Step-by-Step Insertion Instructions
Please read these instructions carefully and please visit LILETTAHCP.com for the full Prescribing Information. You may also visit LILETTAHCP.com/video for a video demonstration.

**NOTE:** LILETTA demonstration IUS is reloadable.

For complete insertion instructions, please refer to the full Prescribing Information for LILETTA at LILETTAHCP.com. Follow the instructions exactly as described to ensure proper insertion. Use aseptic technique during the entire insertion procedure.

First, get to know the LILETTA IUS with inserter:

A Levonorgestrel reservoir with membrane
B Lateral arms
C Blue removal threads
D Knobs
E Flange
F Centimeter markings
G Thickened mark
H First indent (top)
I Second indent (bottom)
J Ring

Please see Important Safety Information on last page of this guide. Please visit LILETTAHCP.com for the full Prescribing Information.
### Items for insertion

The following tools are needed for insertion of LILETTA and should be available before starting the procedure:

- Gloves
- Speculum
- Sterile uterine sound
- Sterile tenaculum
- Antiseptic solution

- LILETTA with inserter in sealed pouch
- Sterile, blunt-tipped scissors

Additional items that may be helpful during insertion could include:

- Local anesthesia, needle, and syringe
- Os finder and/or cervical dilators
- Ultrasound with abdominal probe

### Preparation for insertion

- With the patient comfortably in the lithotomy position, do a bimanual exam to establish the size, shape, and position of the uterus to evaluate any signs of uterine infection
- Gently insert a speculum to visualize the cervix
- Thoroughly cleanse the cervix and vagina with antiseptic solution
- Administer cervical anesthetic, if needed
- Apply a tenaculum to the cervix and use gentle traction to align the cervical canal with the uterine cavity. If the uterus is retroverted, it may be more appropriate to grasp the lower lip of the cervix. Keep the tenaculum in position and maintain gentle traction on the cervix throughout the insertion procedure

#### Sounding the uterus

Carefully sound the uterus to measure its depth

- The uterus should sound to a depth of at least 5.5 cm. Insertion of LILETTA into a uterine cavity that sounds to less than 5.5 cm may increase the incidence of expulsion, bleeding, pain, perforation, and possibly pregnancy. LILETTA should not be inserted if the uterus sounds to less than 5.5 cm

- If you encounter cervical stenosis at any time during uterine sounding or LILETTA insertion:
  
  - Use cervical dilators, not force, to overcome resistance
  - If necessary, dilation, sounding, and insertion may be performed with ultrasound guidance

- After ascertaining that the patient is appropriate for LILETTA, open the pouch containing LILETTA

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Place the LILETTA™ pouch on a flat surface and open from the bottom

- Open the sterile LILETTA pouch from the bottom (end with the rod ring) approximately one-third of the way until the lower ends of the threads, the rod, and the insertion tube are exposed
- If using sterile gloves, you can open the pouch completely before putting on the sterile gloves

Release the threads from the flange and insert the rod

- Pull back the blue threads to dislodge them from the flange. Be careful to not pull the IUS down at the same time
- Hold the exposed end of the insertion tube containing the IUS and threads with HAND B while keeping the end of the insertion tube with the IUS inside the packaging
- Remove the rod from the pouch with HAND A. Do not touch the end of the rod that will go into the insertion tube
- With HAND A, place the rod into the insertion tube (alongside the IUS threads) to about the 5 cm marking

Note: Instructions employ a right-handed method.

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3 Load the IUS into the inserter

- While holding the insertion tube and the rod firmly between your fingers and your thumb of HAND A, pull downward on both blue threads with HAND B to draw the IUS into the insertion tube.
- The arms of the IUS should be kept in a horizontal plane, parallel to the flat side of the flange.
- Do not pull the IUS all of the way through the insertion tube; only pull the thread until the IUS is loaded at the top of the insertion tube. 
  Note: If you accidentally remove the IUS completely out of the insertion tube, do not use or attempt to re-load.

4 Once loaded, pinch to maintain position and adjust the flange to the uterine depth

- MAINTAIN FIRM PINCH of the insertion tube and rod with HAND A.
- With the other hand, adjust the position of the flange (through the sterile packaging if not using sterile gloves) by moving the tube to correspond to the sound measurement.
- The top end of the flange should be at the measurement corresponding to the sounded depth of the uterus.

To maintain position after loading the IUS, firmly pinch and hold with HAND A at the bottom end of the insertion tube where it meets the rod.

