

Avibela[®] Insertion & Removal Procedures

Avibela[®] 
(levonorgestrel-releasing intrauterine system) 52 mg

Timing of insertion

Timing of AVIBELA insertion in women not currently using hormonal or intrauterine contraception:

- AVIBELA can be inserted any time you can be reasonably certain the woman is not pregnant
 - Consider the possibility of ovulation and conception prior to initiation of this product
 - If AVIBELA is inserted after the first 7 days of the menstrual cycle, the patient should:
 - use a barrier method of contraception, or
 - abstain from vaginal intercoursefor 7 days after insertion to prevent pregnancy

Timing of insertion, continued

Switching to AVIBELA from other contraceptives

Population	Insertion Timing Recommendations
Switching from oral, transdermal or vaginal hormonal contraceptive	<ul style="list-style-type: none">• AVIBELA may be inserted at any time<ul style="list-style-type: none">• May be inserted during the hormone-free interval of the previous method• If inserted during active use of the previous method, that method should be continued for 7 days after AVIBELA insertion or until the end of the current treatment cycle• If using continuous hormonal contraception, that method should be discontinued 7 days after AVIBELA insertion
Switching from injectable progestin contraceptive	<ul style="list-style-type: none">• AVIBELA may be inserted at any time• If AVIBELA is inserted more than 3 months (13 weeks) after the last injection, a barrier method of contraception (such as condoms or spermicide) should also be used for 7 days after insertion
Switching from contraceptive implant or another IUD	<ul style="list-style-type: none">• Insert AVIBELA on the same day the implant or IUD is removed• AVIBELA may be inserted at any time during the menstrual cycle

Timing of insertion, continued

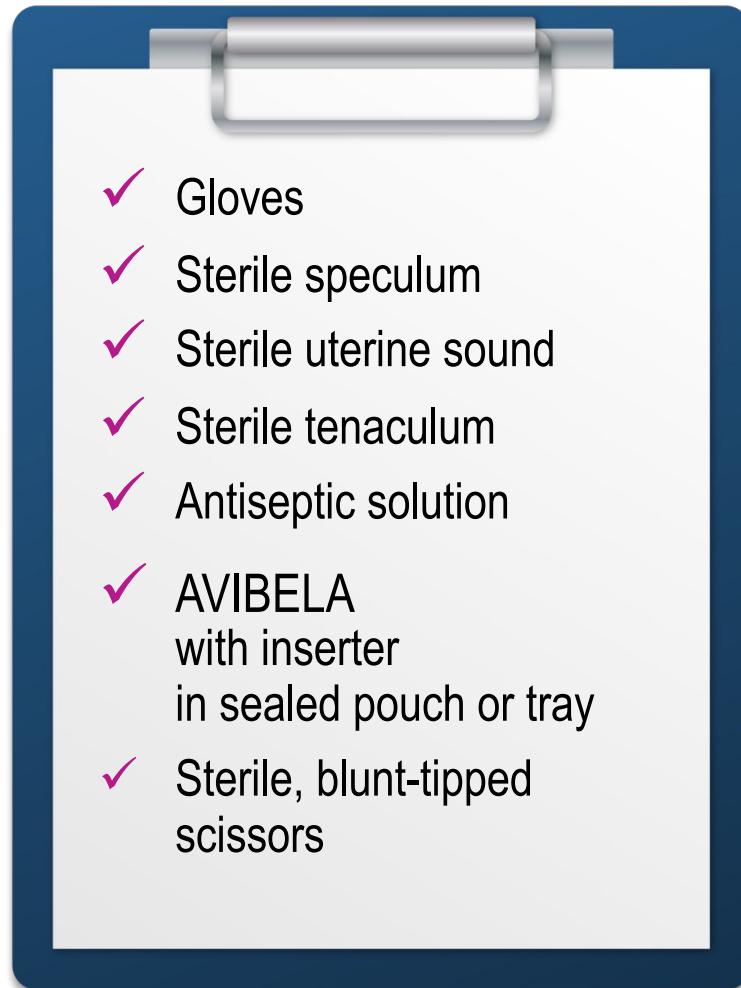
Timing of AVIBELA insertion after first trimester abortion and miscarriage:

- AVIBELA can be inserted immediately

Timing of AVIBELA insertion after second trimester abortion and miscarriage or after childbirth:

- **After at least 4 weeks or until uterus is fully involuted**
 - If the woman has not yet had a period, consider the possibility of ovulation and conception occurring prior to insertion of AVIBELA
 - AVIBELA can be inserted any time the provider can be reasonably certain the woman is not pregnant
 - If AVIBELA is not inserted during the first 7 days of the menstrual cycle:
 - a barrier method of contraception should be used for 7 days, or
 - the patient should abstain from vaginal intercourse for 7 days
 - There appears to be an increased risk of perforation in lactating women

Items required for insertion



Additional items that may be useful include:

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

Planning for insertion

- AVIBELA should only be inserted by a trained healthcare provider
- Be thoroughly familiar with the product, product educational materials, product insertion instructions, prescribing information, and patient labeling before attempting insertion of AVIBELA
- Obtain a complete medical and social history to determine conditions that might influence the selection of AVIBELA for contraception
 - If indicated, perform a physical examination and appropriate tests for genital or sexually transmitted infections

