West of Scotland Protocol *Approved August 2023*

LEVONORGESTREL INTRAUTERINE DEVICE CONTRACEPTION GUIDELINE

What's New

Users of the Mirena 52mg LNG-IUD can now be advised that the device can be used as contraception for 8 years. This also applies to individuals who already have a device in-situ.

There are no changes to the established FSRH and British Menopause Society recommended duration of use when a Mirena 52mg LNG-IUD is being used for endometrial protection as part of HRT (5 years from time of insertion) or to existing guidance about duration of use of Mirena for heavy menstrual bleeding.

Currently there is no change to the recommendations for the other LNG-IUDs

This guideline is in keeping with the FSRH Clinical Guideline: Intrauterine contraception (March 2023)]. https://www.fsrh.org/documents/ceuguidanceintrauterinecontraception/

The terminology used throughout has been updated to align with that used by other international organisations, and LNG devices are now referred to as LNG-IUDs.

This guideline does not cover immediate post partum IUC provision.

Information on the following has been updated

- Efficacy
- Duration of use
- Suitability of IUC in specific populations
- Health risks
- Starting LNG-IUD contraception or switching from another hormonal contraceptive method

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Abbreviations

IUC intrauterine contraception

IUD intrauterine device

LNG-IUD levonorgestrel intrauterine device

UKMEC United Kingdom Medical Eligibility Criteria

Other abbreviations have been defined within the body of the document.

Appendix One Table 1 Comparison of the product characteristics of LNG-IUD devices currently available in the UK

Introduction

Three different doses of LNG-IUS are currently available in the UK containing 52mg, 19.5mg or 13.5mg of levonorgestrel.

1. Efficacy

- The failure rate of LNG-IUD use is very low.
- Pearl Indices (number of pregnancies per 100 users) for the different devices are generally reported as:
  - 0.1–0.2 for 52 mg LNG-IUD over 5–7 years
  - 0.3 for 19.5 mg LNG-IUD over 3–5 years
  - 0.3 for 13.5 mg LNG-IUD over 3 years.

- The contraceptive effectiveness of LNG-IUD is not affected by use of enzyme-inducing drugs or weight/BMI

2. Duration of Use

13.5 mg LNG-IUD for contraception Jaydess®	3 years
19.5 mg LNG-IUD for contraception Kyleena®	5 years
52 mg LNG-IUD for contraception Beneilxa®, Levosert®, Mirena®,	Inserted age under 45 : 6 years Inserted age 45 and over: retain until age 55
52 mg LNG-IUD as part of HRT Beneilxa®, Levosert®, Mirena®	5 years

In individuals aged over 50 years with an LNG-IUD wishing to stop contraception use before age 55 years, take an FSH level. If this is >30 IU/L, they can stop contraception after one further year. If removing an LNG-IUD because contraception is no longer required, ensure they are not using it for endometrial protection as part of HRT.

See appendix one for Comparison of the product characteristics of LNG-IUD devices currently available in the UK

3. Assessing Suitability

Few medical conditions contraindicate use of IUC (see UKMEC (2016 https://www.fsrh.org/documents/ukmec-2016/)

Investigations are not routinely required prior to insertion.

Most LNG-IUD insertions are straightforward and can be undertaken in primary care /community settings. There will be additional considerations for some individuals, for example, pre-insertion investigations, alterations to current medication dosage/timing, discussion with the individual's usual care provider or a requirement to insert the IUD in a specialist setting.

The use of IUC is contraindicated if there is a known or suspected allergy or hypersensitivity to any of the components of the device.

4. LNG-IUS use in specific patient groups

i. Young People, individuals who have never been pregnant and individuals who have never been sexually active can use an LNG-IUD.

ii. Transgender and gender-diverse individuals assigned female at birth (TGD-AFB).

The medical indications and contraindications for IUC are the same for transgender and gender-diverse individuals assigned female at birth (TGD-AFB) and cis-gender women. The Cu-IUD may appeal to TGD-AFB individuals who wish to avoid hormones. The LNG-IUD may help individuals who wish menstrual suppression. Pelvic cramping and bleeding can exacerbate gender dysphoria so clinicians should give adequate pre-procedure counselling about expected side effects and their duration, to improve tolerability. TGD individuals experience varying levels of dysphoria with their anatomy, and genital examination during IUC procedures may cause additional physical or emotional discomfort. Testosterone is teratogenic so TGD-AFB individuals using testosterone therapy and engaging in sex where there is a risk of pregnancy should use effective contraception. Testosterone treatment is not contraceptive, even if the individual is amenorrhoeic. Testosterone can cause vaginal atrophy and dryness, which may add to the physical discomfort of examination- consider pre-procedure treatment with local vaginal estrogen for 2 weeks prior to IUC insertion

iii. After Pregnancy

Immediate postpartum IUC (within 48 hours of childbirth) is safe, effective, convenient and associated with high continuation rates. When inserted within 48 hours of childbirth, the insertion technique is different to that of standard IUC insertion and clinicians need to be appropriately trained in this technique

If >48 hours have passed since childbirth, insertion should be delayed until 28 days after childbirth. The risks of insertion from 48 hours until 28 days after childbirth generally outweigh the benefits (UKMEC3).

IUC insertion after abortion is convenient and acceptable and has been associated with high continuation rates and reduced likelihood of another abortion within the next 2 years.

After medical abortion, or medical or expectant management of miscarriage, IUC can be inserted any time after expulsion of the pregnancy, providing there is no clinical suspicion of sepsis and no new risk of pregnancy. In addition when there has been early medical discharge (products passed at home) ensure there is no ongoing pregnancy prior to insertion with low sensitivity pregnancy testing done no sooner than 2 to 3 weeks post abortion.

