

Long-Acting Reversible Contraceptives Learning Package

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Learner Version

The Maternal and Child Survival Program (MCSP) is a global, United States Agency for International Development (USAID) Cooperative Agreement to introduce and support high-impact health interventions with a focus on 24 high-priority countries with the ultimate goal of ending preventable child and maternal deaths within a generation. The Program is focused on ensuring that all women, newborns and children most in need have equitable access to quality health care services to save lives. MCSP supports programming in maternal, newborn and child health, immunization, family planning and reproductive health, nutrition, health systems strengthening, water/sanitation/hygiene, malaria, prevention of mother-to-child transmission of HIV, and pediatric HIV care and treatment.

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Module 7: Hormonal Intrauterine Device (LNG-IUS) For Learners

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Module Overview for Learner

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Module 7: Hormonal Intrauterine Device (LNG-IUS)

Module Overview for Learner

Time: 10:15 hours

Module Objectives:

By the end of this module, learners will be able to:

- Explain the basic attributes of LNG-IUS, its mechanism of action, timings of insertion, effectiveness, risks, and benefits
- Assess the eligibility of potential LNG-IUS users through targeted history, physical examination, screening, and use of MEC wheel
- Load the LNG-IUS in its sterile package using the “no-touch” technique
- Insert and remove the LNG-IUS correctly using the “no-touch” technique
- Provide key post-insertion instructions, follow-up care, management of side-effects, and addressing rumors and misconceptions
- Correctly record and document the services provided for each LNG-IUS client.

Session Plans

- Session 1: Basic attributes, client assessment, follow-up care, management of side-effects, and addressing rumors and misconceptions
- Session 2: Insertion and Removal of LNG-IUS using models
- Session 3: Record keeping, documentation and clinical practice
- Session 4: Clinical Practice (continued)

Sample Schedule

Sample schedule: Four consecutive days

Day 1 (PM) (2 hrs 15 min)		Day 2 (PM) (2 hrs 40 min)		Day 3 (AM) (2 hrs 25 min)		Day 4 (PM) (2 hrs 55 min)	
Time	Session: Activity	Time	Session: Activity	Time	Session: Activity	Time	Session: Activity
5 min	One: Welcome	5 min	Two: Welcome and Recap	5 min	Three: Welcome and Recap	5 min	Four: Welcome and Recap
10 min	One: Pre test	30 min	Two: Overview of the LNG-IUS Loading and video	15 min	Three: Record keeping	120 min	Four: Pre-clinical Validation and Clinical Practice
40 min	One: Overview of LNG-IUS	30 min	Two: Review of Checklist and demonstration on the Zoe Model	100 min	Three: Pre-clinical Validation and Clinical Practice	20 min	Four: Post-clinical Practice Debrief
30 min	One: Client assessment (Demonstration)	90 min	Two: Practice on models	20 min	Three: Post-clinical Practice Debrief	15 min	Four: Summary
45 min	One: Post-insertion instructions and follow-up care, managing common side-effects & complications	5 min	Two: Summary & Closing	5 min	Three: Summary Closing	10 min	Four: Post test
5 min	One: Summary & Closing session					5 min	Four: Close session

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Pre and Post Test Questionnaire

Instructions

Write the letter of the single **BEST** answer to each question in the blank next to the corresponding number on the attached answer sheet.

Total time: 10 minutes

1. The best person to make the choice about which contraceptive method to use should be the:
 - a. Midwife
 - b. Physician providing health services to the woman
 - c. Partner
 - d. Woman herself

2. Which of the following is the most effective contraceptive method?
 - a. Condoms
 - b. Rhythm Method
 - c. LNG-IUS
 - d. Injectable (DMPA)

3. The hormonal intrauterine device contains the hormone:
 - a. Norgestrel
 - b. Levonorgestrel
 - c. Desogestrel
 - d. Etonorgestrel

4. The LNG-IUS prevents pregnancy by:
 - a. Thickening the cervical mucus
 - b. Interfering with sperm movement
 - c. Altering the lining of the uterus
 - d. All of the above

5. One of the significant characteristics of the LNG-IUS is that:
 - a. It is effective for up to 8 years
 - b. It can also shrink large myomas
 - c. It reduces menstrual blood loss
 - d. It lengthens the light menstrual period

6. Health benefits of the LNG-IUS include:
 - a. Decrease in blood glucose level
 - b. Elevation of mood
 - c. Decrease in blood cholesterol level
 - d. Potential for reduction of iron-deficiency anemia
7. When preparing to insert the LNG-IUS, the provider should:
 - a. Remove the LNG-IUS from the sterile pack before the pelvic examination
 - b. Remove the LNG-IUS from the sterile pack after the pelvic exam confirms the decision to insert
 - c. Provide a paracervical block after the pelvic examination
 - d. Check the client's vital signs before the pelvic examination
8. If a woman becomes pregnant with an LNG-IUS in place, she is more likely to:
 - a. Have increased vaginal discharge if the LNG-IUS is left in place
 - b. Have a child with birth defects
 - c. Expel the LNG-IUS after conception
 - d. Develop a uterine infection if the LNG-IUS is left in place
9. During counseling about the side-effects of the LNG-IUS, it is important to explain that:
 - a. A lighter menstrual flow pattern or no menstruation is to be expected
 - b. Cramping is a signal that the LNG-IUS should be removed
 - c. Assessing the size of uterus by a uterine sound is important
 - d. The LNG-IUS is generally free of side-effects
10. A woman who has had an LNG-IUS placed in the immediate postpartum period should have a follow-up exam:
 - a. Every month in the first year to see that the LNG-IUS is in place
 - b. Every 3 months in the first year to check for side-effects
 - c. Anytime the woman needs to talk to the provider
 - d. Annually to check the strings

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Pre and Post Test Answer Sheet

Q.1 _____

Q.2 _____

Q.3 _____

Q.4 _____

Q.5 _____

Q.6 _____

Q.7 _____

Q.8 _____

Q.9 _____

Q.10 _____

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Checklist 7-1: Long-Acting Reversible Contraceptive Methods Counseling Skills

Adapted for the Interval Period

(To be completed by the Trainer)

Place a “Y” in the case box if the step/task is performed satisfactorily, an “N” if it is not performed satisfactorily, or N/O if it is not observed

Satisfactory: Performs the step or task according to the standard procedure or guidelines

Unsatisfactory: Unable to perform the step or task according to the standard procedure or guidelines

Not Observed: Step, task, or skill not performed by learner during evaluation by trainer

Learner: _____ Activity Dates: _____

Checklist for Long-Acting Reversible Contraceptive (LARC) Methods Counseling (Interval)					
Step/Task	Cases				
General Family Planning Counseling					
1. Greets the woman respectfully and with kindness					
2. Introduces herself/himself and develops a rapport with her					
3. Ensures privacy and confidentiality					
4. Obtains biographic information (name, address, etc.)					
5. Informs the client (and partner, if present) that there will be opportunities to address both health needs and family planning needs during this consultation					
6. Asks the client about her family size, age of her last child, and her current family planning practices and experience					
7. If the client's last pregnancy was less than 2 years ago, tells her about the health benefits—for the mother and the baby—of using family planning to space at least 24–36 months from birth to the next pregnancy					
8. Uses Checklist 7-4: Pregnancy Checklist					
Counseling for All Methods					
1. Asks the woman about her reproductive goals:					
a. Does she want more children in the future?					
b. How long do she and her partner want to wait for the next pregnancy?					
c. Has she used any FP method in the past? What was her experience with the method?					
d. Is she breastfeeding a baby less than 6 months old?					
e. Does she have any FP method in mind?					
f. Will her partner support her in family planning?					
g. Does she have any medical conditions, or is she taking any medication?					

Checklist for Long-Acting Reversible Contraceptive (LARC) Methods Counseling (Interval)					
Step/Task		Cases			
2. Based on the client's responses, talks about methods that are appropriate for her: Starts showing the counseling cards or the Flip book beginning with the most effective method.					
3. Reads the back of each card or Flip book, then places it in front of the client, with the picture facing the client.					
4. Asks the client if she is interested in using any of these methods.					
5. If the client expresses an interest in using one of the LARC methods, continues with the next steps.					
6. Discusses the benefits of long-acting methods: <ul style="list-style-type: none"> a. Can be inserted anytime during the menstrual cycle after ruling out pregnancy b. Are greater than 99% effective in preventing pregnancy c. Have no impact on breastfeeding d. Can be removed when she wants another baby or has any major concerns e. Does not need any daily action. 					
7. If the client expresses an interest in using the IUD, describes the interval copper IUD (Cu IUD)/levonorgestrel intrauterine system (LNG-IUS) insertion and timing of insertion: <ul style="list-style-type: none"> a. Can be inserted anytime during the menstrual cycle (after ruling out pregnancy) b. Is effective for up to 12 years c. The IUD contains no hormones d. The LNG-IUS is effective up to 3-5 years*, contains low doses of hormones, and is safe for breastfeeding women e. Talks upfront about side-effects and changes to be expected in the bleeding patterns initially. Tells her that these are not harmful and she can come back to the provider if it is of concern to her. f. Talks about having some pain after LNG-IUS insertion specifically with nulliparous woman. Reassures that it is for short time and subsides with pain medication. <p>* Note: The effectiveness period varies with the type of LNG-IUS used. Studies to confirm the effectiveness period are ongoing.</p>					
8. If the client expresses an interest in using the contraceptive implant, describes implant insertion and timing of insertion: <ul style="list-style-type: none"> a. Can be inserted anytime during the menstrual cycle after ruling out pregnancy b. The implant is effective for up to 3-5 years (depending on the type) c. The implant contains low doses of hormones and is safe for breastfeeding women d. Talks upfront about side-effects and changes to be expected in the bleeding patterns initially. Tells her that these are not harmful and she can come back to the provider if it is of concern to her. 					
9. Asks the client if she has any questions or would like the provider to repeat the information.					

