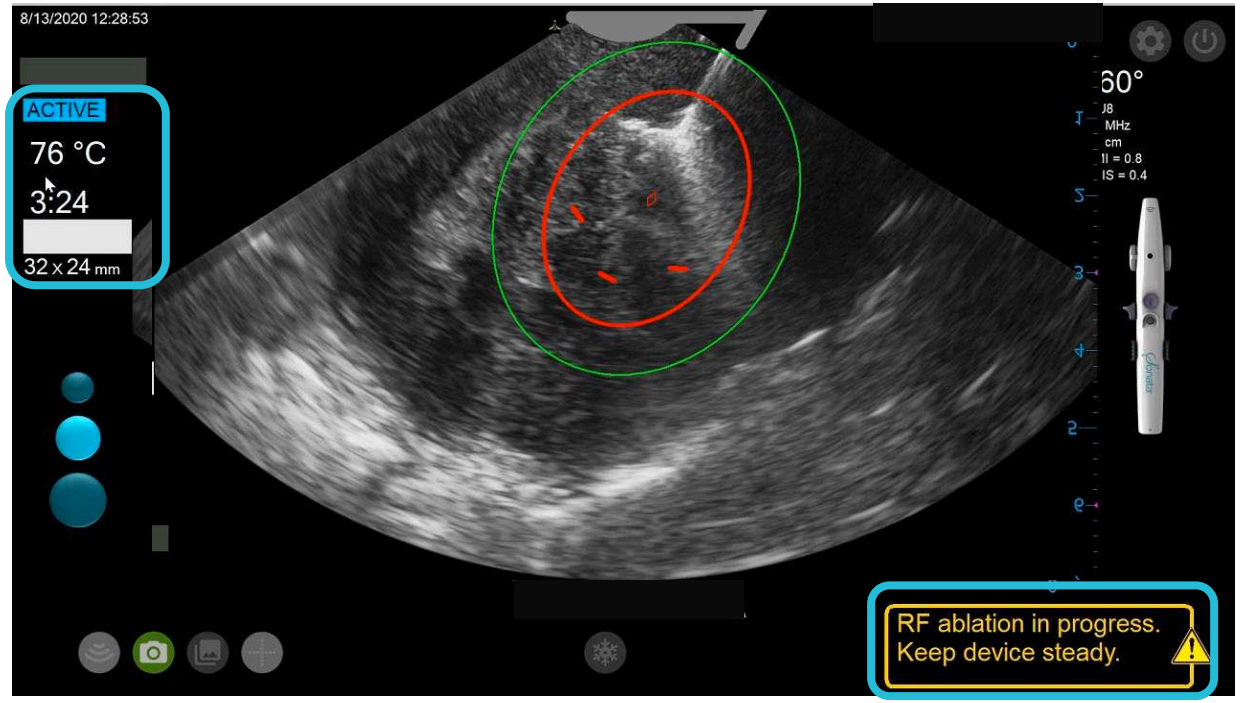
Set Ablation Depth & Size

Depress and Advance Introducer

Deploy Needle Electrodes

Retract

RF Status - Active



Footswitch single press to activate

– remove foot to prevent de-activation.

