

## **LNG-IUS (MIRENA) CONTRACEPTIVE DEVICE GUIDELINE**

### **Introduction**

The levonorgestrel Intra-Uterine System (LNG-IUS), Mirena, consists of a T-shaped plastic frame impregnated with barium sulphate with threads attached to the base with a polydimethylsiloxane reservoir releasing levonorgestrel 20mcg/24hours.

Its main contraceptive effects are local, by endometrial suppression which prevents implantation and changes to the cervical mucus and utero-tubal fluid, which impairs sperm migration and penetration. There may be suppression of ovulation in some women (up to 25%).

### **Indications for LNG-IUS Use**

1. This method is suitable for any gynaecologically normal woman, of childbearing age, who is not pregnant and wishes to minimise the possibility of pregnancy and has no contra-indications to its use.
2. This method may also be chosen by women as therapy for menorrhagia.
3. The LNG-IUS offers endometrial protection as a component of hormone replacement therapy

### **The LNG-IUS is not recommended for post-coital use as emergency contraception**

Eligibility criteria for levonorgestrel intrauterine system (LNG-IUS) use. See Appendix 1. The UK Medical Eligibility criteria for both the levonorgestrel intrauterine system (LNG-IUS/Mirena) and the copper intrauterine device (Cu-IUD) and have been included as this may assist with client assessment and counselling.

### **Drug Interactions**

No evidence of reduced efficacy with liver enzyme-inducers or other drugs.

### **Breast cancer**

Breast cancer is a hormonally sensitive tumour and therefore the prognosis of women with current or recent breast cancer may worsen with progestogen-only contraception. Non-hormonal contraception is most appropriate for a woman with a history of breast cancer. However, the LNG-IUS may be considered individually, and in consultation with the woman's breast surgeon. The LNG-IUS may offer protection against endometrial hyperplasia which may be relevant for tamoxifen users.

### **Efficacy**

Failure rate is low, less than 1 / 100 women years. A Cochrane review found that failure rates for the LNG-IUS to be similar to that for the TCU380A. However, preliminary results from the WHO trial suggests that the LNG-IUS may be more effective at 5 years of use.

### **Side Effects/Risks**

- An increase in the risk of pelvic infection occurs within the 20 days following intrauterine contraceptive insertion but the risk is the same as the non IUD using population thereafter.
- Displacement or expulsion is the commonest cause of intrauterine contraceptive failure. The risk of this happening is around 1 in 20 and is most common in the first year of use, particularly within three months of insertion. There is a small increased risk of expulsion in the nulliparous.
- The overall risk of ectopic pregnancy is reduced with intrauterine contraceptive use compared to using no contraception. The annual ectopic pregnancy rate for IUD is 0.02 per 100 women years, compared to 0.3 to 0.5 per 100 women years for those not using contraception. Similar rates of ectopic pregnancy are reported for the LNG-IUS and Cu-IUDs. Alternative methods of contraception which inhibit ovulation will however reduce the risk of ectopic pregnancy to a greater degree.
- If a woman does become pregnant using intrauterine contraception the risk of ectopic pregnancy is about 1 in 20, and she should seek advice to exclude ectopic pregnancy.
- The risk of uterine or cervical perforation associated with intrauterine contraception insertion is less than 2 per 1000 insertions.
- Bleeding patterns change and may include spotting, shorter or longer menstrual periods or oligo/amenorrhoea. Prolonged bleeding is more common in the early months of use. The product SPC reports that in fertile women the average number of spotting days/months decreases gradually from 9 to 4 during the first six months of use.. Most women develop oligomenorrhoea or amenorrhoea by the end of the first year of use. Women should be advised to seek medical advice, to exclude infection and gynaecological pathology if menstrual abnormalities (apart from women who develop amenorrhoea or oligomenorrhoea) persist beyond the initial 6 months of use. Likewise a woman who has developed a very acceptable bleeding pattern which then deteriorates should also seek medical advice.
- Functional ovarian cysts/delayed follicular atresia may occur in 10-12% of patients. Most are asymptomatic; some may cause pelvic pain or dyspareunia. Most disappear spontaneously over 2-3 months, however, referral for specialist opinion may be appropriate if clinically indicated.
- Allergy.
- Side effects may be attributable to the systemic absorption of progestogen. The CEU state that although systemic absorption of progestogen occurs, rates of discontinuation due to side effects (such as acne and headaches) are not significantly different from Cu-IUD users. NICE report:

- there is no evidence the LNG-IUS causes weight gain
  - any changes in mood and libido are similar whether using the IUD or LNG-IUS, and the changes are small
  - there may be an increased likelihood of developing acne as a result of absorption of progestogen, but few women discontinue LNG-IUS for this reason
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- No evidence to suggest effect on bone mineral density.

