FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

# Faculty of Sexual & Reproductive Healthcare Clinical Guidance



# Male and Female Sterilisation

## Summary of Recommendations

Clinical Effectiveness Unit

September 2014

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This document provides a summary of the main recommendations made in the Faculty of Sexual & Reproductive Healthcare (FSRH) guidance on *Male and Female Sterilisation* (September 2014).

Details of the evidence supporting these recommendations can be found in the full guidance document, available via the FSRH website: http://www.fsrh.org

A key to the Grading of Recommendations, derived from levels of evidence, is provided in the table below.

**GRADING OF RECOMMENDATIONS**

| | |
|---|---|
| A | Evidence based on randomised controlled trials |
| B | Evidence based on other robust experimental or observational studies |
| C | Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities |
| ✓ | Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the guideline group |

NICE accredited
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NICE has accredited the process used by the Faculty of Sexual & Reproductive Healthcare to produce its Male and Female Sterilisation guidance. Accreditation is valid for 5 years from May 2011. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

For full details on our accreditation visit:
*www.nice.org.uk/accreditation.*

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## Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit

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# FSRH Guidance (September 2014)

# Male and Female Sterilisation

### Summary of Recommendations

## Introduction

UK clinical guidance on *Male and Female Sterilisation* was last published by the Royal College of Obstetricians and Gynaecologists (RCOG) in 2004.[1] Updated guidance[2] has been published by the Clinical Effectiveness Unit (CEU) of the Faculty of Sexual & Reproductive Healthcare (FSRH) under an agreed arrangement with the RCOG. This is a summary of the full guidance document, which provides clinical guidance on elective male sterilisation (vasectomy) and female sterilisation (tubal occlusion).

The guidance is intended for any health care professional or service that undertakes vasectomy and/or tubal occlusion in the UK, as well as those who refer individuals for either procedure. The recommendations are intended to inform practice in the UK; therefore methods and practices not utilised in the UK are excluded. The recommendations should be used to guide clinical practice but are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases. Further information on the evidence base that informed the recommendations, including references to specific studies, can be found in the full guidance document.[2] Details of the methods used by the CEU in developing this guidance are described in the CEU section of the FSRH website (www.fsrh.org). A key to the Grading of Recommendations, derived from levels of evidence, is provided in the table on the inside front cover of this document.

Auditable outcomes and questions for continuous professional development can be found in the full guidance document. A supplementary document on consent and sterilisation will be published by the RCOG (www.rcog.org.uk).

## Changes from previous guidance

A key development since the publication of the RCOG document in 2004 has been the widespread adoption of minimally invasive vasectomy (MIV) techniques, as opposed to traditional invasive techniques, as well as an increase in the proportion of vasectomies undertaken in non-hospital settings. A significant change from previous guidance is an updated threshold for providing 'special clearance' to rely on vasectomy for contraception, following post-vasectomy semen analysis (PVSA). The RCOG guidance published in 2004 suggested a threshold of 10 000 non-motile sperm/ml whereas the updated document suggests a threshold of 100 000 non-motile sperm/ml.

In the field of female sterilisation, advice in relation to laparoscopic sterilisation has not altered significantly since 2004. However, hysteroscopic tubal occlusion has become an accepted alternative option to laparoscopic tubal occlusion. Whilst data on long-term follow-up are still emerging, available evidence suggests that post-confirmation failure rates are broadly similar to those of laparoscopic tubal occlusion.

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## Eligibility

There are few medical conditions that would absolutely restrict an individual's eligibility for sterilisation. Specific precautions may apply in certain circumstances, for example, obesity, anticoagulation therapy, cardiovascular disease or previous abdominal surgery. Nickel allergy and other contraindications to the Essure® hysteroscopic implant are listed in the main guidance document.[2] Relative contraindications to vasectomy and laparoscopic tubal occlusion are outlined in the full guidance document and in the *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC).[3]

## Consent and mental capacity

'Valid consent' is obtained by an individual being informed of the nature and purpose of any proposed treatment as well as the likely outcome(s), including any significant potential adverse outcomes and the likely result of not proceeding with the proposed treatment, in order to facilitate an individual making an informed decision.[4–6] Obtaining and giving consent should be regarded as a process, as opposed to a one-off event, and individuals can withdraw consent or change their minds at any time.[5,6]

Verbal and written consent are both considered equally valid in law.[5,6] It is good practice to obtain written consent for procedures that involve significant risks, including sterilisation, and for procedures that involve general/regional anaesthesia or sedation.[5–7] Individuals can be deemed unable to consent if it is clear (having been provided with appropriate help, support and information) that they cannot comprehend, retain, assess or use the information provided to make or communicate their decision.[5–7]

✓ Written consent should be obtained from individuals wishing to undergo vasectomy or laparoscopic or hysteroscopic tubal occlusion.

