

Gynesonics Announces New SMART OS™ Software Technology for Sonata® System Treatment of Uterine Fibroids

2024-09-26

Revolutionizing Fibroid Treatment with Enhanced Precision, Control & Flexibility

REDWOOD CITY, Calif., Sept. 26, 2024 (GLOBE NEWSWIRE) -- Gynesonics Inc., a medical device company focused on the development of minimally invasive solutions for symptomatic uterine fibroids, announced today the launch of its new SMART OS 2.4 software technology for the Sonata System, a treatment that integrates the first and only intrauterine ultrasound system with a proprietary advanced radiofrequency ablation device, providing an incision-free, uterus-preserving, transcervical treatment for symptomatic uterine fibroids.

Uterine fibroids affect up to 80% of women under the age of 50. The Sonata System utilizes radiofrequency energy to ablate symptomatic uterine fibroids from within the uterus without the need for any incisions. This innovative procedure is a breakthrough alternative to more invasive surgical procedures, such as a hysterectomy or myomectomy.

A key feature of the Sonata System is the SMART Guide, an innovative, proprietary technology that provides a graphical overlay on a live ultrasound image, allowing physicians to tailor the desired ablation to the targeted fibroid. Now, with the new SMART OS 2.4 software, physicians can treat fibroids that may have previously been difficult to access. The range of ablation sizes available with the SMART Guide has now been extended, reducing the minimum ablation size and providing increased precision, control and flexibility.

Dr. Taraneh Shirazian, a prominent gynecologist and the Director of the Center for Fibroid Care at NYU Langone Health in New York, performed one of the first Sonata procedures with the new SMART OS 2.4 software and shared her thoughts. "The new SMART OS 2.4 software release is a game-changer in the treatment of uterine fibroids. It

provides me the opportunity to treat fibroids in a faster and more precise and targeted manner, while still preserving normal uterine tissue. This will allow me to treat smaller fibroids and use smaller zones of treatment more efficiently and effectively.”

“We are excited to deliver this innovative update to the Sonata System,” said Skip Baldino, President and Chief Executive Officer of Gynesonics. “This new enhancement to our SMART Guide empowers physicians to treat more fibroids, and ultimately more patients suffering from fibroid disease with an effective, minimally invasive, uterine-sparing solution. Physicians have the ability to offer Sonata to women with symptomatic uterine fibroids and should consider it to be the standard of care.”

Gynesonics remains dedicated to pioneering advancements in the treatment of uterine fibroids, providing healthcare professionals with an innovative solution for the highest quality of care. The successful implementation of the new SMART OS 2.4 software is a significant milestone in achieving this mission.

About the Sonata System

The Sonata System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. Common Side Effects include bleeding, spotting, cramping, post-ablation inflammatory symptoms, and/or discharge. There are potential risks with this treatment such as skin burn and infection. Women who are pregnant, have a pelvic infection, are known to have gynecologic cancer, or have intratubal implants for sterilization should not have this procedure.

The Sonata System is CE marked and is approved for sale in the European Union, the United Kingdom, Switzerland, and the United States. For more information on Sonata, please visit us at www.sonatasystem.com.

About Gynesonics

As pioneers in women’s health, Gynesonics is committed to developing and delivering minimally invasive, incision-free, uterus-preserving, transcervical technologies for diagnostic and therapeutic applications. Our flagship product, the Sonata System, is the first FDA cleared medical device for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids. Gynesonics headquarters is in Redwood City, CA. For more information, go to www.gynesonics.com.

Sonata is a registered trademark of Gynesonics, Inc.

SMART OS is a trademark of Gynesonics, Inc.

Company Contact:

Ana Pollock, Senior Marketing Manager, Communications - Gynesonics apollock@gynesonics.com, (m)

508.726.3820

Media Contact:

David Gutierrez, Dresner Corporate Services, dgutierrez@dresnerco.com, (312) 780-7204

Source: Gynesonics