**SIDE EFFECTS AS DETAILED IN SUMMARY OF PRODUCT CHARACTERISTICS**

System Organ Class	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1000 to < 1/100	Rare ≥ 1/10,000 to < 1/1000
Psychiatric disorders	Depressed mood  Nervousness  Decreased libido	Altered mood	
Nervous system disorders	Headache	Migraine	
Gastrointestinal disorders	Abdominal pain  Nausea	Abdominal distension	
Skin and subcutaneous tissue disorders	Acne	Alopecia  Hirsutism  Pruritus  Eczema	Rash  Urticaria
Musculoskeletal, connective tissue and bone disorders	Back pain		
Reproductive system and breast disorders	Pelvic pain  Dysmenorrhoea  Vaginal discharge  Vulvovaginitis  Breast tenderness  Breast pain	Pelvic inflammatory disease  Endometritis  Cervicitis/  Papanicolaou smear normal, class II	Uterine perforation
General disorders and administration site conditions	Intrauterine contraceptive device expelled	Oedema	
Investigations	Weight increase		

## **Potential Non Contraceptive Benefits Of LNG-IUS**

### Menorrhagia

LNG-IUS can reduce menstrual loss by over 90% and can be used as a first line option to treat menorrhagia after appropriate investigation.

### Fibroids

LNG-IUS can be effective in management of menorrhagia even in the presence of fibroids but use is not generally recommended if fibroids are distorting the uterine cavity.

## **Insufficient Evidence For Use**

### Dysmenorrhoea

Insufficient evidence to support use of LNG-IUS routinely for women with pain in the absence of heavy bleeding.

### Premenstrual syndrome

Paucity of published data.

## **Use As Progestogen Component Of HRT**

There is a license of 4 years for endometrial protection as a component of HRT. However CEU advice is that when used as the progestogen component of HRT, the LNG-IUS should be changed no later than 5 years after insertion irrespective of age at insertion.

## **Assessment Of Client Suitability**

- Accurate information and empathic counseling is the key to user acceptability.
- Clinical history taking and examination allow an assessment of medical eligibility for LNG-IUS use. In this context the history should include:- relevant, social, medical, sexual (to assess risk of sexually transmitted infections – STIs), family and drug history as well as details of reproductive health and previous contraceptive use.
- With this information clinicians can advise on the appropriate contraceptive options taking account of both medical and social factors.
- Women considering a LNG-IUS should be counseled regarding other contraceptive options including a Cu-IUD.
- Counseling should include a discussion about discomfort during/or after LNG-IUS insertion and possible side effects and risks.
- STI risk assessment and relevant testing should be performed in all women considering an LNG-IUS. Testing for *Chlamydia trachomatis* should be undertaken in women at risk of STIs (e.g., age < 25 years, or 25 years or older with a new sexual partner or more than one partner in the last year.)
- Women who are at higher risk of STIs should be advised to use condoms in addition

to the LNG-IUS.

- In women with heavy menstrual bleeding whose history does **not** suggest structural or histological abnormality endometrial assessment is not routinely required prior to insertion of a LNG-IUS. However a pelvic examination should be performed and a full blood count considered as per NICE guidelines for Heavy Menstrual Bleeding. An endometrial biopsy is recommended for all women with menorrhagia over 45 yrs.
- Clients should be given written information on the method.

### **Documentation**

- The patient record should be completed or updated as required.
- Name of chaperone should be recorded.
- Details of the insertion procedure including batch number and expiry date of LNG-IUS inserted should be recorded.
- Details of local anaesthetic used, if any including batch number and expiry date should be recorded.
- Written method information given to patient including name of device, expected date of removal, change or review and contact number in case of problems. It is desirable to record the date of removal, change or review in the patient record.
- Permission should be sought as to whether the client's GP can be notified.

**The Timing of Insertion of an LNG - IUS as a long term contraception**

<b>Circumstances when an LNG-IUS can be inserted</b>	<b>Recommendations for timing of insertion</b>
In all circumstances	<p>Usual practice would be to insert within the first 7 days of a normal menses.</p> <p>A LNG-IUS can be inserted at any time in the menstrual cycle if it is reasonably certain the woman is not pregnant and the clinician is reasonably certain there has been no risk of conception. Condoms or abstinence should be advised for 7 days after inserting the LNG-IUS unless inserted in the first 7 days of the cycle.</p>
Post partum (including post Caesarian section and breastfeeding)	Insert from 4 weeks postpartum as above.
Following abortion	<p>Ideally insert at the time of a first- or second-trimester surgical abortion for immediate contraceptive effect.</p> <p>Following medical or surgical abortion ideally insert within the first 48 hours or delay until 4 weeks postpartum. However, waiting until 4 or more weeks post termination may put women at risk of pregnancy. After counselling and when LNG-IUS is the preferred method it can be inserted by an experienced clinician at any time post-abortion if there is no concern that the pregnancy is on-going.</p>
Switching from another method of contraception	Intrauterine contraception can be inserted at any time if another method of contraception has been used consistently and correctly. Insert at any time if it is reasonably certain that the woman is not pregnant. There is no need to wait for the next period or withdrawal bleed. Condoms or abstinence may need to be advised for 7 days after inserting the LNG-IUS unless the current contraceptive method is still effective during this time.
<p>A provider can be reasonably certain a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any of the following criteria:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Has not had intercourse since last normal menses</li> <li><input type="checkbox"/> Has been correctly and consistent using a reliable method of contraception</li> <li><input type="checkbox"/> Is within the first 7 days after normal menses</li> <li><input type="checkbox"/> Is within the first 7 days post-abortion or miscarriage</li> <li><input type="checkbox"/> Is fully or nearly fully breast feeding, amenorrhoeic, and less than 6 months postpartum.</li> </ul>	