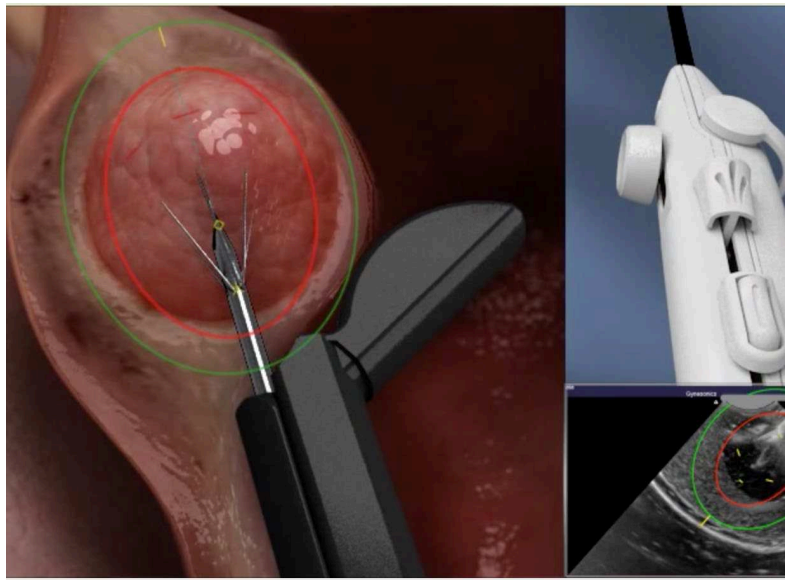
RF is ACTIVE

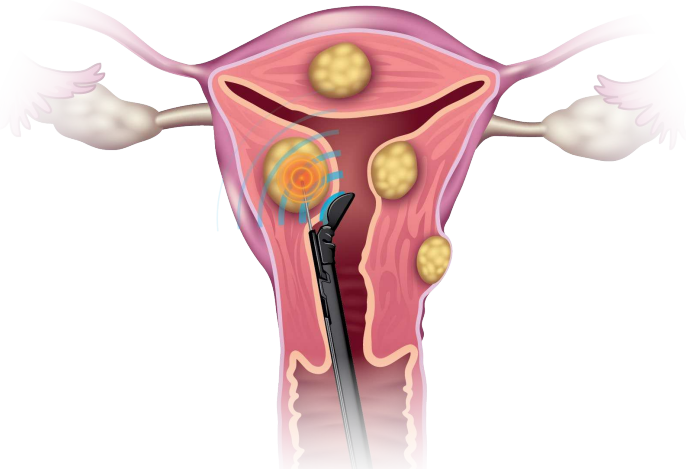
- Stabilize Device
- Temp, Time shown
- Outgassing is normal, maintain position
- Patient should be still, no movement or changes on device
- If change in ablation location or size desired or occurs, STOP ablation. (button or footswitch)
- For large ablations, in some instances, a “staged” treatment is needed. System will instruct on how to stage with smaller ablation.

Sonata SYSTEM

SONOGRAPHY-GUIDED TRANSCERVICAL FIBROID ABLATION (TFA): CLINICAL DATA

DAVID TOUB, MD, MBA, FACOG
MEDICAL DIRECTOR, GYNESONICS





Summary of Key Outcomes

Outcomes associated with sonography-guided transcervical fibroid ablation (TFA) to treat symptomatic uterine fibroids:

- A significant reduction in mean menstrual bleeding
- Low surgical reintervention for HMB through 3 years
- No device-related adverse events
- Well tolerated by patients with rapid return to normal activity
- Significant and durable improvements in fibroid symptoms and health-related quality of life

Intended Use

The Sonata System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

Contraindications

Current pregnancy; active pelvic infection; known or suspected gynecologic malignancy or premalignant disorders such as atypical endometrial hyperplasia; presence of one or more intratubal implants for sterilization; and presence of an intrauterine device (IUD), unless removed prior to the introduction of the Sonata Treatment Device.

Patient Selection Considerations

Safety and effectiveness with regard to fertility and fecundity after the use of the Sonata System have not been established, and effectiveness in women with clinically significant adenomyosis has not been established.

Anticipated Postoperative Events and Potential Risks

Anticipated postoperative events include abdominopelvic pain/cramping; back pain; constipation; dizziness/fatigue; headache; fever; malaise; nausea/vomiting; sloughing and, less commonly, intact expulsion of ablated fibroid tissue per vaginam (particularly after ablation of submucous fibroids), and vaginal spotting/bleeding/dysmenorrhea. Potential risks associated with fibroid ablation using the Sonata System include: allergic reactions (including rash) to device materials; bowel or bladder perforation; cervical/vaginal laceration or tear; dysmenorrhea; electrical shock; hematometrium; hemorrhage; infections: major and minor local and systemic infections, including intrauterine infection; retention of device fragment; skin burn from the dispersion of RF energy; thrombotic events; unintended injury to the uterus, cervix or vaginal vault, adjacent organs or tissue; unknown risk to future pregnancies; and complications including death.