Planning for insertion, continued

- Check the expiration date on the unit carton before opening it
 - **Do not insert AVIBELA after the expiration date**
- After opening the unit carton, visually inspect the sealed pouch or tray containing AVIBELA
 - Verify that it has not been damaged (e.g., torn, punctured, etc.)
 - If the packaging has any visual damage that could compromise sterility or performance, do not use the unit for insertion
- Complete the pelvic examination, speculum placement, tenaculum placement, and sounding of the uterus before opening the sealed pouch or tray
- Do not open the pouch or tray containing AVIBELA 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

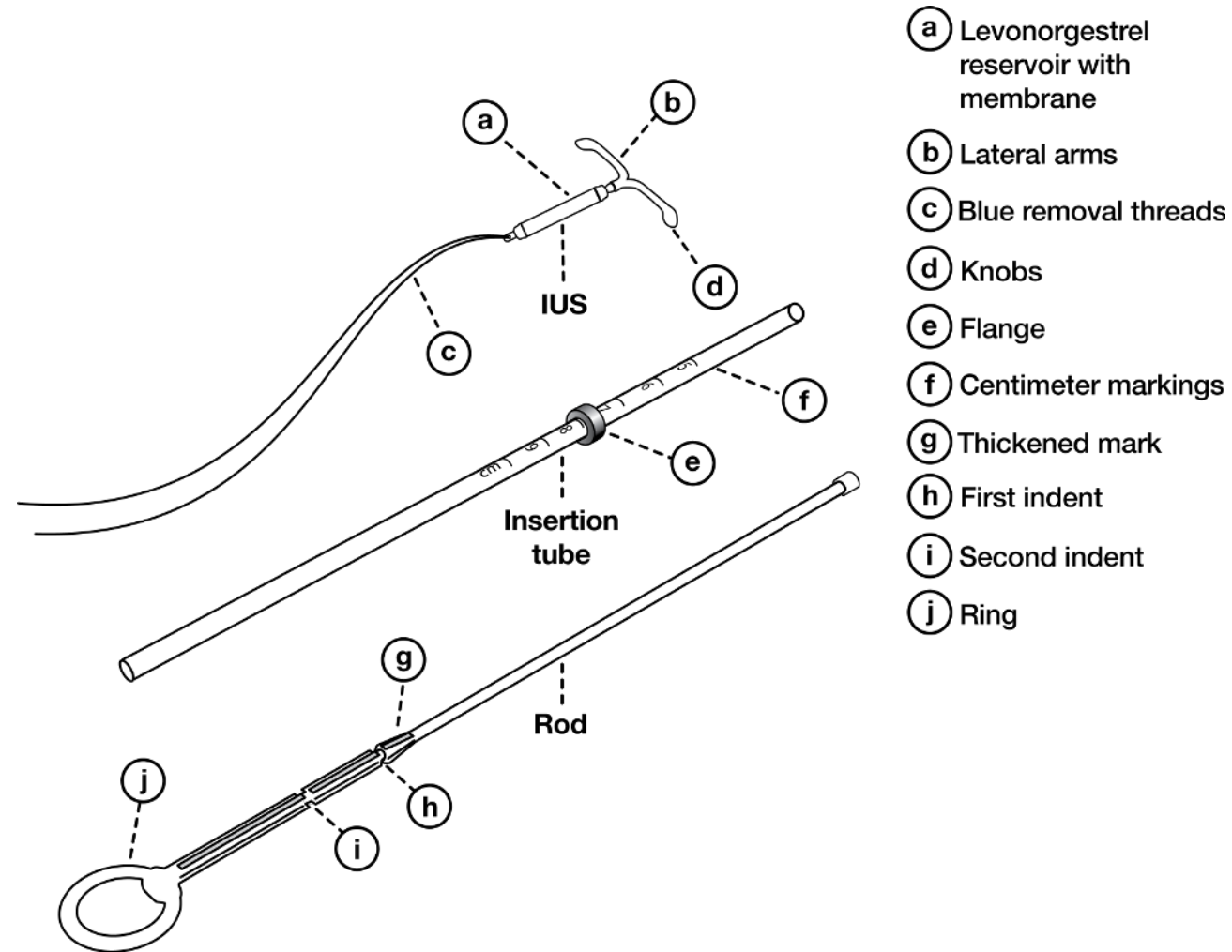
Preparation for insertion

- Exclude pregnancy and confirm that there are no other contraindications to the insertion and use of AVIBELA
- 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 AVIBELA 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

Preparation of the patient for insertion

- With the patient comfortably in lithotomy position, perform 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
- Carefully sound the uterus to measure its depth
- The uterus should sound to a depth of at least 5.5 cm
- After ascertaining that the patient is appropriate for AVIBELA, replace contaminated glove(s) and open the packaging containing AVIBELA, noting the lot number