## **Insertion & Removal Techniques**

- Clinicians who insert LNG-IUS should be appropriately trained, maintain competence and attend regular updates in dealing with emergencies in accordance with Faculty and/or RCN guidelines
- Informed consent should be given by women prior to insertion.
- STI risk assessment should have been done when assessing client suitability.
- Women with symptomatic pelvic infection should be tested, treated and insertion delayed until symptoms resolve.
- If the results of STI tests are unavailable before insertion then prophylactic antibiotics should be considered for women at higher risk of STIs. The antibiotic regimen chosen should treat chlamydia and depending on the local prevalence may also need to cover gonorrhoea.
- Asymptomatic Chlamydia infection should preferably be treated before insertion. In certain circumstances it may be acceptable to treat at the time of insertion.
- There is no indication to routinely test for or treat other lower genital tract organisms (such as Group B streptococcus or bacterial vaginosis) in asymptomatic women attending for LNG-IUS insertion.
- In asymptomatic women at low risk of STIs there is no indication to delay insertion until the results of any screening tests performed are available, unless the client requests to wait for results.
- Antibiotic prophylaxis against infective endocarditis is no longer recommended for women including those with previous endocarditis or prosthetic heart valves undergoing procedures in the genitourinary tract. Any episodes of infection in people at risk of infective endocarditis should, in liaison with other relevant specialists be investigated and treated promptly to reduce the risk of endocarditis developing. The following conditions place patients at risk:
  - acquired valvular heart disease with stenosis or regurgitation
  - valve replacement
  - some forms of structural congenital heart disease (see NICE Clinical Guidance 64 for more details)
  - previous infective endocarditis
  - hypertrophic cardiomyopathy
- An appropriately trained assistant should be present during LNG-IUS insertion to monitor the condition of the patient and help in the event of an emergency.
- Emergency equipment must be available in all settings where LNG-IUS are inserted and local protocols must be in place for patients requiring further medical input.
- Pulse rate and blood pressure should be assessed and documented when clinically appropriate.

- A bimanual pelvic examination should be performed before inserting an LNG-IUS.
- Local anaesthetic techniques (lignocaine gel or injection of local anaesthetic to the cervix) may be used
- Those who have epilepsy, are likely to require local anaesthetic or who have had a previous failed insertion at another clinic should be referred to a clinic with more experienced staff specialising in difficult LNG-IUS insertions.
- A 'no-touch' technique should be used when sounding the uterine cavity and inserting an LNG-IUS.
- The use of a tenaculum is recommended to stabilise the cervix and straighten the uterocervical axis. It should be applied slowly to allow the cervical fibres to displace.
- An assessment should be made of the length of the uterine cavity.

### **Advice following Insertion**

Insertion of an LNG-IUS may cause pain and discomfort for a few hours and women should be informed about appropriate pain relief.

Women should be informed about how to check for the presence of LNG-IUS threads and encouraged to do this regularly with the aim of recognising expulsion.

Women should be informed of the symptoms of pelvic infection (for example pain, dyspareunia, abnormal discharge and fever) and advised as to how and where to seek medical help if these occur particularly in the first three – four weeks after insertion. In addition, women should be advised to seek medical assistance at any time if they develop symptoms of pain, persistent menstrual abnormalities (apart from the gradual onset of amenorrhoea or oligomenorrhoea), cannot palpate their threads or can feel the stem of the LNG-IUS. Women who are concerned that the device may have been expelled should be advised to use another method of contraception or abstain from intercourse until medical review. Consideration may also have to be given to the use of emergency hormonal contraception.

### **Follow-Up**

Routine follow up is not always necessary if the fitting was straight forward. First visit post fitting if required would be at six weeks to exclude infection, perforation or expulsion.

After the initial check women should be asked to return if they develop problems or wish the device to be removed or changed. In addition she should inform her smear taker at the time of cervical screening that she has a LNG-IUS in place so they can check that the threads are still visible.

Persistent deterioration in bleeding patterns should prompt assessment and consideration of referral for investigation to a local gynaecology service.

Women who have chosen a LNG-IUS to control menorrhagia and in whom treatment fails or is ineffective should be referred to a local gynaecology service for further investigations (see NICE Guidelines on Heavy Menstrual Bleeding).

All women using a LNG-IUS should be advised to return for review after 5 year's use to discuss the need for removal and replacement.

### **Removal without reinsertion**

Women who wish to conceive can have their LNG-IUS removed at any time. Women should be advised that if they wish to have a LNG-IUS removed and avoid pregnancy they should abstain or use another method of contraception for at least 7 days before removal. If removal is considered essential, and another method of contraception has not been used in the previous 7 days then consideration should be given to the use of hormonal emergency contraception. This may also have to be considered if a device is being removed after partial expulsion.

### **Change of an LNG-IUS**

Women should be advised to use condoms or abstain from sexual intercourse for 7 days prior to the change in case a new LNG-IUS cannot be inserted immediately.

