

## Outpatient Transcervical Ultrasound Guided Radiofrequency Ablation Treatment of Uterine Fibroids (Sonata) - Standard Operating Procedure

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### **1. Introduction**

Transcervical radiofrequency ablation with the Sonata® System is a minimally invasive ultrasound guided, incision free, uterus-preserving treatment for intramural and type 2 submucosal fibroids, with intraoperative visualisation of fibroids using intrauterine ultrasound guidance. 3-year data post Sonata suggests that 88% of women reported reduced menstrual bleeding and 94% reported treatment satisfaction<sup>1</sup>. It can be performed under local anaesthesia in the outpatient setting.

The procedure is only to be performed by clinicians who have undergone the necessary training and accreditation, with guidance from Sonata Clinical Application Specialist who will attend all these dedicated clinics to offer support to the clinician.

### **2. Aims and Purpose**

Clinical condition: Symptomatic Fibroids, Heavy periods. Gynaecology

Target patient group: Females 18 years or older

Target professional group (clinical competence): GPs, Gynaecologists, Radiology.

### **3. Patient Selection Criteria**

- Pelvic ultrasound or MR scan reporting Type 2-Type 6 uterine fibroids measuring 2-7cm.
- Patients should have had an ultrasound scan within 6-12 months of the decision for sonata and if not, a repeat ultrasound scan should be requested to get an updated size and position of fibroids when listing for sonata procedure.

- For larger Type 2-6 fibroids (eg size between 6-9cm) pre-procedure GNRH analogue treatment for ~3 months may be considered to try to reduce fibroid size. Women should be informed that the fibroid may require multiple treatments in the same or sequential appointments.
- Previous Caesarean section is not a contraindication for Sonata.
- Hysteroscopy assessment to rule out type 0 and 1 fibroids/ uterine anomalies, if ultrasound indicates possible intracavitary lesion/ abnormal shape of cavity

#### Contraindications

- Current pelvic infection
- Suspected gynaecological malignancy (suggest MRI if any suspicious fibroid/ or rapid enlargement noted- this is at discretion of the clinician responsible)
- Uterine Mullerian anomaly
- Hip (e.g. joint replacement) or pelvic (e.g. Essure) implants
- Type 0,1 and 7 fibroids (ie intracavitary submucosal fibroids/ pedunculated subserosal fibroids not suitable for sonata treatment)
- Fibroids greater than 9 cm are less likely to be effectively treated by Sonata
- Fertility – while Sonata is not currently offered to women wishing to conceive there is limited data of successful pregnancies (n=36) without complications post Sonata

#### 4. Pre-requisites

##### 1) Minimum staffing requirements:

- One Clinician trained in using in Transcervical radiofrequency ablation (Sonata)
- One trained registered nurse band 5 or more senior
- One trained health care assistant

##### 2) Patients counselled for procedure and informed consent obtained. This is ideally to be done by the consultant performing the Sonata procedure. The following risks should be discussed during consent:

- Discomfort (can be minimized with preoperative and intraoperative analgesia)
- Duration of treatment- (this is variable treatment times ranging from 5 minutes to 45 minutes based on the volume of fibroid for ablation)
- Secondary bleeding
- Injury to uterus or adjacent organs
- Post-operative infection
- Ensure that patient has post operative analgesia and next of kin for support at home.

##### 3) Written patient information given (see appendix 2).

##### 4) Pre-procedure preparation:

- Inform patients not to fast before the procedure
- Inform patients to remove any abdominal or genital piercings
- Pre-medicate 30 minutes prior to the procedure with the following -

a) Diclofenac 100mg rectal suppository or Modified release Ibuprofen 800mg tablet orally OR codeine 60mg (if unable to take NSAIDs) This will be prescribed by the consultant on the day of the procedure and administered by registered nurse).

b) Paracetamol 1g oral (if patient has not had it at home prior to arrival)

c) Cyclizine 50mg oral

#### 5. Referral Process

- Patients who meet the criteria for Sonata ablation should be referred via the internal process for outpatient hysteroscopy service.
- All patients referred for Sonata to be discussed at BGMDT meeting for consensus and learning

- All cases will be audited using the Sonata procedure record.