✓ A consent form and clinical record should be used to document an individual's agreement to the procedure, discussion that took place, requests made by the individual and any information provided.

C Legal advice should be sought if there is any doubt as to whether a person has the mental capacity to consent to a procedure that will permanently remove their fertility.

## Pre-sterilisation information and advice

Information given to men and women considering sterilisation should:

- include both verbal and written information
- ideally be conducted with both partners together, where acceptable and appropriate
- include information on sterilisation procedures
- highlight the irreversibility/permanence of sterilisation and that sterilisation reversal is not routinely available through the National Health Service (NHS)
- include information on the associated failure rate associated with sterilisation procedures
- include information on risk and complications associated with sterilisation procedures
- discuss myths and misconceptions associated with sterilisation
- inform individuals that vasectomy is safer, quicker to perform and is associated with less morbidity than female sterilisation by laparotomy or laparoscopy
- include information on other methods of contraception, including long-acting reversible contraception (LARC)
- assess individuals for known predictors of regret and highlight the possibility of regret associated with sterilisation


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- ensure that individuals are aware that sterilisation does not confer protection against sexually transmitted infections
- highlight the need to use contraception until sterilisation has been carried out and the potential need to continue use beyond the procedure
- enable individuals to make an informed decision and should include obtaining consent
- be recorded/documented in clinical records
- be carried out at a suitable interval prior to the procedure.

## Alternative sterilisation and contraceptive methods

Vasectomy, tubal occlusion and other methods of contraception should be discussed with all men and women requesting sterilisation. They should be made aware that some LARC methods are as effective as sterilisation and may confer non-contraceptive benefits. They should be advised that vasectomy is safer, quicker to perform and is associated with less morbidity than laparoscopic sterilisation. Hysteroscopic sterilisation, if available, should also be discussed as this is associated with less serious morbidity than laparoscopic tubal occlusion, it does not involve the use of general anaesthesia and can be performed as an outpatient procedure. However, women should be informed that hysteroscopic sterilisation is completely irreversible, that hysteroscopic access or micro-insert placement may be unsuccessful, and that contraception must be continued for at least 3 months until tubal occlusion is confirmed.

C All verbal advice must be supported by accurate, impartial, printed or recorded information (in translation, where appropriate and possible), which the individual requesting sterilisation may take away/download and review before the procedure.

C Counselling and advice on sterilisation procedures should be provided to women and men within the context of a service providing a full range of information about and access to other long-term reversible methods of contraception. This should include information on the advantages, disadvantages and relative failure rates of each method.

C Both vasectomy and tubal occlusion should be discussed with all men and women requesting sterilisation.

## Medical history and examination

A medical, surgical, drug and social history should be taken from men and women requesting sterilisation. Menstrual, obstetric, and cervical cytology history should be obtained from women. It is considered good practice to perform a genital/pelvic examination either at initial consultation or before commencing the surgical procedure.

C A history should be taken from all men and women requesting vasectomy or tubal occlusion. Scrotal or bimanual pelvic examination should be carried out either at initial consultation or before commencing the procedure.

C Individuals should be informed that vasectomy carries a lower failure rate, in terms of post-procedural pregnancies, and that there is less risk associated with the procedure than sterilisation carried out by laparoscopy or laparotomy.

✓ Individuals should be informed of the method of access and tubal occlusion being recommended in their case, the reasons for preferring it over other methods, and the method to be used if the intended procedure cannot be performed.

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C The operating clinician must ensure that counselling, information exchange, history and examination have been completed and must be satisfied that the individual does not suffer from concurrent conditions that may require an additional or alternative procedure or precaution.

