Endometrial Ablation Consent Form

This form should only be used if the patient has capacity to give consent. If the patient does not legally have capacity, please use an appropriate alternative consent form from your hospital or hub.

Note to patients: Please note it is common NHS practice for a patient's consent to be taken by a clinician other than the operating or listing surgeon. This clinician will be suitably trained and competent to take your consent. They will be referred to as your 'responsible healthcare professional' in this form.

You may have questions before starting, during or after your procedure. Contact details are provided for any further queries, concerns or if you would like to discuss your treatment further.

Patient details (print or sticker)

First name: _____ **Last name:** _____

Date of birth: _____ **Patient identifier:** _____

Responsible Healthcare Professional: _____

Special requirements: e.g., transport, interpreter, assistance _____

Details of endometrial ablation

Endometrial ablation procedure:	This procedure involves placing a device into the vagina, passing it through the entrance of the womb (cervix) and into the womb (uterus). Once activated the device uses heat to destroy (ablate) the lining of the womb (endometrium), making periods lighter or stopping them altogether. This procedure is normally accompanied by a hysteroscopy (inserting a thin telescope into the womb via the vagina and cervix to examine the inside of the womb) and an endometrial biopsy (taking small samples of the womb lining to diagnose any problems). Several different devices are available, which all differ slightly in their size and mechanism of action. Your clinician should inform you of the device that will be used and you should have the chance to discuss its relative advantages and disadvantages compared with other devices. The procedure is only suitable for patients who do not wish to become pregnant in the future because, by removing the endometrium, fertility is reduced and may even be prevented. However, patients are still advised to continue to use contraception after the procedure. The patient may be awake or asleep (general anaesthesia) during the procedure.
Extra procedures:	Hysteroscopy Insertion/removal of an intrauterine device (IUD/coil) Endometrial biopsy.
Indication for, and purpose of surgery: (Tick as appropriate)	☐ Heavy menstrual bleeding ☐ Other(s) _____

Alternatives considered: (Tick as appropriate)	☐ **Conservative management** Conservative management is a term used when a condition is managed without surgery or other invasive procedures or treatments. ☐ **Medical management** Medical management is a term used when a condition is managed with medications, without more invasive measures such as surgery. Medications such as tranexamic acid or the combined oral contraceptive pill can be used to help control heavy periods. These treatments will often be tried prior to considering treatments but can be used to help manage symptoms in the long term in some patients. ☐ **Intrauterine system insertion** This involves placing a small T-shaped plastic device inside the womb (uterus), which releases a contraceptive hormone called progesterone. This hormone also thins the womb lining making periods lighter. It lasts 5 years before needing replacement, but it can be removed at any point if desired by the patient. ☐ **Hysterectomy** This is an operation that involves removing the womb (uterus). A hysterectomy is more likely to resolve the symptoms but carries higher risks of complications. ☐ Other(s) _____

Surgical care during the coronavirus (COVID-19) pandemic

During the current coronavirus pandemic there are additional considerations regarding having an operation in a hospital or hub. We need to make you aware that your surgical care may be disrupted, delayed or performed different during the pandemic.

Despite precautions, coming into hospital might increase your chances of contracting COVID-19, and if you come into the hospital and test positive your operation may be cancelled. If COVID-19 infection occurs when you have surgery or while in hospital, this could make your recovery more difficult, or increase your risk of serious illness or death.

We will do everything we can to perform your operation, keep you safe, and to provide you with information at all stages. Your hospital or hub site will provide you with key information regarding infection control, risks and responses and any further relevant information to you.

Additional resources

Information for you after an endometrial ablation – Royal College of Obstetricians and Gynaecologists

https://patient.concentric.health/info/y8ga

If you do not wish to access the additional patient information contained within this consent form digitally, please speak to your responsible healthcare professional and they will provide you with a hard copy. This will be provided in a language and format that suits you.

Pain Management and Anaesthesia

Endometrial ablation can be performed as an outpatient procedure with you awake. In this case, simple pain killers can be taken by mouth before the procedure to reduce pain during and afterwards. You can also choose to take tablets that make you feel more relaxed (oral sedatives) before the procedure, but these do not reduce pain. They may also make you feel drowsy, so you would need to stay in hospital longer and should not drive home or operate machinery for the rest of the day.

