- Visually inspect the packaging containing LILETTA to verify that the packaging has not been damaged (e.g., torn, punctured, etc.). If the packaging has any visual damage that could compromise sterility, do not use the unit for insertion *[see Warnings and Precautions (5.3)]*.
- Ensure that the patient understands the contents of the Patient Information Booklet and obtain consent. A sample consent form that includes the lot number is on the last page of the Patient Information Booklet.
- Complete the pelvic examination, speculum placement, tenaculum placement, and sounding of the uterus before opening the LILETTA packaging.
- Do not open the packaging to insert LILETTA if:
  - the cervix is unable to be properly visualized
  - the uterus cannot be adequately instrumented (during sounding)
  - the uterus sounds to less than 5.5 cm

Planning for Insertion

- Ensure all needed items for LILETTA insertion are readily available:
  - Gloves
  - Speculum
  - Sterile uterine sound
  - Sterile tenaculum
  - Antiseptic solution
  - LILETTA with inserter tray, sealed with a peel-off lid
  - Sterile, blunt-tipped scissors
  - Additional items that may be useful could include:
    - Local anesthesia, needle, and syringe
    - Os finder and/or cervical dilators
    - Ultrasound with abdominal probe
- Exclude pregnancy and confirm that there are no other contraindications to the insertion and use of LILETTA.
- Follow the insertion instructions exactly as described in order to ensure proper insertion.
- 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.
- Insertion may be associated with some pain and/or bleeding or vasovagal reactions (e.g., diaphoresis, syncope, bradycardia, or seizure), especially in patients with a predisposition to these conditions. Consider administering analgesics prior to insertion.

Use aseptic technique during the entire insertion procedure. Loading and inserting LILETTA can be done with or without sterile gloves. If not using sterile gloves, maintain sterility during LILETTA loading and insertion; do not touch LILETTA, the inside of the sterile tray, or parts of any sterile instrument that will pierce tissue (e.g., a tenaculum on the cervix) or go into the uterine cavity. If, at any step, there is a need to touch a sterile surface, sterile gloves should be used.

Preparation for Insertion

The overall insertion process is conducted in 5 steps.

Step 1 – Preparation of Patient for Insertion

- With the patient comfortably in lithotomy position, do a bimanual exam to establish the size, shape, and position of the uterus and 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.
- 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.
- After ascertaining that the patient is appropriate for LILETTA, replace contaminated glove(s) and open the packaging containing LILETTA.

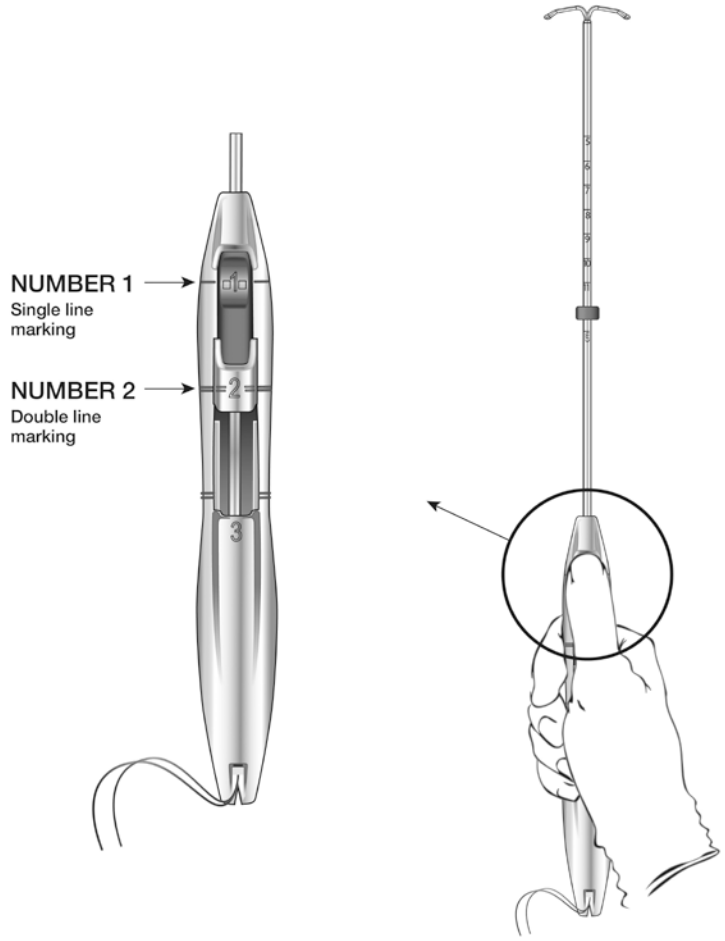
Step 2 – Opening the Sterile LILETTA Packaging