An IUC can be inserted immediately after surgical abortion or surgical management of miscarriage or ectopic pregnancy, providing there is no clinical suspicion of sepsis.

iv. **After gestational trophoblastic disease (GTD.**

IUC should not be inserted after gestational trophoblastic disease (GTD) until human chorionic gonadotropin (hCG) levels are normal.

v. **Peri-menopause:**

An LNG-IUD may help perimenopausal irregular cycles, HMB (heavy menstrual bleeding) and dysmenorrhoea.. Examination and endometrial assessment/investigation should be considered prior to IUC insertion for perimenopausal individuals who have heavy and/or erratic bleeding or a recent change in bleeding pattern, taking into account any risk factors for gynaecological disease. Requirement for investigation should follow local guidelines.

vi. Breast Cancer

Current breast cancer is a UKMEC4 condition for use of an LNG-IUD
Past history of breast cancer is UKMEC3 : refer to specialist if such person wishes an LNG-IUD

vii. Individuals with raised BMI

Assessment of uterine position and gaining access to the uterus IUC insertion can be more challenging in individuals with raised BMI. Some practicalities may need to be considered in order to maximise the chances of insertion success (e.g. having a range of speculum sizes and an examination couch with an appropriate weight limit). In addition, availability of a large blood pressure cuff for measuring blood pressure is essential.

vii. Individuals at Risk of Infection

Current pelvic inflammatory disease (PID), postpartum or post-abortion sepsis, known gonorrhoea infection, symptomatic Chlamydia infection, and purulent cervicitis are all contraindications to IUC insertion (UKMEC4). The risks associated with IUC insertion in the presence of known asymptomatic chlamydia infection are generally considered to outweigh benefits (UKMEC3). Individuals who have symptoms of possible bacterial STI and/or PID should ideally delay IUC insertion until test results are available, until PID or confirmed STI have been treated, and until symptoms have resolved. Offer a bridging contraceptive method if required.

If an individual is considered to be at increased risk for sexually transmitted infections (STIs) but has none of the aforementioned specific conditions and is not a recent contact of gonorrhoea or Chlamydia, benefits of IUC insertion are generally considered to outweigh risks.

Routine STI screening of asymptomatic individuals requesting IUC is not necessary; however, a sexual history should be taken prior to IUC insertion and screening offered, to individuals at risk of sexually transmitted infections. Providing the individual is asymptomatic and the individual is not a current or recent contact of gonorrhoea or Chlamydia, screening can be performed at the time of IUC insertion and the IUC can be inserted without awaiting results and without prophylactic antibiotic treatment so long as the user can be contacted and treated promptly, if indicated, when the results are known.

Asymptomatic individuals who are a **current or recent contact of gonorrhoea or Chlamydia** should delay IUC insertion until infection excluded (based on tests done outwith the window period).

Following a positive chlamydia or gonorrhoea result, an intrauterine method can be inserted if the individual has completed antibiotic treatment (and, if applicable, completed any test of cure requirements and / or additional recommended follow-up or imaging, for example, in the case of complicated pelvic infection such as a tubo-ovarian abscess) and is asymptomatic.

Any treatment for confirmed or suspected chlamydia, gonorrhoea or PID should be in line with British Association for Sexual Health and HIV (BASHH) guidance.

Other infections (and bacterial vaginosis)
There is no indication to screen for other lower genital tract organisms in asymptomatic individuals considering IUC. If bacterial vaginosis, Trichomonas vaginalis or candida infection is diagnosed or suspected, these should be treated but the IUC can be inserted without delay.

There is no need to delay IUC insertion or treat asymptomatic individuals who have been identified as having Group B Streptococcus.

Group A streptococcus (GAS) is a rare but serious infection that can cause life-threatening septicaemia, invasive GAS (e.g. necrotising fasciitis) and streptococcal toxic shock syndrome. Therefore, if GAS is incidentally detected it is important that it is treated urgently. IUC insertion should be delayed until treatment is complete.

Refer to a senior clinician if

- **Uterine cavity distortion**
- **Previous endometrial ablation**
- **After large loop excision of the transformation zone (LLETZ) procedure**
- **Under follow up for gestational trophoblastic disease**
- **Immunosuppression/ taking immunosuppressants including patients with adrenal insufficiency and / or taking corticosteroids**
- **History of postural orthostatic tachycardia syndrome (PoTS)**
- **Known to have inherited bleeding disorders**
- **Anticoagulants**
- **Cardiac disease**

Contraception choice for individuals with cardiac disease will often require a multidisciplinary approach and discussion with the individual's cardiologist is recommended. See also FSRH Clinical Guideline: Contraceptive Choices for Women with Cardiac Disease (June 2014) https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception

5. Potential Non Contraceptive Benefits of the LNG-IUS

The 52 mg LNG-IUD can be used in the management of gynaecological conditions, including polycystic ovary syndrome, endometrial hyperplasia, HMB and dysmenorrhoea. They can also be used for endometrial protection as part of HRT. Although Mirena® is the only LNG-IUD licensed for endometrial protection, the FSRH supports the use of any 52 mg LNG-IUD for up to 5 years as endometrial protection as part of HRT. This recommendation is supported by the Royal College of Obstetricians and Gynaecologists and the British Menopause Society.

6. Health Risks associated with LNG-IUS use

i. Breast cancer

There may be an association between current or recent hormonal contraception use (including LNG-IUDs) and breast cancer; however, any increased risk appears to be small.

i. Ovarian cysts

Ovarian cyst incidence is elevated during LNG-IUD use with 80%–90% resolving spontaneously within 3 months. The vast majority of are asymptomatic. Ovarian cysts can cause pelvic pain, dyspareunia and rare serious adverse events e.g. cyst rupture. LNG-IUD discontinuation rates due to ovarian cysts are about 0.5% across the lifetime of the various LNG-IUDs.

Presence of (or history of) ovarian cysts or polycystic ovary syndrome is not a contraindication to IUC use.

ii. Bone mineral density

Current evidence suggests there is no significant effect on serum estradiol levels or bone mineral density (BMD) in LNG-IUD users.