### **Extended use of an LNG-IUS**

Women who have had an LNG-IUS inserted at the age of 45 years or over may continue to use the method for 7 years if their bleeding pattern is acceptable. NICE guidance advises that if women have an LNG-IUS inserted at or after the age of 45 years and are amenorrhoeic they may continue to use the LNG-IUS until they are postmenopausal (this may be up to age 55).

Given the reduced likelihood of spontaneous pregnancy in women over the age of 50 years, the CEU supports this option, for women who are amenorrhoeic.

Women should be informed about the efficacy of the LNG-IUS, the risks of pregnancy over the age of 50 years, and the risks of removal and replacement. If bleeding/spotting occurs, this indicates ovarian follicular activity and the CEU advises that the device is removed and replaced or alternative contraception provided.

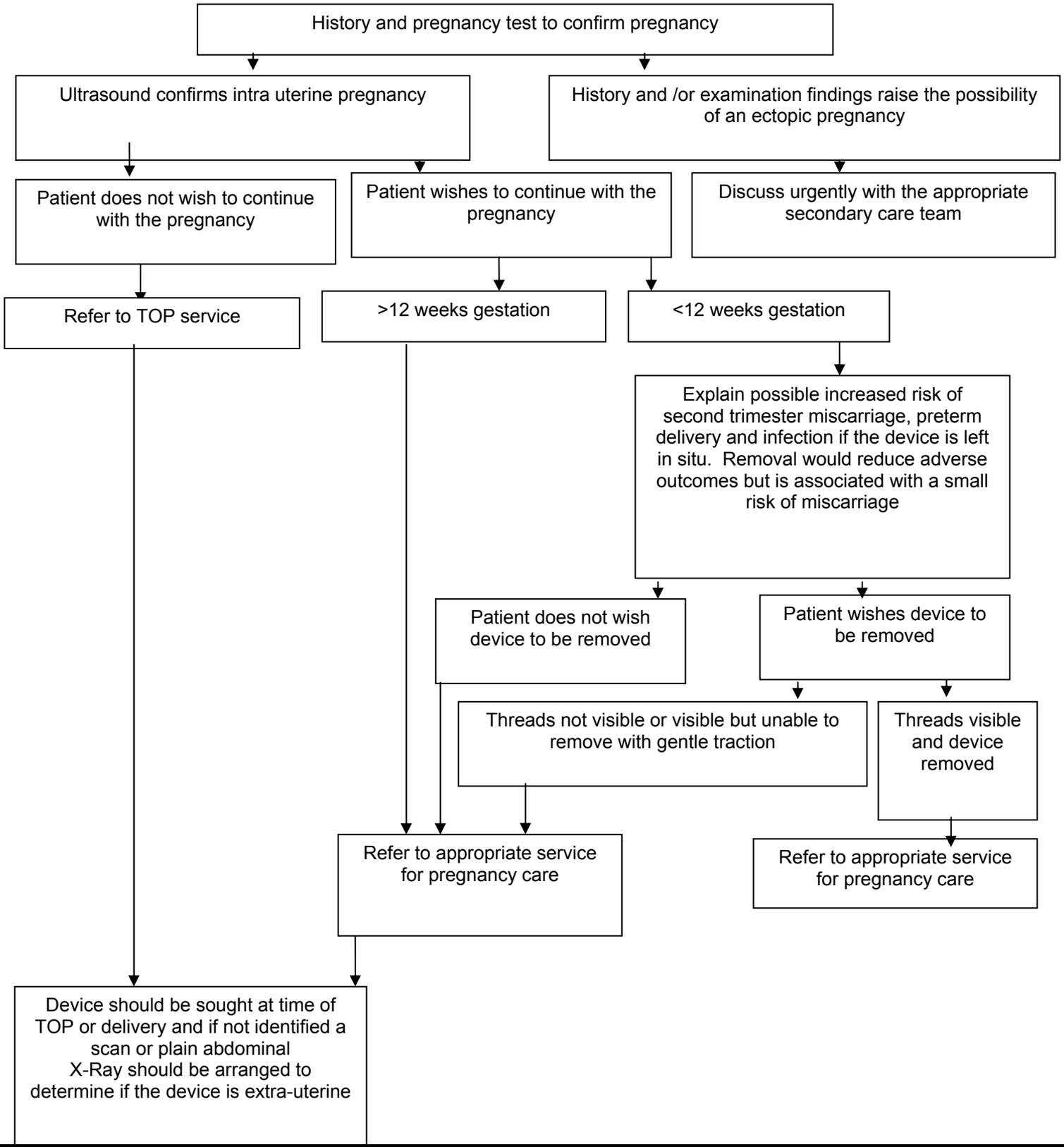
Removal of an IUS in an amenorrhoeic woman aged over 50, should be done 12 months after two Follicle Stimulating Hormone levels have been checked, 6 weeks apart, if both are >30 IU/L.