- Remove the sealed tray containing LILETTA from the box.
- Inspect the sealed tray and do not use the product if the packaging, inserter or IUS is damaged.
- Lay the tray on a flat surface with the peel-off lid side up.
- Remove peel-off lid.

Step 3 – Loading LILETTA into the Inserter

- To remove the inserter from the tray, grasp the handle below the sliders and twist gently.
    - NOTE: Do not attempt to remove the inserter by pulling on the tube.
- Ensure both sliders (numbered 1 and 2) are **fully forward** (Figure 3):
    - The handle single line marking will align with the BLUE (number 1) slider single line marking.
    - The handle double line markings will align with the GREEN (number 2) slider double line markings.
- Grip the handle keeping your thumb or finger in the groove of the BLUE slider (over the numeral 1) and apply **forward pressure** while ensuring both sliders are **fully forward**.

Figure 3: Sliders Completely Forward for Loading LILETTA



- Load LILETTA into the inserter:
    - Ensure the arms of the IUS are horizontal (aligned to the horizontal plane of the handle and flange); adjust the rotation of the IUS as needed using the flat sterile surface of the tray.
    - While maintaining **forward pressure** on the blue slider, pull the threads **straight** back until you feel a hard stop. Ensure even tension is applied to both threads when pulling.

- 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 or inserter.
- 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 uterine perforation [*see Warnings and Precautions (5.5)*].

2.4 Patient Counseling and Record-Keeping

- 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, which includes the website address (www.LILETTA.com). Discuss expected bleeding patterns with LILETTA use. Review the signs and symptoms of LILETTA expulsion. [*See Patient Counseling Information (17)*].
- Prescribe analgesics, if indicated.

2.5 Patient Follow-Up

Re-examine and evaluate patients 4 to 6 weeks after insertion and once a year thereafter, or more frequently if clinically indicated. The healthcare provider should check strings during each routine and follow-up visit.

2.6 Removal of LILETTA

Timing of Removal

- If pregnancy is desired, LILETTA can be removed at any time.
- If pregnancy is not desired, LILETTA can be removed at any time; however, a contraception method should be started prior to removal of LILETTA *[see Dosage and Administration (2.5)]*. Counsel your patient that she is at risk of pregnancy if she has intercourse in the week prior to removal without use of a backup contraceptive method.
- LILETTA should be removed after 4 years. LILETTA can be replaced at the time of removal with a new LILETTA if continued contraceptive protection is desired.

Planning 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, and syringe
    - Os finder and/or cervical dilators
    - Ultrasound with abdominal probe
    - Sterile tenaculum

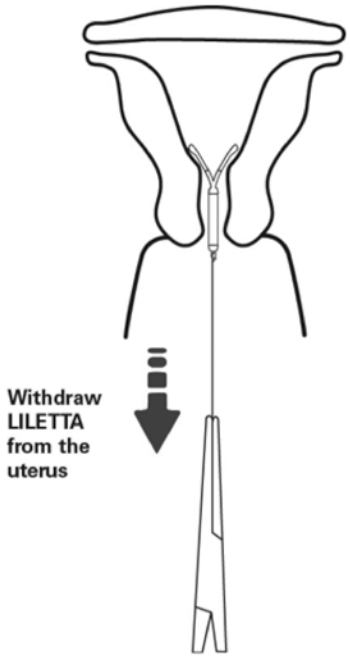
- Antiseptic solution
- Long, narrow forceps

- Removal may be associated with some pain and/or bleeding or vasovagal reactions (e.g., syncope, bradycardia, or seizure), especially in patients with a predisposition to these conditions.
- After removal of LILETTA, examine the system to ensure that it is intact.