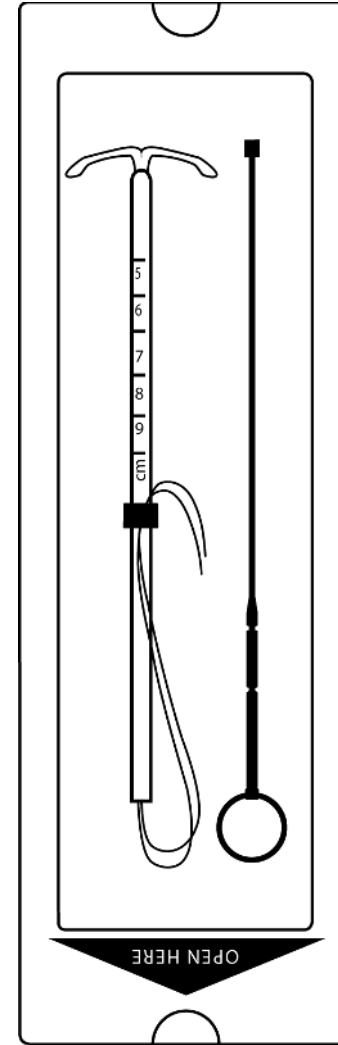
AVIBELA IUD and two-handed inserter



Loading the IUD into the inserter

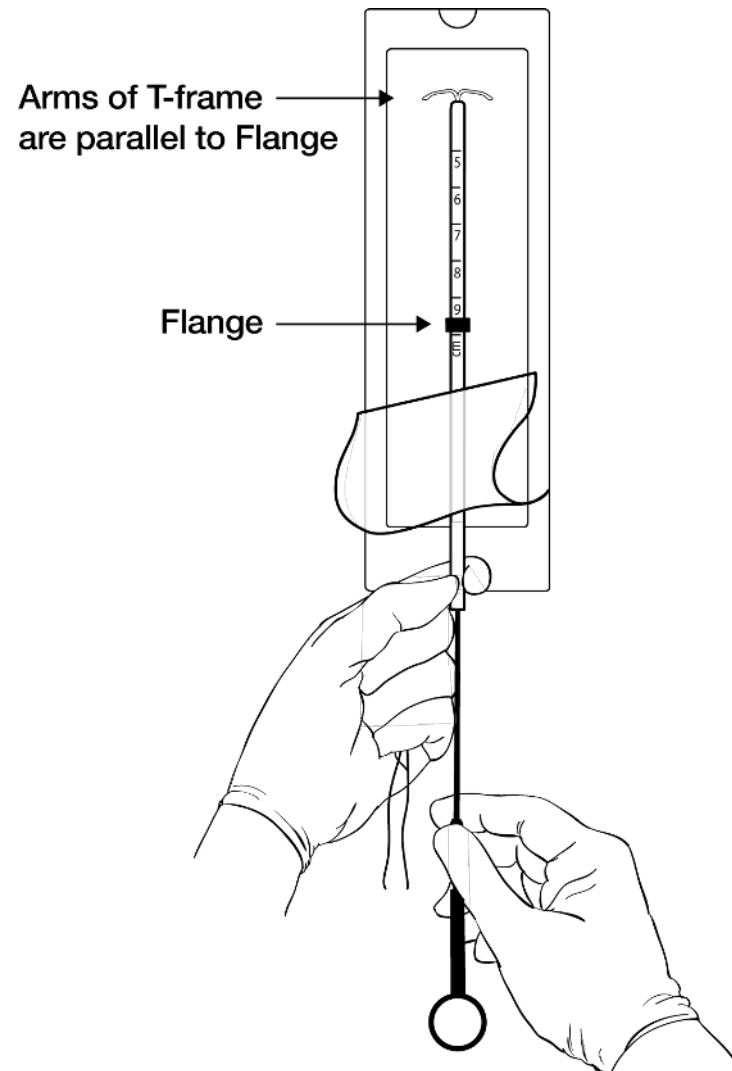
Step 1: Open the sterile packaging

- Remove the sterile pouch from the unit carton
- Place the sterile pouch on a flat surface with the clear side of the pouch facing up
- Open the sterile pouch from the bottom (end with the rod ring) approximately 1/3 of the way (if not using sterile gloves) until the lower end of the IUD 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)



