Innovation Brief

Medical Technology innovation Dynamic purchasing system - Sonata supplied by Gynesonics Inc.

Summary

Disruptive innovation

This briefing introduces a disruptive innovation newly available via NHS Supply Chain: The Sonata system. Reviewed by clinical specialists and supported by key stakeholders, this device offers a novel approach to managing symptomatic uterine fibroids.

Introduction

This document is intended to inform clinical stakeholders and procurement teams about innovative products that have undergone a clinical review and are now accessible through NHS Supply Chain. Products featured in this brief is classified as:

Disruptive innovations

- A disruptive innovation is novel.
- It should offer improvements compared to the existing provision of care.
- The proposed format should not exist elsewhere (either within or beyond the health and care sector).

Note: While robust evidence or validated savings may not yet be available, early data and clinical insights support the potential for patient and system-level improvements.

Departments / stakeholders for engagement

- NHS procurement teams.
- Hospital trusts delivering gynaecological endoscopy services for the management of symptomatic uterine.

Opportunity

The Sonata Ultrasound-guided transvaginal ablation (RFA or MWA) offering clinical advantages over traditional transvaginal fibroid morcellation, and surgical removal of fibroids including:

- Superior safety profile, particularly regarding risk of malignancy dissemination.
- Significant fibroid volume reduction with sustained symptom relief.
- Faster recovery times and minimal complications.
- Favourable outcomes for fertility and overall quality of life.
- Minimally invasive treatment avoiding incisions or surgical removal, enabling quicker recovery vs. traditional surgery.
- Precise, ultrasound-guided targeting to treat fibroids including submucous, intramural, transmural and subserous without harming surrounding tissue.
- Uterus-preserving approach that avoids cutting or removing fibroids, supporting future pregnancy potential.

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Product overview

Sonata® is a modern, minimally invasive treatment designed to address symptomatic fibroids safely and without incisions while preserving the uterus.

Sonata works using real time ultrasound guided transcervical fibroid ablation, a technique where the treatment device is inserted into the uterus through the vagina.

Fibroids are located with the ultrasound at the tip of the device and targeted and fixed with a needle. Unique safety features help physicians target and heat fibroid tissue precisely. The treatment takes only a few minutes per fibroid. Up to 10 fibroids can be targeted during one procedure. After treating the designated fibroids, over time, the fibroids shrink and symptoms improve.

Clinical relevance

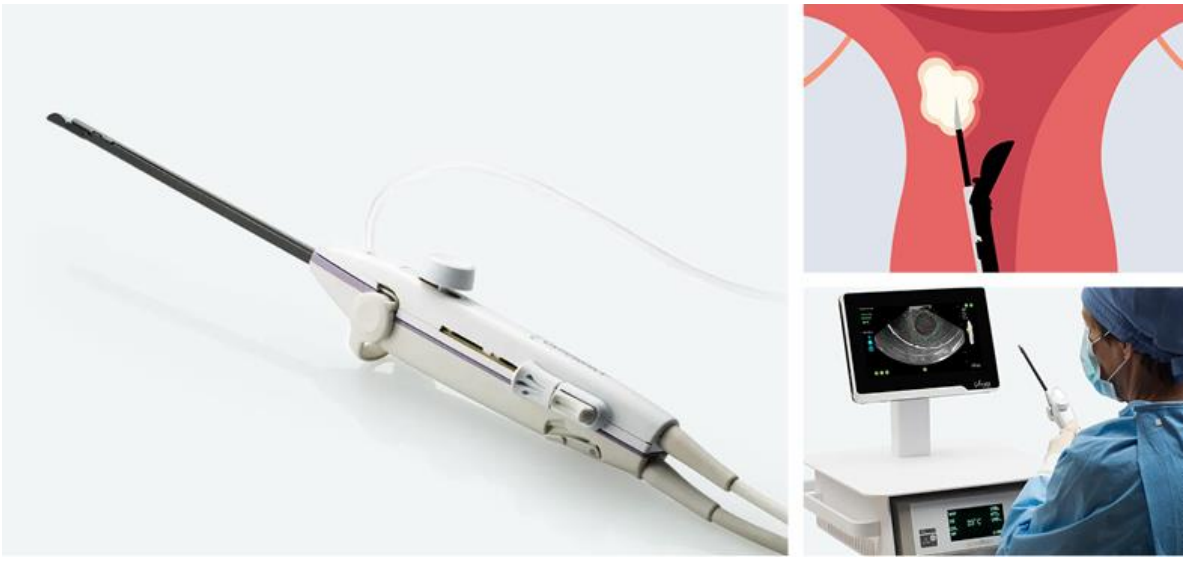
- The Sonata System combines real-time intrauterine ultrasound guidance with targeted radiofrequency ablation in an incisionless procedure.
- Delivers a breakthrough alternative to fibroid morcellation, hysterectomy and myomectomy.
- Transcervical delivery does not require general anaesthetic, can be undertaken in outpatient setting.

Additional benefits

- Increased accuracy with the inclusion of real time ultrasound guided identification of fibroids.
- An alternative to current transvaginal tissue removal (morcellation) techniques for clinically appropriate individuals.
- Morcellation may still have a role where tissue removal is required, but from a clinical-benefit standpoint, ultrasound-guided ablation provides a more effective, safer, and more patient-centred treatment pathway for appropriately selected individuals.

Pathway change

- Outpatient clinic-based pathway of care instead of admission to a day surgery or main operating theatre pathway.



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Supply details

Complete requirements in form on https://www.supplychain.nhs.uk/dps

MPC	Supplier	UOI	Brand	Description
RFA-002	Gynasonics	1	Sonata	Radio Frequency Handpiece single patient use. Class IIb. eDirect Route
DE-001-10	Gynasonics	10	Sonata	Dispersive Electrodes single patient use. Class IIb. E Direct Route
IUSP-002	Gynasonics	1	Sonata	Intrauterine ultrasound probe reusable. Class IIa. eDirect Route
OM-1000-GS	Gynasonics	1	Sonata	Sonata IUUS Reprocessing Tray reusable. Class 1. eDirect Route
ACCY-018	Gynasonics	1	Sonata	Sonata IUUS Probe Connector Cover reusable. Class I. eDirect Route
ACCY-008	Gynasonics	1	Sonata	Sonata reusable RFA handpiece Cable reusable. Class I. eDirect Route
SONATA2-220V	Gynasonics	1	Sonata	Sonata System including RF Generator and U/S Tablet Capital. Class IIb. eDirect Route

Supporting evidence / notes

- Transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids | Guidance | NICE
  https://www.nice.org.uk/guidance/ipg689
- Transcervical Fibroid Ablation (TFA) with the Sonata System: Updated Review of a New Paradigm for Myoma Treatment | Current Obstetrics and Gynecology Reports | Springer Nature Link
  https://link.springer.com/article/10.1007/s13669-022-00341-8
- Clinical Education and Publications - Sonata Treatment UK
  https://sonatatreatment.uk/clinical-education-and-publications/

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