Removal Instructions

- With the patient comfortably in lithotomy position, place a speculum and visualize the cervix.
- When the threads of LILETTA are visible:
  - Remove the IUS by applying traction on the threads with forceps (Figure 13).
  - The arms of the device will fold upward as it is withdrawn from the uterus.
  - If the IUS cannot be removed with traction on the threads, perform an ultrasound examination to confirm location of the IUS, including assessment for partial or total perforation. If the IUS is in the uterus, use long, narrow forceps to grasp LILETTA. Consider use of a tenaculum, cervical anesthesia, cervical dilators, and/or ultrasound guidance as needed.
  - After removal, examine the system to ensure it is intact.
- If the threads of LILETTA are not visible:
  - Determine location of the IUS by ultrasound examination.
  - If the IUS is in the uterine cavity, use long, narrow forceps (e.g., Alligator forceps) to grasp LILETTA. Consider use of a tenaculum, cervical anesthesia, cervical dilators, and/or ultrasound guidance as needed. If LILETTA cannot be removed using the above techniques, consider hysteroscopic evaluation for removal.
  - If the IUS is not in the uterine cavity, consider an abdominal x-ray or CT scan to evaluate if the IUS is in the abdominal cavity. Consider laparoscopic evaluation for removal, as clinically indicated.
  - After removal, examine the system to ensure it is intact.

Figure 13: Removal of LILETTA



2.7 Continuation of Contraception after Removal

- If a patient wishes to continue using LILETTA or another intrauterine contraceptive, insertion can occur immediately after removal.
- If a patient with regular cycles wants to start a different birth control method, time the removal and initiation of a 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 a patient with irregular cycles or amenorrhea wants to start a different birth control method, start the new method at least 7 days before LILETTA removal.
- 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 (e.g., condoms and spermicide) or abstain from vaginal intercourse for 7 days to prevent pregnancy.

3 DOSAGE FORMS AND STRENGTHS

LILETTA is a levonorgestrel-releasing intrauterine system consisting of a T-shaped polyethylene frame with a drug reservoir containing 52 mg levonorgestrel, packaged within a sterile inserter.

4 CONTRAINDICATIONS

The use of LILETTA is contraindicated when one or more of the following conditions exist:

- Pregnancy or suspected pregnancy

abortion and preterm labor. Removal of LILETTA or probing of the uterus may also result in spontaneous abortion. In the event of an intrauterine pregnancy with LILETTA, consider the following:

Septic abortion

In patients becoming pregnant with an IUS in place, septic abortion – with septicemia, septic shock, and death – may occur. Septic abortion typically requires hospitalization and treatment with intravenous antibiotics. Septic abortion may result in spontaneous abortion or a medical indication for pregnancy termination. Should severe infection of the uterus occur, hysterectomy may be required, which will result in permanent infertility.

Continuation of pregnancy

If a woman becomes pregnant with LILETTA in place and if LILETTA cannot be removed or the woman chooses not to have it removed, warn her that failure to remove LILETTA increases the risk of miscarriage, sepsis, premature labor, and premature delivery. Prenatal care should include counseling about these risks and that she should report immediately any flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leakage of fluid, or any other symptom that suggests complications of the pregnancy.

5.3 Sepsis

Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of other LNG-releasing IUSs. In some cases, severe pain occurred within hours of insertion followed by sepsis within days. Because death from GAS is more likely if treatment is delayed, it is important to be aware of these rare but serious infections. Aseptic technique during insertion of LILETTA is essential in order to minimize serious infections such as GAS.

5.4 Pelvic Inflammatory Disease 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 [*see Contraindications (4)*]. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion.

In the clinical trial with LILETTA, pelvic infection was diagnosed in 0.8% of women. The infection was diagnosed as PID in 0.5% of women and as endometritis in 0.3% of women. One woman diagnosed with PID developed the infection within a week of LILETTA insertion, while the remainder were diagnosed more than six months after insertion. The cases of endometritis had onset less than 40 days after LILETTA insertion except for one occurring at 43 months after insertion.

Counsel women who receive LILETTA to notify a healthcare provider if they have complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding, fever, or genital lesions or sores. In such circumstances, perform a pelvic examination promptly to evaluate for possible pelvic infection. Remove LILETTA in cases of recurrent PID or endometritis, or if an acute pelvic infection is severe or does not respond to treatment.