Checklist for Long-Acting Reversible Contraceptive (LARC) Methods Counseling (Interval)					
Step/Task	Cases				
10. Consults World Health Organization (WHO) Medical Eligibility Criteria (MEC) Wheel for Contraceptive Use or Job Aid 7-3: WHO MEC Quick Reference Chart to check whether the chosen method is safe for her. If not, helps her to choose another method.					
11. Confirms the client's understanding by asking open-ended questions and repeating key information about the chosen method.					
12. Allows the client to make a final decision by herself (informed choice) without any coercion					
13. Documents the family planning method chosen in the client's record card					
14. Tells the client that she can change her decision at any time and inform the provider about it					
15. Thanks the client and helps her get the method of her choice					
Systematic Screening for Other Services					
1. Asks the client when she last had a cervical and breast cancer screening, and offers to perform these if the last check was more than 3 years ago					
2. Follows national guidelines for prevention of mother-to-child transmission (PMTCT) of HIV and screening for syphilis, tetanus toxoid immunization, intermittent preventive treatment for malaria and iron/folate deficiency					
3. Discusses sexually transmitted infection (STI)/HIV transmission and prevention and dual protection with the client, using the BCS+ Counseling Cards or Flip book.					
4. Asks the client if she knows her HIV status <ul style="list-style-type: none"> a. If positive: <ul style="list-style-type: none"> i. Talk about Positive Health, Dignity, and Prevention with the client ii. Refers the client to a center for wellness care and treatment b. If the client knows that she is negative: <ul style="list-style-type: none"> i. Discusses timing for repeat testing c. If the client does not know her HIV status: <ul style="list-style-type: none"> i. Discuss HIV counseling and testing (HCT) with the client and help her get the HIV testing as per national protocols 					
5. Gives follow-up instructions, and offers condoms for dual protection					
6. Thanks the client for completing the counseling session					
Skill/Activity Performed Satisfactorily					

Trainer Certification

Learner is ☐ Qualified ☐ Not Qualified to counsel clients, based on the following criteria:

Counseling performed competently: ☐ Yes ☐ No

Trainer's Signature: _____ Date: _____

Checklist 7-2: Screening Clients Who Want to Initiate Use of the LNG-IUS

11. Have you ever been told that you have lupus?

This question is intended to identify women who have been diagnosed with systemic lupus erythematosus (SLE). If a woman with SLE also has severe thrombocytopenia, she is at an increased risk of bleeding and should usually not initiate use of an LNG-IUS.

Note: Questions 12–15 are intended to identify clients at very high individual risk/likelihood of sexually transmitted infections (STIs), because there is a possibility that they may currently have chlamydia and/or gonorrhea infection. Unless these STIs can be reliably ruled out, clients at very high individual risk are not good candidates for LNG-IUS insertion. Inserting an LNG-IUS in the presence of gonorrhea or chlamydia may increase risk of pelvic inflammatory disease (PID). These clients should be counseled about other contraceptive options and provided with condoms for STI protection. However, if other contraceptive methods are not available or acceptable, and there are no signs of STI, an LNG-IUS still can be inserted. Careful follow-up is required in such cases.

12. Within the last 3 months, have you had more than one sexual partner?

Clients who have multiple sexual partners are at very high individual risk of contracting STIs. Unless chlamydia and/or gonorrhea infection can be reliably ruled out, these clients are not good candidates for LNG-IUS insertion. (See note above regarding questions 12–15).

13. Within the last 3 months, do you think your partner has had another sexual partner?

Clients whose partners have more than one sexual partner are at very high individual risk of contracting STIs. Unless chlamydia and/or gonorrhea infection can be reliably ruled out, these clients are not good candidates for LNG-IUS insertion. In situations where polygamy is common, the provider should ask about sexual partners outside of the union. (See note above regarding questions 12–15).

14. Within the last 3 months, have you been told you have an STI?

There is a possibility that these clients currently have chlamydia and/or gonorrhea infection. Unless these STIs can be reliably ruled out, these clients are not good candidates for LNG-IUS insertion. (See note above regarding questions 12–15).

15. Within the last 3 months, has your partner been told that he has an STI, or do you know if he has had any symptoms – for example, penile discharge?

(Note: There are two parts to this question. Answering “yes” to either part or both parts of the question restricts LNG-IUS insertion). Clients whose partners have STIs may have these infections as well. Unless chlamydia and/or gonorrhea infection can be reliably ruled out, these clients are not good candidates for LNG-IUS insertion. (See note above regarding questions 12–15.)

16. Are you HIV-positive, and have you developed AIDS?

If the woman is HIV-positive but has not developed AIDS, an LNG-IUS may generally be used. However, if the woman has developed AIDS, ask whether she is taking ARVs and make sure she is doing clinically well. If she is doing

clinically well, she can have an LNG-IUS inserted. If she is not, an LNG-IUS usually is not recommended unless other more appropriate methods are not available or not acceptable. There is concern that clients with HIV who have developed AIDS and are not taking ARVs may be at increased risk of STIs and PID because of a suppressed immune system. LNG-IUS use may further increase that risk.

Pelvic Examination

17. Is there any type of ulcer on the vulva, vagina, or cervix?

Genital ulcers or lesions may indicate a current STI. While an ulcerative STI is not a contraindication for LNG-IUS insertion, it indicates that the woman is at high individual risk of STIs, in which case LNG-IUS use is not generally recommended. Diagnosis should be established and treatment provided as needed. An LNG-IUS can still be inserted if co-infection with gonorrhea and chlamydia are reliably ruled out.

18. Does the client feel pain in her lower abdomen when you move the cervix?

Cervical motion tenderness is a sign of PID. Clients with current PID should not use an LNG-IUS. Treatment should be provided as appropriate. An LNG-IUS can be inserted after treatment is complete. Provide condoms to use in the meantime.

19. Is there adnexal tenderness?

Adnexal tenderness and/or an adnexal mass is a sign of PID or a malignancy. Clients with PID or genital cancer should not use an LNG-IUS. Diagnosis and treatment should be provided as appropriate. If necessary, refer for evaluation. Provide condoms to use in the meantime.

20. Were you unable to determine the size and/or position of the uterus?

Determining size and position of the uterus is essential before LNG-IUS insertion to ensure high fundal placement of the LNG-IUS and to minimize the risk of perforation.

21. Is there purulent cervical discharge?

Purulent cervical discharge is a sign of cervicitis and possibly PID. Clients with current cervicitis or PID should not have an LNG-IUS inserted. Treatment should be provided as appropriate. An LNG-IUS can be inserted after treatment is complete. Provide condoms to use in the meantime.

22. Does the cervix bleed easily when touched?

If the cervix bleeds easily at contact, it may indicate that the client has cervicitis or cervical cancer. Clients with current cervicitis or cervical cancer should not have an LNG-IUS inserted. Treatment or referral should be provided as appropriate. Provide condoms to use in the meantime.

23. Is there an anatomical abnormality of the uterine cavity that will not allow appropriate LNG-IUS insertion?

If there is an anatomical abnormality that distorts the uterine cavity, proper LNG-IUS placement may not be possible.

Checklist for Screening Clients Who Want to Initiate Use of the LNG-IUS



Intrauterine contraceptives are among the safest and most effective options available to women including those who have not given birth, who want to space births, and those living with or at risk of HIV infection. For some women, a levonorgestrel intrauterine system (LNG-IUS) is not recommended because of the presence of certain medical conditions, such as genital or breast cancer and current cervical infection. For these reasons, women who desire to use an LNG-IUS must be screened for certain medical conditions to determine if they are appropriate candidates for the LNG-IUS.

FHI 360, with support from the U.S. Agency for International Development (USAID) and the Bill & Melinda Gates Foundation, has developed a simple checklist (see center spread) to help health care providers screen clients who were counseled about contraceptive options and made an informed decision to use an LNG-IUS. This checklist complies with the recommendations of the *Medical Eligibility Criteria for Contraceptive Use* (WHO, updated 2015). The checklist consists of 23 questions designed to identify medical conditions and high-risk behaviors that would prevent safe LNG-IUS use or require further evaluation. Clients who are ruled out because of their response to some of the medical eligibility questions may still be good candidates for an LNG-IUS if the suspected condition can be excluded through appropriate evaluation.

A health care provider should complete the checklist before inserting an LNG-IUS. In some settings the responsibility for completing the checklist may be shared — by a counselor who completes questions 1–16, and an appropriately trained health care provider who determines the answers to the remaining questions during the pelvic exam.

This checklist is part of a series of provider checklists for reproductive health services. The other checklists include the *Checklist for Screening Clients Who Want to Initiate Use of the Copper IUD*, *Checklist for Screening Clients Who Want to Initiate Combined Oral Contraceptives*, the *Checklist for Screening Clients Who Want to Initiate DMPA (or NET-EN)*, the *Checklist for Screening Clients Who Want to Initiate Contraceptive Implants*, and the *Checklist on How to be Reasonably Sure a Client is Not Pregnant*. For more information about the provider checklists, please visit www.fhi360.org.

Determining Current Pregnancy

Questions 1–6 are intended to help a provider determine, with reasonable certainty, whether a client is not pregnant. If a client answers “yes” to any of these questions, it is highly likely that she is not pregnant. An LNG-IUS should never be inserted in a woman who is pregnant, as it may result in a septic miscarriage. Note, if a client answers “yes” to question 4, an LNG-IUS can be inserted by a trained professional within the first 48 hours after the client has given birth. Otherwise, insertion should be delayed until four weeks postpartum. There is an increased risk of perforating the uterus when an LNG-IUS is inserted after 48 hours and up to four weeks postpartum.

Assessing Medical Eligibility for the LNG-IUS

7. Do you have bleeding between menstrual periods that is unusual for you, or bleeding after intercourse (sex)?

Unexplained vaginal bleeding may be a sign of an underlying pathological condition, such as genital malignancy (cancer) or infection. These conditions must be ruled out before an LNG-IUS can be inserted. If necessary, refer the client to a higher-level provider or specialist for evaluation and diagnosis. Counsel the client about other contraceptive options available and provide condoms to use in the meantime.