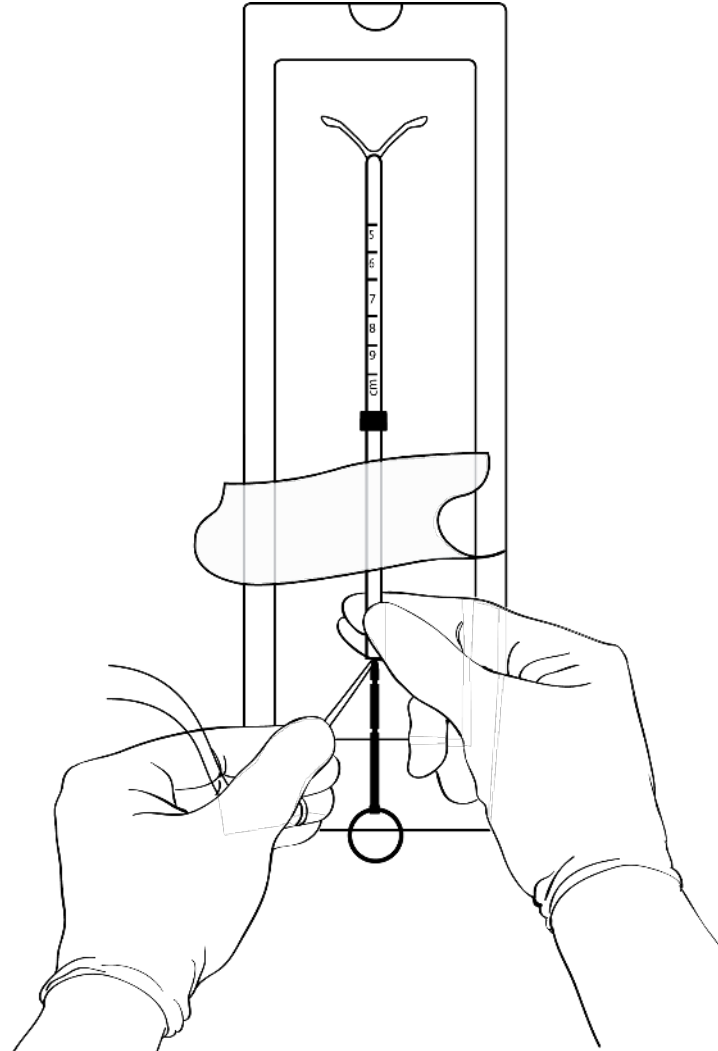
Loading the IUD into the inserter

Steps 2 and 3: Release the threads from the flange and insert the rod



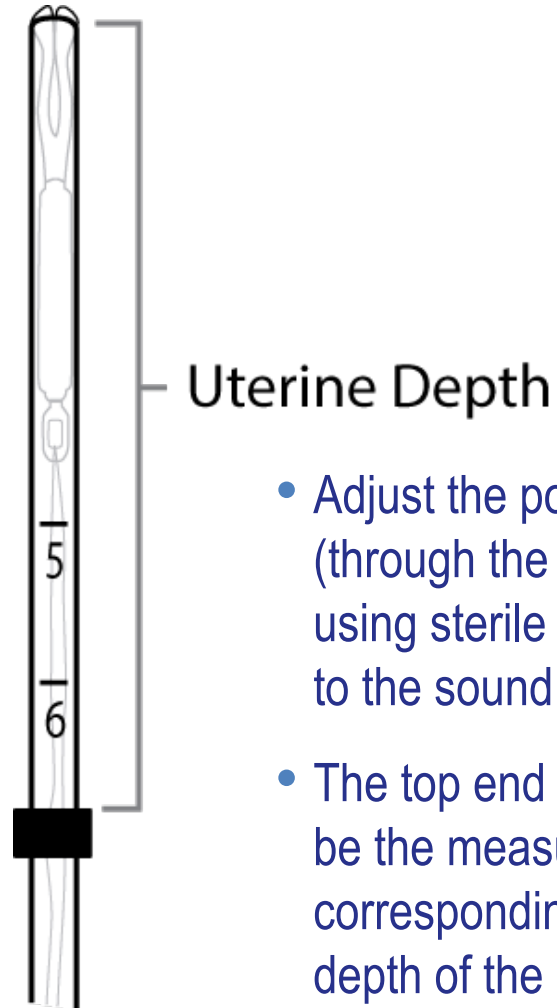
Loading the IUD into the inserter

Step 4: Draw the IUD into the insertion tube by pulling on the threads



Loading the IUD into the inserter

Step 5: Adjust the flange to the uterine depth



- Adjust the position of the flange (through the sterile package if not using sterile gloves) to correspond to the sound measurement
- The top end of the flange should be the measurement corresponding to the sounded depth of the uterus

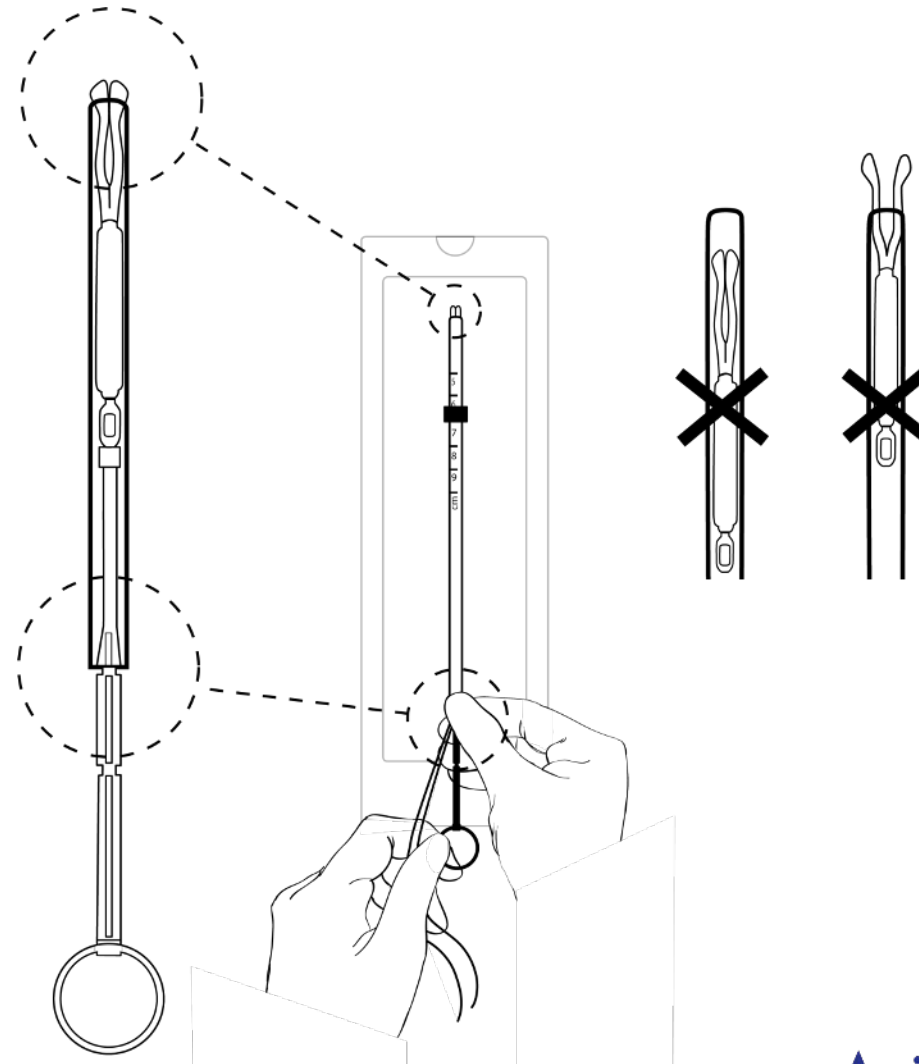
Loading the IUD into the inserter

Step 6: Final IUD positioning

**ENSURE A HEMISPHERICAL DOME
IS ACHIEVED**

The hemispherical dome facilitates
passage through the cervical os

- Position the IUD in the tube so that the knobs of the lateral arms form a hemispherical dome
- When the IUD tips are in the correct position (slightly protruding), pinch and hold the proximal 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



