

HOLOGIC



Sonata[®]

Transcervical Fibroid Ablation System

A new point of view: intrauterine ultrasound.

Combines real-time ultrasound and radiofrequency ablation to treat fibroids without incisions

The Sonata System: An Incisionless Fibroid Ablation Solution

Transcervical fibroid ablation for the treatment of symptomatic uterine fibroids

The Sonata system combines real-time intrauterine ultrasound guidance with targeted radiofrequency energy to treat fibroids. This incisionless procedure reduces symptoms, such as heavy menstrual bleeding, with most patients returning to normal activities the next day.¹

The system features proprietary SMART OS™ guide software which enables the treatment of multiple fibroids in a single procedure, addressing a wide range of fibroid types and sizes in various uterine locations. The SMART OS guide overlays graphical indicators on the ultrasound to help target fibroids and accurately position the introducer and needle electrodes, while the **ablation zone** and **thermal safety border** help protect adjacent tissue.

Access without Incisions

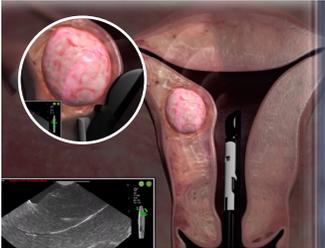
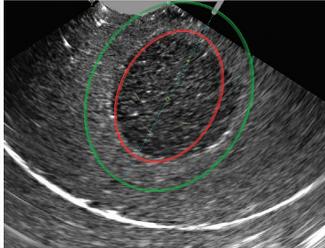
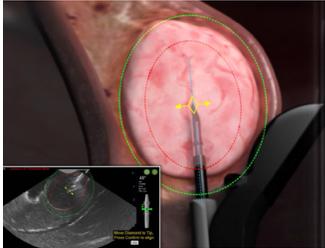
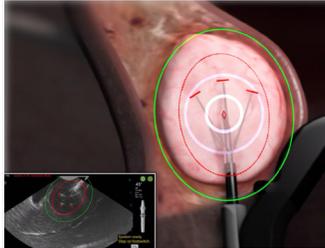
Preserve the uterus and treat multiple fibroids of various types and sizes in a single procedure without incisions or uterine distension.

Visualize with Precision

Locate fibroids from inside the uterus using ultrasound guidance and graphically tailor the **ablation zone** using SMART OS guides to target each fibroid.

Treat with Control

Make controlled ablations confined to the fibroid using a **thermal safety border** that adjusts automatically, relative to the ablation zone and real-time control.

The Sonata Procedure			
ACCESS & VISUALIZE	TARGET	DEPLOY	TREAT
			
Insertion & Ultrasound The Sonata device is inserted through the vagina and cervix to access the uterus, where the intrauterine ultrasound (IUUS) probe is used to visualize and locate fibroids.	SMART Guide Planning The IUUS probe, paired with SMART OS guide software, displays graphics on the ultrasound to target and plan the ablation zone and thermal safety border for a specific fibroid.	Introducer The introducer (sharp cannula) is deployed from the shaft of the RFA handpiece into the center of the fibroid and the SMART OS guides are manually aligned to the introducer.	Needle Electrodes Once the thermal safety border is confirmed within the serosa, seven nickel-titanium needles are advanced radially from the introducer tip to distribute radiofrequency energy to treat the desired tissue.

Reference

1. Chudnoff S, Guido R, Roy K, Levine D, Mihalov L, Garza-Leal JG. Ultrasound-Guided Transcervical Ablation of Uterine Leiomyomas: The SONATA Trial. *Obstet Gynecol.* 2019 Jan; 133(1): 13-22

Important Safety Information

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. **Anticipated Postoperative Events:** abdominopelvic pain/cramping; back pain; constipation; dizziness/fatigue; headache; fever; malaise; post-ablation inflammatory symptoms; nausea/vomiting; sloughing and, less commonly, intact expulsion of ablated fibroid tissue per vaginam (particularly after treatment 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 radiofrequency 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. **Pregnancy:** Safety and effectiveness with regard to fertility and fecundity after use of the Sonata System have not been established. As a uterus-conserving alternative to hysterectomy, treatment with the Sonata System does not eliminate the possibility of pregnancy. **Adenomyosis:** Effectiveness in women with clinically significant adenomyosis has not been established.

For detailed benefit and risk information, please refer to the product IFUs.

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