

Treating Uterine Fibroids and Their Symptoms with the

Sonata[®] Treatment





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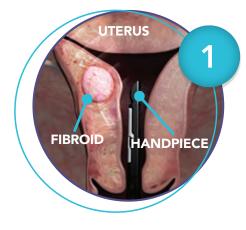
WELCOME! We are glad you want to learn more about the Sonata Treatment. The information in this booklet should give you all you need to know about the procedure and **what to expect both before and after,** as well as some testimonials and results from women who have had the treatment.

What is the SONATA TREATMENT?

The Sonata Treatment is an incision-free solution, clinically proven to reduce fibroid symptoms. This treatment can address a wide range of fibroid types, sizes, and uterine locations. Multiple fibroids can be treated during the procedure. The fibroids are treated from inside the uterus, so there are no incisions (which means no scarring), no tissue needs to be cut or surgically removed – **and the uterus is preserved.**

How does the SONATA TREATMENT work?

The Sonata Treatment uses a **handpiece with a miniature high-resolution ultrasound tip** that allows the doctor to see the fibroids from inside the uterus during the procedure, and then treat each fibroid with a process called an "ablation."



The doctor passes the Sonata Treatment handpiece through the vagina and into the uterus.



Ultrasound waves from the tip are used to locate the fibroid. The Sonata Treatment handpiece delivers radiofrequency energy to shrink the fibroid and reduce symptoms.

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WILL I RECEIVE ANESTHESIA during the procedure?

Your doctor will ensure that you are comfortable during the procedure. General anesthesia is typically not required but is an option along with conscious sedation and regional anesthesia (epidural or spinal anesthesia). Your physician will discuss anesthesia options and determine what is best for you.

HOW LONG does the procedure take?

The procedure typically takes less than one hour, depending on the number and size of fibroids treated.

WHERE is the procedure performed?

The Sonata Treatment can be performed at an outpatient surgical facility or in-office procedure room. Patients are scheduled to return home the same day. On average, the Sonata procedure time takes less than one hour.

WHAT TYPES OF FIBROIDS can be treated during the procedure?

The Sonata Treatment can be used to treat almost all symptomatic uterine fibroid types. Most fibroids occur within the muscle wall of the uterus, and are classified as subserosal, intramural, transmural, and submucosal.

Your doctor can treat multiple fibroids during the procedure. He or she will determine the optimal number to treat based on your individual case.



Is the Sonata Treatment COVERED BY INSURANCE?

Most insurance plans require pre-authorization for the Sonata Treatment. Our Sonata Authorization Support Team will work directly with your insurance company to educate and advocate on your behalf. If your doctor recommends the Sonata Treatment and you have specific questions about your health plan, you can contact us at 1-877-590-0389.

AM I A CANDIDATE for the procedure?

The Sonata Treatment is an appropriate option for many women with symptomatic uterine fibroids. You may be a candidate if your:

- period lasts longer than 7 days and affects your work and daily activities
- fibroids are located in the wall of the uterus

The Sonata Treatment is not appropriate for women who have:

- Current pregnancy
- Permanent birth control implant
- Active pelvic infection
- Suspected gynecologic cancer

Can I get the Sonata Treatment if I wish to get **PREGNANT IN THE FUTURE?**

The safety and effectiveness of the Sonata Treatment in women who wish to get pregnant has not been determined. Potential risks or benefits regarding pregnancy are unknown but patients have reported getting pregnant post-treatment. **Talk to your doctor about any fertility questions regarding the Sonata Treatment.**

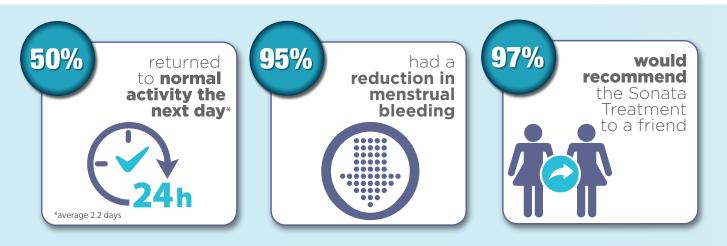


Is the Sonata Treatment **SAFE**? What are the **TYPICAL RESULTS**?

The Sonata Treatment has been **clinically proven to be safe and effective in women** with symptomatic uterine fibroids. Some patients see improvements in heavy menstrual bleeding within their first cycle. In general, it may take 2-3 cycles, or in some cases, longer.