8. Do you currently have a blood clot in your legs or lungs?

This question is intended to identify women with known acute blood clots, not to determine whether a woman might have an undiagnosed blood clot. Women with acute blood clots in their legs or lungs usually experience symptoms that prompt them to seek health care. For this reason, they would likely be aware of the condition and would answer “yes.” Because

LNG-IUS use may make these conditions worse, answering “yes” to the question means that the woman is usually not a good candidate for an LNG-IUS. However, women with blood clots in their legs or lungs who are on established anticoagulant therapy generally can use an LNG-IUS.

9. Do you have a serious liver disease or jaundice (yellow skin or eyes)?

This question is intended to identify women who know that they currently have a serious liver disease such as severe cirrhosis, malignant liver tumors, and most benign liver tumors. Women with these conditions should usually not use an LNG-IUS, because the hormones used in an LNG-IUS are processed by the liver and may further compromise liver function. Women with other liver problems, such as acute or chronic hepatitis and focal nodular hyperplasia (a benign tumor that consists of scar tissue and normal liver cells), can use an LNG-IUS safely.

10. Have you been told that you have breast cancer or any type of cancer in your genital organs, trophoblastic disease, or pelvic tuberculosis?

This question is intended to identify women who know they have one of these conditions. Women who had or currently have breast cancer are not good candidates for an LNG-IUS because breast cancer is a hormone-sensitive tumor and LNG-IUS use may adversely affect the course of the disease. Clients with genital cancer or trophoblastic disease are at higher risk of perforation and bleeding at the time of insertion. LNG-IUS insertion in clients with current pelvic tuberculosis may lead to a higher risk of secondary infection and bleeding. If a woman has any of these conditions, she should not have an LNG-IUS inserted. Offer her other appropriate contraceptive options.

Checklist for Screening Clients Who Want to Initiate Use of the LNG-IUS

First, be reasonably sure that the client is not pregnant. If she is not menstruating at the time of her visit, ask the client questions 1–6. As soon as the client answers **YES** to *any question*, stop, and follow the instructions after question 6.

← YES	1. Did your last menstrual period start within the past 7 days?	NO
← YES	2. Have you abstained from sexual intercourse since your last menstrual period, delivery, abortion or miscarriage?	NO
← YES	3. Have you been using a reliable contraceptive method consistently and correctly since your last menstrual period, delivery, abortion or miscarriage?	NO
← YES	4. Have you had a baby in the last 4 weeks?	NO
← YES	5. Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then?	NO
← YES	6. Have you had a miscarriage or abortion in the last 7 days?	NO

If the client answered **YES** to *any one of questions 1–6*, you can be reasonably sure that she is not pregnant. Proceed to questions 7–16. However, if she answers **YES** to *question 4*, the insertion should be delayed until 4 weeks after delivery. Ask her to come back at that time.

If the client answered **NO** to *all of questions 1–6*, pregnancy cannot be ruled out using the checklist. Rule out pregnancy by other means. Give her condoms or another appropriate method to use until pregnancy can be ruled out.

To determine if the client is medically eligible to use an LNG-IUS, ask questions 7–16. As soon as the client answers **YES** to *any question*, stop, and follow the instructions after question 16.

← NO	7. Do you have bleeding between menstrual periods that is unusual for you, or bleeding after intercourse (sex)?	YES
← NO	8. Do you currently have a blood clot in your legs or lungs?	YES
← NO	9. Do you have a serious liver disease or jaundice (yellow skin or eyes)?	YES
← NO	10. Have you been told that you have breast cancer or any type of cancer in your genital organs, trophoblastic disease, or pelvic tuberculosis?	YES
← NO	11. Have you ever been told that you have lupus?	YES
← NO	12. Within the last 3 months, have you had more than one sexual partner?	YES
← NO	13. Within the last 3 months, do you think your partner has had another sexual partner?	YES
← NO	14. Within the last 3 months, have you been told you have an STI?	YES
← NO	15. Within the last 3 months, has your partner been told that he has an STI, or do you know if he has had any symptoms – for example, penile discharge?	YES
← NO	16. Are you HIV-positive, and have you developed AIDS?	YES

If the client answered **NO** to *all of questions 7–16*, proceed with the **PELVIC EXAM**.

During the pelvic exam, the provider should determine the answers to questions 17–23.

If the client answered **YES** to *any of questions 7–11*, an LNG-IUS cannot be inserted. Further evaluation of the condition is required.

If the client answered **YES** to *any of questions 12–15*, she is not a good candidate for an LNG-IUS unless chlamydia and/or gonorrhea infection can be reliably ruled out.

If she answered **YES** to the *second part of question 16* and is not currently taking ARV drugs, LNG-IUS insertion is not usually recommended. If she is doing clinically well on ARVs, the LNG-IUS may generally be inserted. HIV-positive women without AIDS generally can initiate use.

If use of an LNG-IUS is delayed or denied, offer an alternative contraceptive method.

← NO	17. Is there any type of ulcer on the vulva, vagina, or cervix?	YES
← NO	18. Does the client feel pain in her lower abdomen when you move the cervix?	YES
← NO	19. Is there adnexal tenderness?	YES
← NO	20. Were you unable to determine the size and/or position of the uterus?	YES
← NO	21. Is there purulent cervical discharge?	YES
← NO	22. Does the cervix bleed easily when touched?	YES
← NO	23. Is there an anatomical abnormality of the uterine cavity that will not allow appropriate LNG-IUS insertion?	YES

If the answer to *all of questions 17–23* is **NO**, you may insert the LNG-IUS now. If the client began her last menstrual period within the past 7 days, no additional contraceptive protection is needed. If the client began her last menstrual period more than 7 days ago, instruct her to use condoms or abstain from sex for the next 7 days. Give her condoms to use for the next 7 days.

If the answer to *any of questions 17–23* is **YES**, the LNG-IUS cannot be inserted without further evaluation. See explanations for more instructions.

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Checklist 7-3: LNG-IUS Clinical Skills

Adapted for the LNG-IUS

(To be completed by the Trainer)

Place a ☒ in case box if step/task is performed **satisfactorily**, and ☐ if it is **not** performed **satisfactorily**, or **N/O** if not observed.

- **Satisfactory:** Performs the step or task according to the standard procedure or guidelines
- **Unsatisfactory:** Unable to perform the step or task according to the standard procedure or guidelines
- **Not Observed:** Step or task or skill not performed by learner during evaluation by clinical trainer

Learner: _____ Date Observed: _____

Checklist for IUD Insertion and Removal Clinical Skills Levonorgestrel Intrauterine System (LNG-IUS)					
Step/Task	Cases				
Method-Specific Counseling					
1. Once the woman has chosen to use the LNG-IUS, assess her knowledge of the method					
2. Ensure that she knows that menstrual changes, including amenorrhea, are a common side-effect among LNG-IUS users, and are not harmful, and that the LNG-IUS does not protect against sexually transmitted infections (STIs)					
3. Describe the medical assessment required before IUS insertion, as well as the procedures for IUS insertion and removal					
4. Encourage her to ask questions. Provide additional information and reassurance, as needed.					
Skill/Activity Performed Satisfactorily					
LNG-IUS Insertion					
Client Assessment (Use: World Health Organization [WHO] Medical Eligibility Criteria [MEC] Wheel for Contraceptive Use to confirm that the woman is eligible for LNG-IUS use.)					
1. Review the client's medical and reproductive history					
2. Ensure that equipment and supplies are available and ready to use					
3. Have the client empty her bladder and wash her perineal area					
4. Help the client onto the examination table					
5. Tell the client what is going to be done, and ask her if she has any questions					
6. Wash hands thoroughly and dry them					
7. Palpate the abdomen					
8. Put clean examination gloves on both hands					

Checklist for IUD Insertion and Removal Clinical Skills Levonorgestrel Intrauterine System (LNG-IUS)					
Step/Task	Cases				
9. Inspect the external genitalia Note: <ul style="list-style-type: none"> Routinely, perform the bimanual exam first and the speculum exam second If indicated, (e.g., cervical smear, bleeding, etc.) perform the speculum exam first, followed by the bimanual examination 					
10. a. Perform a bimanual exam (see Note above)					
b. Perform a rectovaginal exam, only if indicated					
c. If a rectovaginal exam is performed, change gloves before continuing					
11. Perform a speculum exam (see Note above) Note: If laboratory testing is indicated for bleeding, cervical smear, etc., and available, take samples now					
Skill/Activity Performed Satisfactorily					
Pre-Insertion and Insertion Steps (Using the aseptic, “no-touch” technique throughout)					
1. Provide an overview of the insertion procedure. Remind her to let you know if she feels any pain (especially to nulliparous women and reassure them)					
2. Gently insert the high-level disinfected (HLD) (or sterile) speculum to visualize the cervix (if not already done), and cleanse the cervical os and vaginal wall with antiseptic twice					
3. Gently grasp the cervix with an HLD (or sterile) tenaculum and apply gentle traction					
4. Insert the HLD (or sterile) sound using the “no-touch” technique, and measure the uterine length					
5. Load the LNG-IUS in its sterile package, using the “no-touch” technique					
6. Gently apply traction on the tenaculum to straighten the alignment of the cervical canal and the uterine cavity					
7. Slide the loaded LNG-IUS insertion tube through the cervical canal until the upper edge of the flange is 1.5 cm to 2.0 cm from the cervical os					
8. Release the hold on the tenaculum					
9. Hold the inserter tube with the dominant hand and the rod with the non-dominant hand					
10. Hold the rod still and pull the inserter tube back to the edge of the second indent (bottom) of the rod					
11. Wait for 10-15 seconds for the arms of the LNG-IUS to open fully					
12. Apply gentle traction on the tenaculum before advancing the LNG-IUS up into the uterine cavity					
13. Advance the inserter tube, with the rod up into uterine cavity to the fundus, until you feel a slight resistance (the flange is at the cervical opening)					
14. Hold the rod stable with one hand and pull the inserter tube back to the ring of the rod with the other hand					
15. While holding the inserter tube, first withdraw the rod from the inserter tube and then withdraw the inserter tube 3-4 cms					
16. Use HLD (or sterile) sharp Mayo scissors to cut the LNG-IUS strings to a 3 cm to 4 cm length, while threads are still in the inserter tube					