## 6. **Operative Procedure**

- Designate a nurse/HCA to stay with the patient throughout the procedure to offer support and a 'vocal-local'.
- Position- dorso-lithotomy
- Bimanual examination +/- ultrasound scan pelvis
- Administer intra-cervical block local anaesthesia e.g. 3% Prilocaine + Felypressin 0.54 micrograms/ml (Citanest with Octopressin). OR Scandonest 3% Plain (mepivacaine hydrochloride 3% without vasoconstrictors. This is an established but off-label use.
- Perform a pre-procedure diagnostic hysteroscopy to check for intrauterine polyps, type 0 and 1 fibroids and Mullerian anomalies eg uterine septum.
- Insert the intra-uterine Sonata device (combination of miniature U/S probe and treatment device).
- Additional analgesia such as heat pack, Entonox (or Pentrox can be prescribed when available) administered if required
- Locate individual fibroid lesions, fix and treat as per manufacturer's instructions.
- If the patient cannot tolerate the procedure, consider either fractionating the treatment (do in more than one visit if multiple fibroids) or abandon and re-arrange under sedation/GA.
- Record procedure using proforma in Appendix 1 (to be included electronically into pre-existing infoflex outpatient hysteroscopy database) and notes.

## 7. **Post-Operative Procedure Care**

- Recover patient in the designated ambulatory recovery area for at least 20 minutes.
- Patient to complete service evaluation/ patient experience questionnaire including self-assessment of peri-operative pain.
- Offer / ensure patient has adequate post-procedure analgesia. Administer further simple oral analgesia as necessary.
- Observations performed prior to discharge home and recorded in patient hysteroscopy record as per usual process in place.
- A patient information leaflet, describing expected post-operative symptoms and instructions including contact details if needed, is to be given to patients on discharge

## 8. **Follow-up**

- Follow up with Consultant in 4 months with repeat ultrasound scan.
- Open access to the Gynaecology Assessment Unit.
- Instruct to contact the unit if bleeding excessively, develops an offensive vaginal discharge, worsening abdominal pain or feeling unwell.

## 9. **Antibiotic Prophylaxis**

Antibiotics are not routinely indicated because the risk of uterine / pelvic infection is low (<1:200)

## 10. **Device Failure and Incident Reporting Guidance**

- Complete a Datix incident report
- Inform both the manufacturer and MHRA  
<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm>

## 11. **Roles and Responsibilities**

The Gynaecology Matron and the Clinical Director have delegated responsibility for:

- Ensuring the guideline is implemented according to the agreed process
- Ensuring that the effectiveness of the guideline is monitored
- Reviewing current risk assessments, control measures, procedures, and training within the service to ensure that deficiencies are identified and reported on and that recommendations and action plans are developed and monitored according to the Clinical Effectiveness strategy
- Staff members are accountable to the gynaecology lead clinician and gynaecology matron to ensure they comply with the guideline

## 12. **Monitoring Compliance**

Elements of the guideline may be audited in accordance with the Gynaecology divisional audit plan. The findings of associated evaluations and audit reports will be shared with staff via the relevant clinical teams and where appropriate an action plan will be developed and monitored by the relevant team's governance committee.

Auditable standards include:

- 1) Percentage of women who undergo sonata who fulfil the patient selection criteria- 100%
- 2) Percentage of women who undergo sonata in whom there are contraindications for sonata- 0%
- 3) Percentage of women planned for sonata as outpatient who complete planned treatment- 90%
- 4) Percentage of women with intraoperative complications or readmission within 4 weeks of Sonata

## 13. **References**

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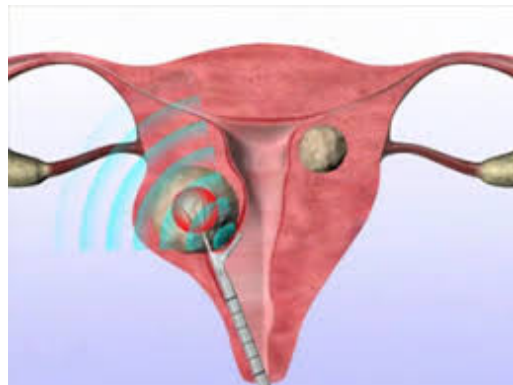
**Sonata Procedure Record**

## Patient Information

# Outpatient Transcervical Ultrasound Guided Radiofrequency Treatment of Uterine Fibroids (SONATA)

### What is Sonata Fibroid Ablation?

SONATA or Sonography-Guided Transcervical Fibroid Ablation is an incision-free treatment option for women with symptomatic uterine fibroids. Using an intrauterine ultrasound device to locate and target individual fibroids, radiofrequency energy is delivered directly to the fibroid to reduce their size and ease symptoms.



### Before your procedure

As you will not be having a general anaesthetic, you do not need to fast for this procedure. It is important that you have breakfast or lunch before you attend for your appointment. Please remove all abdominal/ genital piercings before the procedure. You need to **provide an early morning urine sample** to perform a pregnancy test upon arrival. If there is any possibility that you may be pregnant, your procedure will be cancelled. If you are sexually active, you must be using reliable contraception or have refrained from sexual intercourse for at least 4 weeks.