During the procedure you can choose to breathe in a gas that may help to reduce pain and anxiety. The most common gas available is nitrous oxide, also known as 'gas and air', which is used by pregnant women in labour.

Local anaesthesia is usually used if the operator thinks that the entrance to the womb (the cervix) needs to be stretched a little (dilated) to be able to perform the procedure. This is normally if the cervix is too narrow for the ablation device. Local anaesthetic is not normally given before starting the procedure because it is usually not possible to tell in advance which patients may need the cervix to be dilated. Also, using modern small diameter instruments and insertion techniques it is not clear that local anaesthetic given in advance helps reduce pain and for this reason it is normally used for helping dilate the cervix without pain.

Local anaesthetic is usually injected into the cervix using a small needle. This can sting a little, just like having a needle for an injection or blood test. Sometimes local anaesthetic is sprayed or instilled onto or through the opening of the cervix. Local anaesthesia numbs the cervix to allow the cervix to be dilated painlessly. However, it cannot take away sensation from the inside of the womb where the ablation device will need to be inserted.

You can discuss choices of pain control and the risks further with your clinician on the day of your procedure. This is a shared decision-making process, and you will jointly decide and agree the type of pain management that is best for you.

You can choose the type of pain management before the endometrial ablation, but you can also request other pain management options not initially chosen during the procedure. If you decide during the procedure that you would like regional or general anaesthesia, or deep intravenous sedation (medicine given by an anaesthetist through a drip to keep you almost asleep but not unconscious) then the outpatient procedure will be stopped immediately and it can be rescheduled at a later date in hospital.

Endometrial ablation can also be performed with you asleep. In this case, a general anaesthetic is used to allow surgery to take place painlessly and put you to sleep. Your anaesthetist will advise you on your options and talk to you about the risks, complications and benefits of your choice. There is no legal requirement to obtain written consent for the type of anaesthesia given to a patient; this section of the consent form is for your information only.

On the day of surgery, an anaesthetist will discuss anaesthetic options and risks with you. This is a shared decision-making process, and you will jointly decide and agree the anaesthetic option that is best for you. Please remember that if there are any complications during surgery, your anaesthetist may need to alter the type of anaesthesia and they will explain this to you during the procedures.

For further information about the types of anaesthetic you may receive, and potential risks, please see the information below.

Types

Risks

https://www.rcoa.ac.uk/documents/anaesthesia-explained/types-anaesthesia

https://www.rcoa.ac.uk/sites/default/files/documents/2019-11/Risk infographics_2019web.pdf

If you do not wish to access the additional patient information via link or QR code, please speak to your responsible healthcare professional and they will provide you with hard copies. These will be provided in a language and format that suits you.

TO BE FILLED OUT BY CLINICIAN ON THE DAY OF SURGERY:

Name of anaesthetist on the day: Date: _____

_____

□ I confirm I have discussed the different anaesthetic options with the patient, including risks and benefits, and we have jointly decided the preferred anaesthetic.

Please note the preferred methods of anaesthesia as discussed between the patient and anaesthetist below:

You will be told of any additional procedures in addition to those described on this form that may become necessary during your treatment. Please list below any procedures **YOU DO NOT WISH TO BE CARRIED OUT** without further discussion.

Patient name: **Patient unique identifier:**

Immediate risks (during the procedure)

(Your responsible healthcare professional will delete as appropriate)