Women at increased risk for PID or endometritis

PID and endometritis are often associated with a sexually transmitted infection (STI), and LILETTA does not protect against STIs. The risk of PID or endometritis is greater for women who have multiple

	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Number of bleeding days	5.8	5.2	2.3	3.3	1.6	2.7	1.2	2.4	0.8	1.8
Number of spotting days	9.0	5.9	4.3	4.2	3.2	3.6	2.7	3.4	1.9	2.8

Note: Includes all LILETTA subjects.

In the LILETTA clinical trial, 429 of 439 (97.7%) women evaluated experienced menses after LILETTA removal. Excluding nine women who became pregnant or had a hysterectomy before having a return of their menses, 429 of 430 (99.8%) had a return of their menses, 99.1% within three months.

If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology. Consider the possibility of pregnancy if menstruation does not occur within six weeks of the onset of a previous menstruation. Once pregnancy has been excluded, repeated pregnancy tests are generally not necessary in amenorrheic women unless indicated, for example, by other signs of pregnancy or by pelvic pain.

5.9 Breast Cancer

Women who currently have or have had breast cancer, or have a suspicion of breast cancer, should not use hormonal contraception, including LILETTA, because some breast cancers are hormone-sensitive *[see Contraindications (4)]*.

Spontaneous reports of breast cancer have been received during postmarketing experience with another LNG-releasing IUS. Observational studies have not provided consistent evidence of an increased risk of breast cancer with use of a LNG-releasing IUS.

5.10 Clinical Considerations for Use and Removal

Obtain a complete medical and social history, including partner status, to determine conditions that might influence the selection of an IUS for contraception.

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.

Special attention must be given to ascertaining whether the woman is at increased risk of infection (for example, leukemia, acquired immune deficiency syndrome [AIDS], IV drug abuse), or has a history of PID unless there has been a subsequent intrauterine pregnancy. LILETTA does not protect against HIV/STI transmission. *[See Warnings and Precautions (5.4).]*

Use LILETTA with caution after careful assessment if any of the following conditions exist, and consider removal of the IUS if any of them arise during use:

- Coagulopathy or use of 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

Table 5: Pregnancy Rates

LILETTA Clinical Trial	**Number of 28-Day Cycles of Exposure By Year**	**Year-by-Year Pearl Index** Pregnancy Rate (95% CI)	**Cumulative 28-Day Cycles of Exposure**	**Cumulative Year Life Table** Pregnancy Rate (95% CI)
Year 1	17,175	0.15 (0.02, 0.55)	17,175	0.14 (0.04, 0.57)
Year 2	14,205	0.37 (0.10, 0.94)	31,380	0.49 (0.22, 1.09)
Year 3	11,760	0.11 (0.00, 0.62)	43,140	0.59 (0.28, 1.25)
Year 4	9,755	0.13 (0.00, 0.74)	52,895	0.73 (0.36, 1.47)

The use of LILETTA does not appear to alter the course of female fertility after removal of the IUS. Of 153 women who desired pregnancy after study discontinuation, 78% conceived within 6 months following LILETTA removal, and 88% conceived within 12 months after removal of LILETTA.

15 REFERENCES

(1) Workowski KA, Berman S; Centers for Disease Control and Prevention (CDC). Sexually transmitted diseases treatment guidelines, 2010. MMWR Recomm Rep. 2010 Dec 17;59(RR-12):1-110.

16 HOW SUPPLIED/STORAGE AND HANDLING

LILETTA (levonorgestrel-releasing intrauterine system), containing 52 mg levonorgestrel, is supplied partially preloaded within the inserter and packaged in a clear plastic tray with lid. LILETTA is available in a carton of one sterile unit. NDC # 0023-5858-01.

LILETTA is supplied sterile. LILETTA is sterilized with ethylene oxide. Do not resterilize. For single use only. Do not use if the packaging is damaged, or if the packaging is opened. Insert before the end of the month shown on the packaging. Store at 20 – 25°C (68 – 77°F), with excursions permitted between 15 – 30°C (59 – 86°F) [See USP Controlled Room Temperature]. Store the sealed tray with peel-off lid in outer carton until use to protect from light.

17 PATIENT COUNSELING INFORMATION

17.1 Information for Patients

Advise the patient to read the FDA-approved patient labeling (Patient Information).