Please take pain relieving medication as discussed during your consultation. If you are able to take **Paracetamol**, we recommend **1 gram** approximately 60 minutes before your appointment. **Please arrive 30 minutes before your appointment** as you will be offered further pain-relief and anti-sickness medication prior to your procedure. If you are on regular pain relief medication for another condition, please continue with this; do not take both. **Failing to take adequate analgesia may lead to delays or cancellation of your appointment.**

## What happens during the procedure?

SONATA involves inserting a device through the cervix, which means that it does not involve cutting your tummy (incisionless). The device has two parts: the first is a thin camera which allows the surgeon to see and guides the procedure; and the second is a specially designed probe that uses radiofrequency energy to treat the fibroid. The fibroid will shrink over several months, reducing or eliminating symptoms.

## What to expect?

The out-patient procedure is performed at Royal Derby Hospital in Ambulatory Hysteroscopy Suite. In the room there will usually be four-five members of staff; the doctor performing the procedure, two members of our nursing team and the technician. As we are a teaching hospital, it is possible that a trainee may also be in clinic. If you would prefer not to have a trainee present, please inform a member of staff.

## How will you feel after the procedure?

Before you go home your nurse will provide you with the times that you may take further doses of pain-relieving medication if required. During the first 24 hours, you might experience cramping type pain, nausea, or brown discharge. Most women will feel back to normal within two days after the procedure. You should avoid activities such as swimming, taking a bath (you can shower), sexual intercourse and using tampons for at least two weeks to avoid the risk of infection.

Call the Gynaecology outpatient clinic nursing station (01332789217) if you have any concerns:

- Persistent nausea or vomiting
- Excessive bleeding (greater than 4 pads in 2 hours or as otherwise directed by your doctor)
- Severe abdominal pain
- Fever of 38°C or above
- Greenish or offensive vaginal discharge.

## What are the main side effects of the procedure?

- There is a possibility that the procedure cannot be completed. For example, if the fibroids are found to be too large or too close to other organs outside the uterus.
- Any operation inside the uterus carries a small risk of injury (perforation) to the uterus (estimated to be 1 in 200 risk). If this happens, you may need a camera check inside the abdomen.
- There is a rare risk of a burn injury to the bladder or bowel or other pelvic organs.
- Any procedure inside the uterus carries a small risk of infection.
- You may have period-like bleeding whilst the uterus heals after surgery.

## What are the results expected from the procedure?

The trials have shown that:

- About 90% of women reported that their period (menstrual) blood loss was reduced at 3 months after the operation.
- 88% of women were satisfied with the outcome after 12 months.


## Can I get pregnant after Sonata treatment?

Currently Sonata is not offered to women wishing to conceive although there is limited data of successful pregnancies without complications post Sonata.

**If you have any questions about your procedure or appointment, please contact us:**

 **Appointment enquiries** (Monday - Friday, 09:00 - 17:00) **Tel: 01332 785464**

**For any emergency advice following symptoms post procedure, please contact:**

 **Emergency Gynaecology Assessment Unit** (at Royal Derby Hospital, Open 9am to 6pm Monday to Friday and 9am to \_\_\_pm Saturday & Sunday).  
**Tel: 01332 786525**

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## Documentation control

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Version Amendment	Version	Date	Author	Reason
	1	August 2023	Miss S Kolhe - Lead Consultant for Ambulatory Gynaecology	New
<b>Intended Recipients:</b> All staff with responsibility for caring for women in the Antenatal period				
<b>Training and Dissemination:</b> Cascaded through lead nurses/doctors / Published on Intranet NHS mail circulation / Article in BU newsletter				
<b>To be read in conjunction with:</b>				
Consultation with:	Gynaecology outpatient and assessment unit manager Gynaecology and paediatrics CGF General manager for Womens and childrens Consultant Gynaecology			
Business Unit Sign off:	/ /2023: Gynaecology Guidelines Group: Miss B Purwar– Chair / /2023: Gynaecology Development &Governance Committee - Mr J Dasgupta <b>Exceptional ratification - Mr J Dasgupta CD, Sharon Hill gynaecology matron, Gwen Hatton Director of nursing gynaecology and paediatrics, Sue Whale divisional director. 31/08/23</b>			
Notification Overview sent to TIER 3 Divisional Quality Governance Operations & Performance: / /2023 <b>Exceptional ratification - Mr J Dasgupta CD, Sharon Hill gynaecology matron, Gwen Hatton Director of nursing gynaecology and paediatrics, Sue Whale divisional director. 31/08/23</b>				
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