Loading the IUD into the inserter

Step 7: Check that the IUD is correctly loaded

- ✓ The IUD 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 IUD
- ✓ The blue threads are hanging through the end of the insertion tube
- ✓ The flange is marking the depth of the uterus based on pre-insertion sounding

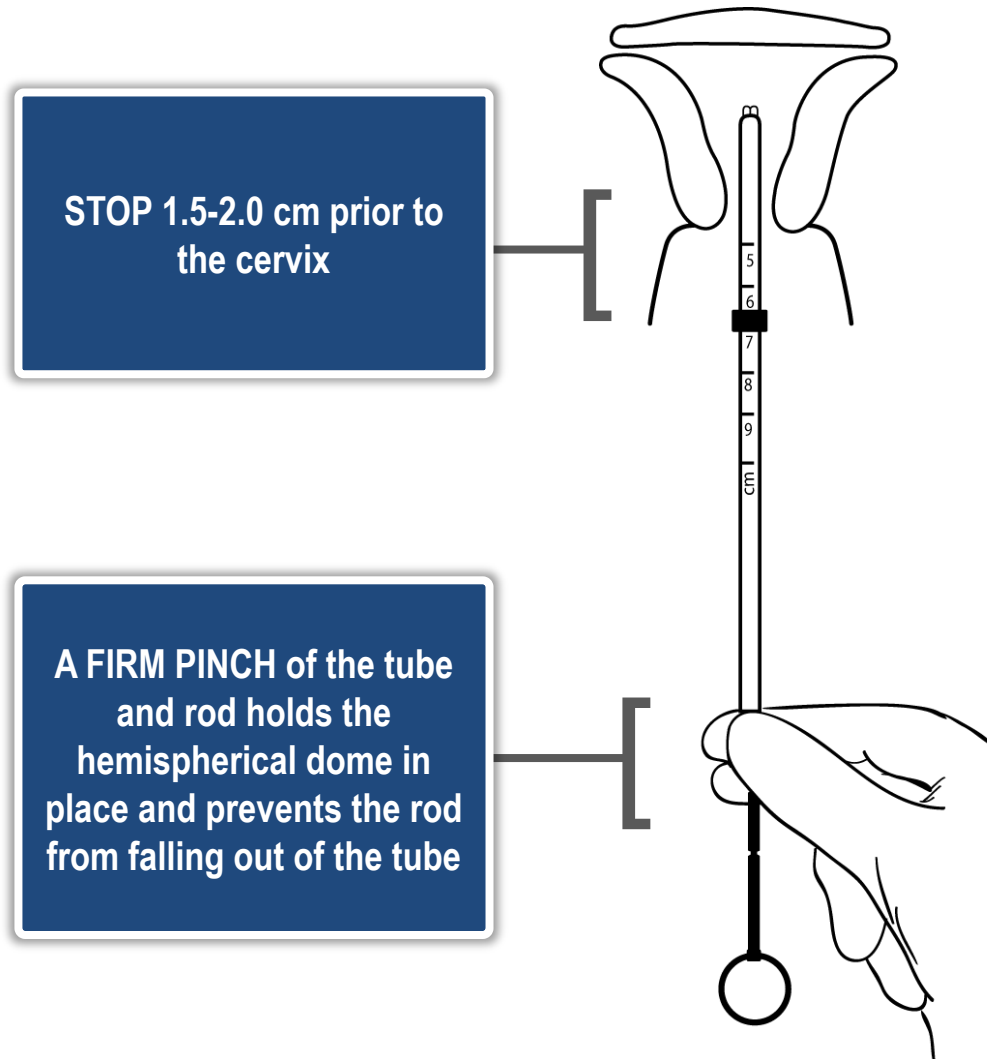
Loading the IUD into the inserter

Step 8: Remove insertion tube from the pouch

- Remove the loaded IUD insertion tube from the pouch while holding the lower end of the tube firmly between your fingers and thumb
- If not using sterile gloves, do not touch the flange and any part of the insertion tube above the flange during this step and through the IUD insertion procedure