- Advise the patient that this product does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).
- Advise the patient about the risks of ectopic pregnancy, including the loss of fertility. Advise her to recognize and report to her healthcare provider promptly any symptoms of ectopic pregnancy, including lower abdominal pain, especially in association with missed periods *[see Warnings and Precautions (5.1).]*
- Advise the patient that if pregnancy occurs while using LILETTA:

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How is LILETTA placed?

LILETTA is placed by your healthcare provider during an in-office visit.

First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then clean your vagina and cervix with an antiseptic solution and slide a slim plastic tube containing LILETTA through the cervix into your uterus. Your healthcare provider will then remove the plastic tube, and leave LILETTA in your uterus. Your healthcare provider will trim the threads to the right length. Placement takes only a few minutes.

You may experience pain, bleeding, or dizziness during and after placement. If your symptoms do not pass within 30 minutes after placement, LILETTA may not have been placed correctly. Your healthcare provider will examine you to see if LILETTA needs to be removed or replaced.

Should I check that LILETTA is in place?

Yes, you should check that LILETTA is in proper position by feeling the threads. It is a good habit to do this 1 time a month. Your healthcare provider should teach you how to check that LILETTA is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the threads. Do not pull on the threads.

If you feel more than just the threads or if you cannot feel the threads, LILETTA may not be in the right position and may not prevent pregnancy. Use non-hormonal back-up birth control (such as condoms and spermicide) and ask your healthcare provider to check that LILETTA is still in the right place.

How soon after placement of LILETTA should I return to my healthcare provider?

Call your healthcare provider if you have any questions or concerns (see “When should I call my healthcare provider?”). Otherwise, you should return to your healthcare provider for a follow-up visit 4 to 6 weeks after LILETTA is placed to make sure that LILETTA is in the right position.

Can I use tampons with LILETTA?

Yes, tampons may be used with LILETTA.

What if I become pregnant while using LILETTA?

Call your healthcare provider right away if you think you are pregnant. If possible, also do a urine pregnancy test. If you get pregnant while using LILETTA, you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain especially with missed periods may be a sign of ectopic pregnancy.

Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

There are also risks if you get pregnant while using LILETTA and the pregnancy is in the uterus. Severe infection, miscarriage, premature labor premature delivery, and even death can occur with pregnancies that continue with an intrauterine system (IUS). Because of this, your healthcare provider may try to remove LILETTA, even though removing it may cause a miscarriage. If LILETTA cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your healthcare provider regularly. Call your healthcare provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

It is not known if LILETTA can cause long-term effects on the fetus if it stays in place during a pregnancy.

How will LILETTA change my periods?

For the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding and cramping. Some women have heavy bleeding during this time. After you have used LILETTA for a while, the number of bleeding and spotting days is likely to lessen. For some women, menstrual periods will stop altogether. When LILETTA is removed, your menstrual periods will likely return to their former pattern.

Is it safe to breastfeed while using LILETTA?

You may use LILETTA when you are breastfeeding if more than 6 weeks have passed since you had your baby. If you are breastfeeding, LILETTA is not likely to affect the quality or amount of your breast milk or the health of your nursing baby. However, isolated cases of decreased milk production have been reported among women using progestin-only birth control pills. The risk of LILETTA becoming attached to (embedded) or going through the wall of the uterus is increased when LILETTA is placed in breastfeeding women.

Will LILETTA interfere with sexual intercourse?

You and your partner should not feel LILETTA during intercourse. LILETTA is placed in the uterus, not in the vagina. In some cases, your partner may feel the threads. If this occurs, or if you or your partner experience pain during sex, talk with your healthcare provider.

Can I have an MRI with LILETTA in place?

LILETTA is MR Safe. It is safe to have an MRI following LILETTA placement.

What are the possible side effects of LILETTA?