Checklist for IUD Insertion and Removal Clinical Skills Levonorgestrel Intrauterine System (LNG-IUS)					
Step/Task	Cases				
17. Gently remove the tenaculum and place it in 0.5% chlorine solution for 10 minutes for decontamination.*					
18. Examine the cervix for bleeding; if no bleeding, gently remove the speculum					
19. Ask the client how she is feeling and begin performing the post-insertion steps					
Skill/Activity Performed Satisfactorily					
Post-Insertion Steps					
1. Before removing the gloves, place all used instruments in 0.5% chlorine solution for 10 minutes for decontamination*					
2. Properly dispose of waste materials					
3. Process gloves according to recommended infection prevention practices					
4. Wash hands thoroughly and dry them					
5. Provide post-insertion instructions Key messages for IUS users include: <ul style="list-style-type: none"> • Basic facts about her IUS (e.g., type, how long it is effective, when to replace/remove it) • No protection against STIs; need for condoms if at risk • Possible side effects • Warning signs (PAINS) (See Handout 7-1: LNG-IUS Fact Sheet for details about PAINS) • Checking for possible IUS expulsion • When to return to the clinic 					
Skill/Activity Performed Satisfactorily					
LNG-IUS Removal					
Pre-Removal Steps					
1. Ask the woman her reason for having the IUS removed					
2. Review the client's reproductive goals and the need for STI protection, and counsel her, as appropriate					
3. Determine whether she will have another IUS inserted immediately, start a different method, or neither					
4. Ensure that equipment and supplies are available and ready to use					
5. Have the client empty her bladder and wash her perineal area					
6. Help the client onto the examination table					
7. Wash hands thoroughly and dry them					
8. Put new or HLD gloves on both hands					
Skill/Activity Performed Satisfactorily					
Removal Steps					
1. Provide an overview of the removal procedure. Remind her to let you know if she feels any pain.					
2. Gently insert the HLD (or sterile) speculum to visualize the strings, and cleanse the cervical os and vaginal wall with antiseptic					
3. Alert the client immediately before you remove the LNG-IUS					

Checklist for IUD Insertion and Removal Clinical Skills Levonorgestrel Intrauterine System (LNG-IUS)					
Step/Task	Cases				
4. Grasp the LNG-IUS strings close to the cervix with an HLD (or sterile) long artery/ring forceps or Kelly forceps					
5. Apply steady but gentle traction, pulling the strings toward you, to remove the IUS. Do not use excessive force.					
6. Show the LNG-IUS to the client					
7. Dispose the LNG-IUS following safe infection prevention practices					
8. If the woman is having a new LNG-IUS inserted, insert it now, if appropriate (If she is not having a new LNG-IUS inserted, gently remove the speculum and place it in 0.5% chlorine solution for 10 minutes for decontamination*)					
9. Ask the client how she is feeling and begin performing the post-removal steps					
Skill/Activity Performed Satisfactorily					
Post-Removal Steps					
1. Before removing the gloves, place all used instruments and the LNG-IUS in 0.5% chlorine solution for 10 minutes for decontamination*					
2. Properly dispose of waste materials					
3. Process gloves according to recommended infection prevention practices					
4. Wash hands thoroughly and dry them					
5. If the woman has had a new LNG-IUS inserted, review the key messages for IUS users in post insertion step 5 (If the woman is starting a different method, provide the information she needs to use it safely and effectively [and a back-up method, if needed])					
Skill/Activity Performed Satisfactorily					

* WHO's 2016 Infection Prevention Guidelines no longer recommend soaking instruments in disinfectant prior to cleaning. Please refer to in-country guidelines for this step.

Trainer Certification

Learner is ☐ Qualified ☐ Not Qualified to deliver LNG IUS services, based on the following criteria:

Clinical Skills performed competently: **With Models** ☐ Yes ☐ No **With Clients** ☐ Yes ☐ No

Trainer's Signature: _____ **Date:** _____

Source: Adapted from Bluestone J, Chase R, Lu ER, eds. IUD Guidelines for Family Planning Service Programs: A Problem-Solving Reference Manual. Third Edition. Baltimore, MD: Jhpiego, 2006.

Checklist 7-4: Pregnancy Checklist

How to Be Reasonably Sure a Client is Not Pregnant

Before initiating a medical regimen, health care providers often need to assess whether a woman is pregnant because some medications may have side effects that are potentially harmful to the fetus. According to the World Health Organization (WHO), there is no known harm to the woman, the course of her pregnancy, or fetus if hormonal contraceptive methods are accidentally used during pregnancy. However, it is recommended that family planning providers assess whether a woman seeking contraceptive services might already be pregnant, because women who are currently pregnant do not require contraception. In addition, methods such as IUDs should never be initiated in pregnant women because doing so might lead to septic miscarriage, a serious complication.

Providers often rely on the presence of menses as an indicator that a woman is not pregnant. However, providers often see women who want to start a contraceptive method when they are between menstrual periods. Since pregnancy cannot be confirmed or ruled out with a pregnancy test until a woman has missed her period, providers often require women to wait until they menstruate and then come back for method initiation. The pregnancy checklist helps providers rule out pregnancy with reasonable certainty when women are between menstrual periods, allowing women to initiate their method of choice without a delay.

FHI 360 (formerly Family Health International) developed the checklist with support from the U.S. Agency for International Development (USAID). The checklist is based on criteria endorsed by the WHO to determine with reasonable certainty that a woman is not pregnant. Evaluation of the checklist in family planning clinics has demonstrated that the tool is very effective in correctly identifying women who are not pregnant. Furthermore, studies in Guatemala, Mali, and Senegal have shown that use of these checklists by family planning providers significantly reduced the proportion of clients being turned away due to menstrual status, and improved women's access to contraceptive services.

Although the original checklist was developed for use by family planning providers, it can be used by both clinical and nonclinical health care providers to determine whether a client is pregnant. For example, pharmacists may use this checklist when selling medications that don't require a prescription, but should be avoided during pregnancy (e.g., certain antibiotics or certain common painkillers).

This checklist is part of a series of provider checklists for reproductive health services. The six questions that comprise the pregnancy checklist are integrated into these other checklists: the *Checklist for Screening Clients Who Want to Initiate DMPA (or NET-EN)*, the *Checklist for Screening Clients Who Want to Initiate Combined Oral Contraceptives (COCs)*, the *Checklist for Screening Clients Who Want to Initiate Use of the Copper IUD*, and the *Checklist for Screening Clients Who Want to Initiate Contraceptive Implants*. For more information about the provider checklists, please visit www.fhi360.org.

Explanation of the Questions

The checklist consists of six questions that providers ask clients while taking their medical history. If the client answers "yes" to any of these questions, and there are no signs or symptoms of pregnancy, then a provider can be reasonably sure that the woman is not pregnant.

Women who are in the first seven days of their menstrual cycle or who have had a miscarriage/abortion in the past seven days are protected from unplanned pregnancy because the possibility of ovulation in these situations is extremely low. With the IUD, this period is extended to day 12 of the menstrual cycle because of the additional contraceptive effectiveness of the copper IUD. The probability of ovulation is also very low for women who are in their first four weeks postpartum. Women who satisfy the lactational amenorrhea method criteria (e.g., women who are in their first six months postpartum, are fully or nearly-fully breastfeeding, and are amenorrheic) are protected from

unplanned pregnancy because of the effects of lactational amenorrhea on the reproductive cycle. Likewise, women who consistently and correctly use a reliable contraceptive method are effectively protected from pregnancy, as are those who have abstained from sexual intercourse since their last menstrual period.

Sources:

- ¹ Technical Guidance/Competence Working Group (TG/CWG). *Recommendations for Updating Selected Practices in Contraceptive Use: Volume II*. Washington: U.S. Agency for International Development, 1997.
- ² Stanback J, Qureshi Z, Nutley T, Sekadde-Kigundu C. Checklist for ruling out pregnancy among family-planning clients in primary care. *Lancet* 1999;354(August 14):566.
- ³ Stanback, John, Diabate Fatimata, Dieng Thierno, Duarter de Morales, Cummings Stirling, and Traore Mahamadou. Ruling Out Pregnancy Among Family Planning Clients: The Impact of a Checklist in Three Countries. *Studies in Family Planning* 2005;36[4]:311–315.

How to be Reasonably Sure a Client is Not Pregnant

Ask the client questions 1–6. As soon as the client answers **YES** to *any question*, stop, and follow the instructions.

NO	1. Did your last menstrual period start within the past 7 days? *	YES
NO	2. Have you abstained from sexual intercourse since your last menstrual period or delivery?	YES
NO	3. Have you been using a reliable contraceptive method consistently and correctly since your last menstrual period or delivery?	YES
NO	4. Have you had a baby in the last 4 weeks?	YES
NO	5. Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then?	YES
NO	6. Have you had a miscarriage or abortion in the past 7 days? *	YES

* If the client is planning to use an IUD, the 7 day window is expanded to 12 days.

If the client answered **NO** to *all of the questions*, pregnancy cannot be ruled out using the checklist.[†]
Rule out pregnancy by other means. Give her condoms to use until pregnancy can be ruled out.

If the client answered **YES** to *at least one of the questions* and she is free of signs or symptoms of pregnancy, you can be reasonably sure she is not pregnant.

[†] If the client is concerned about an unintended pregnancy, offer emergency contraception if every unprotected sex act since last menses occurred within the last 5 days.