### **Problems Associated with LNG-IUS usage**

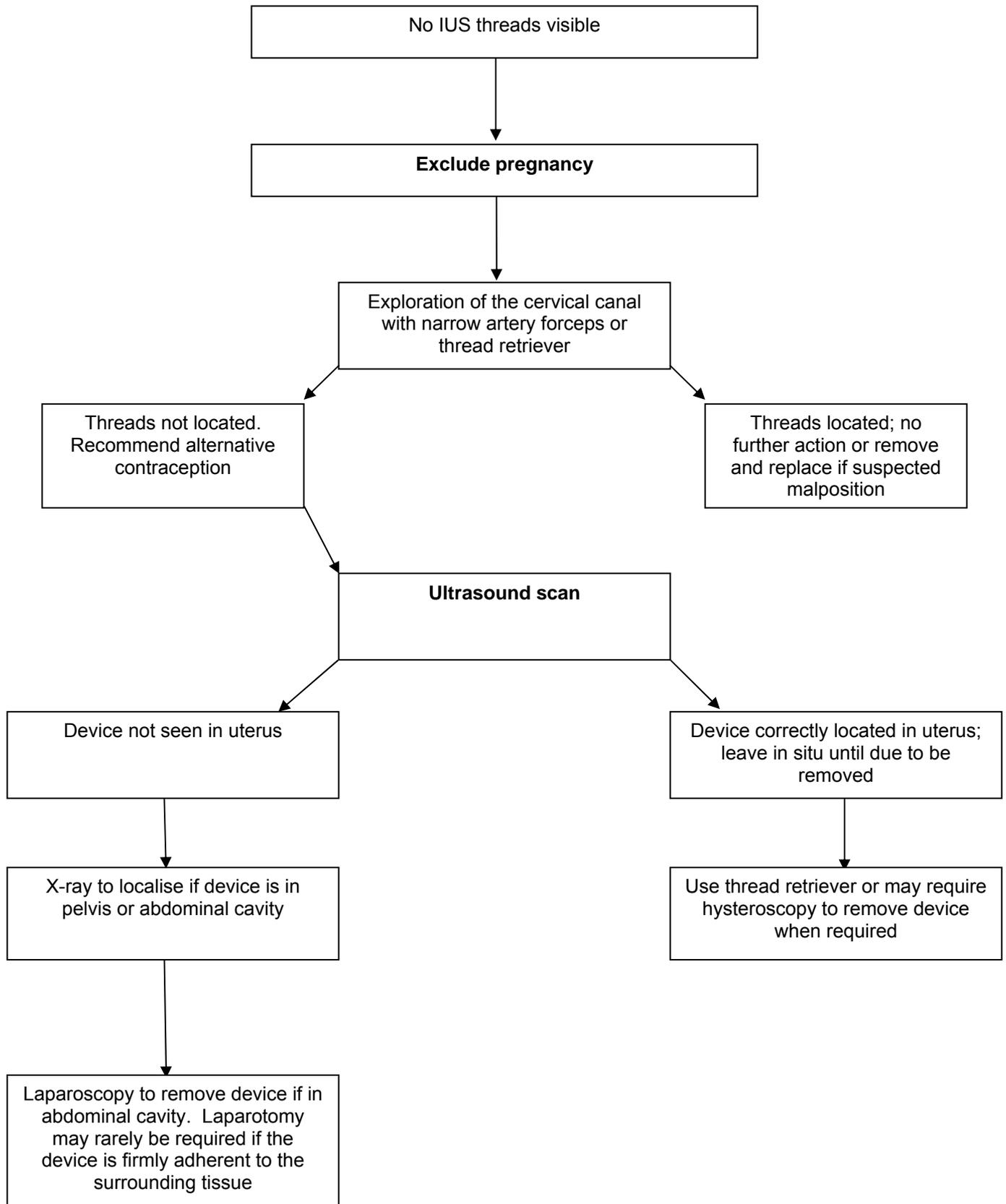
<p>Suspected perforation                  Perforation as a cause of pain and deterioration of bleeding pattern should be considered at any time.</p>	<p>If suspected at the time of insertion the procedure should be stopped and vital signs (blood pressure and pulse rate) and level of discomfort monitored until stable. Management needs to be discussed with a senior clinician.                  If suspected at follow up, an ultrasound scan and/or plain abdominal X Ray to locate the device should be arranged.  <b>A recent review of the reported cases of uterine perforation found that only 8% were suspected or detected at the time of insertion.</b></p>
<p>Lost threads</p>	<p>See flow chart</p>
<p>Abnormal bleeding</p>	<p>Although abnormal bleeding is common in the first 3-6 months after insertion clinicians should also be aware that abnormal bleeding in any women may indicate the presence of an STI or gynaecological pathology and when appropriate women should be investigated accordingly.</p> <p>When abnormal bleeding persists beyond the first 6 months following</p>