7. Side effects

i. Bleeding

Ensure potential LNG-IUD users are informed about possible bleeding pattern changes, to inform decision-making and improve satisfaction rates.

Prolonged, frequent and irregular bleeding and number of bleeding/spotting days generally reduce over the first year of LNG-IUD use and rates of amenorrhoea and infrequent bleeding increase. After this, prolonged, frequent and irregular bleeding reduces, and amenorrhoea increases. By the end of licensed duration of use, amenorrhoea is 11%–12% of 13.5 mg users, 23% of 19.5 mg users and 42% of 52 mg users.

LNG-IUD replacement appears to induce a small, temporary increase in bleeding/spotting in the first 90 days after the procedure. Bleeding/spotting then returns to a very low and constant level, with higher rates of amenorrhoea than in first-time users at 4-6 weeks post-insertion.

Bleeding is one of the commoner reasons cited for LNG-IUD discontinuation, but discontinuation due to bleeding is low across the 13.5 mg, 19.5 mg and 52 mg devices at ≤ 5% over 3–5 years.

ii. Other Side effects

Acne, breast tenderness, headache and mood changes are reported. Evidence is too limited to confirm or exclude a causative effect. These symptoms are more prevalent in the first few months after insertion but decrease with time.

For most users an IUC has either no impact or a positive impact on sexual experiences.

In the general population there are no significant differences in weight gain when LNG-IUDs are compared with Cu-IUDs and no evidence to support a causal association between IUC use and weight gain.

8. LNG-IUS insertion

i. Discussion

IUC discussion and assessment is essential to ensure the method and procedure will be safe for the individual, that they make an informed choice about their contraception options and are able to give informed consent. Discussion may be at the time of the procedure, or at a prior appointment, depending on local service pathways and the urgency of the IUC insertion. Discussion and assessment may be undertaken face-to-face, via telephone or virtual appointment, or by self-assessment and signposting to patient resources. Women can be encouraged to watch an eight minute information film produced by Lothian Sexual Health available at https://www.lothiansexualhealth.scot/contraception/iud-ius/

ii. When can LNG-IUS be inserted

IUC can be inserted at any time during the menstrual cycle providing that pregnancy can be reasonably excluded (see Box 1). Recommendations for starting or switching to IUC can be found in Table 1 and Table 2.

Box 1: Critieria for reasonably excluding pregnancy

Healthcare practitioners can be ***reasonably certain*** that an individual is ***not currently pregnant*** if any one or more of the following criteria are met ***and*** there are no symptoms or signs of pregnancy:

- They have not had intercourse since the start of their last normal (natural) menstrual period, since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- They have been correctly and consistently using a reliable method of contraception. (For the purposes of being reasonably certain that an individual is not currently pregnant, barrier methods of contraception can be considered reliable providing that they have been used consistently and correctly for every episode of intercourse.)
- They are within the first 5 days of the onset of a normal (natural) menstrual period. They are less than 21 days postpartum (non-breastfeeding individuals).*
- They are fully breastfeeding, amenorrhoeic ***and*** less than 6 months' postpartum.*
- They are within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- They have not had intercourse for >21 days ***and*** have a negative high-sensitivity urine pregnancy test (able to detect human chorionic gonadotrophin (hCG) levels around 20 mIU/ml).

*See UKMEC 2016[2] and FSRH Guideline Contraception after Pregnancy[103] for recommendations regarding use of combined hormonal contraception after childbirth.

Table 1: Starting intrauterine contraception (no recent hormonal contraception) [from FSRH Clinical Guideline: Intrauterine contraception (March 2023)]

Current Situation	Timing of insertion of LNG-IUD	Additional Precautions required
No recent hormonal contraception and no recent pregnancy	Any time in a natural menstrual cycle if reasonable certain the individual is not pregnant* or at risk of pregnancy	Yes, for 7 days (unless inserted in the first 5 days† of the menstrual cycle)
Cu-IUD within licensed duration of use	Any time if no UPSI within the last 7 days (otherwise defer until no UPSI for 7 days)	Yes, for 7 days (unless inserted in the first 5 days† of the menstrual cycle)
Cu-IUD past licensed duration of use	Any time in a natural menstrual cycle if reasonable certain the individual is not pregnant* or at risk of pregnancy	Yes, for 7 days (unless inserted in the first 5 days† of the menstrual cycle)
Post partum (vaginal birth or Caesarian section, breastfeeding or non-breast feeding	Within 48hrs after childbirth	No
	From 4 weeks after childbirth certain that the individual is not pregnant* or at risk of pregnancy	Yes, for 7 days (unless inserted in the first 5† days of the menstrual cycle or criteria for LAM are met)
Following abortion of miscarriage	Post-surgical abortion or surgical management of miscarriage: ideally insert at the time of the procedure Post-medical abortion or miscarriage: IUC can be inserted any time after expulsion of pregnancy	If an LNG-IUD is inserted after day 5† post abortion or miscarriage, additional precautions are required for 7 days
Following use of oral emergency contraception	Should not be inserted following administration of oral EC until pregnancy can be excluded by a high-sensitivity pregnancy test taken ≥21 days after last UPSI	Condoms or bridging contraception until LNG-IUD can be inserted

LAM (Lactation amenorrhoea method) UPSI (unprotected sexual intercourse)
*See Box 1 for how to exclude pregnancy. † Summary of Product Characteristics suggests this applies also to days 6 and 7 of a natural cycle.