IUD insertion into the uterus

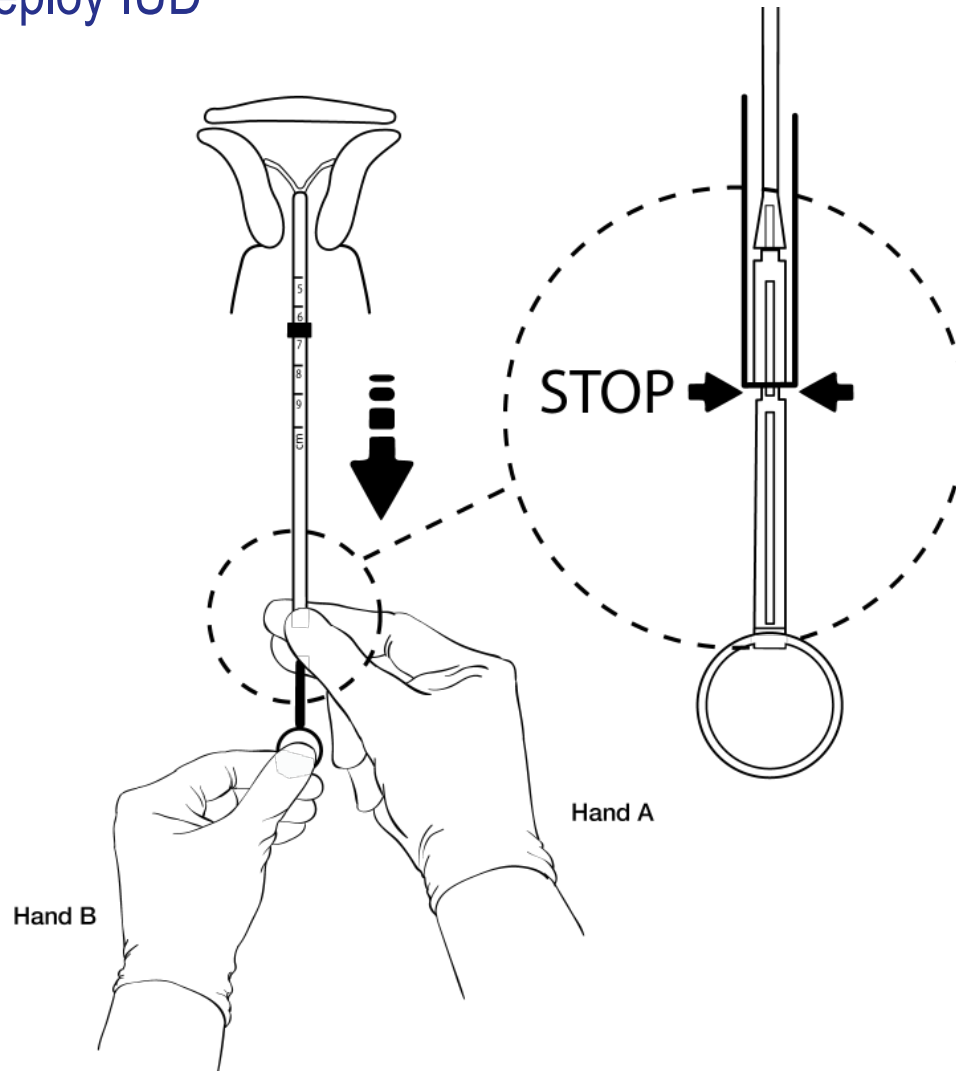
Step 1: Insert insertion tube into the uterus



- Apply gentle traction on the tenaculum to straighten the alignment of the cervical canal and uterine cavity
- While still firmly pinching the proximal end of the insertion tube, slide the loaded IUD insertion tube through the cervical canal until the upper edge of the flange is approximately 1.5–2.0 cm from the cervix
- DO NOT advance flange to the cervix at this step
- DO NOT force the inserter. If necessary, dilate the cervical canal