Expected	**Pain** (*outpatient procedure only*) If the procedure is performed as an outpatient with you awake, then you will feel some abdominal pain during the procedure and immediately afterwards. This pain is usually of mild-to-moderate severity and period-like cramping in nature. You are recommended to take pain relief 30 to 60 minutes before your appointment. If you find the procedure too painful or distressing, then it is important to let a member of your clinical team know and they will stop the procedure immediately. Simple pain killers (analgesics) such as paracetamol and ibuprofen can help to ease pain after the procedure, which is usually of a mild-to-moderate intensity. If the pain is more severe then you will be kept in hospital, offered stronger pain killers and observed for a while until you feel you can manage the pain at home with simple pain killers. Pain normally subsides within 30 to 60 minutes of the procedure.
Common (more than 1 in 20)	**Feeling faint or giddy** (*outpatient procedure only)* If the procedure is performed as an outpatient with you awake, then this feeling can occur during or immediately after the procedure. You may feel cold and clammy, as well as feel sick or actually be sick. These feelings settle after a short period of lying flat on a reclining couch or bed and drinking water. Occasionally a drip is needed to give you fluids. Sometimes, you might need an injection of medicine to make you feel back to normal. **Unable to complete the procedure, meaning a repeat procedure or different management plan is needed** It may not always be possible to complete the procedure because of the shape and size of the womb, unexpected findings, or pain (*outpatient procedures only*). Sometimes, equipment problems may mean that the procedure cannot be completed.
Uncommon (fewer than 1 in 20)	**Uterine perforation** This is when a hole (perforation) is made through the muscular wall of the womb while placing the ablation device inside the womb. When this happens, the procedure is abandoned. The hole usually heals by itself and antibiotics are prescribed to prevent infection. The procedure can usually be rescheduled after a few weeks, once the womb has healed.
Rare (fewer than 1 in 100)	**Injury with or without excessive bleeding, or damage to the womb (uterus) and/or internal pelvic organs following a uterine perforation** If the ablation device is activated after being placed incorrectly, or if the womb is fully perforated, then bleeding and damage to the womb can occur. The ablation device may also cause heat damage to other pelvic organs, such as the bowel, bladder, ureters (the tubes that carry urine from the kidneys to the bladder) and major blood vessels in this area. If this happens, you might need keyhole (laparoscopic) surgery, or open surgery under general anaesthesia to find and repair any damage. Rarely, a blood transfusion is needed.
Specific risks to you from your treatment (to be input by your responsible healthcare professional)	

Patient name: **Patient unique identifier:**

Early and late risks (in the days, weeks or months after the procedure)

(Your responsible healthcare professional will delete as appropriate)

Expected	**Vaginal bleeding** You should expect some unscheduled vaginal bleeding. This may be heavy, like a menstrual period, or light spotting of fresh red blood or old brown blood. **Abdominal cramps** You should expect some period-like cramps in your abdomen (tummy) for the first 2 weeks after the procedure.
Common (more than 1 in 20)	**Infection of the genital tract/urinary tract** Infections of the womb (uterus) are called endometritis. They can cause a smelly vaginal discharge, abdominal pain and fever. A urinary tract infection (UTI), commonly known as cystitis, can cause a burning feeling when passing urine and can make you feel like you need to pass urine more often. A short course of oral antibiotic (antibiotic taken by mouth) is needed to treat these infections. **Pain** Simple pain killers (analgesics) such as paracetamol and ibuprofen can help to ease pain, which is usually of a mild-to-moderate intensity. One in five patients report some continuing pain within 2 weeks of the procedure. **Vaginal bleeding** A small amount of vaginal bleeding, no more than you would experience during a period, is to be expected following the procedure, especially if small samples of tissue (biopsies) of the lining of the womb (uterus) are taken. You might experience some fresh red, old altered brown blood, or blood-stained discharge for a few days after the procedure. **Adhesion formation** Endometrial ablation is designed to remove the lining of the womb (uterus). When this happens, scar tissue (adhesions) forms. In the future, if you ever developed any abnormal bleeding symptoms, this means you would not be able to undergo two common tests: hysteroscopy (use of a telescope to look inside the womb) and endometrial biopsy (when a small straw-shaped device is placed in the womb to take a sample of the lining). If you are not able to have these tests, it can make it harder to diagnose any issues. Because of this, you might be more likely to need a hysterectomy (an operation to remove the womb). **Continuing or new menstrual symptoms** Despite the procedure, up to one in five patients may have continued or new abnormal bleeding symptoms and/or period pain. Up to one in six patients will have a hysterectomy (an operation to remove the womb) by 2 years after the endometrial ablation because of menstrual symptoms.
Uncommon (fewer than 1 in 20)	**Blood infections and pelvic abscess** Bacteria from the genital tract can occasionally enter the blood circulation after a hysteroscopy, causing symptoms such as fever, rigors (feeling hot and cold), nausea and vomiting, tiredness, weakness, abdominal pain and feeling faint. If this happens, you will need to be admitted to hospital for intravenous fluids (a drip) and treatment with antibiotics. Sometimes further tests are needed to rule out damage to internal pelvic organs or collections of pus (abscesses) within the pelvis, which may need further keyhole or open surgery.
Rare (fewer than 1 in 100)	**Damage to the womb (uterus) and/or internal pelvic following a uterine perforation that was missed at the time of the procedure** Injury that was missed at the time of the procedure can lead to symptoms within a few days, such as severe abdominal pain, fever and severe tiredness/weakness. If this happens, you will need urgent admission to hospital for fluids, assessment, investigations and antibiotics. Keyhole (laparoscopic) surgery, or open surgery under general anaesthesia may be needed to find and treat or repair any damage. Rarely, hysterectomy (removal of the womb), a stoma (permanently or temporarily placing part of the bowel outside the body to divert faeces into a bag), and/or blood transfusion is needed. **Blood clots (deep vein thrombosis or pulmonary embolus)** Blood clots can form in the veins of the legs (deep vein thrombosis), causing pain and redness in the leg. These are more likely to occur after an operation when people move around less. These clots can occasionally travel from the legs to the lung (pulmonary embolus) and can cause problems with breathing. Clots in the leg or lung require treatment, such as with blood-thinning medications.