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Handout 7-1: Levonorgestrel Intrauterine System (LNG-IUS) Fact Sheet

The Levonorgestrel intrauterine system (LNG-IUS) is a type of hormone-containing intrauterine contraceptive device that is placed in the uterus to prevent pregnancy. It is made up of a “T”-shaped plastic frame and a white cylinder-shaped hormone reservoir around the vertical arm of the frame with two nylon threads at the end for removal.

The vertical stem of the system has the reservoir containing the hormone Levonorgestrel. It contains 52 mg of Levonorgestrel (LNG) and is effective for 5 years*. The LNG-IUS can be replaced if continued use is desired.

* Note: The effectiveness period varies with the type of LNG-IUS used. Studies to confirm the effectiveness period are ongoing.

Mechanism of Action

- Thickening of cervical mucus
- Interfering with sperm movement
- Thinning the lining of the uterus (making the menstrual cycle lighter)

Timing of Insertion

- At any time, if you are reasonably sure the client is not pregnant
- During the menstrual cycle
 - Within 7 days, no need for a backup method;
 - If more than 7 days, make sure she is not pregnant, and give a backup method.
- Switching from another non-hormonal method
 - Immediately, if using the method correctly and consistently; otherwise, make sure she is not pregnant. Give a backup method for 7 days.
- Switching from another hormonal method
 - If the woman is switching from an injectable contraceptive, the LNG-IUS can be inserted prior to the next scheduled injection. No backup method is needed.
- Soon after childbirth (breastfeeding or non-breastfeeding)
 - Within 48 hours of delivery, or during a cesarean section
 - If more than 48 hours, then delay until 4 weeks

- Post abortion/miscarriage
 - Immediately or within 7 days after a 1st or 2nd trimester abortion, if no infection
 - Delay after medical (non-surgical) abortion until confirmed that the uterus is completely empty
 - After taking emergency contraceptive pills (ECP), give her a backup method to start on the day she finishes taking (ECPs) until the LNG-IUS is inserted
- No monthly bleeding (amenorrhea that is not related to childbirth or breastfeeding)
 - At any time, if reasonably sure she is not pregnant; give a backup method for the first 7 days.

Note: LNG-IUS cannot be used as an emergency contraceptive

Characteristics of the LNG-IUS

- Contraceptive Effectiveness
 - Highly effective: Less than 1 pregnancy per 100 women (2 per 1,000 women) using it over the first year. Over 5 years of use, less than 1 pregnancy per 100 women (5–8 per 1,000 women)
- Effective Lifespan
 - The LNG-IUS is effective for 5 years* (depending on the type of product)
- Removal or Replacement
 - The LNG-IUS should be replaced or removed no later than the full lifespan of 5 years* (depending on the type of LNG-IUS) from the date of insertion. It can be removed any time when a woman wants, before completion of the total duration
- Return to Fertility
 - The LNG-IUS does not interfere with normal fertility after removal. The woman can become pregnant in the same menstrual cycle.

Advantages of LNG-IUS

- No constant/daily supplies needed
- No user action required
- Does not interfere with intercourse
- Rapid return to fertility
- Significantly reduces menstrual blood loss; periods become shorter, lighter, or no periods and less painful
- Approved treatment for women suffering from heavy menstrual bleeding
- More cost-effective than oral contraceptives, condoms, and injectable contraception over five years
- Long-acting and reversible
- Can be used by lactating women
- Has minimum systemic hormonal side-effects

Limitations of LNG-IUS

- Trained provider needed to insert and remove the LNG-IUS
- Pelvic examination before LNG-IUS and IUD insertion is mandatory, which is not so for other spacing methods
- May cause pain or discomfort during insertion and removal procedures
- Provide no protection from sexually transmitted infections including HIV

Side-effects

(generally not signs of a health problem; may diminish or change over time)

- Pain or cramping during menses
- Amenorrhea is more common with LNG-IUS
- Irregular and lighter menses
- Bleeding or spotting between monthly periods
- Benign ovarian cysts
- Headache, nausea, breast tenderness, acne
- Mood changes, mild depression (less common)

Health Benefits:

Helps protect against:

- Risk of pregnancy
- Potential reduction of iron-deficiency anemia due to amenorrhea or reduced menstrual blood loss.

Reduces:

- Menstrual cramps
- Pelvic pain
- Menstrual bleeding

Who can have the LNG-IUS inserted?

Safe and suitable for almost all women of all ages:

- Young adolescents and nulliparous women
- Women in the immediate postpartum or post abortion period, if not infected
- Breastfeeding women

Who should not have the LNG-IUS inserted?

Women who have the following known conditions:

- Known or suspected pregnancy
- Congenital or acquired uterine anomaly, including fibroids, that distorts the uterine cavity
- Current or recurrent PID
- Postpartum endometritis

- Post abortion sepsis
- Known or suspected uterine or cervical cancer
- Known or suspected breast cancer or other progestin-sensitive cancer, now or in the past
- Abnormal uterine bleeding
- Untreated acute cervicitis or vaginitis, including bacterial vaginosis, known chlamydial or gonococcal cervical infection, or other lower genital tract infections, until the infection is controlled
- Acute liver disease or liver tumor (benign or malignant)
- Acute venous thrombosis (Category 3) if not established on anticoagulation therapy
- A previously inserted LNG-IUS that has not been removed
- Hypersensitivity to any component of the LNG-IUS

When to return for follow-up?

A woman should return for follow up after 4 weeks of insertion **OR**
At any time, if having any concerns or side-effects related to the LNG-IUS

Warning Signs

Tell the client to return to the clinic if any of the following signs develop:

PAINS:

- Period related problems Or Pregnancy
- Acute abdominal cramping during the first three to five days after insertion (perforation)
- Infection: Fever and chills, unusual vaginal discharge, low abdominal pain (possible infection)
- Not feeling well
- String-related problems

Sources: International Contraceptive Access (ICA) Foundation. *LNG-IUS Training Manual for Family Planning*. Turku, Finland: ICA Foundation, 2004; ICA Foundation Levonorgestrel releasing (Actavis & Medicines 360) presentation 2012; Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (JHSPH/CCP) and World Health Organization (WHO). *Family Planning: A Global Handbook for Providers*. 2011 Update. Baltimore, MD, and Geneva: JHSPH/CCP and WHO, 2011.

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Handout 7-2: Infection Prevention for the IUD/LNG-IUS

Decontamination

1. After completing either an IUD/IUS insertion or removal, and while still wearing gloves, dispose of contaminated objects (gauze, cotton, and other waste items) in a properly marked leakproof container (with a tight-fitting lid) or a plastic bag.
2. Fully immerse all metal instruments in a plastic bucket containing 0.5% chlorine solution (bleach) for 10 minutes before allowing staff and cleaning personnel to handle or clean them. (This pre-wash soak kills most microorganisms, including hepatitis B [HBV] and HIV.)
3. All surfaces (such as the procedure table or the instrument stand) that could have been contaminated by blood and mucus should also be decontaminated by wiping down with chlorine solution.
4. If single-use (disposable) gloves were used, carefully remove them by inverting and then place them in the leakproof container. Deposit reusable gloves in the chlorine solution.

Cleaning and Rinsing

After decontamination, thoroughly clean the instruments with water, detergent, and a soft brush, taking care to brush all teeth, joints, and surfaces. Next, rinse the instruments well after cleaning to remove all detergent (some detergents can render chemical disinfectants inert). Dry the instruments before further processing.

High-Level Disinfection (HLD)

High-level disinfection through boiling for 20 minutes or the use of chemicals is the recommended practice. Surgical (metal) instruments and reusable gloves should be boiled for 20 minutes. Alternatively, instruments can be soaked for 20 minutes in 0.5% chlorine solution and then thoroughly rinsed with HLD water. After cooling (if boiled) or chemical disinfection, air dry instruments. These are now ready to use. Use them immediately or store for up to one week in a clean, dry, high-level disinfected container with a tight-fitting lid or cover.

Sterilization

Alternatively, instruments and reusable gloves used for IUD/LNG-IUS insertion and removal can be sterilized by autoclaving (121oC [250oF] and 106 kPa [15 lb/in2] for 20 minutes if unwrapped and 30 minutes if wrapped.

Note: Dry heat sterilization (170oC [340oF] for 60 minutes) can be used only for metal or glass instruments.

Storage

Unwrapped instruments must be used immediately. Wrapped instruments, gloves, and drapes can be stored for up to one week if the package remains dry and intact, one month if sealed in a plastic bag.

Infection Prevention Tips

IUD/LNG-IUS Insertion

To minimize the client's risk of post-insertion infection, clinic staff should strive to maintain an infection-free environment. To do this:

- Assess and exclude clients who are by history and physical examination at risk for sexually transmitted infections (STIs).
- Wash hands thoroughly with soap and water before and after each procedure or use alcohol hand rub.
- When possible, have the client wash her genital area before doing the screening pelvic examination.
- Use sterilized or high-level disinfected instruments and disposable clean examination gloves (both hands).
- After inserting the speculum and while looking at the cervix, thoroughly apply antiseptic solution at least two times to the cervix and vagina before beginning the procedure.
- Load the IUD/LNG-IUS in the sterile package using the “no-touch” technique
- Use a “no-touch” insertion technique to reduce contamination of the uterine cavity (i.e., do not pass the uterine sound or loaded IUD/LNG-IUS through the cervical os more than once).
- Properly dispose of waste material (gauze, cotton, and disposable gloves) after inserting the IUD/LNG-IUS.
- Decontaminate instruments and reusable items immediately after use by immersing them in 0.5% chlorine solution.

When these tips are followed, post-insertion infection rates are low; therefore, use of prophylactic antibiotics is not recommended.

IUD/LNG-IUS Removal

IUD/LNG-IUS removal should be performed with similar care. To minimize the risk of infection during IUD/LNG-IUS removal:

- Wash hands thoroughly with soap and water before and after each procedure.
- When possible, have the client wash her genital area before doing the screening pelvic examination.
- Use clean, high-level disinfected (or sterilized) instruments and clean (single-use) examination gloves.
- After inserting the speculum and while looking at the cervix, and before beginning the procedure, apply antiseptic solution several times to the cervix and vagina.
- Properly dispose of waste material (gauze, cotton, and the removed IUD/LNG-IUS and disposable gloves) as per guidelines.
- Decontaminate instruments and reusable items immediately after use by immersing them in 0.5% chlorine solution.