## Advice post-vasectomy

Men should be instructed to:

- contact their health care provider if they have any concerns following the procedure: for example, persistent bleeding, pain, possible infection, or rapidly enlarging one-sided scrotal haematoma that would indicate being seen as a matter of urgency
- use non-steroidal anti-inflammatory drugs (NSAIDs) for pain/discomfort following the procedure, unless contraindicated
- rest following the procedure and refrain from strenuous activity
- abstain from sexual activity for between 2 and 7 days post-procedure
- wear tight underpants/athletic support for the first few days following the procedure, including at night for the initial 48 hours or longer according to symptoms
- men should be provided with instructions regarding PVSA and be provided with sample bottles if PVSA postal samples are used.

✓ Men who have undergone vasectomy should be provided with a post-procedural information leaflet that outlines appropriate self-care and instructions.

✓ Individuals who have undergone vasectomy should be informed of the need to use additional contraception until sterility is confirmed.

## Advice post-tubal occlusion

Women should also be advised about appropriate self-care, for example, information relating to wound care, sutures used, activity following the procedure and the use of analgesia for post-procedural pain/discomfort. They should also receive instructions about contacting their health care provider if they have specific concerns following the procedure. This information should be contained within a postoperative/self-care information leaflet, such as the RCOG's 'Recovering Well: Information for you after a laparoscopy' leaflet (http://www.rcog.org.uk/files/rcog-corp/LaparoscopyRecoveringWell.pdf).

✓ Women should be provided with information about the method of tubal occlusion undertaken and of any complications that occurred during the procedure.

✓ Women who have undergone tubal occlusion should be provided with a post-procedural information leaflet that outlines appropriate self-care and instructions.

✓ Individuals who have undergone hysteroscopic sterilisation with micro-inserts should be informed of the need to use additional contraception until sterility is confirmed.

## Regret

Regret following sterilisation is experienced by a minority of individuals particularly if they are under 30 years of age, nulliparous, recently pregnant or have relationship issues. A list of known risk factors is listed in the full guidance document. The guidance recommends that:

B Additional care must be taken when counselling individuals under the age of 30 years or individuals without children who request sterilisation.


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C If tubal occlusion is performed at the same time as a caesarean section, counselling and agreement should be given at least 2 weeks in advance of the procedure.

✓ When a pregnancy occurs while an individual is on a waiting list for sterilisation they should be offered further counselling about future contraceptive choices due to the change in their circumstances.

## Vasectomy

Vasectomy is the technique of interrupting the vas deferens with an intention to provide permanent contraception. A relatively newer technique to expose the vas, the no-scalpel vasectomy (NSV), involves a puncture wound in the scrotal skin to access and occlude the vas. For the purposes of this guideline, the term minimally invasive vasectomy (MIV) is used to encompass NSV and any modified versions of this technique, where the skin opening is ≤10 mm, the dissection area surrounding the vas deferens is minimised and skin sutures are not required. MIV may include the use of a variety of surgical instruments, including a scalpel, to expose the vas. MIV techniques have been shown to reduce the level of bleeding and intraoperative pain when compared to other methods of exposing the vas deferens.

### Anaesthesia

B Vasectomy should be performed under local anaesthesia wherever possible.

A Consideration may be given to warming local anaesthetic to approximately 37°C before infiltration to reduce pain associated with injection.

✓ Local anaesthetic with or without adrenaline (epinephrine) can be used during vasectomy (outside product licence for bupivacaine with adrenaline).

✓ Local anaesthetic should be administered via infiltration of the subcuticular tissue and by direct injection to the vas deferens.

✓ Local anaesthetic should be administered using a fine-gauge needle to reduce pain.

### Isolating and interrupting the vas deferens

A A minimally invasive approach should be used to expose and isolate the vas deferens during vasectomy, as this approach results in fewer early complications in comparison to other methods.

A Cauterisation followed by division of the vas deferens, with or without excision, is associated with the lowest likelihood of early recanalisation (failure) when compared to other occlusion techniques.

A Division of the vas on its own is not an acceptable technique because of the associated failure rate. It should be accompanied by diathermy or ligation and fascial interposition.

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A Clips are not recommended for occluding the vas deferens as their use is associated with a potentially high failure rate when compared to other occlusion methods.

### Intraoperative complications

✓ If a vas deferens cannot be palpated or located, unilateral vasectomy can be carried out following appropriate counselling, and the man advised to comply with additional contraception until sterility is confirmed. These men should be informed of the probability of ipsilateral renal agenesis and may be referred for renal ultrasound.