Adjust the position of the flange (through the sterile packaging if not using sterile gloves) to correspond to the sound measurement.

Uterine depth

Please see Important Safety Information on last page of this guide. Please visit LILETTAHCP.com for the full Prescribing Information.
Final IUS positioning

- Position the IUS in the tube so that the knobs of the lateral arms are opposed to each other and protrude slightly above the tip of the insertion tube to form a hemispherical dome.
- When the IUS tips are in the correct position, PINCH AND HOLD the bottom end of the tube FIRMLY to maintain rod position.
- The proximal end of the insertion tube will be approximately at the top of the first indent on the rod.
- Maintain a FIRM PINCH with HAND A at the bottom of the insertion tube and remove the loaded IUS insertion tube from the pouch.

Check that the IUS is correctly loaded

- The IUS is completely within the insertion tube with the knobs of the arms forming a hemispherical dome at the top of the tube.
- The top of the rod is touching the bottom of the IUS.
- The blue threads are hanging through the end of the insertion tube.
- The flange is marking the length of the uterus based on pre-insertion sounding.

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7 Insert IUS into the uterus

- Maintain a FIRM PINCH with HAND A at the bottom of the insertion tube
- With HAND B, apply gentle traction on the tenaculum to straighten the alignment of the cervical canal with the uterine cavity
- Slide the loaded insertion tube through the cervical canal until the upper edge of the flange is approximately 1.5 cm-2 cm from the cervix

**STOP, DO NOT** advance flange to the cervix at this step

8 Deploy the IUS

- Hold the insertion tube with the fingers of HAND A and the rod with the fingers of HAND B
- HOLD THE ROD STILL with HAND B
- Relax the firmness of the pinch on the tube, AND PULL THE INSERTION TUBE BACK with HAND A to the edge of the second (bottom) indent of the rod
- Wait 10-15 seconds for the arms of the IUS to fully open
- Release hold on the tenaculum

Please see Important Safety Information on last page of this guide. Please visit LILETTAHCP.com for the full Prescribing Information.
**Advance IUS to fundus**

- Apply gentle traction with tenaculum before advancing IUS. With HAND A still holding the bottom end of the tube, gently advance both the insertion tube and rod simultaneously up to the uterine fundus.
- You will feel slight resistance when the IUS is at the fundus.
- The flange should be touching the cervix when the IUS reaches the uterine fundus.

**Release the IUS and withdraw the inserter**

- Hold the rod still with HAND B while pulling the insertion tube back with HAND A to the ring on the rod.
- While holding the inserter tube with HAND A, withdraw the rod from the insertion tube **all of the way out** to prevent the rod from catching on the knot at the lower end of the IUS.
- Completely remove the insertion tube.
- Removing the rod first and then the tube prevents the IUS from being pulled out of the uterus.

*Note: Ensure the insertion tube is held firmly in place until the rod is completely pulled outside of the tube as there will be some slight resistance while removing the rod from the tube.*
Cut the threads

- Use blunt-tipped sharp scissors to cut the IUS threads perpendicular to the thread length, leaving about 3 cm outside of the cervix. Cutting threads at an angle may leave sharp ends.
- Do not apply tension or pull on the threads when cutting to prevent displacing the IUS.

Insertion of LILETTA™ is now complete

- Keep a copy of the consent form and LILETTA lot number for your records.
- Counsel the patient on what to expect following LILETTA insertion. Give her the Patient Information Booklet and website address (www.LILETTA.com) to assist with registration for sign-up reminders and product information.
- Discuss expected bleeding patterns with LILETTA use. Review the signs and symptoms of LILETTA expulsion.
- Prescribe analgesics, if indicated.

Important information to consider during and after insertion

If you suspect the IUS is not in the correct position:

- Check insertion with an ultrasound or other appropriate radiologic test.
- If incorrect insertion is suspected, remove LILETTA.
- A removed LILETTA must not be re-inserted.

If insertion is difficult because the uterus cannot be appropriately instrumented, the following measures can be considered:

- Use of cervical anesthesia to make sounding and manipulation more tolerable.
- Use of dilators to dilate the cervix if needed to allow passage of the sound.
- Abdominal ultrasound guidance during dilation and/or insertion.
- If there is clinical concern, exceptional pain, or bleeding during or after insertion, take appropriate steps, such as physical examination and ultrasound, immediately to exclude perforation.

