STANDARD APRN PROTOCOL FOR
IUD INSERTION: Levonorgestrel (LNG) Releasing Intrauterine System®

DEFINITION

The **LNG**-releasing intrauterine systems (Mirena®, **Liletta®** and Skyla®) are on the market. The **LNG**-releasing system consists of a small T-shaped frame with a steroid reservoir that contains levonorgestrel, a potent progestin found in many combination oral contraceptives, progestin-only pills, and implants.

The **LNG** intrauterine system releases a low dose of **LNG** into the uterine cavity, a system similar to that of **LNG** implants or **LNG**-containing mini-pills. As with these methods, thickening the cervical mucus and inhibition of ovulation, sperm motility and function are considered the primary means of preventing pregnancy. A weak foreign-body effect is also noted which could decrease implantation. Unlike the copper IUD, the **LNG** IUD is not approved for use as emergency contraception.

SUBJECTIVE

1. Desires an IUD for long-term contraception.

2. Not at high risk for sexually transmitted infections.

3. Has detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the *CDC Medical Eligibility Criteria for Contraceptive Use.* Conditions that present an unacceptable health risk for use of the LNG IUD include:
   a. Unexplained vaginal bleeding, suspicious for serious underlying condition, before evaluation.
   b. Postpartum metritis
   c. Immediately post septic abortion
   d. Current PID or within the past 3 months
   e. Current purulent cervicitis or chlamydial or gonorrhea infection
   f. AIDS
   g. Uterine anomalies that distort the endometrial cavity
   h. Cervical or endometrial cancer waiting to be treated
   i. Gestational trophoblastic disease
   j. Lupus with positive or unknown antiphospholipid antibodies
   k. Breast cancer
   l. Cirrhosis – severe (decompensated)
   m. Liver Tumors – benign hepatocellular adenoma; malignant (hepatoma)Pelvic tuberculosis
   n. Pelvic tuberculosis
   o. Complicated solid organ transplantation: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy.

4. Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk if they develop while using the **LNG**-releasing intrauterine system. Women with these conditions may initiate the implant. However, if women who did not have these conditions at the time of initiation develop these conditions after using the implant, the implant should not be continued. Medical conditions include:
   a. Migraines with aura
   b. Ischemic heart disease
   c. Stroke

5. May desire lighter periods or no periods at all

OBJECTIVE

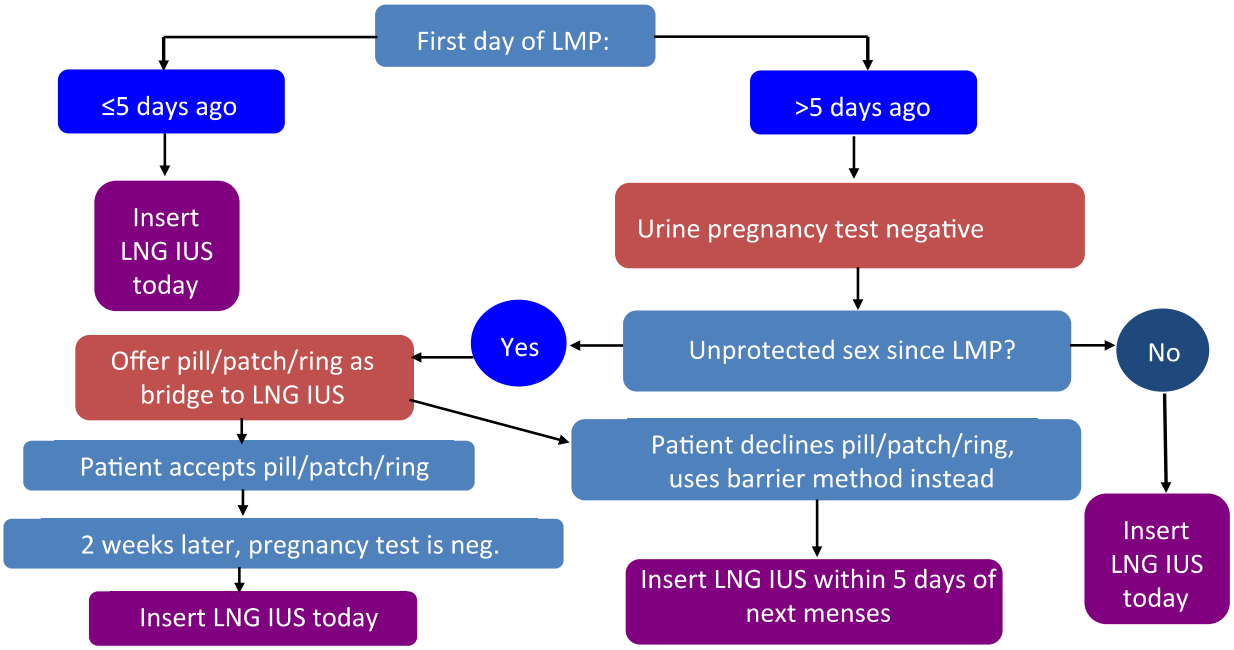
1. Physical examination and laboratory tests **as indicated**. See protocol for Preventative Care and Health Screening.