✓ Where apparent bilateral absence of the vas deferens is encountered, men should be referred to a urology specialist.

✓ If a double or duplicate vas deferens is encountered or suspected, a Doppler ultrasound should be used to determine whether it is a 'true' double vas or an ectopic ureter.

✓ Where an anomaly of the vas deferens is suspected, the need for further investigation should be individually assessed by a urology specialist.

✓ Health professionals should cauterise or suture any bleeding perivasal and subdermal blood vessels to ensure haemostasis.

✓ If pain is experienced during vasectomy, health professionals should consider administration of additional anaesthesia/analgesia.

✓ Health professionals should ensure that the clinical room is well ventilated and a comfortable temperature.

✓ Health professionals can consider playing music in the clinical room if the patient wishes, as listening to music has been shown to reduce patient anxiety.

✓ Health professionals should engage men undergoing vasectomy in conversation and provide reassurance over the course of the procedure.

### Immediate and delayed postoperative complications

✓ The routine use of prophylactic antibiotics is not recommended prior to vasectomy.

✓ Skin cleansing in advance of vasectomy should be undertaken in accordance with local infection control protocols.

✓ The decision to shave the scrotum prior to vasectomy should be based on local infection control/preoperative policies.


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B Clinicians should modify their technique if their overall failure attributable to technical failure, recanalisation and non-compliance with additional contraception is more than 1%.

C The incidence of bleeding, haematoma formation and infection is low and can be further reduced by the adoption of minimally invasive vasectomy techniques.

**Vasectomy failure, post-vasectomy semen analysis and special clearance**

Vasectomy failure can be classified as either early failure (i.e. before PVSA) or late failure (i.e. pregnancy or the reappearance of motile spermatozoa following confirmation of sterility at PVSA). The rationale for PVSA is to confirm clearance of stored spermatozoa downstream of the vasectomy site and to identify early failure or early recanalisation. The time necessary for complete expulsion of stored sperm may vary, depending in part upon the frequency of ejaculation and age. A number of studies have assessed compliance and outcomes with different frequencies and numbers of PVSA tests with most studies advocating PVSA at 12 weeks post-vasectomy, others at 16 weeks. If any sperm are observed in a postal sample then sperm motility must be assessed using a fresh sample (processed within hours of production in accordance with local protocols).

C Routine histological examination of the excised portions of vas deferens is no longer recommended.

B Post-vasectomy semen analysis (PVSA) should be carried out to identify early failure. Additional contraception should be used until azoospermia is confirmed or special clearance given.

B Evidence suggests that 12 weeks post-vasectomy is the optimal timing to schedule the first PVSA. Earlier or later testing is acceptable taking into account that earlier testing increases the probability of additional tests and later testing prolongs the need for additional contraception.

✓ Postal semen samples can be used for PVSA; however, such samples will not be suitable for the assessment of sperm motility.

✓ Packaging and labelling of postal samples should conform to local laboratory policy/requirements and must comply with Royal Mail standards for the posting of biological specimens.

B A routine second PVSA is not required if azoospermia is found in the first sample.

B In a small proportion of men non-motile sperm will persist following vasectomy. In such cases special clearance can be given to cease using additional contraception when less than 100 000 non-motile sperm/ml are observed in a fresh semen sample post-vasectomy.

C If motile sperm are observed in a fresh sample 7 months post-procedure, the vasectomy should be considered a failure.

✓ If more than 100 000 non-motile sperm/ml are observed in a fresh sample 7 months after vasectomy, clinical judgement and/or local protocols may be used to determine whether or not the procedure should be deemed a failure.

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A Routine irrigation of the vas deferens does not reduce time to achieve azoospermia and is not recommended.

A Centrifugation is not recommended for establishing the absence of sperm post-vasectomy and may interfere with evaluation of sperm motility.

B Individuals should be informed that vasectomy has an associated failure rate and that pregnancy can occur several years after vasectomy. The contraceptive failure rate should be quoted as approximately 1 in 2000 (0.05%) after clearance has been given.

### Long-term complications of vasectomy

B Vasectomy is associated with a risk of postoperative testicular, scrotal, penile or lower abdominal pain that is rarely severe and chronic in some men.

✓ Non-steroidal anti-inflammatory drugs (NSAIDs) and treatment to alleviate neuropathic pain are common first-line treatment options for chronic post-vasectomy pain (CPVP) and are preferable to surgery which involves the reversal of vasectomy.