Source: McIntosh N, Kinzie B, Blouse A. *IUD Guidelines for Family Planning Service Programs: A Problem Solving Reference Manual*. Baltimore, MD: Jhpiego, 1992.

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Handout 7-3: Managing Side-Effects and Potential Complications of the LNG-IUS

Giving Advice on Side-Effects

Important: Up-front counseling about bleeding changes must come before LNG-IUS insertion. Counseling about bleeding changes may be the most important understanding a woman needs to be satisfied with the method and keep using it.

Describe the most common side-effects

Changes in bleeding patterns may occur with many possibilities that include:

No monthly bleeding (20% of women), lighter bleeding, fewer days of bleeding, infrequent or irregular bleeding

Acne, headaches, breast tenderness and pain, and possibly other minor hormonal side-effects, which are uncommon

Explain about these side-effects

- Bleeding changes are not signs of illness and may subside after the first few 3-6 months (the “adjustment period”). During the adjustment period, some women may have irregular bleeding or prolonged bleeding. These changes are not permanent.
- After adjustment period, most women experience light, regular periods, or no periods at all.
- Amenorrhea due to LNG-IUS is not harmful and dirty blood do not collect inside the body. It helps to improve your blood hemoglobin level.
- side-effects are generally mild, are localized to the uterus, and usually do not require any treatment
Hormonal
- The client can come back at any time if the side-effects bother her
- Once LNG-IUS is removed, regular periods return within a few months. It is possible to get pregnant even before periods return.

Management of Side-Effects

- Amenorrhea
 - First rule out possible pregnancy. Once it is established that she is not pregnant, you should reassure her that her reproductive system is still functioning normally and that the absence of monthly bleeding will not cause any complication.
- Irregular bleeding (bleeding at unexpected times that bothers the client)
 - For modest short-term relief: nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen 600 mg to 800 mg orally three times a day with food, twice a day, beginning when irregular bleeding starts and stopped sooner if the irregular bleeding stops sooner.

- Cramping and pain
 - Some cramping and pain is common and can be expected for the initial 1-2 days
 - Pain relievers such as paracetamol/ibuprofen can be recommended
 - If cramping continues and occurs outside of monthly bleeding: Evaluate the client for underlying health conditions or partial expulsion, or suspect uterine perforation and treat or refer. If no underlying condition is found and cramping is severe, discuss removing the LNG-IUS.

Potential Complications of the LNG-IUS

Complications	Risk	Linked to	Reduced through	Management
Perforation	Very Rare	Skill and experience of the provider	Supervised training and using the correct insertion technique	<p>Occurs during insertion and usually heals without treatment. Stop the procedure immediately and gently remove all instruments. Keep client under observation for approximately 2 hours and monitor vital signs. Look for signs of shock if she is having severe pain, fainting, rapid pulse, low blood pressure. Manage for shock immediately. If not recovering and symptoms aggravating, refer immediately to higher level facility for management and ultrasound. Advise follow-up in a week, or as needed.</p> <p>If uterine perforation is suspected within 6 weeks after insertion or if it is suspected later and is causing symptoms, such as severe pain or cramping, refer the client for evaluation and ultrasound* (if available) to a clinician experienced in removing such IUDs.</p> <p>* availability of ultrasound is not a prerequisite for the facility providing IUD insertion services.</p>
Infection	Rare	Lack of infection prevention practices during insertion	Use of aseptic technique	<p>Treat with an appropriate antibiotic; no need to remove the IUD unless no signs of improvement or if there is an abscess or sepsis.</p> <p>If diagnosis of pelvic inflammatory disease is confirmed, treat or refer immediately; give appropriate antibiotic therapy; no need to remove the IUD if she wants to continue using it.</p>
Expulsion	Rare	Provider's skill, and timing of insertion	Careful screening, examination, and insertion technique	<p>Confirm complete expulsion by speculum examination/ultrasound/X-ray. If expelled, offer her another method of her choice, or reinsert LNG-IUS if she wants.</p> <p>If the LNG-IUS is partially expelled, then examine and remove it. If removal is difficult, then refer the client to an expert for removal.</p> <p>If LNG-IUS is found outside uterus in abdomen, refer immediately for managing perforation and removal of LNG-IUS.</p> <p>Reassess the client for eligibility. If there is no obvious reason, then exclude pregnancy and do the insertion if she still wants it, or offer other methods.</p> <p>Note: Ultrasound is never recommended for confirming placement under normal conditions.</p>
Pregnancy	Rare	Undetected or partial expulsion, provider's skill	Careful screening, examination, and proper insertion technique	<p>The LNG-IUS protects well against ectopic pregnancy. In the unlikely event that a woman with the LNG-IUS becomes pregnant, however, ectopic pregnancy must always be excluded first.</p> <p>An LNG-IUS in the uterus during pregnancy increases the risk of preterm delivery or miscarriage. Remove the LNG-IUS if pregnancy is confirmed.</p>

Complications	Risk	Linked to	Reduced through	Management
Missing Thread				<p>Rule out pregnancy. Conduct speculum examination to visualize thread; if not visible, then conduct X-ray/ultrasound for localization of the LNG-IUS.</p> <p>Once pregnancy has been ruled out: Probe the cervical canal using a high-level disinfected (or sterile) long artery forceps or cyto-brush to locate the strings, and gently draw them out so that they are protruding into the vaginal canal.</p> <p>If the strings are not located in the cervical canal (or cannot be drawn out), and the woman does not want to keep the LNG- IUS, refer her for LNG-IUS removal by a specially trained provider. A specially trained provider can do an ultrasound to check whether the LNG-IUS is in place or has been expelled. If the LNG-IUS is still in place, the strings can be drawn out using a long artery forceps or alligator forceps.</p>

Sources: Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (JHSPH/CCP) and World Health Organization (WHO). *Family Planning: A Global Handbook for Providers*. 2011 Update. Baltimore, MD, and Geneva: JHSPH/CCP and WHO, 2011; International Contraceptive Access (ICA) Foundation. *LNG-IUS Training Manual for Family Planning*. Turku, Finland: ICA Foundation, 2004.

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Handout 7-4: Rumors and Misconceptions about LNG-IUS

Rumors are unconfirmed stories that are transferred from one person to another by word of mouth. In general, rumors arise when:

- An issue or information is important to people, but it has not been clearly explained.
- There is nobody available who can clarify or correct the incorrect information.
- The original source is perceived to be credible.
- Clients have not been given enough options for contraceptive methods.
- People are motivated to spread them for political reasons.

A misconception is a mistaken interpretation of ideas or information. If a misconception is imbued with elaborate details and becomes a fanciful story, then it acquires the characteristics of a rumor.

Unfortunately, rumors or misconceptions are sometimes spread by health workers who may be misinformed about certain methods or who have religious or cultural beliefs pertaining to family planning that they allow to have an impact on their professional conduct.

The underlying causes of rumors have to do with people's knowledge and understanding of their bodies, health, medicine, and the world around them. Often, rumors and misconceptions about family planning make rational sense to clients and potential clients. People usually believe a given rumor or piece of misinformation due to immediate causes (e.g., confusion about anatomy and physiology).

Methods for Counteracting Rumors and Misinformation

1. When a client mentions a rumor, always listen politely. Don't laugh.
2. Define what a rumor or misconception is.
3. Find out where the rumor came from and talk with the people who started it or repeated it. Check whether there is some basis for the rumor.
4. Explain the facts.
5. Use strong scientific facts about family planning methods to counteract misinformation.
6. Always tell the truth. Never try to hide side-effects or problems that might occur with various methods.
7. Clarify information with the use of demonstrations and visual aids.
8. Give examples of people who are satisfied users of the method (only if they are willing to have their names used). This kind of personal testimonial is most convincing.
9. Reassure the client by examining her and telling her your findings.
10. Counsel the client about all available family planning methods.
11. Reassure and let the client know that you care by conducting home visits.

Rumors or Misinformation and Facts and Realities

Rumor or Misinformation	Facts and Realities: Information to Combat Rumors
The LNG-IUS might travel through the woman's body.	Show the client a picture or a model of a uterus, and explain that the LNG-IUS usually stays in the uterus until it is removed. If it comes out by itself, it comes out through the vagina. It is very rare that LNG-IUS perforates the wall of the uterus and remains in the abdomen.
The LNG-IUS prevents pregnancy by causing an abortion.	Explain that the mechanism of action of the LNG-IUS is the inhibition of sperm motility and transfer through the cervix, thereby preventing the sperm from fertilizing the egg and inhibiting pregnancy.
Absence of bleeding with the LNG-IUS means that her ovaries stopped functioning and the woman is no longer fertile.	Absence of bleeding that occurs in some women with the LNG-IUS is caused by the local action of LNG at the level of the uterus. The functioning of the ovaries is not affected. When the system is removed, menstrual bleeding will reappear and fertility is restored.
Absence of bleeding is unhealthy, because it means that the dirty blood remains in the body.	Normally, menstrual bleeding consists of the inner lining of the uterus, the endometrium, and its vessels, that bleed away once a month as the hormones from the ovary regulate the cycle. Explain to the woman that with the LNG-IUS bleeding is scant or remains totally absent, because the local levonorgestrel in the uterus keeps the inner lining of the uterus in the resting phase, very thin. There simply is nothing to bleed away, and no dirty blood remains in the uterus. Instead, this may be beneficial as anemia is prevented and the iron stores are restored.
The LNG-IUS causes discomfort in coitus	The LNG-IUS is inside the uterus and it does not interfere with coitus. It is not possible for the partner to feel the LNG-IUS itself. However, sometimes the partner may feel the strings during intercourse. This is harmless, but if it causes discomfort for the partner, the strings can be cut shorter.
Note: The information and misconceptions below apply more directly to health workers.	
An LNG-IUS can't be inserted until 6 weeks postpartum.	The LNG-IUS can be inserted by a trained provider immediately after delivery (within 10 minutes of delivery of the placenta), or during a cesarean section, or up to 48 hours following delivery. Postpartum insertion of an LNG-IUS has been shown to be safe, effective, and convenient for women like the regular or interval IUS. Postpartum insertion appears to have a lower chance of perforation as the instrument used is blunt and uterine wall is thick just after the pregnancy. After the 48-hour postpartum period, a LNG-IUS may be safely inserted at four or more weeks postpartum. It has been shown that the LNG-IUS does not affect breast milk and can be safely used by breastfeeding women postpartum.
The LNG-IUS causes ectopic pregnancy.	There is no evidence that the use of an LNG-IUS increases the risk of an ectopic pregnancy. Clinical studies have shown that the LNG-IUS is extremely protective against ectopic pregnancies, ranking with the most effective contraceptive methods in its protection. However, if client becomes pregnant with LNG-IUS, ectopic pregnancy must be excluded.
Women who have never given birth and adolescents cannot use an LNG-IUS.	WHO carefully reviewed all of the literature before listing nulliparity and adolescent as Category 2 (generally use; some follow-up may be needed). However, women who have never been pregnant have an increased rate of expulsion.
Women infected with HIV cannot use an LNG-IUS.	IUS use appears to be safe for HIV-infected women who are well and for women with AIDS who remain well on antiretroviral treatment (ART).
LNG-IUS increases the risk of pelvic inflammatory disease (PID) and must be removed when it occurs.	Good infection prevention procedures should be practiced. Antibiotic prophylaxis should not be used routinely prior to insertion. If condition develops while using LNG-IUS, a woman can continue using it during treatment (WHO MEC).