Table 3: Switching to intrauterine contraception from a hormonal contraceptive method

Current Situation	Timing of insertion	Additional Precautions required
CHC use	Weeks 2 or 3 of CHC use (or subsequent weeks of continuous CHC use) or Day 1 of the HFI	No, providing CHC used correctly
	After day 1 of the HFI or in week 1 of CHC use	If no UPSI since the start of the HFI – use condoms for 7 days or restart/continue CHC until used correctly for 7 days after HFI OR If UPSI since the start of the HFI – restart/continue CHC use for 7 days
POP (traditional)	At any time if POP has been used correctly	Continue POP for 7 days or use condoms for 7 days
POP (desogestrel)	At any time if POP has been used correctly	No
POP – drospirenone	During HFI (placebo pills, days 25– 28) assuming prior correct use of active pills or Days 1–7 of active pills (taken correctly) after HFI	If no UPSI since start of the HFI – use condoms for 7 days OR If UPSI since the start of the HFI – restart/continue DRSP POP until 7 consecutive active pills taken
	Days 8–24 of active pills (taken correctly)	No
ENG implant within 3 years after insertion	Any time	No
ENG implant in situ for 3-4 years	Any time if PT negative	Yes (7 days) Repeat PT 21days after last UPSI
ENG implant in situ for >4 years and no UPSI in the last 21 days	Any time if PT negative	Yes (7 days)
ENG implant in situ for >4 years and UPSI in the last 21 day	LNG-IUD cannot be inserted until pregnancy can be excluded*	Consider PT and EC. Bridge with alternative contraception until pregnancy can be excluded by a high sensitivity PT taken ≥21 days after last UPSI

Table 2: Switching to intrauterine contraception from a hormonal contraceptive method (contd)

Current Situation	Timing of insertion	Additional Precautions required
Progestogen-only injectable (DMPA) ≤14 weeks post-injection	Any time	No
Progestogen-only injectable (DMPA) >14 weeks post-injection and no UPSI since 14 weeks	Any time	Yes (7 days)
Progestogen-only injectable (DMPA) >14 weeks post-injection AND UPSI since 14 weeks post-injection, all of which took place ≥21 days ago	Any time if PT negative	Yes (7 days)
Progestogen-only injectable (DMPA) >14 weeks post-injection AND UPSI since 14 weeks post-injection, some of which took place within the last 21 day	LNG-IUD cannot be inserted until pregnancy can be excluded	Consider PT and EC. Bridge with alternative contraception until pregnancy can be excluded by a high-sensitivity PT taken ≥21 days after last UPSI

Table 2: Switching to intrauterine contraception from a hormonal contraceptive method (contd)

Current Situation	Timing of insertion	Additional Precautions required
52 mg LNG-IUD in situ for < 6 years OR 19.5 mg LNG-IUD in situ for < 5 years OR 13.5 mg LNG-IUD in situ for < 3 years	Any time	No Ideally abstain/use condoms for 7 days prior to change in case new device can not be inserted
52 mg LNG-IUD in situ for 6–7 years†	Any time if PT negative on day of replacement	Ideally abstain/use condoms for 7 days prior to change. Abstain/use condoms for 7 days after change and repeat PT 21 days after last UPSI
52 mg LNG-IUD in situ for >7 years† AND no UPSI within the last 21 days OR 19.5 mg LNG-IUD in situ for >5 years AND no UPSI within the last 21 days OR 13.5 mg LNG-IUD in situ for >3 years AND no UPSI within the last 21 days	Any time if PT negative on day of replacement	Yes (7 days)
52 mg LNG-IUD in situ for >7 years† AND UPSI within the last 21 days OR 19.5 mg LNG-IUD in situ for >5 years AND UPSI within the last 21 days OR 13.5 mg LNG-IUD in situ for >3 years AND UPSI within the last 21 days	LNG-IUD cannot be inserted until pregnancy can be excluded	Consider PT and EC. Bridge with alternative contraception until pregnancy can be excluded by a high-sensitivity PT taken ≥21 days after last UPSI

CHC, combined hormonal contraception; Cu-IUD, copper intrauterine device; DMPA, depot medroxyprogesterone acetate; DRSP, drospirenone; EC, emergency contraception; ENG, etonogestrel; HFI, hormone-free interval; IUC, intrauterine contraception; LNG-IUD, levonorgestrel intrauterine device; POP, progestogen-only pill; PT, pregnancy test; UPSI, unprotected sexual intercourse. *See Box 1 for how to exclude pregnancy. †Recommendations for the 52 mg LNG-IUD insertion relate to devices inserted before age 45 years. If replacing a 52 mg LNG-IUD that has been in situ for >6 years but was inserted after age 45 years, follow guidance for replacing a 52 mg LNG-IUD that has been in situ for < 6 years

iii. Insertion Checklist

Intrauterine contraception pre-insertion checklist for the minimum criteria that should be met prior to insertion.

The clinician inserting the intrauterine contraception (IUC) should ensure that (as a minimum) the following criteria are met prior to insertion:

- ☐ Individual assessed as medically eligible
- ☐ Checked there are no indications for IUC to be inserted in an alternative setting/service
- ☐ Checked there are no allergies to IUC content or local anaesthetic
- ☐ Checked it is a suitable time to insert and any requirement for additional contraception/follow-up pregnancy testing
- ☐ Considered and offered sexually transmitted infection (STI) testing and/or cervical screening as appropriate
- ☐ Individual advised about:
- ☐ Different IUC types available
- ☐ Contraceptive effectiveness and time to effect (including need for additional contraception and/or follow-up pregnancy test)
- ☐ Duration of use (for contraception and other indications)
- ☐ Potential bleeding patterns
- ☐ Other potential side effects and risks
- ☐ Insertion procedure and associated risks including: pain, infection, expulsion, perforation, failure, ectopic pregnancy, non-visible threads
- ☐ Analgesia options and option to stop at any time during the procedure
- ☐ Signs/symptoms that require review
- ☐ How and when to check threads
- ☐ Removal procedure
- ☐ Individual given opportunity to ask questions and to reflect on new information and return for procedure or alternative at another time if they wish
- ☐ Type of IUC device confirmed with patient and assistant
- ☐ Expiry date on IUC and analgesia checked
- ☐ Suitably trained assistant present
- ☐ Appropriate equipment available (e.g. resuscitation equipment, appropriate examination couch/lighting, range of speculum sizes, analgesia options)

iv. Safe LNG-IUS Insertion

Training: Clinicians offering IUC insertion should hold the appropriate FSRH Letter of Competence in Intrauterine Techniques or have achieved equivalent recognised competencies and show evidence of recertification/reaccreditation.