C Surgical interventions can be effective in alleviating CPVP, however permanent relief is not achieved in every case.

B There is no evidence of an increase in testicular cancers associated with vasectomy. The weak association observed in some studies between vasectomy and prostatic cancer is unlikely to be causal.

B There is no evidence to support an association between vasectomy and cardiovascular disease.

## Tubal occlusion

Elective female sterilisation may be achieved by the occlusion or interruption of the fallopian tubes. During laparoscopy, the fallopian tube can be occluded (with a tubal ring or clip); a modified Pomeroy technique can be performed using endoscopic sutures; or diathermy (either unipolar or bipolar) can be used to destroy a segment of the tube. Major complications associated with laparoscopic surgery are injuries to the bowel, bladder and blood vessels that require laparotomy. The risk of laparotomy as a consequence of a severe complication reported in a large prospective study was 1.9/1000 procedures. Two other practice surveys reported laparotomy rates of 1.4–3.1/1000 cases. The risk of death associated with laparoscopy is reported as being 1/12 000.

### Approach to the fallopian tubes

A Culdoscopy should not be used as a method of approach for sterilisation

A The laparoscopic approach to the fallopian tubes is quicker to perform and results in less minor morbidity compared to mini-laparotomy.


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B All women should be informed of the risks associated with laparoscopy and when this may proceed to laparotomy.

✓ In some cases laparoscopy/laparotomy may be contraindicated and consideration should be given to other methods.

### Occlusion methods

B Any effective surgical or mechanical method of tubal occlusion can be used when a mini-laparotomy is the method of approach for an interval sterilisation.

A For postpartum sterilisation, both Filshie clips and modified Pomeroy technique are effective. Filshie clip application is quicker to perform.

A Mechanical occlusion of the fallopian tubes by Filshie clips should be the method of choice for laparoscopic tubal occlusion.

C The routine use of more than one Filshie clip is not recommended.

### Anaesthesia and analgesia

B Laparoscopic tubal occlusion can be performed using general, regional or local anaesthesia but general anaesthesia is routinely used in the UK for laparoscopic tubal occlusion.

A Topical application of local anaesthesia to the fallopian tubes may be used whenever mechanical occlusive devices are being applied as short-term postoperative pain is reduced.

### Postpartum and post-abortion sterilisation

B Tubal occlusion should be performed at an appropriate interval after pregnancy wherever possible. Should tubal occlusion be requested either postpartum or post-abortion, women should be made aware of the increased rate of regret and the possible increased failure rate.

### Failure of tubal sterilisation

B Late failures resulting in a pregnancy can occur any time after tubal occlusion.

B The lifetime risk of laparoscopic tubal occlusion failure, using a mix of occlusion methods, is estimated to be 1 in 200.

C The longest period of available follow-up data for the most commonly used method in the UK, the Filshie clip, suggests a failure rate of 2–3 per 1000 procedures at 10 years.

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## Hysteroscopic sterilisation

Transcervical sterilisation is usually performed without the need for anaesthesia and involves a hysteroscope being inserted into the vagina and cervix vaginoscopically or by using a speculum. Flexible micro-inserts (Essure®) are then passed through the hysteroscope and inserted into the proximal section of each fallopian tube. The micro-inserts elicit a benign tissue response (fibrosis) resulting in the permanent occlusion of each tube after approximately 3 months. Additional contraception is required until successful placement of the micro-inserts and tubal occlusion is confirmed by imaging at least 3 months after the procedure.

### Anaesthesia and analgesia for hysteroscopic sterilisation

**A** There is insufficient evidence to recommend the routine use of oral NSAIDs or intravenous sedation for hysteroscopic sterilisation. The use of such pharmacological agents should be based on clinical judgement.

**A** Local anaesthesia is not routinely required prior to hysteroscopic sterilisation as it does not alleviate pain associated with the placement of micro-inserts into the fallopian tubes. However, local anaesthesia should be used when dilatation of the cervix is necessary to aid passage of the hysteroscope into the uterine cavity.

### Insertion of the micro-inserts

There is broad consensus that insertion of the micro-inserts should be scheduled during the proliferative phase of the menstrual cycle where possible. Advantages of insertion during the proliferative phase are that a negative pregnancy test is likely to rule out pregnancy, and visualisation of the tubal ostia is easier as the endometrium is not thickened.