Source: Solter C. *Intrauterine Devices (IUDs)*. Second Edition. Watertown, MA: Pathfinder International, 2008. LNG-IUS Training Manual for Family Planning (ICA Foundation), WHO MEC Wheel 2015.

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Handout 7-5: Sample Client Follow-Up Card

Front of Card

Client's Follow-Up Card
Client Full Name: _____
Last Menstrual Period: _____
Type of IUS Inserted: _____
Date of insertion: Month _____ Year _____
Provider's Signature: _____
Date of removal OR replacement: Month _____ Year _____
If you have any problem or question go to: _____

(Name and address of the nearby clinic/center. Take this card with you.)

Back of Card

Client Follow-Up Visit

Date	Reason /Complaint	Advise/Treatment Given	Provider Signature

Note: If you are experiencing any of the following warning signs, please return to your clinic immediately

- **P**eriod problems or Pregnancy
- **A**cute abdominal cramping: during the first three to five days after insertion
- **I**rregular bleeding: irregular bleeding or pain in every cycle
- **N**ot feeling well: fever and chills, unusual vaginal discharge, or low abdominal pain
- **S**tring problems: missing strings

Module 7: Hormonal Intrauterine Device (LNG-IUS)

Handout 7-6: LNG-IUS Post Insertion Follow-Up Care

Follow-up care after insertion of LNG-IUS is a vital component for ensuring client satisfaction and quality of care. It is the responsibility of the service provider to provide regular and need-based follow-up care and manage any problems experienced by the woman or observed during assessment.

Key Objectives

- Assess the woman's overall satisfaction with the IUS and address any questions or concerns she may have.
- Identify and manage potential problems
- Reinforce key messages

After the LNG-IUS insertion, a woman should be advised to return to the clinic after a month, unless she has serious problems that require emergency services. The serious problems requiring immediate care include:

- **P:** Period-related problems or pregnancy symptoms
- **A:** Abdominal pain or pain during intercourse
- **I:** Infections or unusual vaginal discharge
- **N:** Not feeling well, fever, chills
- **S:** String problems

The woman is encouraged to return anytime:

- If she is experiencing the above problems.
- If she wants the LNG-IUS to be removed, or for any reason she feels that she needs to consult a health provider.

If the woman lives far from the health facility where the insertion was done, she should be counseled and supported by the community health workers to go to the nearby health facility for follow-up care.

During a follow-up visit:

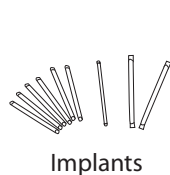
- Ask the woman about her satisfaction with the method.
- Conduct a per speculum examination to visualize the strings. Cut them shorter if the woman finds them uncomfortable or her partner feels uncomfortable.
- Reinforce the messages on warning signs and spontaneous expulsion of the IUS during the first few months.
- If the LNG-IUS has been expelled, offer the woman another contraceptive method of her choice OR reinsert the LNG-IUS if she so desires.
- Encourage use of condoms for STI protection, as appropriate.

- If the LNG-IUS is in place and the woman has no problems, no other follow-up visits are required.
- The woman should be advised to return for removal as desired or at the end of the recommended period of use.
- If the woman is not satisfied or has any of the following problems the IUS may be removed:
 - Partial expulsion
 - Infection
 - Perforation
 - Persistent uterine cramping
 - Pregnancy
 - Remind her of the date (month/year) when her LNG-IUS needs to be removed/replaced.

Comparing Effectiveness of Family Planning Methods

More effective

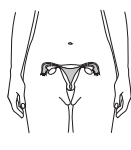
Less than 1 pregnancy per 100 women in 1 year



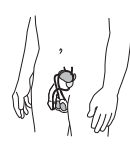
Implants



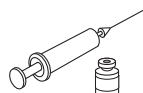
IUD



Female sterilization



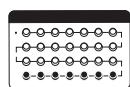
Vasectomy



Injectables



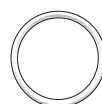
LAM



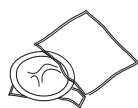
Pills



Patch



Vaginal ring



Male condoms



Diaphragm



Female condoms



Fertility awareness methods



Withdrawal



Spermicides

Less effective

About 30 pregnancies per 100 women in 1 year

How to make your method more effective

Implants, IUD, female sterilization: After procedure, little or nothing to do or remember

Vasectomy: Use another method for first 3 months

Injectables: Get repeat injections on time

Lactational amenorrhea method, LAM (for 6 months): Breastfeed often, day and night

Pills: Take a pill each day

Patch, ring: Keep in place, change on time

Condoms, diaphragm: Use correctly every time you have sex

Fertility awareness methods: Abstain or use condoms on fertile days. Newest methods (Standard Days Method and TwoDay Method) may be easier to use.

Withdrawal, spermicides: Use correctly every time you have sex



































































































































































Sources:

Steiner MJ, Trussell J, Mehta N, Condon S, Subramaniam S, Bourne D. Communicating contraceptive effectiveness: a randomized controlled trial to inform a World Health Organization family planning handbook. *Am J Obstet Gynecol* 2006;195:85–91.

World Health Organization Department of Reproductive Health and Research (WHO/RHR), Johns Hopkins Bloomberg School of Public Health (JHSPH)/Center for Communication Programs (CCP). *Family Planning: A Global Handbook for Providers*. Baltimore, MD and Geneva: CCP and WHO, 2007.

Trussell J. Choosing a contraceptive: efficacy, safety, and personal considerations. In: Hatcher RA, Trussell J, Stewart F, Nelson AL, Cates W Jr., Guest F, Kowal D, eds. *Contraceptive Technology, Nineteenth Revised Edition*. New York: Ardent Media, Inc., in press.

Job Aid 7-2: Method Effectiveness Chart

Method	If method is used consistently and correctly (<i>perfect use</i>):	If method is occasionally used incorrectly or not used (<i>typical use</i>):
Implants	less than 	less than 
IUD	less than 	less than 
Male and Female Sterilization	less than 	less than 
Injectables	less than 	     
Pills	less than 	        
Male condoms	 	                
Standard Days Method	    	         
Female condoms	    	                 
Diaphragm	     	         
Withdrawal	   	                 
Spermicides	                  	                        

If 100 Women Use a Method for One Year, How Many Will Become Pregnant?

Note: The lactational amenorrhea method (LAM) is a highly effective *temporary* method with 1 to 2 pregnancies per 100 women in the first 6 months after childbirth.

Job Aid 7-3: WHO MEC Quick Reference Chart

2016 WHO Medical Eligibility Criteria for Contraceptive Use: Quick Reference Chart for Category 3 and 4

to initiate or continue use of combined oral contraceptives (COCs), depot-medroxyprogesterone acetate (DMPA), progestin-only implants, copper intrauterine device (Cu-IUD), levonorgestral intrauterine system (LNG-IUS)

CONDITION	Sub-condition	COC	DMPA	Implants	Cu-IUD	LNG-IUS
Pregnancy		NA	NA	NA		
Breastfeeding	Less than 6 weeks postpartum					
	6 weeks to < 6 months postpartum				See i.	See i.
	6 months postpartum or more					
Postpartum not breastfeeding <small>VTE = venous thromboembolism</small>	< 21 days					
	< 21 days with other risk factors for VTE*				See i.	See i.
	≥ 21 to 42 days with other risk factors for VTE*					
Postpartum timing of insertion	≥ 48 hours to less than 4 weeks	See i.	See i.	See i.		
	Puerperal sepsis					
Postabortion (immediate post-septic)						
Smoking	Age ≥ 35 years, < 15 cigarettes/day					
	Age ≥ 35 years, ≥ 15 cigarettes/day					
Multiple risk factors for cardiovascular disease						
Hypertension <small>BP = blood pressure</small>	History of (where BP cannot be evaluated)					
	BP is controlled and can be evaluated					
	Elevated BP (systolic 140-159 or diastolic 90-99)					
	Elevated BP (systolic ≥ 160 or diastolic ≥ 100)					
	Vascular disease					
Deep venous thrombosis (DVT) and pulmonary embolism (PE)	History of DVT/PE					
	Acute DVT/PE					
	DVT/PE, established on anticoagulant therapy					
	Major surgery with prolonged immobilization					
Known thrombogenic mutations						
Ischemic heart disease (current or history of)				I C		I C
Stroke (history of)				I C		
Complicated valvular heart disease						
Systemic lupus erythematosus	Positive or unknown antiphospholipid antibodies					
	Severe thrombocytopenia		I C		I C	

Source: Adapted from *Medical Eligibility Criteria for Contraceptive Use, 5th Edition*. Geneva: World Health Organization, 2015.
Available: http://www.who.int/reproductivehealth/publications/family_planning/en/index.html

- Category 1** There are no restrictions for use.
- Category 2** Generally use; some follow-up may be needed.
- Category 3** Usually not recommended; clinical judgment and continuing access to clinical services are required for use.
- Category 4** The method should not be used.