IUD insertion into the uterus

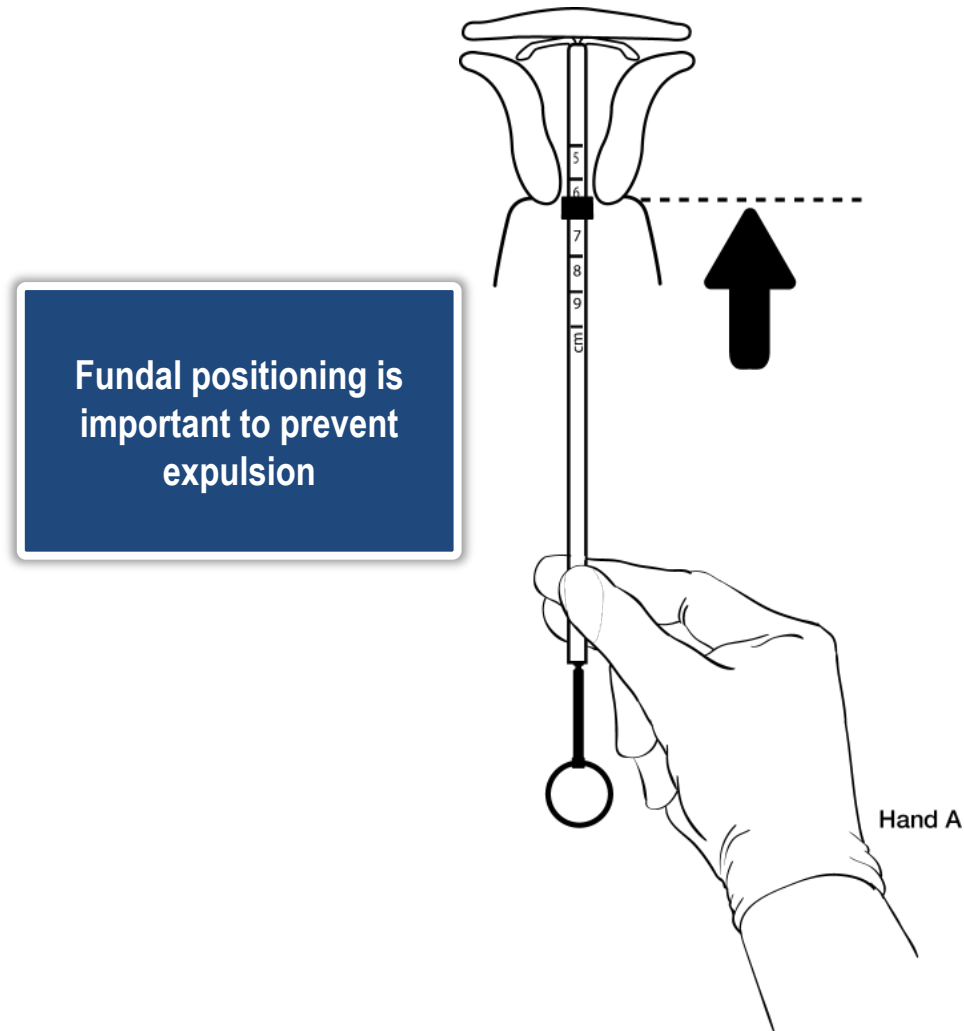
Step 2 and 3: Deploy IUD



- Release hold on tenaculum
- Hold the insertion tube with the fingers of one hand (Hand A) and the rod with the fingers of other hand (Hand B)
- Holding 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 indent on the rod
- Wait 10 – 15 seconds for the arms of the IUD to fully open