Immediate postpartum intrauterine contraception (PPIUC) technique is different to standard IUC insertion and should only be performed by those who have trained in this technique.

All staff involved with IUC insertion should undergo training and regular updates in resuscitation.

Informed consent: Informed consent for undertaking an IUC procedure should be obtained in line with local policy

Assistants and Chaperones: A chaperone should be offered for all intimate examinations. The chaperone's role is to support the patient. An appropriately trained assistant should be present during all cervical instrumentation procedures. The assistant can also fill the role of a chaperone if trained. The assistant should support the individual during the IUC procedure and monitor the patient for any signs of pain or distress.

Check the device has not expired: Prior to inserting an IUC, check it has not expired. If an expired device is inadvertently inserted, inform the individual of the error and offer the option of retaining the device or having it removed and replaced. The expiry date relates to the microbiological sterility of the device. Risk of infection from loss of microbiological sterility could well be lower than the risk of infection if the device is replaced again when Intrauterine contraception. Manage the error according to local clinical governance policies and for more information refer to FSRH Clinical Guideline: Intrauterine contraception (March 2023) https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception

v. Practical aspects of IUC insertion

Examination: A bimanual pelvic examination should be performed on all individuals prior to inserting IUC to allow the clinician to assess the position, size, shape and mobility of the uterus.

Measurement of pulse rate and blood pressure: Routine measurement of pulse rate and/or blood pressure before, during and/or after IUC procedures is not required but can be considered on a case-by-case basis, guided by the clinical picture.

Cervical cleansing: Cleansing the vulva, vagina or cervix prior to IUC insertion is not required.

Sterile gloves: There is no requirement to use sterile gloves when inserting IUC if a 'no touch' technique is used.

vi. Pain associated with LNG-IUS insertion

Individuals should be advised that most IUC insertions are associated with mild-to-moderate pain or discomfort, but that pain can range from none to severe. Analgesia options should be discussed and offered to individuals having IUC inserted. Referral processes should be in place for circumstances where an individual requests an analgesia option that the clinician is unable to provide.

Clinicians should support and encourage users to tell them if they are experiencing pain or discomfort and reassure them that the procedure can be paused or stopped at any time.

Post-procedure analgesia NSAIDs such as ibuprofen can reduce pain after IUC insertion and can be offered to individuals who experience pain after insertion of an intrauterine method.

9. Emergency management for problems at IUC insertion

IUC insertion can trigger a vasovagal response. Drugs and equipment required for resuscitation must be available, accessible, clearly labelled, adequately maintained and their location known to all staff. Recommended drugs required for resuscitation are:

- Adrenaline 500mcg IM (0.5ml of 1:1000) (two doses if needed)
- Atropine 500 or 600 mcg IV/IM (two doses if needed) for the treatment of symptomatic bradycardia
- Oxygen.

Locally agreed risk management policies for the treatment of emergencies should be in place and take into account national recommendations.

10. Documentation

Clinicians inserting or removing IUC should document the procedure and consultation in line with local policy and protocol and notify (where applicable and with consent) other relevant healthcare providers (e.g. primary care) of the type of device, date of insertion and recommended duration of use.

11. Aftercare advice and follow-up

After IUC insertion, individuals should be given information on the device inserted, including the name of the device, its mode of action, duration of use and time to become effective. The manufacturer's booklet/card will usually be given to the patient.

Where IUC has been inserted outside of product licence information about how and when to perform a pregnancy test should be given.

With the exception of PPIUC, routine post-insertion check-ups with a clinician are not required. However, individuals who have had an IUC inserted should be advised they can seek review at any time if they have concerns, cannot locate their threads, or wish to change their method of contraception. They should be given information on who to contact and how.

Due to the increased risk of expulsion or long or non-visible threads with PPIUC, routine IUC check-ups are recommended when IUC has been inserted within 48 hours of a vaginal or caesarean birth. These check-ups are undertaken 4–6 weeks post-insertion and IUC users should be advised where this will take place, in line with local PPIUC pathways.

IUC users should be advised to feel for their threads within the first 4–6 weeks after insertion and then at regular intervals (e.g. monthly or after menses) and if they have any concerns suggestive of IUC displacement (e.g. change in bleeding pattern, new-onset pelvic pain). Clinicians should explain how to feel for IUC threads and that users should seek review if threads are not palpable, thread length becomes shorter or longer, or the stem of the device is felt. Clinicians should explain that any of these changes could mean the IUC is incorrectly sited and therefore effectiveness cannot be guaranteed. The individual should be advised to abstain or use an alternative method of contraception until the IUC position is confirmed, and if there has been any recent, condomless sex they should seek advice as emergency contraception may be required.

In addition to seeking review if there are concerns when they check their threads, individuals should be advised to seek urgent review if they have:

- Symptoms of pelvic infection (e.g. change in vaginal discharge, pelvic pain and intermenstrual/ postcoital bleeding)
- Concerns regarding their bleeding pattern
- A positive pregnancy test.

Women can be encouraged to watch a 4 minute video produced by The West of Scotland Managed Clinical Network for Sexual Health for women who have recently had a IUD inserted which gives advice on what to expect, how to check for threads and when to seek advice. https://sexualhealthdg.co.uk/iuc.php

12. Advice about use of menstrual cups, discs and tampons

Evidence suggests that there could be increased risk of expulsion associated with menstrual cup use. With many different brands available, users should be advised to follow the manufacturer's instructions, including any special considerations for IUC users. With any of these methods, care should be taken not to dislodge the IUC by accidently pulling the IUC threads when removing the menstrual device and, where applicable, users should be advised to ensure they release any suction from the menstrual device prior to removal.