Timing of removal of LILETTA IUS

- LILETTA can be removed at any time.
- If pregnancy is not desired, a contraceptive method should be started prior to removal of LILETTA.
- Counsel your patient that if she has intercourse the week prior to removal without a backup contraceptive method, she is at risk of pregnancy.
- LILETTA should not remain in the uterus after 3 years. LILETTA can be replaced at the time of removal with a new LILETTA if continued contraceptive protection is desired.

Please see Important Safety Information on last page of this guide. Please visit LILETTAHCP.com for the full Prescribing Information.
Removal instructions

Items for removal
Ensure all needed items for LILETTA™ removal are readily available:

- Gloves
- Speculum
- Sterile forceps

Additional items that may be required could include:

- Local anesthetic, needle, syringe
- Os finder and/or cervical dilators
- Ultrasound with abdominal probe
- Sterile tenaculum
- Antiseptic solution
- Long, narrow forceps* (eg, Alligator forceps)

*Alligator forceps  *Packing forceps  *Ring forceps

Removal process

- Remove LILETTA by applying gentle traction on the threads with forceps
- If the threads of LILETTA are not visible or if it cannot be removed with traction on the threads, perform an ultrasound examination to confirm location, including assessment for partial or total perforation
- If LILETTA is in the uterine cavity, use a long, narrow forceps to grasp it
  - Consider use of a tenaculum, cervical anesthesia, cervical dilators, and/or ultrasound guidance as needed
- If the IUS cannot be removed using the above techniques, consider:
  - Referral to a Family Planning specialist
  - Hysteroscopic removal
- If the IUS is not in the uterine cavity consider:
  - Abdominal x-ray or CT scan to evaluate if the IUS is in the abdominal cavity
  - Laparoscopic evaluation for removal, as clinically indicated

Please see Important Safety Information on last page of this guide. Please visit LILETTAHCP.com for the full Prescribing Information.
**Continuation of contraception after removal**

- If pregnancy is not desired and if a woman wishes to continue using LILETTA, a new system can be inserted immediately after removal at any time during the cycle.

- If a patient with regular cycles wants to start a different birth control method, time the removal and initiation of the new method to ensure continuous contraception. Either remove LILETTA during the first 7 days of the menstrual cycle and start the new method or start the new method at least 7 days prior to removing LILETTA if removal is to occur at other times during the cycle.

- If LILETTA is removed but no other contraceptive method has already been started, the new contraceptive method can be started on the day LILETTA is removed. The patient should use a backup barrier method of contraception or abstain from vaginal intercourse for 7 days to prevent pregnancy.
**LILETTA™ IMPORTANT SAFETY INFORMATION**

**Who is not appropriate for LILETTA**

Use of LILETTA is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity; known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; known or suspected uterine or cervical neoplasia; liver disease, including tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in the past 3 months; unexplained acute cervicitis or vaginitis (eg, with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of LILETTA.

**Clinical considerations for use and removal of LILETTA**

Use LILETTA with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing the intrauterine system if these or the following arise during use: uterine or cervical malignancy or jaundice. If LILETTA is displaced (eg, expelled or perforated the uterus), remove it.

**Pregnancy related risks with LILETTA**

If pregnancy should occur with LILETTA in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal or manipulation may result in pregnancy loss. Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with LILETTA. Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

**Educate her about PID**

IUDs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. Inform women about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death. PID is often associated with sexually transmitted infections (STIs); LILETTA does not protect against STIs, including HIV.

**Expect changes in bleeding patterns with LILETTA**

Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months. Periods may become shorter and/or lighter thereafter. Cycles may remain irregular, become infrequent, or even cease. Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation.

**Be aware of other serious complications and most common adverse reactions**

Some serious complications with IUDs like LILETTA are expulsion, sepsis, and perforation. Perforation may reduce contraceptive efficacy. The risk of perforation is higher if inserted in lactating women and may be higher if inserted in women who are postpartum or when the uterus is fixed retroverted.

Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent ovarian cysts.

In the clinical trial of LILETTA the most common adverse reactions (≥5% users) were vaginal infections (13.6%), vulvovaginal infections (13.3%), acne (12.3%), headache or migraine (9.8%), nausea or vomiting (7.9%), dyspareunia (7.0%), abdominal pain or discomfort (6.8%), breast tenderness or pain (6.7%), pelvic discomfort or pain (6.1%), depression or depressed mood (5.4%), mood changes (5.2%).

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Evaluate patients 4 to 6 weeks after insertion of LILETTA and then yearly or more often if clinically indicated.

Please visit LILETTAHCP.com for the full Prescribing Information.