

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/Placement.



INDICATION

LILETTA® is a sterile, levonorgestrel-releasing intrauterine system indicated for prevention of pregnancy for up to 6 years. The system should be replaced after 6 years if continued use is desired.

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 fibroids, if they distort the uterine cavity and would be incompatible with correct IUS placement; known or suspected breast cancer or other hormone-sensitive cancer, now or in the past; known or suspected uterine or cervical neoplasia; acute liver disease or liver tumor; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; infected abortion in the past 3 months; unexplained uterine bleeding; a current IUS; acute pelvic inflammatory disease (PID) or endometritis or history of PID (except with later intrauterine pregnancy); 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**

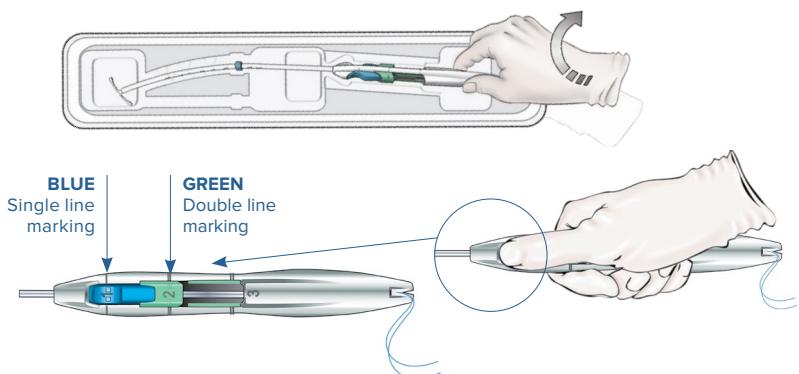
STEP 1 | Loading LILETTA® Into the Inserter

- 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

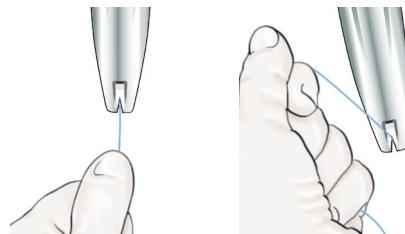


REMINDER

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.



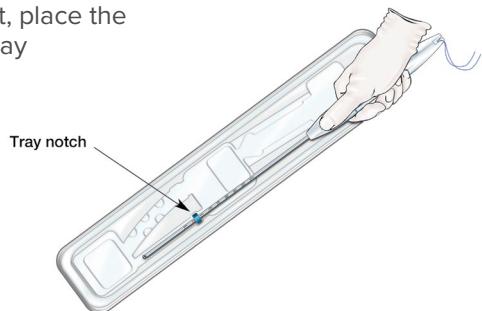
STEP 2 | Adjusting the Flange

- 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 with the flange against objects that can change its position once properly positioned.



IMPORTANT SAFETY INFORMATION (continued)

Clinical considerations for use and removal of LILETTA

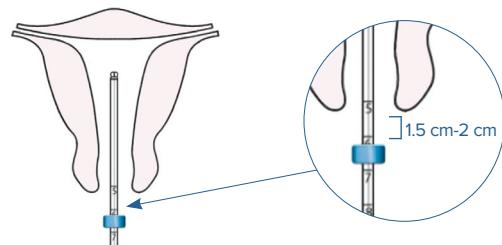
Use LILETTA with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia; exceptionally severe or frequent headache; marked increase of blood pressure; or severe 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, expelled or perforated the uterus), remove it.

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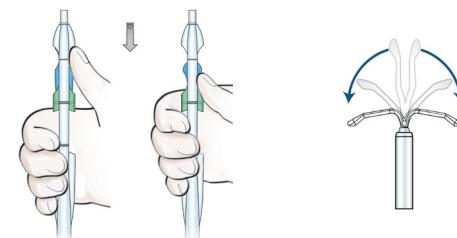
STEP 3 | Inserting LILETTA® Into the Uterus

- 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

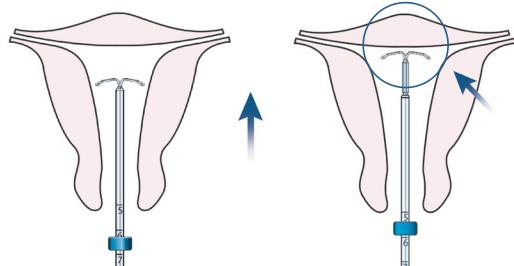


STEP 4 | Releasing LILETTA in the Uterus

- 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



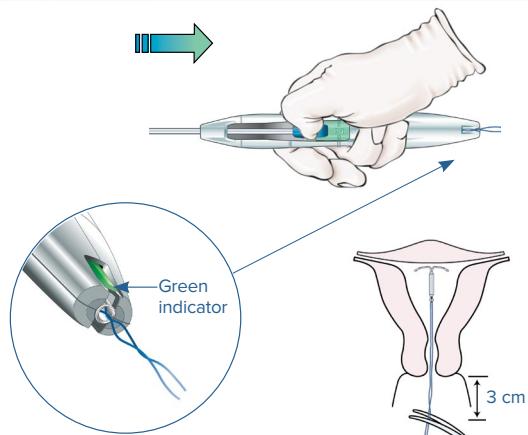
- Without moving the sliders, advance the inserter to the fundal position. Do not continue to advance if fundal resistance is encountered
 - The flange should now be at the top of the cervix



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 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.

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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 or a history of PID unless there has been a subsequent intrauterine pregnancy. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. 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. Counsel women who receive 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 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 higher if inserted in lactating women and may be higher if inserted in women who are postpartum or when the uterus is fixed retroverted.

Partial or complete expulsion of LILETTA may occur, resulting in the loss of contraceptive protection.

Delay LILETTA insertion a minimum of 4 weeks or until uterine involution is complete following a delivery or a second trimester abortion. Remove a partially expelled LILETTA. If expulsion has occurred, a new LILETTA may be inserted within 7 days after the onset of a menstrual period after pregnancy has been ruled out.

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

In the LILETTA clinical trial, the most common adverse reactions ($\geq 5\%$ users) were vulvovaginal mycotic infections (19.2%), vaginal bacterial infections (18.6%), acne (15.3%), nausea or vomiting (10.3%), abdominal discomfort or pain (9.9%), headache (9.5%), breast tenderness or pain (9.5%), dyspareunia (9.3%), anxiety (8.8%), pelvic discomfort or pain (8.4%), depression (8.3%), dysmenorrhea (6.4%), mood changes (6.3%), increased weight (5.9%), back pain (5.9%), and vaginal discharge (5.5%).

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.

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