To learn more about the Sonata System, visit us at gynesonics.com/sonata-system or sonatatreatment.com

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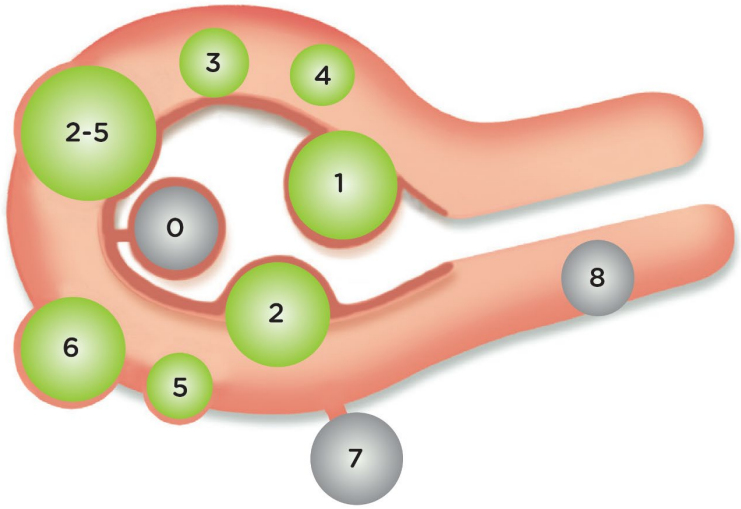
Transcervical Fibroid Ablation (TFA)

Volumetric, image-guided radiofrequency ablation

- Enables optimized ablated volume of targeted fibroid
- Avoids multiple passes of energized needles through the serosa
- Not a global therapy; can treat the fibroids that are likely to be symptomatic
- Incites thermal fixation and coagulative necrosis
  - Not associated with infarction-related post-embolization syndrome

TFA Treats a Wide Range of Fibroid Types and Sizes



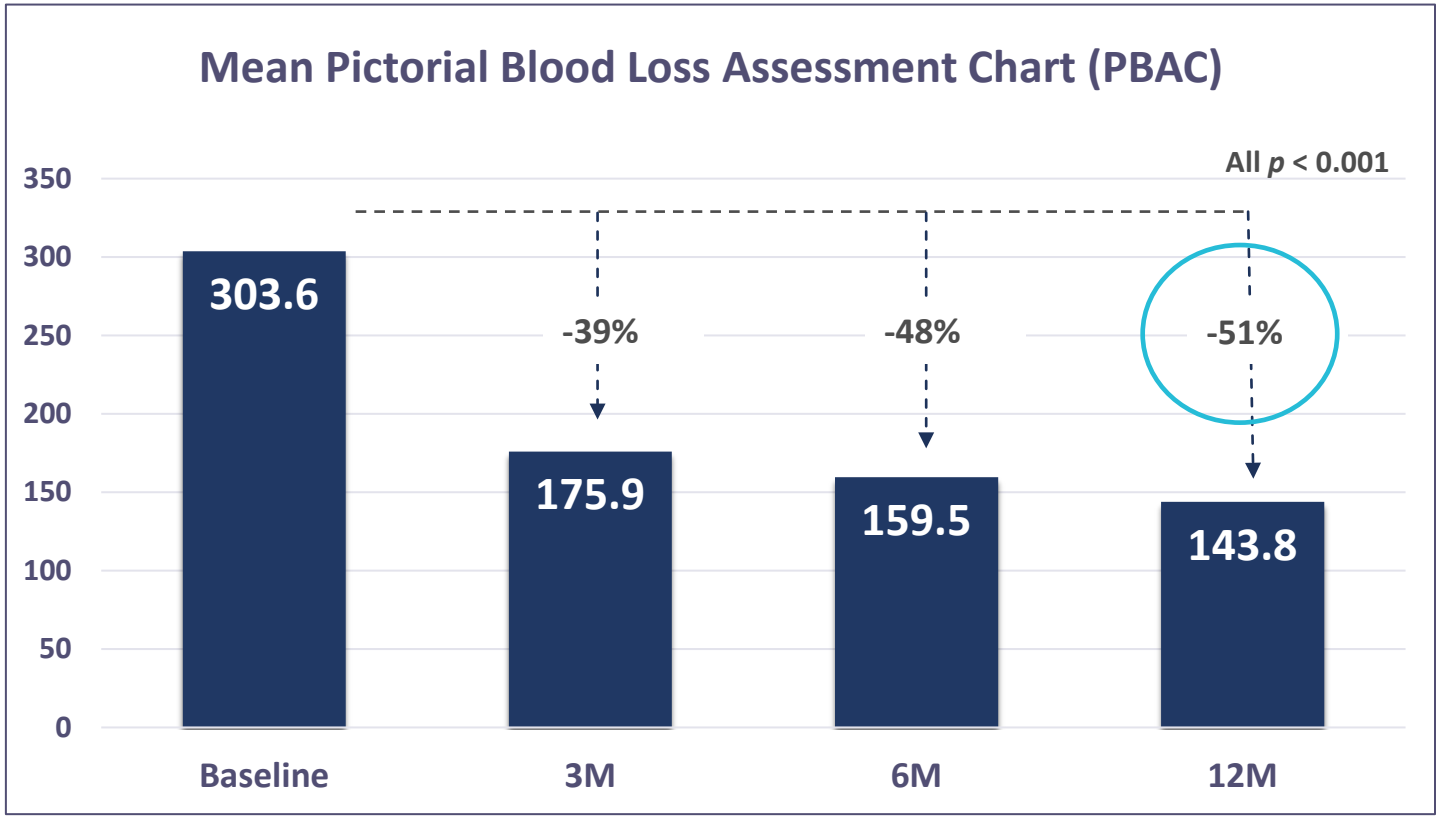
The Sonata System is designed to ablate or partially ablate all non-pedunculated fibroid types in GREEN