2. **Pelvic** exam must be completed

3. **No pelvic exam findings that are contraindications to placement at the time of insertion**.

4. Follow the algorithm below for initiation. If switching from a hormonal method, may do so at any time when the patient has been consistently using the method.

Timing of Insertion for LNG IUS



Hatcher RA et al. *A Pocket Guide to Managing Contraception*. 2005.

ASSESSMENT Patient has no condition representing an unacceptable risk if using a **LNG** IUD. **Not allergic to any component of the IUD**.

PLAN **DIAGNOSTIC STUDIES**

1. Negative pregnancy test at the time of insertion.

2. Laboratory tests:
   a. Negative gonorrhea and chlamydia tests, if indicated. Tests may be performed on the day of placement, and the woman can return for treatment (if necessary). Clarification on this comes from the CDC's Selected Practice Recommendations: Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at http://www.cdc.gov/std/treatment).
   b. If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed.

c. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occur.

c. Wet mount, if indicated. **NOTE**: Trichomonas, yeast and BV are not contraindications to IUD placement. Clinicians may diagnose, treat, and place an IUD on the same day.

THERAPEUTIC

PHARMACOLOGIC

Handling and disposal Note: Hazardous agent; use appropriate precautions for handling and disposal (NIOSH 2014 [group 2]).

1. May encourage an over-the-counter (OTC) non-steroidal anti-inflammatory agent 30-60 minutes before the procedure to reduce discomfort.

2. Insert **LNG** IUD per manufacturer's directions.

3. **In women not using hormonal contraception**, may be inserted any time in the cycle as long as pregnancy has been ruled out. **If not inserted during the first 7 days of the menstrual cycle, a barrier method should be used for 7 days.**

4. **Switching from an oral, transdermal, or vaginal hormonal contraceptive,** may be inserted any time in the cycle as long as pregnancy has been ruled out.

5. **If inserted during active use of the previous method, continue the previous method for 7 days or until the end of the current cycle.**

6. **If using continuous hormonal contraception, discontinue the method 7 days after insertion.**

7. **Switching from an injectable progestin contraceptive**, may be inserted any time in the cycle as long as pregnancy has been ruled out. **A barrier method should be used for 7 days if inserted more than 13 weeks after the last injection**.

8. **Switching from an implant or another IUD**, may be inserted any time in the cycle as long as pregnancy has been ruled out. **Insert on the same day that removal of the implant or other IUD occurs**.

9. **After Childbirth may be inserted within 10 minutes following delivery of the placenta or within 7 days following a spontaneous induced abortion; do not insert if puerperal sepsis or septic abortion is present. If IUD had not been placed immediately postpartum and patient desires an IUD postpartum for contraception, wait a minimum of 6 weeks after delivery or until the uterus is fully involuted and pregnancy is ruled out.**

10. **If lactating, there appears to be an increased risk of perforation.**

11. Mirena® releases 20mcg per day initially then declines and is approved for use for 5 years

12. Skyla® releases 14 mcg per day initially then declines and is approved for use for 3 years

13. **Liletta® releases 18.6 mcg per day initially then declines and is approved for 3 years**

    NOTE: Before insertion, the patient must read and sign the consent form if provided by the manufacturer in addition to the program's method specific consent form.