Some clinicians advise avoiding tampons and menstrual cups for up to several weeks after IUC insertion, citing increased risk of expulsion or infection. There are not robust studies to inform effect of use of tampons on risk of expulsion.

There is no clear evidence of increased risk of infection associated with use of tampons, menstrual cups/discs or intercourse in the days or weeks after IUC insertion.

13. Advice for individuals requiring magnetic resonance imaging

Mirena®, Levosert® and Benilexa® contain no metallic, magnetic or conductive material and are safe at any magnetic field strength. Individuals requiring magnetic resonance imaging (MRI) with a device containing a metallic component should inform their MRI department so that local guidelines can be followed. The limited published Intrauterine contraception that it is safe for an individual with a Kyleena or Jaydess to undergo MRI at a strength of 1.5 Tesla (T) or 3 T and therefore removal of the device would not normally be necessary unless the area of interest is very close to the position of the device (this could result in some imaging artefacts). IUC inserted outside of the UK may contain different metals and might not be MRI safe. Advice should be sought from the local radiology department. Devices containing stainless steel (e.g. the Chinese ring) are not MRI safe and should be removed prior to MRI.

14. Managing problems associated with IUC

i. Bleeding

Tranexamic acid or NSAIDs can be offered for management of HMB during use of IUC. A 3-month trial of COC can be offered to medically eligible individuals with problematic bleeding during use of IUC.

As bleeding patterns will often change with IUC, provision of information about expected bleeding patterns is important. Although unscheduled bleeding may be caused by the IUC itself, other causes (e.g. pregnancy, infection, pathology) should be considered and investigated in line with FSRH Clinical Guideline Problematic Bleeding with Hormonal Contraception. Risk factors for endometrial cancer include older age, raised BMI, early menarche, late menopause, nulliparity, use of HRT, use of tamoxifen, history of polycystic ovary syndrome, diabetes and a family history of endometrial cancer.

ii. New Onset Pelvic Pain

New-onset pelvic pain in an IUC user should be assessed, and pregnancy should be excluded. There are a number of possible causes for new-onset pelvic pain in an IUC user, many of which are not related to the IUC. A clinical history and physical examination will identify the differential diagnoses and guide the investigation and management. The history will determine the examination and investigations required; however, an abdominal and pelvic examination (speculum ± bimanual examination) and a pregnancy test would usually be required. Due to the potential serious consequences of an ectopic pregnancy, pregnancy should be excluded in all IUC users with new-onset pelvic pain. Other investigations/examinations that may be indicated would be urinalysis, STI screening, measurement of temperature/blood pressure/heart rate, pelvic ultrasound, rectal examination, blood tests. Where alternative causes have been excluded and the individual wishes IUC removal and replacement, that clinicians could consider offering replacement with an alternative device (e.g. switching to a device with a smaller or different-shaped frame). There is, however, insufficient evidence to suggest one particular device over another.

Table Three: Possible causes if new onset pelvic pain [from FSRH Clinical Guideline: Intrauterine contraception (March 2023)]

Gynaecological causes	Other causes
IUC malposition/partial expulsion/expulsion	Appendicitis (± sepsis)
IUC perforation	Diverticulitis (± sepsis)
Pregnancy (ectopic, miscarriage, labour)	Irritable bowel syndrome/constipation
Pelvic inflammatory disease (± abscess/sepsis)	GI infection (± sepsis)
Ovarian cyst accident	GI obstruction/perforation/necrosis
	Urinary tract infection/pyelonephritis (± sepsis)
	Hernia

iii. **Pregnancy**

The risk of any pregnancy, including ectopic pregnancy, during use of LNG-IUS is very low. Risk of ectopic pregnancy during use of LNG-IUD is lower than using no contraception. However, among pregnancies that occur with LNG-IUD in situ, the proportion that is ectopic is greater than among pregnancies occurring without LNG-IUD in situ.

A previous ectopic pregnancy is not a contraindication to use of IUC (UKMEC1).

If someone with an LNG-IUD in situ has a positive pregnancy test, follow local assessment pathways

Explain that the risk of adverse pregnancy outcomes (including miscarriage, preterm delivery and septic abortion) is greater than that for pregnancies without an IUC in situ. Removal of the device may improve pregnancy outcomes and is advised when pregnancy is less than 12 weeks' gestation, as long as the threads are visible or can be easily removed from the endocervical canal. After 12 weeks' gestation or if threads are not visible, the decision to remove or retain the device should be considered on an individual basis in conjunction with the obstetric team. When a LNG-IUD IUC is in situ in pregnancy, the individual's obstetric/maternity team should be made aware of the presence of the device.

iv. **Infection**

Pelvic inflammatory disease (PID) occurs as a result of upper genital tract infection, often due to ascending infection from the vagina or endocervix. Chlamydia trachomatis is the commonest causative organism (35% of PID cases). Instrumentation of the uterus for gynaecological procedures, including IUC insertion, can facilitate upward ascent of infection and therefore purulent cervicitis, gonorrhoea and symptomatic chlamydia infection are considered contraindications to IUC insertion (UKMEC4). A sexual history should be taken prior to IUC insertion and screening offered to any individual at risk of an STI. For asymptomatic individuals, testing can be undertaken at the time of IUC insertion. The risk of PID appears to increase in the first 3 weeks after IUC insertion but overall the risk is very low and (<1% of all IUC users)

IUC users with a clinical presentation suggestive of PID should be given antibiotic treatment, managed in accordance with BASHH guidance, and reviewed after 48–72 hours. For individuals with mild-to-moderate PID, whose clinical condition is improving over the first 48–72 hours, the IUC can remain in situ. For individuals whose clinical condition does not improve after 48–72 hours of antibiotics, removal of IUC is normally recommended but should be considered alongside any potential risk of pregnancy if there has been unprotected vaginal sex within the preceding 7 days. An alternative method of contraception should be offered for ongoing contraception, and the need for EC and follow-up pregnancy testing considered. Insertion of IUC when an individual has PID is a UKMEC4. Therefore, for individuals with PID that have their IUC removed but wish another IUC inserted, it is recommended that IUC insertion is delayed until antibiotic treatment has been completed and all signs and symptoms have resolved.