**B** The incidence of unsuccessful placement of intra-fallopian implants is reported as ranging between 0% and 19%, following up to two attempts in an outpatient setting.

**B** The likelihood of successful micro-insert placement is increased if the procedure is scheduled during the proliferative phase of the menstrual cycle.

**C** Clinicians should undergo a period of supervised training to become proficient in the hysteroscopic insertion of micro-inserts.

**B** Hysteroscopic sterilisation via the placement of intra-fallopian micro-inserts is associated with a low level of intraoperative complications in a minority of patients.

### Post-procedure imaging

In Europe, the licence for Essure states that transvaginal ultrasound scan (TVUSS), pelvic X-ray or hysterosalpingogram (HSG) can be used to confirm placement of micro-inserts.[8] Bayer[8] state that pelvic X-ray or TVUSS may be used as the first-line confirmatory test in Europe but that HSG should be used in the following circumstances:

- there was concern regarding possible perforation due to either excessive force and/or a sudden loss of resistance at insertion
- there was difficulty identifying the tubal ostia due to anatomical variation or technical factors (e.g. poor distension, suboptimal lighting or endometrial debris)
- health professional uncertainty regarding micro-insert placement at insertion


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- procedure time >15 minutes (from insertion to removal of hysteroscope)
- micro-insert placement with 0 (zero) or >8 trailing coils (i.e. coils protruding inside the uterine cavity)
- unusual post-procedural pain, either transient or persistent, or onset at some later point post-procedure, without any identifiable cause
- if X-ray or TVUSS is equivocal or unsatisfactory.[8]

**B** A confirmatory imaging test should be undertaken 3 months after the insertion of intra-fallopian micro-inserts. This may be via X-ray or transvaginal ultrasound scanning (TVUSS) in the first instance, followed by hysterosalpingogram (HSG) in selected patients where X-ray or TVUSS cannot confirm satisfactory placement.

**B** HSG should be used as a first-line test where the hysteroscopic procedure was considered suboptimal, according to local protocols.

**B** HSG can be used as a routine test to confirm tubal occlusion following insertion of intra-fallopian micro-inserts.

✓ Women who do not attend for confirmatory testing should be informed that they need to continue using additional contraception until tubal occlusion is confirmed.

✓ Training in interpretation and performance of confirmatory imaging techniques specifically for sterilisation using Essure is essential, as a number of pregnancies have been attributed to the misinterpretation of images.

### Efficacy of hysteroscopic sterilisation

The majority of the studies in the literature, to date, which examined hysteroscopic sterilisation via insertion of the Essure micro-insert do not report any pregnancies during the study period. However, because hysteroscopic sterilisation is a relatively novel procedure there is a paucity of longitudinal data available, and many studies cease follow-up once confirmatory testing has taken place.

In the studies that did report pregnancies the majority occurred in women who had either no follow-up confirmatory testing or inadequate confirmation of tubal occlusion or micro-insert placement.

**B** Available evidence suggests that tubal occlusion by intra-fallopian micro-insert has a low associated failure rate which is approximately 1 in 500 at 5 years of follow-up; this includes cases where luteal-phase pregnancy or non-adherence with post-procedural instructions was documented.

### Hysteroscopic sterilisation and other procedures

**C** Limited available evidence suggests that intra-fallopian micro-insert insertion can be carried out in combination with endometrial ablation.

### Patient satisfaction with hysteroscopic sterilisation

**B** Available evidence suggests that the use of intra-fallopian micro-inserts for tubal occlusion is a procedure that is well tolerated by the majority of women and results in good long-term satisfaction in terms of comfort and tolerance of the insert.

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### Postoperative complications of hysteroscopic sterilisation

Reported complications following hysteroscopic sterilisation include infection, micro-insert expulsion and a low number of uterine perforations.

**B** Hysteroscopic sterilisation via the placement of intra-fallopian micro-inserts is associated with a low level of postoperative complications. The majority of post-procedural adverse events are self-limiting, with most women able to return to daily activities 1–2 days following the procedure.

✓ Hysteroscopic sterilisation with micro-inserts is contraindicated if there is documented proven patch test for nickel allergy.