14. The provider should fill out the IUD **Insertion** Procedure Note as indicated.

NON-PHARMACOLOGIC MEASURES

1. Take precautions to avert a vasovagal reaction (syncope/ fainting) caused by uterine manipulation and sounding. After IUD insertion, allow the patient to lie still for at least 30 seconds (while explaining how to check for strings).

Ask about pain or cramping. If the patient says she feels okay, have her sit up slowly while being supported. If no problems in 30 seconds, allow her to stand.

2. Treat signs of vasovagal reaction (pallor/cyanosis, pinched-face look, dilated pupils, weak and rapid pulse, rapid shallow breathing, hypotension) according to the Emergency Guidelines, Policies and Procedures section **of the protocol** manual.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to seven basic elements of informed consent (BRAIDED – Benefits Risks Alternatives Inquiries Decision Explanation Documentation).

2. Discuss checking for IUD strings.
   a. The IUD can be expelled without being noticed, and the package insert suggests that women check for the strings monthly. However, checking for the strings has not been shown to add to optimal use of the IUD. If a patient feels reassured by checking the strings, she may do so. However, she should not be instructed that this practice is necessary.
   b. If the patient does check for her strings routinely and cannot feel the strings, or if the plastic part is felt, use another method of contraception and return to the clinic.
   c. Women who had an IUD placed immediately postpartum may require a string trim when they present for postpartum follow-up.
   d. Most likely cause of IUD failure is expulsion with risk highest during the first year, particularly within the first 3 months after insertion.

3. Review warning signs and symptoms of possible problem: abdominal pain, vaginal discharge, pain with intercourse, missing string, pregnancy symptoms, heavy bleeding.

4. There is a small increased risk of PID, which is most likely to occur within the first 2-3 weeks after insertion. Patient should be instructed to return for signs and symptoms of infection.

5. Discuss common side effects:
   a. 1 to 4 months: may have frequent spotting
   b. After 3- 6 months: reduced duration and amount of bleeding.

c. Overall 90% reduction in menstrual bleeding.
d. After 12 months, about 20% of women have no bleeding.
e. The patient should keep a menstrual record and report a sudden change in menses or suspected pregnancy immediately.
f. The Mirena system is the only one approved by FDA to reduce dysmenorrhea and leads to a significant reduction in the amount and length of bleeding.
g. As with other progestin-only methods, persistent ovarian follicles can occur. They do not require treatment or removal of the LNG system, and they usually resolve spontaneously. However, regular follow-up by ultrasound is recommended until cysts disappear.
h. Give patient copy of LNG system post-insertion instructions.

6. Take over-the-counter ibuprofen or naproxen sodium per package directions if needed for discomfort.

7. Should strongly consider adding condoms for STD protection if patient is at risk for STDs (multiple partners, partner with multiple partners).

8. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit) **http://www.fpm.emory.edu/preventive/research/projects/**

9. Use condoms to reduce the risk of STD, including HIV.

10. The Mirena is approved for use for 5 years, however clinical data affirms its effectiveness for up to 7 years. This information can be used when counseling patients who have used their IUD for 5 years. If the patient would like to continue using it, evidence indicates that it still provides excellent contraception through 7 years. If she would like to have it removed, this should be honored. **Liletta is currently approved for three years, but studies are currently ongoing for evaluating use up to seven years.**

11. Some drugs or herbal products may decrease the serum concentration of LNG, please advise to check with a health care professional for potential interactions.

FOLLOW-UP

1. Outside of clinic hours, seek physician or emergency care if warning signs develop.

2. Re-examine and evaluate the patient shortly after the first post-insertion menses, but no later than three months afterwards.

3. If evidence of pelvic inflammatory disease, see Nurse Protocol for Pelvic Inflammatory Disease (PID). IUD removal is not necessary unless no improvement after 2-3 days of antibiotic treatment.

4. If pregnancy occurs, counsel patient that IUD should be removed at time of diagnosis whether pregnancy is continued or terminated.

5. After **the IUD has been in for the FDA-approved length of time**, check with manufacturer regarding possible approval for a longer time.

CONSULTATION/REFERRAL

1. Difficult IUD insertion or removal.

2. Suspected uterine or ectopic pregnancy.

3. To MD for IUD removal if pregnant.

4. Other complications related to IUD use.

5. Presence of actinomyces on Pap smear report with evidence of pelvic infection.

REFERENCES

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