LILETTA can cause serious side effects, including:

- **ectopic pregnancy**. If you get pregnant while using LILETTA, you might have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain especially with missed periods may be a sign of ectopic pregnancy. Ectopic pregnancy is a medical emergency that

often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

- **intrauterine pregnancy risks**. There are also risks if you get pregnant while using LILETTA and the pregnancy is in the uterus. Severe infection, miscarriage, premature labor, premature delivery, and even death can occur with pregnancies that continue with an intrauterine system (IUS). Because of this, your healthcare provider may try to remove LILETTA, even though removing it may cause a miscarriage. If LILETTA cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy. If, after seeing your healthcare provider, you choose to continue your pregnancy, see your healthcare provider regularly. Call your healthcare provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection. It is not known if LILETTA can cause long-term effects on the fetus if it stays in place during a pregnancy.
- **life-threatening infection**. Life-threatening infection can occur within the first few days after LILETTA is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after LILETTA is placed.
- **pelvic inflammatory disease (PID) or endometritis**. Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID) or endometritis. PID and endometritis are usually sexually transmitted. You have a higher chance of getting PID or endometritis if you or your partner has sex with other partners. PID or endometritis can cause serious problems such as infertility, ectopic pregnancy or pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID or endometritis may require surgery. Removal of the uterus (hysterectomy) is sometimes needed. In rare cases, infections that start as PID or endometritis can even cause death.

  Tell your healthcare provider right away if you have any of these signs of PID or endometritis: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal pain, painful sex, chills, or fever.
- **perforation**. LILETTA may become attached to (embedded) or go through the wall of the uterus. This is called perforation. If this occurs, LILETTA may no longer prevent pregnancy. If perforation occurs, LILETTA may move outside the uterus and can cause internal scarring, infection, or damage to other organs. You may need surgery to have LILETTA removed if perforation or embedment occurs. The risk of perforation is increased in breastfeeding women.
- **expulsion**. LILETTA may come out of your uterus. This is called expulsion. Expulsion occurs in about 4 out of 100 women, most often in the first year of use. You may become pregnant if LILETTA comes out. If you think that LILETTA has come out, use another birth control method like condoms and spermicide or do not have sex (vaginal intercourse) until you are seen by a healthcare provider.
- **cysts on the ovary.** Some women using LILETTA develop a painful cyst on the ovary. These cysts usually disappear on their own in 2 to 3 months. However, a cyst can cause pain and sometimes cysts will need surgery.

- **changes in bleeding.** You may have bleeding and spotting between menstrual periods, especially during the first 3 to 6 months. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than usual and may be irregular. Call your healthcare provider if the bleeding remains heavier than usual or increases after it has been light for a while.

The most common side effects of LILETTA include:

• vaginal bacterial infection	• yeast infection of the outer part of your vagina (vulvovaginal)
• acne	• headache
• nausea or vomiting	• pain during sex
• abdominal pain	• breast pain
• pelvic pain	• depression
• weight increase	• vaginal discharge
• mood changes	• anxiety

- **Pain, bleeding, or dizziness during and after placement.** If these symptoms do not stop within 30 minutes after placement, LILETTA may not have been placed correctly. Your healthcare provider will examine you to see if LILETTA needs to be removed or replaced.
- **Missed menstrual periods.** About 2 out of 10 women stop having periods after 1 year of LILETTA use. If you do not have a period for 6 weeks during LILETTA use, call your healthcare provider. If you have any concerns that you may be pregnant while using LILETTA, do a urine pregnancy test and call your healthcare provider. When LILETTA is removed, your menstrual periods will usually return to your previous pattern.

These are not all the possible side effects of LILETTA. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Allergan at 1-800-433-8871.

After LILETTA has been inserted, when should I call my healthcare provider?

Call your healthcare provider if you have any concerns about LILETTA. Be sure to call if you:

- think you are pregnant
- have pelvic pain or pain during sex
- have unusual vaginal discharge or genital sores

- have unexplained fever, flu-like symptoms or chills
- might be exposed to sexually transmitted infections (STIs)
- are concerned that LILETTA may have been expelled (came out)
- cannot feel LILETTA's threads
- develop very severe or migraine headaches
- have yellowing of the skin or whites of the eyes. These may be signs of liver problems.
- have had a stroke or heart attack
- you or your partner becomes HIV positive
- have severe vaginal bleeding, bleeding that lasts a long time, or you miss your period

General information about the safe and effective use of LILETTA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

You can ask your pharmacist or healthcare provider for information about LILETTA that is written for health professionals.

For more information, go to www.LILETTA.com or call 1-855-LILETTA (1-855-545-3882).

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