## Contraceptive advice and excluding pregnancy

A proportion of sterilisation 'failures' are attributable to luteal-phase pregnancies, which occur when patients are sterilised after unknowingly conceiving in the same cycle as the sterilisation procedure is performed. Iatrogenic ectopic pregnancy can occur in the luteal-phase by occluding the fallopian tube before the blastocyst has passed the site of occlusion. Contraception must be used up to the procedure and most methods need to be continued for at least 7 days (or until confirmatory imaging).

Theoretically, combined hormonal contraception (CHC) could be stopped at the time of laparoscopic tubal occlusion if it has been consistently and correctly used in the previous 7 days. The guideline multidisciplinary group considered that a simple, safe approach is to advise that CHC (combined pill, patch or ring) should be continued for at least 7 days after sterilisation.

Removing a copper intrauterine device (Cu-IUD) or levonorgestrel intrauterine system (LNG-IUS) at the time of tubal occlusion may result in unintended pregnancy if ovulation has occurred prior to the procedure and a blastocyst has already passed the site of tubal occlusion.

**B** A pregnancy test must be performed before sterilisation to exclude the possibility of a pre-existing pregnancy. However, a negative test result does not exclude the possibility of a luteal-phase pregnancy.

**B** Tubal occlusion can be performed at any time during the menstrual cycle, providing that the woman has a negative pregnancy test and is not at risk of luteal-phase pregnancy [no unprotected sexual intercourse (UPSI) in the past 3 weeks]. If this is not the case, the procedure should be deferred and contraception used until at least 3 weeks from the last instance of UPSI.

**B** During tubal occlusion, curettage should not be performed for the purpose of preventing luteal-phase pregnancy.

**B** Following sterilisation via hysteroscopy and the insertion of intra-fallopian micro-inserts, additional contraception must be used until either successful insert placement and/or tubal occlusion are confirmed, depending upon the confirmatory test employed.

**C** If the progestogen-only injectable or implant is being used, laparoscopic tubal occlusion can be carried out at any time during the period of licensed use without the need for additional contraception.


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C The progestogen-only implant can be removed at the time of the procedure or any time following laparoscopic tubal occlusion.

C There is no evidence to support stopping combined hormonal contraception (CHC) use prior to sterilisation or to support the routine use of thromboprophylaxis.

B Women using CHC, the progestogen-only pill or non-hormonal contraception should be advised to continue their contraceptive method for at least 7 days after laparoscopic sterilisation.

C If laparoscopic sterilisation is scheduled for the hormone-free interval or Day 1 of a cycle of CHC, the hormone-free interval should be omitted or CHC should be restarted, and CHC should be continued for at least 7 days after sterilisation.

C If a Cu-IUD or LNG-IUS is *in situ* prior to sterilisation, this should be retained and removed at least 1 week after laparoscopic tubal occlusion.

✓ Hysteroscopic sterilisation may be safely and effectively undertaken when intrauterine contraception is already *in situ* (outside the terms of the manufacturer's instructions for use). Women should be advised to use additional contraception or abstain from intercourse for 7 days before the procedure in case the intrauterine device needs to be removed to gain access to the fallopian tubes.

## Long-term complications of female sterilisation

A Tubal occlusion is not associated with an increased risk of ovarian cancer. Evidence suggests that the procedure may have a protective effect against developing ovarian cancer that persists over time.

A There is no available evidence of an association between tubal occlusion and breast cancer risk.

B Available evidence suggests that there is no association between tubal occlusion and cervical or endometrial cancer risk.

B There is no evidence that tubal occlusion results in significant changes to hormone levels.

B Evidence suggests that there is an association between tubal occlusion and an increased risk of subsequent hysterectomy but there is no evidence of causation.

B Women may report worsening menstrual symptoms following tubal occlusion but there is no evidence to suggest a causal effect.

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## Ectopic pregnancy

Pregnancies following female sterilisation are rare, but when they do occur there is an increased risk of ectopic gestation. The incidence of ectopic pregnancy post-female sterilisation varies depending on the method used to occlude the fallopian tubes.

C Women should be informed that if tubal occlusion fails, the resulting pregnancy may be ectopic.

✓ Women should be informed about symptoms of ectopic pregnancy, and the possibility of ectopic pregnancy should be considered in women who have undergone sterilisation and present with abdominal pain, especially in connection with missed periods.

## Sterilisation reversal

The NHS does not currently offer sterilisation reversal routinely. Reversal of tubal occlusion is associated with an increased risk of ectopic pregnancy.