FIGO Leiomyoma Subclassification System

OTHER	Submucosal	0	Pedunculated intracavity
		1	<50% Intramural
		2	≥50% Intramural
	Intramural	3	Contacts endometrium; 100% intramural
		4	Intramural
	Subserosal	5	Subserosal, ≥50% intramural
		6	Subserosal, <50% intramural
		7	Subserosal pedunculated
		8	Other (specify e.g. cervical, parasitic)
HYBRID	Transmural	Two numbers are listed separated by a dash. By convention, the first refers to the relationship with the endrometrium while the second refers to the relationship to the serosa. One example is below.	
		2-5	Submucosal and subserosal, each with less than half the diameter in the endometrial and peritoneal cavities respectively.

Adapted from: Munro MG, Critchley HOD, Fraser IS, FIGO MDC. *Int J Gynaecol Obstet*. 2018;393-408.

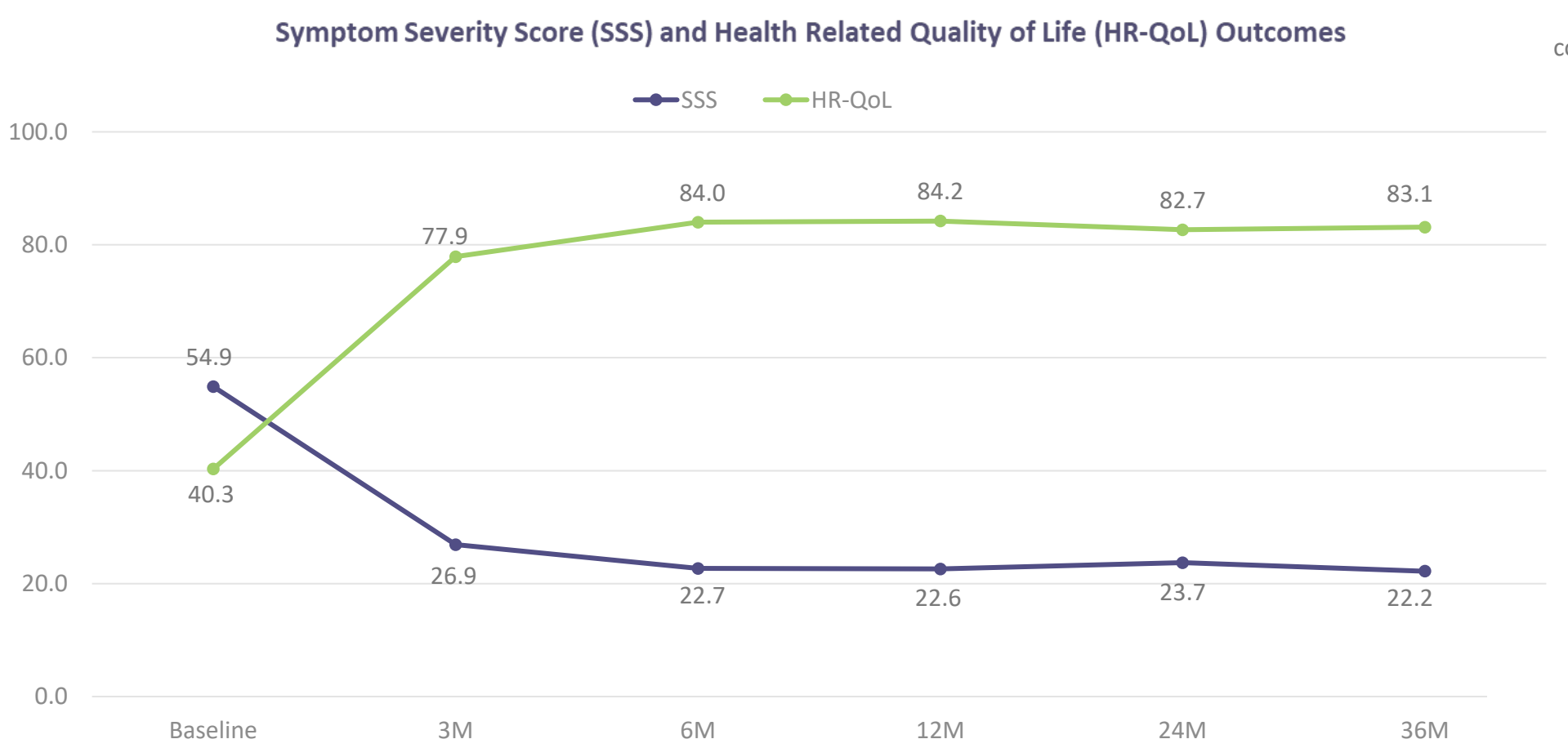
How effective is TFA?
Significant Reductions in Menstrual Bleeding through 12 Months



- 86% of patients reported a reduction in menstrual bleeding at 3 months post-procedure.
- 95% of patients reported a reduction in menstrual bleeding at 12 months
- 65% of women reported >50% reduction in menstrual bleeding.
- Sonata was effective in patients where their only qualifying fibroid was one or more intramural type 3.

How effective is TFA?
Significant Improvements in Symptoms, QOL Persist Through 3 Years

All *p-values* < 0.001 compared to baseline



Sonata Pivotal IDE Trial

Will My Patients Need to be Retreated?
Low Cumulative Rate of Surgical Reintervention for HMB through 3 Years

Timepoint	Cumulative Surgical Reinterventions	Cumulative Surgical Reintervention Rate (Kaplan-Meier)
1 Year	1	0.7%
2 Year	7	5.0%
3 Year	11	8.2%

Sonata
Pivotal IDE Trial

Is TFA Safe?

Serious Adverse Events (SAEs) [ie, major complications]

- No device-related SAEs in the 1st, 2nd, or 3rd year of follow-up
- No bowel injury/burns or uterine perforation with the device in >1700 global cases to date

Sonata
Pivotal IDE Trial

How long does TFA take, and how soon can my patients return to normal activity?

Procedure time depends on the number and size of fibroids treated.