	<p>insertion of intrauterine contraception gynaecological pathology and infections should be excluded.</p> <p>Women using the LNG-IUS who present with a change in pattern of bleeding (<i>apart from gradual onset of amenorrhoea or oligomenorrhoea</i>) should be advised to return for further investigations to exclude infection, pregnancy and gynaecological pathology.</p>
Pregnancy	<p>Most pregnancies in women using an LNG-IUS will be intra-uterine but an ectopic pregnancy must be excluded.</p> <p>See flow chart to determine whether attempt should be made at LNG-IUS removal and on going management.</p>
Suspected pelvic infection	<p>For women using an LNG-IUS with symptoms and signs suggestive of pelvic infection appropriate antibiotics should be started. There is no need to remove the LNG-IUS unless symptoms fail to resolve within the following 72 hours or unless the woman wishes removal.</p> <p>All women with confirmed or suspected PID should be followed up to ensure: resolution of symptoms and signs, their partner has also been treated when appropriate, completion of the course of antibiotics, STI risk assessment, counseling regarding safer sex and partner notification.</p>
Presence of actinomyces-like organisms (ALO) on cervical screening	<p>LNG-IUS users with ALO detected on a smear who have no symptoms should be advised there is no reason to remove the LNG-IUS unless signs and symptoms of infection occur. There is no indication for follow-up screening. If symptoms of pelvic pain occur women should be advised to seek medical advice: other causes of infection (in particular STIs) should also be considered and it may be appropriate to remove the LNG-IUS.</p>

**Management of a pregnancy in a woman using intrauterine contraception**



**Management Of Lost LNG - IUS Threads**



**Appendix 1: UK Medical Eligibility Criteria for Intrauterine Contraception (2009)**

UKMEC	DEFINITION OF CATEGORY
<b>CATEGORY 1</b>	A condition for which there is <b>no restriction</b> for the use of the contraceptive method
<b>CATEGORY 2</b>	A condition where the <b>advantages of using the method generally outweigh the theoretical or proven risks</b>
<b>CATEGORY 3</b>	A condition where the <b>theoretical or proven risks usually outweigh the advantages of using the method</b> . The provision of a method requires expert clinical judgement and/or referral to a specialist contraceptive provider, since the use of the method is not usually recommended unless other more appropriate methods are not available or not acceptable
<b>CATEGORY 4</b>	A condition which represents an <b>unacceptable health risk if the contraceptive method is used</b>

<b>Initiation (I)</b>	Starting a method of contraception in a woman with a specific medical condition
<b>Continuation (C)</b>	Continuing the method already being used by a woman who develops a new medical condition.

Condition	UKMEC CATEGORY	
	Cu-IUD	LNG-IUS

Personal characteristics & reproductive history		
<b>PREGNANCY</b>	4	4
<b>AGE</b>		
a) Menarche to <20	2	2
b) ≥20	1	1
<b>PARITY</b>		
a) Nulliparous	1	1
b) Parous	1	1
<b>POSTPARTUM</b> (breastfeeding or non-breastfeeding, including post caesarian section) This includes all deliveries including stillbirth from 24 weeks gestation.		
a) 48 hours to < 4 weeks	3	3
b) ≥4 weeks	1	1
c) Puerperal sepsis	4	4
<b>POST ABORTION</b> This includes all induced or spontaneous abortions < 24 weeks gestation.		
a) First trimester	1	1
b) Second trimester	2	2
c) Immediate post septic abortion	4	4
<b>PAST ECTOPIC PREGNANCY</b>	1	1
<b>HISTORY OF PELVIC SURGERY</b>	1	1
<b>SMOKING</b>	1	1
<b>OBESITY</b>	1	1

	Cu-IUD	UKMEC CATEGORY	LNG-IUS
<b>Cardiovascular disease</b>			
<b>MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE</b> (such as older age, smoking, diabetes, hypertension and obesity)	C=Continuation		
<b>HYPERTENSION</b>	1		2

a) Adequately controlled hypertension	1	1		
b) Consistently elevated blood pressure levels	1	1		
c) Vascular disease (includes coronary heart disease presenting with angina; peripheral vascular disease presenting with intermittent claudication; hypertensive retinopathy, and transient ischaemic attacks)	1	2		
<b>HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY</b>	1	1		
<b>VENOUS THROMBO-EMBOLISM (VTE)</b> (including deep vein thrombosis and pulmonary embolism)				
a) History of VTE	1	2		
b) Current VTE (on anticoagulants) Women who have a current VTE may consider the use of the CU-IUD or LNG-IUS but should perhaps consider delaying insertion until anticoagulants have stopped, due to the potential risk of bleeding during the insertion procedure	1	2		
c) Family history of VTE	1	1		
d) Major surgery				
I. with prolonged immobilisation	1	2		
II. without prolonged immobilisation	1	1		
e) Minor surgery without immobilisation	1	1		
f) Immobility (unrelated to surgery) eg: wheelchair use, debilitating illness	1	1		
<b>KNOWN THROMBOGENIC MUTATIONS</b> (eg: Factor V Leiden; Prothrombin mutation; Protein S, Protein C and Antithrombin deficiencies)	1	2		
<b>SUPERFICIAL VENOUS THROMBOSIS</b>				
a) Varicose veins	1	1		
b) Superficial thrombophlebitis	1	1		
<b>CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE</b> (the method may be continued if women develop ischaemic heart disease while using the LNG-IUS. Clinical judgement and assessment of pregnancy risk and other factors required.)	1		<b>I</b>	<b>C</b>
			2	3
<b>STROKE</b> (history of cerebrovascular accident including TIA)	1		2	3
<b>KNOWN HYPERLIPIDAEMIAS</b> (routine screening is not appropriate because of the rarity of the conditions and the high cost of screening)	1	2		
<b>VALVULAR AND CONGENITAL HEART DISEASE</b>				
a) Uncomplicated	1	1		
b) Complicated (pulmonary hypertension, atrial fibrillation, a history of subacute bacterial endocarditis)	2	2		
<b>Neurological conditions</b>				
<b>HEADACHES</b>				
a) Non-migrainous (mild or severe)	1	1		
b) Migraine without aura at any age	1	2		
c) Migraine with aura at any age	1	2		
d) Past history ( $\geq$ 5 yrs ago) of migraine with aura, at any age	1	2		
<b>EPILEPSY</b> (see section on drug interactions)	1	1		
<b>Depressive disorders</b>				
<b>DEPRESSIVE DISORDERS</b>	1	1		
<b>Breast and Reproductive Tract Infections and Disorders</b>				
<b>VAGINAL BLEEDING PATTERNS</b>				
a) Irregular pattern without heavy bleeding	1	1	<b>I</b>	<b>C</b>
b) Heavy or prolonged bleeding (includes regular and irregular patterns). Unusually heavy bleeding should raise the suspicion of a serious underlying condition.	2	1		2
<b>UNEXPLAINED VAGINAL BLEEDING (suspicious for serious underlying condition)</b> Before evaluation (If pregnancy or an underlying pathological condition (such as pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation. There is no need to remove the IU method before evaluation)			<b>I</b>	<b>C</b>
	4	2	4	2
<b>ENDOMETRIOSIS</b> (A Cu-IUD IUD may worsen dysmenorrhoea associated with endometriosis)	2	1		
<b>BENIGN OVARIAN TUMOURS (including cysts)</b>	1	1		