B Vasectomy reversal involves complex surgery that can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility.

B Fallopian tube re-anastomosis following sterilisation can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility.

✓ To date, reversal of sterilisation with micro-inserts cannot be achieved via fallopian tube re-anastomosis, therefore consideration should be given to *in vitro* fertilisation.

## References


1 Royal College of Obstetricians and Gynaecologists (RCOG). *Male and Female Sterilisation* (Evidence-based Clinical Guideline Number 4). London, UK: RCOG Press, 2004.

2 Faculty of Sexual & Reproductive Healthcare. *Male and Female Sterilisation*. 2014. http://www.fsrh.org/pdfs/MaleFemaleSterilisation.pdf [Accessed 8 September 2014].

3 Faculty of Sexual & Reproductive Health Care. *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC 2009). 2009. http://www.fsrh.org/admin/uploads/UKMEC2009.pdf [Accessed 8 September 2014].

4 International Federation of Gynecology and Obstetrics (FIGO). *Ethical Issues in Obstetrics and Gynecology by the FIGO Committee for the Study of Ethical Aspects of Human Reproduction and Women's Health*. London, UK: FIGO, 2012.

5 Faculty of Sexual & Reproductive Healthcare. *Service Standards for Record Keeping*. 2010. http://www.fsrh.org/pdfs/ServiceStandardsRecordKeeping.pdf [Accessed 8 September 2014].

6 Faculty of Sexual & Reproductive Healthcare. *Service Standards on Obtaining Valid Consent in Sexual Health Services*. 2011. http://www.fsrh.org/pdfs/ServiceStandardsObtainingValidConsent.pdf [Accessed 8 September 2014].

7 General Medical Council (GMC). *Consent: Patients and Doctors Making Decisions Together*. London, UK: GMC, 2008.

8 Conceptus Inc. Essure: instructions for use. ESS305 Purple handle. 2012. http://www.essuremd.com/App_Themes/BaseTheme/PDFs/Link%20Essure%20IFU.pdf [Accessed 8 September 2014].



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# APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

**GUIDELINE DEVELOPMENT GROUP**

**Dr Louise Melvin** – Director, Clinical Effectiveness Unit

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**VASECTOMY**

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**INDEPENDENT PEER REVIEWER**

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**Declared Interests**

Professor John Guillebaud receives consultancy and lecture fees from pharmaceutical companies, including Bayer, Consilient, Glaxo, HRA Pharma, Janssen and MSD.

Professor Michael Labrecque accepted stock options for Contravac Inc. in return for conducting a study of SpermCheck. Part of his income is obtained by performing vasectomies.

Ms Pauline Bagnall has received exhibition sponsorship from Lilly and Pfizer.

Dr Kay McAllister has received payment from pharmaceutical companies for educational meetings.

Dr Stephen Searle has received sponsorship from pharmaceutical companies for educational events.

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# APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

**FEMALE STERILISATION**

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**Declared Interests**

Professor John Guillebaud receives consultancy and lecture fees from pharmaceutical companies, including Bayer, Consilient, Glaxo, HRA Pharma, Janssen and MSD.

Dr Sebastiaan Veersema, Mr Andrew Baxter and Mr T Justin Clark have been consultants and Essure trainers for Bayer.

Dr Sue Milne's department receives endowment funds from Bayer for acting as a training centre for Essure.

Dr Farah Chaudhry has acted as a speaker at events sponsored by Bayer and MSD and was a member of an advisory board for Bayer.

Mr T Justin Clark is a scientific editor for *BJOG* and receives an honoraria for each article edited.

**Patient Consultation**

A questionnaire on the proposed guidance content was completed by a sample of potential users.

Clinical Effectiveness Unit (CEU) guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The CEU guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialities, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings Committee and FSRH Council in the multidisciplinary guideline development group.

The process for the development of CEU guidance is detailed on the FSRH website (www.fsrh.org). The methods used in the development of this guidance have been accredited by NHS Evidence.


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## COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published guidance can be sent directly to the Faculty of Sexual & Reproductive Healthcare (FSRH) at **mail@fsrh.org.**

The FSRH is unable to respond individually to all feedback. However, the FSRH will review all comments and provide an anonymised summary of comments and responses, which are reviewed by the Clinical Effectiveness Committee and any necessary amendments made.