- In SONATA, patients were d/c'd 2.5 hours on average (including the procedure time)

Patients typically recover promptly

- In SONATA, mean return to normal activity = 2.2 days, with half of the patients reporting a return to normal activity within 1 day

Sonata
Pivotal IDE Trial

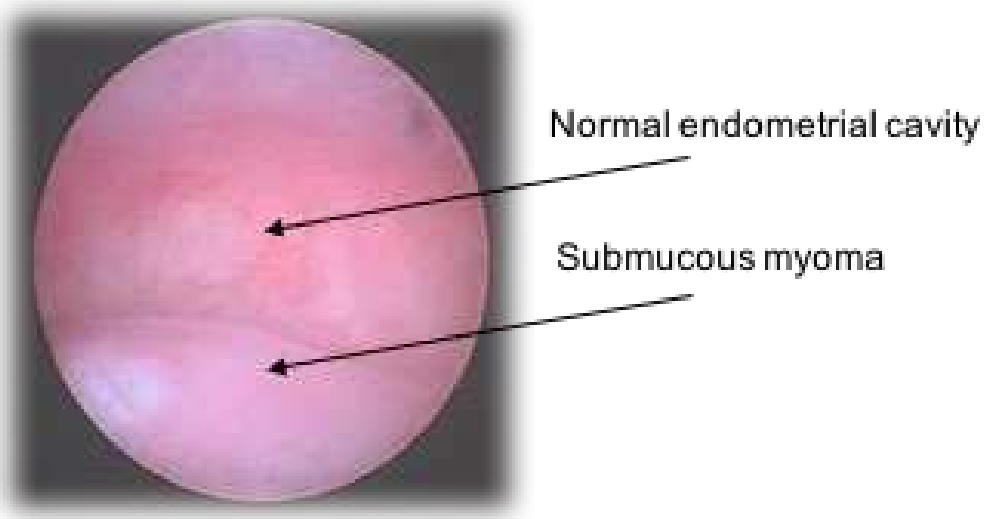
What about pregnancy?

- Current FDA and CE labelling for Sonata System notes safety and effectiveness re: fertility and fecundity have not been established and potential risks/benefits remain unknown

- Normal pregnancy outcomes reported at term after treatment with TFA and other ablative treatments, including vaginal and elective R C/S, and after assisted reproduction[1,2,3,4]

[1]Keltz J, Levie M, Chudnoff S. *J Minim Invasive Gynecol*. 2017; 24: 538-545.
[2]Bends R, Toub DB, Römer T. *Int J Womens Health*. 2018; 10: 367-369.
[3]Garza-Leal JG, León IH, Toub D. *Gynecological Surgery*. 2014; 11: 145-149.
[4]Pschadka G, Engelhardt M, Niehoff C, Toub D. *J Gynecol Surg*. 2019;253-255.

What about intrauterine adhesions?

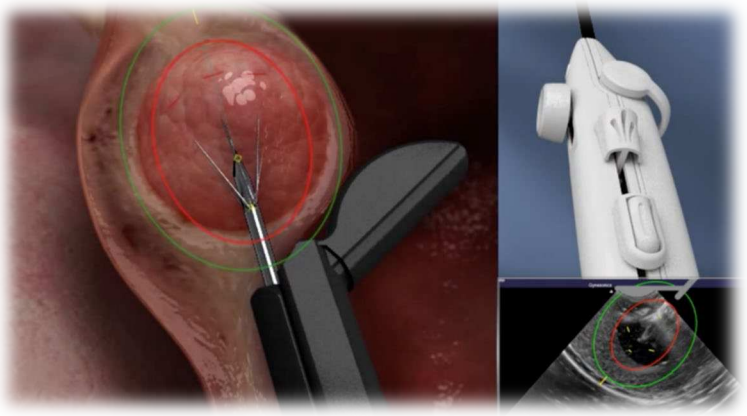


34 evaluable paired baseline and second-look hysteroscopy videos for patients treated at 6 sites

- Mean patient age: 42.4 ± 7.2 years (range 29-55)
- Mean ablated fibroid diameter: 3.2 ± 1.6 cm (range 1-8 cm)
- All showed no sign of adhesions after TFA per agreement in evaluation by 2 independent readers with 1 as adjudicator
- Six patients had apposing submucous fibroids ablated with no resulting adhesions
- The authors concluded “These results suggest the potential for adhesiogenesis after transcervical fibroid ablation, including in women with apposing submucous and/or transmural myomata, may be minimal.’