	UKMEC CATEGORY I=Initiation C=Continuation			
	Cu-IUD		LNG-IUS	
<b>SEVERE DYSMENORRHOEA</b> (Dysmenorrhoea may intensify with Cu-IUD use, the LNG-IUS has been associated with a reduction)	2		1	
<b>GESTATIONAL TROPHOBLASTIC NEOPLASIA (GTD)</b> (includes hydatidiform mole, invasive mole, placental site trophoblastic tumour)				
a) Decreasing or undetectable $\beta$ -hCG levels	1		1	
b) Persistently elevated $\beta$ -hCG levels or malignant disease (Avoid use due to the possible risks of perforation and irregular bleeding)	4		4	
<b>CERVICAL ECTROPION</b>	1		1	
<b>CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)</b>	1		2	
<b>CERVICAL CANCER</b> (awaiting treatment) There is concern about the increase risk of infection and bleeding at insertion	<b>I</b>	<b>C</b>	<b>I</b>	<b>C</b>
	4	2	4	2
<b>BREAST DISEASE</b>				
a) Undiagnosed mass	1		2	
b) Benign breast disease	1		1	
c) Family history of cancer	1		1	
d) Carriers of known gene mutations associated with breast cancer (eg: BRCA1)	1		2	
e) Breast cancer				
I. Current	1		4	
II. Past and no evidence of current disease for 5 years	1		3	
<b>ENDOMETRIAL CANCER</b> (There is concern about the increase risk of infection, perforation and bleeding at insertion.)	<b>I</b>	<b>C</b>	<b>I</b>	<b>C</b>
	4	2	4	2
<b>OVARIAN CANCER</b>	<b>I</b>	<b>C</b>	<b>I</b>	<b>C</b>
	3	2	3	2
<b>UTERINE FIBROIDS</b>				
a) Without distortion of the uterine cavity	1		1	
b) With distortion of the uterine cavity	3		3	
<b>ANATOMICAL ABNORMALITIES</b>				
a) Distorted uterine cavity (any congenital or acquired uterine abnormality distorting the uterine cavity in a manner that is incompatible with insertion)	3		3	
b) Other abnormalities (including cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with insertion	2		2	
<b>PELVIC INFLAMMATORY DISEASE</b>	<b>I</b>	<b>C</b>	<b>I</b>	<b>C</b>
a) Past PID (assuming no known current risk factors for STIs)	1	1	1	1
b) PID – current	4	2	4	2
<b>SEXUALLY TRANSMITTED INFECTIONS (STIs)</b>	<b>I</b>	<b>C</b>	<b>I</b>	<b>C</b>
a) Chlamydia infection				
I. Symptomatic	4	2	4	2
II. Asymptomatic	4	2	4	2
b) Current purulent cervicitis or gonorrhoea	4	2	4	2
c) Other STIs excluding HIV and hepatitis	2	2	2	2
d) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	2	2	2	2
e) Increased risk of STIs	2/3	2	2/3	2
<b>HIV/AIDS</b>				
<b>HIGH RISK OF HIV</b>	2		2	
<b>HIV INFECTED</b>				
a) Not using anti-retroviral therapy	2		2	
b) Using anti-retroviral therapy (see section on drug interactions)	2-2/3		2-2/3	
<b>*AIDS excluding those clinically well on anti-retroviral therapy</b> (intrauterine contraceptive users with AIDS should be closely monitored for pelvic infection)	<b>I</b>	<b>C</b>	<b>I</b>	<b>C</b>
	3	2	3	2
<b>*AIDS but clinically well on anti-retroviral therapy</b> (intrauterine contraceptive users with AIDS should be closely monitored for pelvic infection and see section on drug interactions)	2	2	2	2