In a CLINICAL STUDY¹:

Women reported the following results 12 months after their Sonata Treatment:



1. Chudnoff S, Guido R, Roy K et al. Ultrasound-Guided Transcervical Ablation of Uterine Leiomyomas. Obstet Gynecol. 2019;13-22.

HOW WILL I FEEL after the procedure?

Most side effects are typically minor and temporary. Any discomfort is generally managed with over-the-counter medications. Clinical data indicates that pain can be readily managed with NSAID pain medications such as ibuprofen. **On average, women return to normal activity in a couple of days.**



"The procedure was minimal, so easy... I almost couldn't believe that I was already feeling better. I don't even think about my periods anymore because they're usually only a couple of days and they're very light.**"**

- Jackie*

*Interviewed 4 years post treatment

WHAT IS THE DIFFERENCE between the Sonata Treatment and other fibroid treatments?

There are several options for those suffering from fibroids. Two of the common ones are both surgical procedures.

- HYSTERECTOMY The most common solution for uterine fibroids in the US to date is a hysterectomy, **which removes the entire uterus**. This is a significant surgical procedure performed under general anesthesia which typically requires 2-6 weeks of recovery.
- MYOMECTOMY Myomectomy is a surgical procedure that removes the fibroids but spares the uterus. This procedure has limitations depending on the location of the fibroids, and is usually performed under general anesthesia. It usually requires **incisions in the abdomen** and presents similar risks to other surgery.
- UTERINE ARTERY EMBOLIZATION (UAE) UAE (sometimes known as UFE) is the injection of small particles to block the blood vessels around the uterus, causing the fibroids to die and shrink over time. While effective, UAE can be associated with significant discomfort, earlier menopause, and may change how the uterus and ovaries work.

WHAT TO EXPECT THE DAY OF your Sonata Treatment procedure

PREPARATION

- Have nothing to eat or drink after midnight the day before your procedure.
- **Someone should drive you** to and from the procedure.
- Wear comfortable loose clothing.

DURING THE PROCEDURE

Your physician passes the Sonata Treatment handpiece through the vagina and into the uterus where it remains throughout the procedure. The handpiece uses ultrasound waves to target individual fibroids, then delivers radiofrequency energy to one fibroid at a time (if more than one is being treated). The fibroid will shrink over several months, reducing or eliminating symptoms.

RECOVERY

After the procedure you will rest a bit and then be ready for discharge. Most patients get cleared to go home within 2-3 hours after starting the procedure.

⁶⁶I would tell a woman thinking about Sonata that you want to try this. Your life can be so much better.⁹⁹ - Marcela* **"Today I have normal periods. Much shorter duration.** The amount of blood that I have each month has been reduced significantly - 80%. It's incredible!**"**

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WHAT HAPPENS AFTER the procedure?

ACTIVITY

After the Sonata Treatment, there may or may not be specific restrictions to physical activities. However, we recommend that you gradually increase activities at a comfortable pace. Many patients return to normal activity by the next day.

- You should NOT drive a car or operate machinery or power tools for 24 hours after the procedure due to medications used during your procedure. You may resume driving when not taking pain medication that may impair judgement and response while driving.
- You may bathe or shower as directed by your physician. Your doctor will indicate how long you should avoid intercourse and how long to wait before using a tampon.
- You may resume a regular diet as tolerated.

Most side effects are typically minor and temporary. Your doctor should discuss all potential risks in detail. For complete safety information, visit sonatatreatment.com/safety-information.

WHEN TO NOTIFY your physician

Call your physician if you develop any of the following symptoms:

- Persistent nausea or vomiting
- Excessive bleeding (greater than 4 pads in 2 hours or as otherwise directed by your physician)
- Severe abdominal pain
- Fever (your doctor's office will indicate at which temperature they should be notified)

If you cannot contact your physician, go to your Emergency Room or call 911.

To learn more about the Sonata Treatment visit **sonatatreatment.com**



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The Sonata® System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. For Indication and Safety Information, or to learn more about the Sonata Treatment, visit www.sonatatreatment.com.

Sonata is a registered trademark of Gynesonics, Inc. Gynesonics products are covered by US and foreign patents. See www.gynesonics.com/us/patents.

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