LILETTA® and its design are registered trademarks of Odyssea Pharma SPRL, an Allergan affiliate.

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

- **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 significant period without symptoms.**
- **Educate her about PID**
  - **Risk of ectopic pregnancy.**
  - **Associated risks, including loss of fertility.**
  - **Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of PID.**
- **If pregnancy should occur with LILETTA in place, remove the intrauterine system because leaving it in place may increase the risk of ectopic pregnancy.**
- **Clinical symptoms that may indicate PID:**
  - **Lower abdominal or pelvic pain,**
  - **Odorous discharge,**
  - **Unexplained bleeding,**
  - **Nausea,**
  - **Fever.

**Concerns about PID**

- **PID may be asymptomatic,**
- **PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae.**
- **Inform women about the need to notify a healthcare provider if they have complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding,**
- **Many women present with symptoms of PID only after fertility has been lost.**

**PID in Women with an IUS**

- **Risk of PID in women using an IUS is higher than in women who do not use an IUS.**
- **PID during LILETTA use may be asymptomatic.**
- **If perforation occurs, locate and remove LILETTA. Surgery may be required. Delayed detection or removal of LILETTA in case of perforation may reduce contraceptive efficacy.**
- **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 reduce contraceptive efficacy.**
- **If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology.**
- **Partial or complete expulsion of LILETTA may occur, resulting in the loss of contraceptive protection.**
- **LILETTA is essential in order to minimize serious infections such as GAS.**
- **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 other LNG-releasing IUSs. Aseptic technique during insertion of LILETTA is recommended.**
- **In women with a history of PID, the risk of PID recurrence is increased.**
- **Women with persistent or uncharacteristic bleeding. If the threads are not visible or are significantly shortened, they may have broken.**
- **In women with known or suspected PID, avoid use of IUS until after PID is treated and the patient is asymptomatic.**
- **This recommendation is based on experience with similar agents.**

**Insertion**

- **Insertion of LILETTA should be performed by health professionals with appropriate experience and training.**
- **Insertion of LILETTA is contraindicated in women with a known or suspected PID or endometritis unless there has been a significant period without symptoms.**
- **Prior to insertion of LILETTA, conduct a clinical examination to evaluate the cervical os and identify evidence of PID, endometritis, or related infections.**
- **Insert LILETTA in women with persistent or uncharacteristic bleeding. If the threads are not visible or are significantly shortened, they may have broken.**
- **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 significant period without symptoms.**

**Camille E. Resnick, MD, MPH**

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**CEI-20161028**

**Date of Review: October 2016**
Loading the Inserter

- Remove the inserter and hold it with the buttons facing up
- Ensure both sliders are pushed fully forward and aligned with their respective markings

Use aseptic technique during the entire loading and insertion procedure.

To load the IUS into the inserter, maintain forward pressure on the BLUE slider and pull the threads until you feel a hard stop
- Pull and lock the threads into the cleft at the bottom of the handle

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

If the IUS is not correctly loaded or is discharged from the insertion tube unintentionally before insertion, DO NOT ATTEMPT INSERTION. You can repeat the loading process.

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 the insertion tube to accommodate the anatomical orientation of the uterus
- Be careful to avoid sharp bends to prevent kinking

Inserting LILETTA® into the Uterus

- Apply gentle traction on the tenaculum, as needed
- Insert the loaded tube through the cervical os
  - Maintain forward pressure on the BLUE slider throughout the insertion process
  - Advance until the upper edge of the flange is 1.5 to 2.0 cm from the cervix
  - DO NOT advance flange to the cervix at this time

Releasing LILETTA in the Uterus

- Gently slide only the BLUE slider back until the BLUE and GREEN sliders form a common thumb recess
- This will allow the IUS arms to open
- Wait 10 to 15 seconds to allow for the arms of the IUS to fully open

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
- Remove the inserter from the uterus
- Look at the cleft to ensure the threads were properly released; if not released, grab the threads and gently pull the threads out of the cleft
- Cut the threads perpendicularly, leaving about 3.0 cm outside the cervix
- Insertion is now complete

Please see important Safety Information on the last page of this refresher sheet and accompanying full Prescribing Information enclosed with this kit.
Inside you will find key points and images from the Healthcare Provider’s Reference for Preparing and Inserting LILETTA.

IMPORTANT: Use this refresher sheet only as a reminder.

For complete insertion instructions please refer to either of the following:

- The full Prescribing Information on the inside lid of the LILETTA intrauterine system (IUS) demonstration kit
- LILETTAHCP.com/Resources to view a demonstration video online

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Adjusting the Flange

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![Image](https://via.placeholder.com/150)

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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; breast tenderness or pain (6.7%), pelvic discomfort or pain (6.1%), depression or depressed mood (5.4%), and mood changes (5.2%).

•  LILETTAHCP .com/Resources to view a demonstration video online

Preparing and Inserting LILETTA.

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INDICATION

LILETTA is a levonorgestrel-releasing intrauterine system indicated for prevention of pregnancy for up to 3 years. The system should be replaced after 3 years if continued use is desired.

IMPORTANT SAFETY INFORMATION

Contraindications

Contraindicated in the presence of known or suspected pregnancy or endometritis or a history of PID unless there has been a subsequent menstrual period or normal bleeding for 28 days following LILETTA removal. Because LNG-releasing IUSs like LILETTA may cause an increase in the likelihood of ectopic pregnancy, conditions increasing susceptibility to pelvic infection or hyperstimulation may increase the risk of uterine perforation.

Abscesses, and erosion of adjacent viscera. The risk of perforation is higher if inserted in lactating women and may be higher if inserted in postmenopausal women. Pregnancy may result in continued use, the risk of dilation and cerclage may increase. Risk of ectopic pregnancy increases as the plasma concentration of estrogen increases during the menstrual cycle.

Counsel women who receive LILETTA insertion, while the remainder were diagnosed more than six months after insertion. About 1/3 of women diagnosed with PID developed the infection within a week of insertion of LILETTA while the remainder were diagnosed more than six months after insertion.

Educate her about PID

Risk of ectopic pregnancy.

Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

Tell women about the signs of ectopic pregnancy and perforation (total or partial, including penetration/embedment of LILETTA in the uterine wall or cervix) may occur, most often during the first months of LILETTA use. Perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and peritonitis of the appendix.

The risk of perforation is higher if inserted in lactating women and may be higher if inserted in postmenopausal women. Pregnancy may result in continued use, the risk of dilation and cerclage may increase. Risk of ectopic pregnancy increases as the plasma concentration of estrogen increases during the menstrual cycle.

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

Cases of LILETTA expulsion have occurred as a result of mechanical failure, infection, or gestational uterine overgrowth resulting in uterine rupture. Women with a history of abnormal uterine bleeding may be at increased risk if insertion is elective.