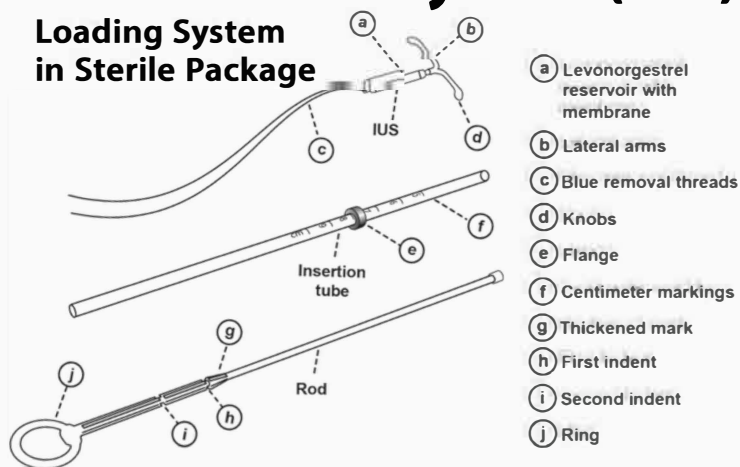
CONDITION	Sub-condition	COC	DMPA	Implants	Cu-IUD	LNG-IUS
Headaches	Migraine without aura (age < 35 years)	I C				
	Migraine without aura (age ≥ 35 years)	I C				
	Migraines with aura (at any age)		I C	I C		I C
Unexplained vaginal bleeding (prior to evaluation)					I C	I C
Gestational trophoblastic disease	Regressing or undetectable β-hCG levels					
	Persistently elevated β-hCG levels or malignant disease					
Cancers	Cervical (awaiting treatment)				I C	I C
	Endometrial				I C	I C
	Ovarian				I C	I C
Breast disease	Current cancer					
	Past w/ no evidence of current disease for 5 yrs					
Uterine distortion (due to fibroids or anatomical abnormalities)						
STIs/PID	Current purulent cervicitis, chlamydia, gonorrhea				I C	I C
	Current pelvic inflammatory disease (PID)				I C	I C
	Very high individual risk of exposure to STIs				I C	I C
Pelvic tuberculosis					I C	I C
Diabetes	Nephropathy/retinopathy/neuropathy					
	Diabetes for > 20 years					
Symptomatic gall bladder disease (current or medically treated)						
Cholestasis (history of related to oral contraceptives)						
Hepatitis (acute or flare)		I C				
Cirrhosis (severe)						
Liver tumors (hepatocellular adenoma and malignant hepatoma)						
AIDS	No antiretroviral (ARV) therapy	See ii.	See ii.	See ii.	I C	I C
	Not improved on ARV therapy				I C	I C
Drug interactions	Rifampicin or rifabutin					
	Anticonvulsant therapy **					

This chart shows a complete list of all conditions classified by WHO as Category 3 and 4. Characteristics, conditions, and/or timing that are Category 1 or 2 for all methods are not included in this chart (e.g., menarche to < 18 years, being nulliparous, obesity, high risk of HIV or HIV-infected, < 48 hours and more than 4 weeks postpartum).

- I/C** Initiation/Continuation: A woman may fall into either one category or another, depending on whether she is initiating or continuing to use a method. Where I/C is not marked, the category is the same for initiation and continuation.
- NA** Not Applicable: Women who are pregnant do not require contraception. If these methods are accidentally initiated, no harm will result.
- i** The condition, characteristic and/or timing is not applicable for determining eligibility for the method.
- ii** Women who use methods other than IUDs can use them regardless of HIV/AIDS-related illness or use of ART.
- *** Other risk factors for VTE include: previous VTE, thrombophilia, immobility, transfusion at delivery, BMI > 30 kg/m², postpartum hemorrhage, immediately post-caesarean delivery, pre-eclampsia, and smoking.
- **** Anticonvulsants include: phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, and lamotrigine. Lamotrigine is a category 1 for implants.

Intra-Uterine System (IUS)¹

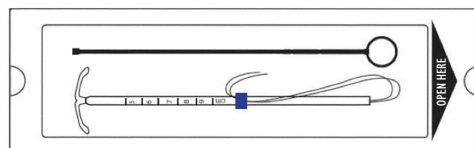
Loading System in Sterile Package



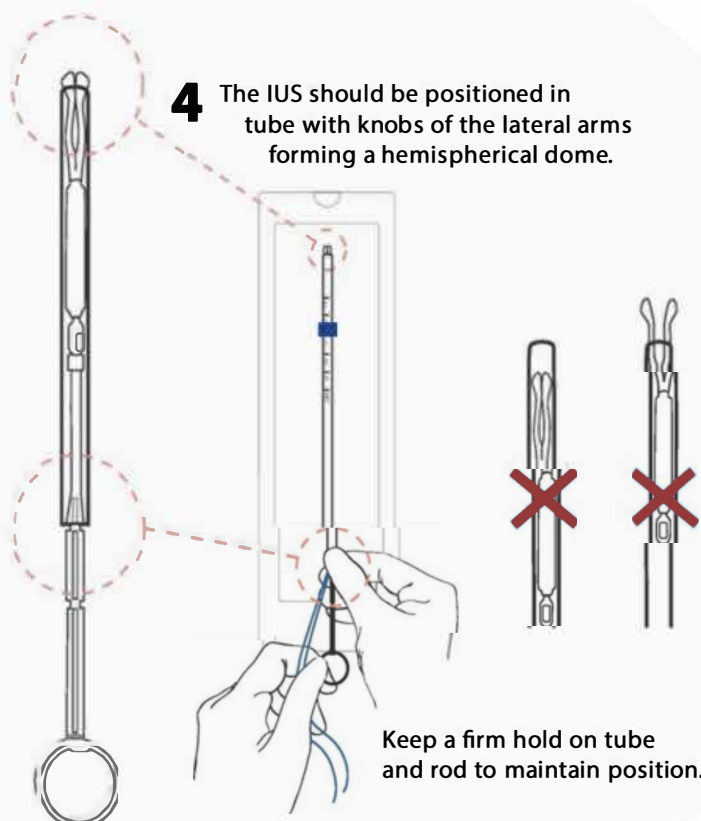
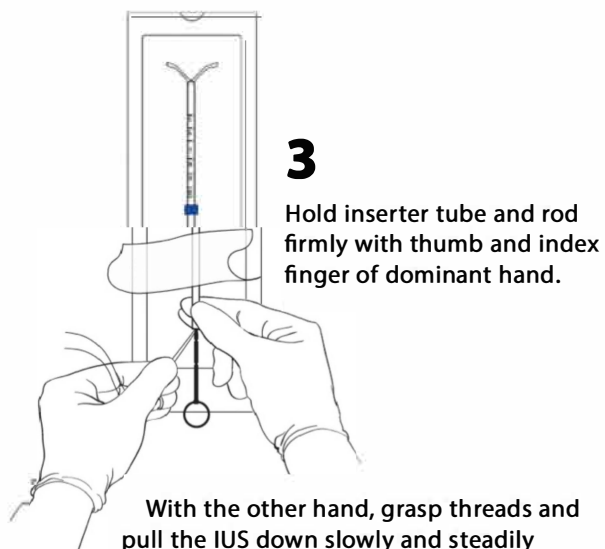
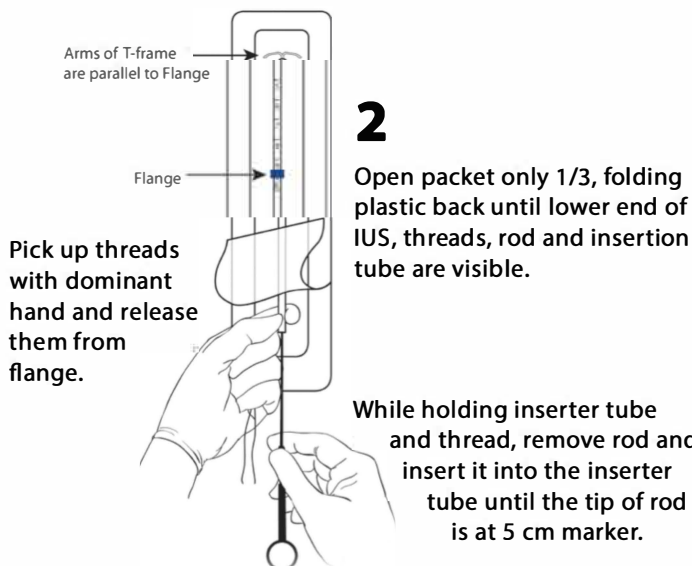
Maternal and Child
Survival Program



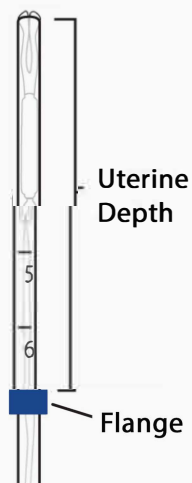
USAID
FROM THE AMERICAN PEOPLE



1 Place IUS packet on a flat surface and open from bottom.



5 Set blue flange to measurement of uterus through the sterile package and ensure it is parallel to the arms of IUS.



6 Maintain a FIRM HOLD at the bottom of insertion tube and remove loaded IUS insertion tube from packet.