Candida & Bacterial vaginosis (BV):; IUC users with symptomatic, recurrent, confirmed VVC/BV not controlled by standard management may wish to switch to an alternative method of contraception.

Actinomycosis and presence of actinomyces-like organisms (ALO): Incidental findings of ALO are rare now that liquid-based cytology (LBC) and/or primary human papillomavirus (HPV) testing is now used for cervical screening. For more information refer to FSRH Clinical Guideline: Intrauterine contraception (March 2023)
https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception

v. Malposition

If malposition is suspected clinically or detected on a scan refer to senior clinician
Advise use of an alternative method of contraception meantime

vi. Perforation

The rate of uterine perforation associated with IUC use is very low, with an overall risk of perforation in the general population of approximately 1–2 per 1000.
Perforation risk is greater if breastfeeding and postpartum at the time of insertion

Perforation identified at the time of insertion. Stop procedure: remove IUC; monitor blood pressure and pulse rate and level of discomfort monitored until stable. Consider broad-spectrum antibiotics reduce the risk of peritonitis. Offer alternative contraception and advise to seek review if significant pain or signs/symptoms of infection develop.

Delayed identification of perforation. Lower abdominal pain, non-visible threads or changes in bleeding could indicate uterine perforation but are non- specific.

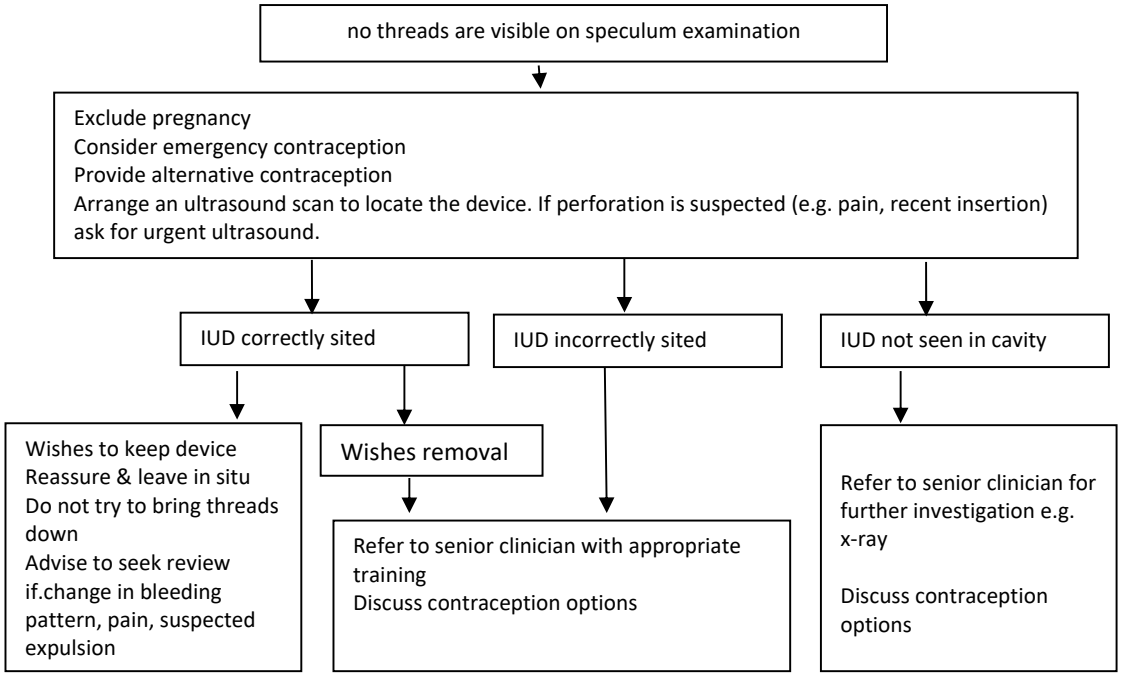
The presence of threads does not exclude perforation as the IUC could have breached the myometrium/other surrounding tissue or perforated the cervix.

Arrange urgent USS ± plain abdominal and pelvic X-ray should be arranged to locate the device. In the interim, consider EC, and offer alternative contraception.

Morbidity associated with detection and removal of an intraabdominal IUC appears to be low but uterine perforation can involve damage to the abdominal or pelvic viscera, bladder or bowel. If confirmed perforation liaise with gynaecology to consider laparoscopy

Wait at least 6 weeks after a known or suspected uterine perforation before inserting a subsequent IUD. Refer to a specialist service, where ultrasound is available.

vii. **Non-visible threads**



Thread problems after immediate PPIUC insertion – FSRH Clinical Guideline: Intrauterine contraception (March 2023)
https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception

viii. Expulsion

The overall risk of IUC expulsion is approximately 1 in 20 and expulsion appears to be most common in the first year of use, particularly within 3 months of insertion.

Expulsion rates are higher

- in immediate postpartum insertion compared with interval postpartum insertion
- in adolescents
- insertion after late first-trimester or second-trimester surgical abortions,
- in individuals with fibroids and HMB
- with use of a menstrual cup with IUC
- those who have had a previous expulsion
- when IUC is inserted for gynaecological indications: the risk of expulsion may be higher when IUC is inserted on days 1–8 of the menstrual cycle than later in the cycle.