OPEN Trial
EvaluatiOn of Uterine PatENcy following Sonography-guided Transcervical Ablation of Fibroids

Sonata® SYSTEM



Patient Selection & Expectations

David Levine, MD
St. Louis, MO

gynesonics®

How do I select which patients are most appropriate for TFA?

- Fibroid size
  - Published experience includes fibroids 7-8 cm
    - 80% of fibroids treated were 1-4cm
  - Fibroids ≥ 6 cm require multiple ablations to optimize volume reduction
- Number of fibroids - up to 9 fibroids were ablated/patient during the SONATA Trial
  - The average number of fibroids treated was 3.5 per patient in the SONATA Trial
- Safety and effectiveness regarding fertility and fecundity after the use of the Sonata System have not been established
- Effectiveness in women with clinically significant adenomyosis has not been established
- Other conditions as stated in the Sonata System Operator's Manual

Fibroid Size and Volume

- RF ablation is volumetric
- Assume sphere where $V = 4/3\ \pi r^3$
- An 8-cm myoma = 268.1 cc but a 9-cm myoma = 381.7 cc (42.4% increase)
- 5 cm x 4 cm Sonata ablation (largest size) = 41.9 cc

Fibroid Diameter (cm)	Volume (cc)	60% Ablation Volume	# large (42 cc) ablations to get 60% ablation
8	268.1	160.8	3.8
8.2	288.7	173.2	4.1
8.4	310.3	186.2	4.4
8.6	333.0	199.8	4.8
8.8	356.8	214.1	5.1
9	381.7	229.0	5.5
9.2	407.7	244.6	5.8
9.4	434.9	260.9	6.2
9.6	463.2	277.9	6.6
9.8	492.8	295.7	7.0
10	523.6	314.2	7.5

Which patients should I consider for my first cases?

Ideal patient selection for **new** Sonata users:

- Prefer patients with type 1, 2 or 3 myomata ≤6 cm in diameter
  - Higher likelihood of success/symptom improvement
  - Fibroid associated with HMB
  - Ability to target
  - Treat fibroid with single ablation
  - Associated with increased safety margin between fibroid and serosa
- Limited number of fibroids to treat, preferably no more than 3 fibroids
- Avoid patients presenting with isolated subserous fibroids

Sonata® SYSTEM

Perioperative Care

- Bladder drainage not mandatory for imaging but helpful for patient comfort
  - Always best for patient to void on her own just before TFA
- Antibiotics?
  - As with operative hysteroscopy, no clear need except for other indications (eg, SBE)
  - In SONATA, 0.7% of patients received prophylaxis
- General anesthesia not required but may be indicated for specific patients
  - Better to have proper airway control if deep sedation is needed for pain control
- Postop
  - Patients typically on NSAIDs
  - Similar expected events to operative hysteroscopy (leukorrhea x days, spotting, cramping)
  - Postop visit or call as per your customary practice

Sonata® SYSTEM

What should my patients expect postop?

Setting appropriate expectations is critical to avoiding patient regret and need for potentially-avoided surgical reintervention

- Most patients will see improvement in HMB within 3 months (in SONATA, significant 39% reduction at 3 months; a 22% reduction is considered clinically meaningful)
- The goal is meaningful improvement in symptoms
  - This may or may not meet the definition of eumenorrhea (≤ 80 cc MBL)
- Important for patients to not expect
  - Amenorrhea (this is not endometrial ablation)
  - Immediate results
- Patients should be counselled about potential fibroid sloughing
  - It can result in intermenstrual spotting
- Refer to the Operator's Manual for additional counselling

7 Women, 7 Sonata Stories

THANK YOU!