\*Taken from WHOMEK 2009 following discussion with Clinical Effectiveness Unit

	UKMEC CATEGORY I=Initiation C=Continuation	
	Cu-IUD	LNG-IUS
<b>Other Infections</b>		
<b>SCHISTOSOMIASIS</b>		
a) Uncomplicated	1	1
b) Fibrosis of liver (if severe, see cirrhosis)	1	1
<b>TUBERCULOSIS</b> (see section on drug interactions)		
a) Non-pelvic	I 1	C 1
b) Known pelvic	I 4	C 3
<b>MALARIA</b>		
	1	1
<b>Endocrine Conditions</b>		
<b>DIABETES</b>		
a) History of gestational disease	1	1
b) Non vascular disease		
I. non insulin dependent	1	2
II. insulin dependent	1	2
c) Nephropathy/retinopathy/neuropathy	1	2
d) Other vascular disease	1	2
<b>THYROID DISORDERS</b> (simple goitre, hyperthyroid, hypothyroid)		
	1	1
<b>Gastrointestinal conditions</b>		
<b>GALL BLADDER DISEASE</b>		
a) Symptomatic		
I. treated by cholecystectomy	1	2
II. medically treated	1	2
III. current	1	2
b) Asymptomatic	1	2
<b>HISTORY OF CHOLESTASIS</b>		
a) Pregnancy-related	1	1
b) Past COC-related	1	2
<b>VIRAL HEPATITIS</b>		
a) Acute or flare	1	1
b) Carrier	1	1
c) Chronic	1	1
<b>CIRRHOSIS</b>		
a) Mild (compensated without complications)	1	1
b) Severe (decompensated): development of major complications (ascites, jaundice, encephalopathy or gastrointestinal haemorrhage)	1	3
<b>LIVER TUMOURS</b>		
a) Benign		
I. Focal nodular hyperplasia	1	2
II. Hepatocellular adenoma	1	3
b) Malignant (hepatoma)	1	3
<b>WILSON'S DISEASE</b>		
UKMEC does not include Wilson's Disease. The CEU state that may be due to lack of evidence and potential toxic effects of copper, the use of a Cu-IUD in a women with Wilson's Disease is not recommended		
<b>INFLAMMATORY BOWEL DISEASE</b> (includes Crohn's disease, Ulcerative colitis)		
	1	1

	UKMEC CATEGORY I=Initiation C=Continuation			
	Cu-IUD	LNG-IUS		
<b>Anaemias</b>				
<b>THALASSAEMIA</b>	2	1		
<b>SICKLE CELL DISEASE</b>	2	1		
<b>IRON DEFICIENCY ANAEMIA</b>	2	1		
<b>Raynaud's disease</b>				
a) Primary	1	1		
b) Secondary				
I. without lupus anticoagulant	1	1		
II. with lupus anticoagulant	1	2		
<b>Rheumatic Diseases</b>				
<b>SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)</b> People with SLE are at an increased risk of ischaemic heart disease, stroke and venous thromboembolism. Categories are based on the assumption that no other risk factors for cardiovascular disease are present: these must be modified in th presence of such risk factors.	<b>I</b>	<b>C</b>		
a) Positive (or unknown) antiphospholipid antibodies	1	1	3	
b) Severe thrombocytopenia	3	2	2	
c) Immunosuppressive treatment	2	1	2	
d) None of the above	1	1	2	
<b>DRUG INTERACTIONS</b>				
<b>ANTIRETROVIRAL THERAPY</b>				
<b>This section relates to the SAFETY of contraceptive use in women using these antiretroviral.</b>				
There is no known interaction between antiretroviral therapy and intrauterine contraceptive use. However, AIDS as a condition is classified as Category 3 for insertion and Category 2 for continuation unless the woman is clinically well on antiretroviral therapy, in which case both insertion and continuation are classified as Category 2. (See AIDS condition).	<b>I</b>	<b>C</b>	<b>I</b>	<b>C</b>
a) Nucleoside reverse transcriptase inhibitors	2/3	2	2/3	2
b) Non-nucleoside reverse transcriptase inhibitors	2/3	2	2/3	2
c) Ritonavir-boosted protease inhibitors	2/3	2	2/3	2
<b>ANTICONVULSANT THERAPY</b>				
<b>This section relates to the SAFETY of contraceptive use in women using anticonvulsants.</b>				
a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)		1		1
b) Lamotrigine (lamotrigine concentrations in LNG-IUS users are similar to those in non-hormonal users)		1		1
<b>ANTIMICROBIAL THERAPY</b>				
<b>This section relates to the SAFETY of contraceptive use in women using these in antimicrobials.</b>				
a) Broad spectrum antibiotics		1		1
b) Antifungals		1		1
c) Antiparasitics		1		1
d) Rifampicin or rifabutin therapy		1		1

## References

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With sincere thanks to the West of Scotland Sexual Health Managed Clinical Network for sharing their guidelines and protocols <http://www.centralsexualhealth.org/west-of-scotland-managed-clinical-network>