If the individual wishes to have another IUC this can be inserted once expulsion is confirmed. Users should be advised that the risk of expulsion appears to be higher in those who have had a previous expulsion. There is no evidence to suggest that switching to a different IUD may reduce the risk of a further expulsion.

If there have been ≥2 IUC expulsions, a pelvic ultrasound to assess the uterine cavity may be helpful prior to insertion of a further IUC.

Post-insertion USS is not predictive of the likelihood of further expulsion but can provide immediate confirmation of correct positioning.

When LNG-IUD is being inserted for gynaecological reasons, clinicians may wish to consider inserting the IUC after day 8 of the menstrual cycle. Alternatively, or in addition, clinicians could offer individuals treatment to suppress menses (e.g. tranexamic acid, oral progestogen or continuation of their usual treatment for menstrual management/contraception) for one to three cycles post-insertion.

15. <u>IUC removal</u>

i. Facilitating Safe Removal

There is no formal FSRH training for IUC removal: follow local pathways for developing and maintaining competence. FSRH resources to support clinicians removing IUC:

- IUC removal consultation video IUC removal procedure video IUC removal ‘Top tips’ (requires FSRH log-in)
- E-lfh eSRH Module 15, Section 10 “Removal of IUC”.

Clinicians removing IUC should be:

- Able to discuss ongoing contraception needs and provide this or signpost to another provider.
- Able to provide preconception counselling or signpost to another provider.
- Able to recognise pregnancy risk and the need for Emergency Contraception
- Competent at speculum examination
- Able to recognise an abnormal cervix and know how to refer for further examination.
- Aware of how to manage non-routine findings (e.g. non-visible threads).
- Up to date with basic life support training.

ii. Timing of LNG-IUS removal or replacement

- Individuals who do not wish to become pregnant should be advised to avoid UPSI for 7 days prior to IUC removal.
- Individuals should be advised to avoid UPSI for 7 days prior to IUC removal and replacement in case it is not possible to insert the new device.

Table 4: LNG-IUS removal [from FSRH Clinical Guideline: Intrauterine contraception (March 2023)]

Situation	Advice
Removal for a planned pregnancy	• Offer preconception advice • IUC can be removed at any time • User should be advised that pregnancy is possible as soon as IUC removed
Removal – not for planned pregnancy and not switching to an alternative	• Abstain/use condoms in the 7 days prior to removal • If there has been UPSI in the 7 days prior to removal, ideally defer IUC removal until no UPSI for 7 days • Where this is not possible, consider EC AND Recommend a PT 21 days after the last episode of UPSI
Removal – menopause	• Contraception is no longer required when an individual: o Is aged 55 years o OR Is an LNG-IUD user, aged >50 years, and an FSH ≥12 months ago was ≥30 IU/L • IUC should normally be removed when it is no longer required and not left in situ indefinitely • Although no longer required for contraception, an individual may continue to use a 52 mg LNG-IUD for endometrial protection as part of HRT. This should be replaced very 5 years.
Removal and replacement	See table 3 – timing of insertion
Removal – switching to an alternative method of contraception	See FSRH Guidance Switching or Starting Methods of Contraception

iii. Unexpected findings at IUC removal

On removal of an IUC check the device is intact and that it is the expected device and therefore the correct information about duration of use/follow-up/ongoing contraception has been given.

For advice with regards to broken or /incomplete device refer to FSRH Clinical Guideline: Intrauterine contraception (March 2023)
https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception

iv. Removal of an unusual device

For advice with regards to IUCs inserted abroad where the clinician is not familiar with the device refer to FSRH Clinical Guideline: Intrauterine contraception (March 2023)
https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception

v. Difficult removals:

Most IUC removals are straightforward. Difficult IUC removals may be due to a number of factors including anatomical variations, IUC malposition (including perforation), clinician experience and/or the level of pain or discomfort experienced. When there is difficulty in removing an IUC, a referral should be made to an experienced provider.

References

FSRH Clinical Guideline: Intrauterine contraception (March 2023)**https://www.fsrh.org/documents/ceuguidanceintrauterinecontraception/**

Appendix 1: Types of LNG-IUDs

Comparison of the product characteristics of LNG-IUD devices currently available in the UK [from FSRH Clinical Guideline: Intrauterine contraception (March 2023)]

Parameter	Type of LNG-IUD				
	Benilexa®	Levosert®	Mirena®	Kyleena®	Jaydess®
Total LNG content (mg)	52	52	52	19.5	13.5
LNG release rate (mcg/24 h) **Initial** **At end of licensed use**	 20.1 8.6	 20.1 8.6	 20 9	 17.5 7.4	 14 5
Frame size (W x L, mm)	32 x 32	32 x 32	32 x 32	28 x 30	28 x 30
Inserter	One-handed inserter	Two-handed inserter	One-handed EvoInserter™	One-handed EvoInserter™	One-handed EvoInserter™
Insertion tube diameter (mm)	4.8	4.8	4.4	3.8	3.8
Silver ring for improved visibility on USS?	No	No	No	Yes	Yes
Colour of threads	Blue	Blue	Brown	Blue	Brown
Recommended duration of use for contraception (years)†	6	6	6	5	3
Licensed duration of use for contraception (years)	6	6	5	5	3
Recommended duration of use for endometrial protection as part of HRT (years)‡	5	5	5	Not recommended	Not recommended
Licensed for endometrial protection?	No	No	Yes	No	No
Licensed for HMB?	Yes	Yes	Yes	No	No
Minimum uterine cavity length (cm)	5.5	5.5	Not indicated in SPC	Not indicated in SPC	Not indicated in SPC

HMB, heavy menstrual bleeding; HRT, hormone replacement therapy; L, length; LNG, levonorgestrel; LNG-IUD, levonorgestrel intrauterine device; SPC, Summary of Product Characteristics; USS, ultrasound scan; W, width.