Specific risks to you from your treatment **(to be input by your responsible healthcare professional)**	

Patient name: **Patient unique identifier:**

Statement of health professional

- I am suitably trained and competent and have sufficient knowledge to consent this patient in line with the requirements of my regulatory body.
- I have discussed what the treatment is likely to involve, the benefits and risks of this procedure.
- I have also discussed the benefits and risks of any available alternative procedures or treatments including no treatment.
- I have discussed any particular concerns of this patient.

Patient information leaflet provided: ☐ Yes ☐ No – Details:

Copy of consent form accepted by patient: ☐ Yes ☐ No

Signature: **Date:**

Name: **Job title:**

Statement of patient

Please read this form carefully. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

- I agree to the course of treatment described on this form.
- I have had the benefits and possible risks of treatment explained to me.
- I have had the opportunity to discuss treatment alternatives, including no treatment.
- If I have agreed to be awake, I communicate to the clinical team that the procedure is too painful or distressing, then the procedure will be stopped immediately and rescheduled with alternative pain management.
- I understand that a guarantee cannot be given that a particular person will perform the procedure. The person will, however, have appropriate expertise.
- I understand I have been/will be given the opportunity to discuss my anaesthetic options with an anaesthetist, or my pain management options with a clinician (if I have agreed to be awake), and we will jointly decide which option is best for me. I understand that the type of anaesthesia may need to be altered if there are any complications during the procedure.
- I have been told about additional procedures that are necessary prior to treatment or may become necessary during my treatment. This may include permanent skin marks and photographs to help with treatment planning and identification.
- I understand that there may be people present for my procedure who are learning, such as junior doctors, medical students, and trainee nurses, and that I may decline to have any of these people present.

☐ I agree that people who are learning, such as junior doctors, medical students and trainee nurses may participate in examinations if supervised by a fully qualified professional.

☐ I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

☐ I understand that information collected during my procedure/ treatment, including images and video, may be used for education, audit and research (which may be published in medical journals). All information will be anonymised and used in a way that I cannot be identified.

☐ I agree that my health records may be used by authorised members of staff, who are not directly involved in my clinical care, for research approved by a research ethics committee and in compliance with the Data Protection Act (2018).

☐ I understand that patient specific data will be collected and may be used in the context of providing clinical care, in compliance with the Data Protection Act (2018).

☐ I confirm that I have read and understood pages 1 to X of the consent form above.

Please inform your responsible healthcare professional if you wish to withdraw consent for information use.

Statement of interpreter / witness (where appropriate)

□ I have interpreted the information contained in the form to the patient to the best of my abilities and in a way in which I believe they can understand.

or

Patient name: **Patient unique identifier:**

□ I confirm that the patient is unable to sign but has indicated their consent.

Signature:

Name:

Tick if relevant

☐ I confirm that there is no risk that I could be pregnant.

Please inform your responsible healthcare professional and/or your clinical care team on the day of your procedure if you could be pregnant. Please note that a pregnancy test may give a negative result if a pregnancy has occurred within 2 weeks of the test.

Date:

Name (PRINT):

Signature: