Updated inserter designed with HCPs in mind

A Quick Reference Guide for

LILETTA® INSERTION

Inside you will find key points and images from A Healthcare Professional's Reference for Preparing and Inserting LILETTA.

IMPORTANT: Use this refresher sheet only as a reminder.

For complete insertion instructions, refer to the full Prescribing Information inside the LILETTA Intrauterine System (IUS) Demonstration Kit

To see a demonstration video, go to LILETTAhcp.com/resources

INDICATIONS

LILETTA® is a sterile, levonorgestrel-releasing intrauterine system indicated for prevention of pregnancy for up to 8 years; replace after 8 years if continued use is desired. LILETTA is indicated for the treatment of heavy menstrual bleeding (HMB) for up to 5 years in women who choose intrauterine contraception as their method of contraception; replace after 5 years if continued HMB treatment is needed.

IMPORTANT SAFETY INFORMATION

Who is not appropriate for LILETTA

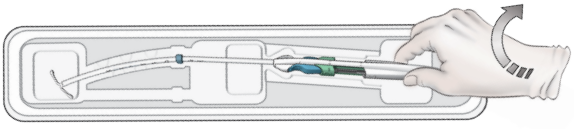
Use of LILETTA is contraindicated in women with the following: pregnancy; for use as post-coital contraception; congenital or acquired uterine anomaly, including leiomyomas, that distorts the uterine cavity and would be incompatible with correct intrauterine system (IUS) placement; known or suspected breast cancer or other hormone-sensitive cancer, now or in the past; known or suspected uterine or cervical malignancy; acute liver disease or liver tumor; 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 uterine bleeding; a current IUS; acute pelvic inflammatory disease (PID); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of LILETTA.

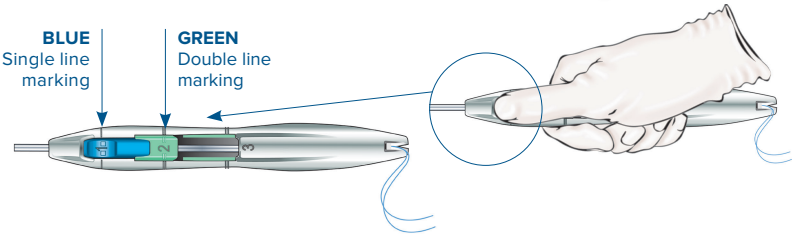
Please see Important Safety Information throughout and click here for full Prescribing Information.

Liletta®
(levonorgestrel-releasing intrauterine system) 52 mg

STEP 1 | Loading LILETTA® Into the Inserter

- Remove the inserter from the tray by gently twisting and pulling up the handle
- Ensure both sliders are pushed **fully forward**
  - The BLUE slider aligns with the single line marking
  - The GREEN slider aligns with the double line marking

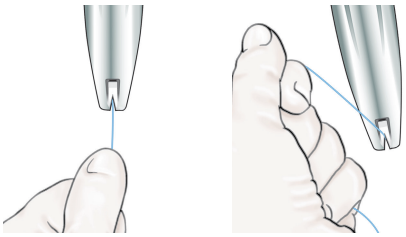




REMINDER

Use aseptic technique during the entire loading and insertion procedure.

- To load LILETTA into the inserter, maintain **forward pressure** on the BLUE slider and gently pull the threads **straight** back. Maintain even tension on both threads when pulling
  - Pull the threads upward or downward to lock them into the cleft at the bottom end of the handle
  - Once they are locked in the cleft, stop holding the threads



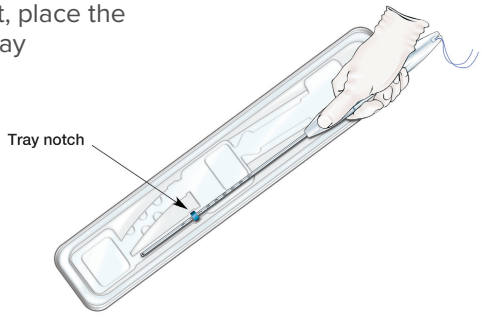
- When correctly loaded, the IUS is completely within the insertion tube, with the tips of the arms forming a hemispherical dome at the top of the tube

REMINDER

If the IUS is not correctly loaded, DO NOT ATTEMPT INSERTION. To reload, pull the BLUE slider back with your thumb until the groove becomes aligned with the GREEN slider to release the IUS, manually pull the threads out of the cleft, and return the BLUE slider to the forward position and repeat the loading steps.

STEP 2 | Adjusting the Flange

- Adjust the flange to the measured uterine depth based on sounding. To adjust, place the flat side of the flange in the tray notch or against a sterile edge inside of the tray
- If required, bend or straighten the insertion tube to accommodate the anatomical orientation of the uterus
- Be careful to avoid sharp bends to prevent kinking



REMINDER

If bending or straightening the insertion tube, do not touch above the flange without sterile gloves and avoid contact of flange against objects that can change its position once properly positioned.

IMPORTANT SAFETY INFORMATION (continued)

Clinical considerations for use and removal of LILETTA

Use LILETTA with caution after careful assessment in women with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe or frequent headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing LILETTA if the following arise during use: uterine or cervical malignancy or jaundice. Because irregular bleeding/spotting is common during the first months of LILETTA use, exclude endometrial pathology (polyps or cancer) prior to the insertion of LILETTA in women with persistent or uncharacteristic bleeding. If the threads are not visible or are significantly shortened, they may have broken or retracted into the cervical canal or uterus. If LILETTA is displaced (eg, expulsed or perforated the uterus), remove it.

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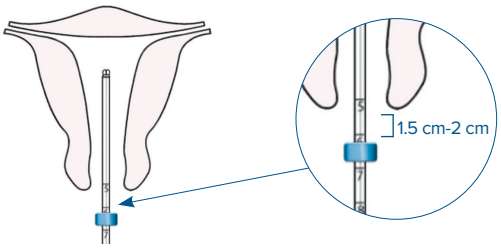
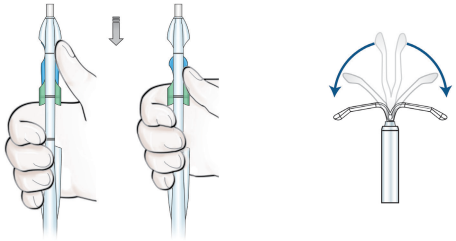
STEP 3 | Inserting LILETTA® Into the Uterus

- Apply gentle traction on the tenaculum, as needed
- Insert the loaded insertion tube through the cervical os
  - Maintain **forward pressure** on the BLUE slider throughout the insertion process
- Advance the tube until the upper edge of the flange is 1.5 cm to 2 cm from the external cervical os

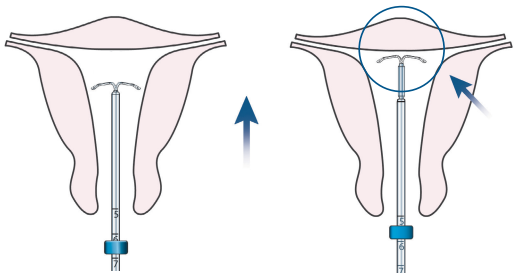


STEP 4 | Releasing LILETTA in the Uterus

- Gently slide only the BLUE slider back until the BLUE and GREEN sliders form a **joint slider recess**
  - You will feel slight resistance initially when moving the BLUE slider out of its starting position
  - Continue to move the BLUE slider back until you feel slight resistance again as the BLUE and GREEN sliders merge together
- This will allow the IUS arms to open
- Do not pull the sliders back any further to avoid premature release of the IUS at the incorrect location
- Wait 10 to 15 seconds to allow for the arms of the IUS to fully open



- Without moving the sliders, advance the inserter to the fundal position. Do not continue to advance if fundal resistance is encountered
  - The flange should now be at the top of the cervix

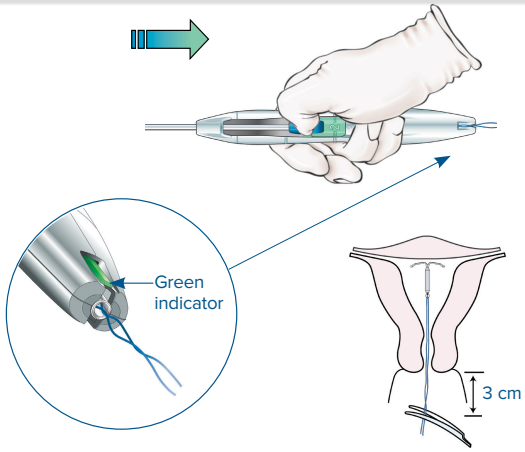


REMINDER

Fundal position is important to prevent expulsions.

STEP 5 | Completing the Insertion

- Move both sliders down the handle until **a click is heard**
- The GREEN indicator at the bottom of the handle should now be visible, signifying deployment
- Look at the cleft to ensure the threads were properly released; if not released or if a click is not heard, grasp the threads and gently pull the threads out of the cleft
- Withdraw the inserter from the uterus
- Use blunt-tipped sharp scissors to cut the threads perpendicularly, leaving about 3 cm outside the cervix
- Insertion of LILETTA is now complete



IMPORTANT SAFETY INFORMATION (continued)

Pregnancy-related risks with LILETTA

If pregnancy should occur with LILETTA in place, remove the IUS 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. 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 have a higher risk of ectopic pregnancy.

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IMPORTANT SAFETY INFORMATION (continued)

Educate her about PID or endometritis

Insertion of LILETTA is contraindicated in the presence of known or suspected PID or endometritis. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. In the LILETTA contraception study, one woman diagnosed with PID and two women diagnosed with endometritis developed the infection within a week of insertion. One endometritis case was diagnosed at 39 days after insertion. The remaining 11 cases of PID and endometritis were diagnosed more than 6 months after insertion, including one at 30 days after IUS removal. In the HMB study, one woman was diagnosed with PID about 5 months after LILETTA insertion. Counsel women who use LILETTA to notify a healthcare provider if they develop lower abdominal or pelvic pain, fever, chills, unusual or malodorous discharge, unexplained bleeding, genital lesions or sores, or dyspareunia. PID and endometritis are often associated with sexually transmitted infections (STIs); LILETTA does not protect against STIs, including HIV. PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae. Inform women about the possibility of PID or endometritis and that these infections can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death.

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, including ectopic pregnancy, if menstruation does not occur within 6 weeks of the onset of previous menstruation. If a significant change in bleeding develops during prolonged use, conduct diagnostic tests to assess possible endometrial pathology.

Be aware of other serious complications and most common adverse reactions

Some serious complications with IUSs like LILETTA are sepsis, perforation, and expulsion. Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of LNG-releasing IUSs. Aseptic technique during insertion of LILETTA is essential to minimize serious infections such as GAS.

Perforation (total or partial, including penetration/embedment of LILETTA in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may also occur at any time during use. Perforation may reduce contraceptive efficacy. If perforation is suspected, locate and remove LILETTA as soon as possible. Surgery may be required. Delayed detection or removal of LILETTA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. The risk of perforation is increased if inserted in women who have fixed retroverted uteri, are postpartum, or are lactating. Delay LILETTA insertion a minimum of 4 weeks or until uterine involution is complete following a delivery or a second-trimester abortion.

Partial or complete expulsion of LILETTA may occur, resulting in the loss of contraceptive protection. Expulsion risk is increased when inserted immediately after delivery; it appears to be increased with insertions after second-trimester abortion, based on limited data. Risk of expulsion is increased for patients with a history of HMB or greater than normal BMI at the time of insertion. Remove a partially expelled LILETTA. If expulsion has occurred, a new LILETTA may be inserted when there is reasonable certainty the patient is not pregnant.

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

In the LILETTA contraception study, the most common adverse reactions (≥5% users) were vulvovaginal mycotic infections (20.2%), vaginal bacterial infections (19.2%), acne (15.5%), nausea or vomiting (10.5%), headache (10.1%), breast tenderness or pain (10.1%), abdominal discomfort or pain (10.0%), dyspareunia (9.6%), anxiety (9.6%), depression (9.1%), pelvic discomfort or pain (8.7%), dysmenorrhea (7.3%), mood changes (6.5%), back pain (6.5%), increased weight (6.1%), and vaginal discharge (5.8%). In the LILETTA HMB study, the adverse reaction profile was consistent with the adverse reaction profile in the contraception study.

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Consider evaluating patients 4 to 6 weeks after LILETTA insertion and during routine care, or more often if clinically indicated. Check threads during each evaluation.

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