IUD insertion into the uterus

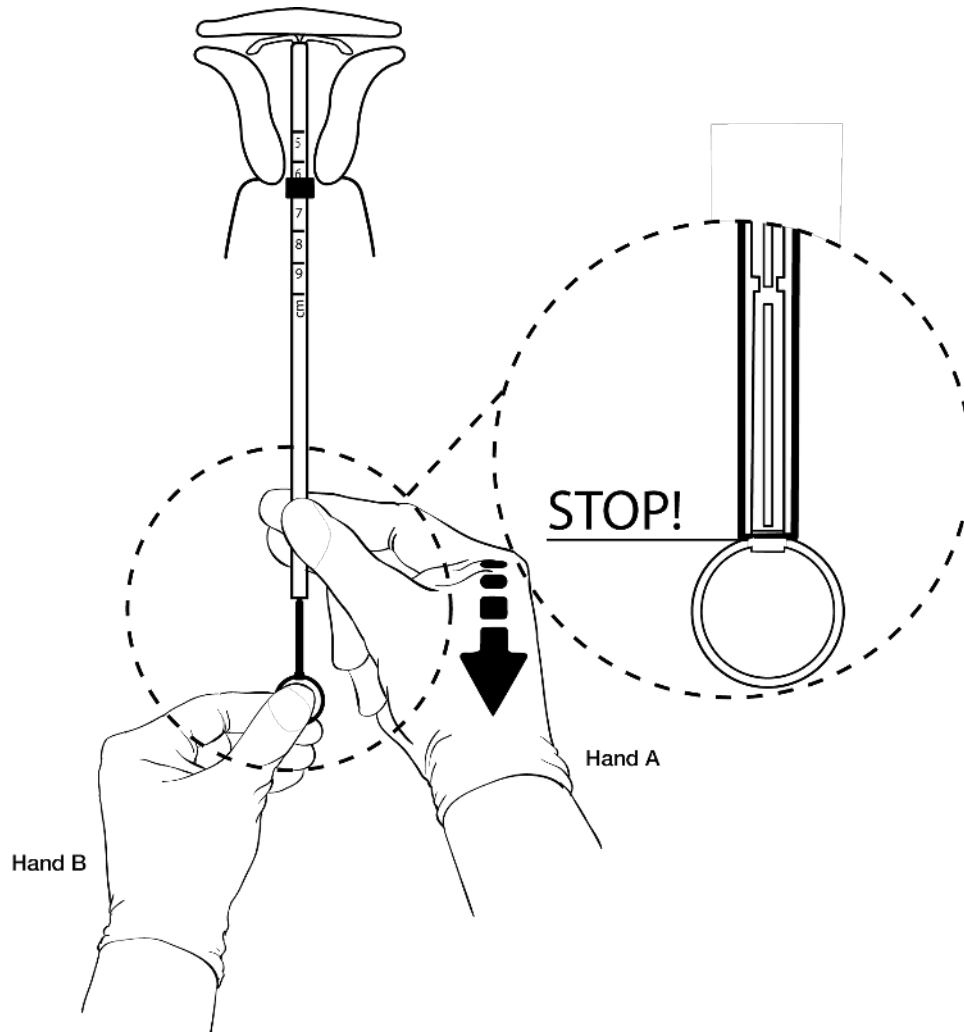
Step 4: Advance IUD to fundus



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

IUD insertion into the uterus

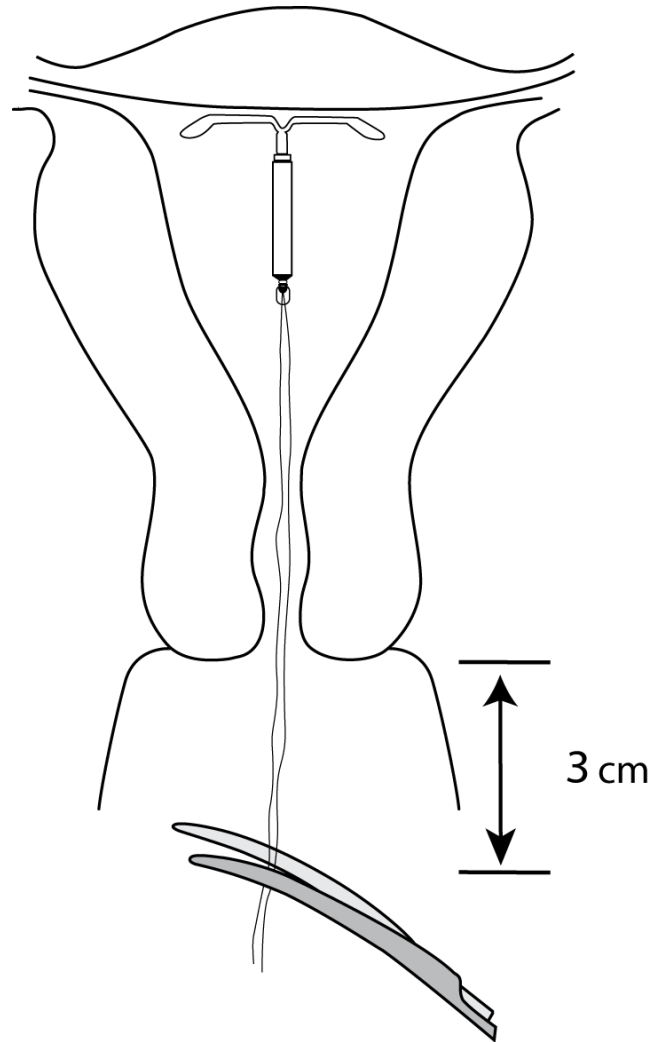
Steps 5-7: Release the IUD and withdraw the inserter



- Hold the rod still with Hand B while pulling the insertion tube back with Hand A to the ring of the rod
- While holding the inserter tube firmly in place with Hand A, withdraw the rod from the insertion tube all the way out to prevent the rod from catching on the knot at the lower end of the IUD
- Completely remove the insertion tube

IUD insertion into the uterus

Step 8: Cut the threads



- Use blunt-tipped sharp scissors to cut the IUD 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 IUD

IMPORTANT INFORMATION AND FOLLOW UP

Important information to consider during or after insertion

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

- Check insertion with an ultrasound or other appropriate radiologic test
- If incorrect insertion is confirmed, remove AVIBELA
 - A removed AVIBELA 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 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 perforation

Patient counseling and follow-up

- Counsel the patient on what to expect following AVIBELA insertion
 - Discuss expected bleeding patterns with AVIBELA use
 - Review the signs and symptoms associated with infection, perforation, and expulsion that may occur with use of AVIBELA
- Prescribe analgesics, if indicated
- Consider re-examining and evaluating patients 4 to 6 weeks after insertion and during routine care, or more frequently if clinically indicated
 - You should check the IUD strings during each evaluation

REMOVAL OF AVIBELA

Planning and timing of removal

- If pregnancy is desired, AVIBELA can be removed at any time
- If pregnancy is not desired, AVIBELA can be removed at any time; however, a contraception method should be started prior to removal of AVIBELA
 - 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
- AVIBELA should be removed at the end of the approved duration of use
 - AVIBELA can be replaced at the time of removal with a new AVIBELA if continued contraceptive protection and/or continued treatment of heavy menstrual bleeding is desired

Preparation for removal

Ensure all needed items for AVIBELA removal are readily available:

- Gloves
- Sterile speculum
- Sterile forceps

Additional items that may be required:

- Local anesthetic, needle, and syringe
- Sterile os finder, and/or cervical dilators
- Ultrasound with abdominal transducer
- Sterile tenaculum
- Antiseptic solution
- Sterile long, narrow forceps or intrauterine thread remover



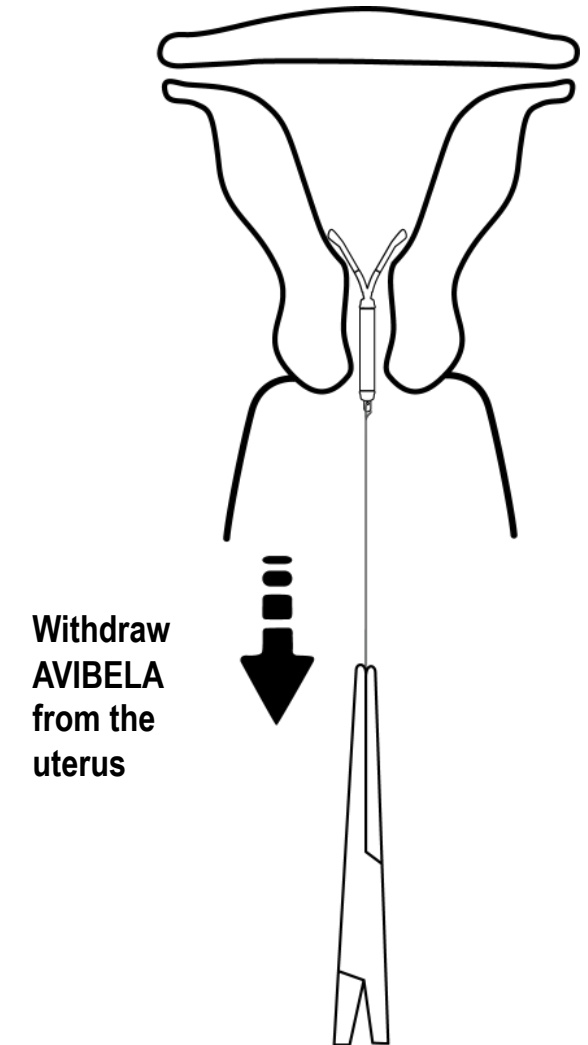
Alligator forceps

Preparation for removal, continued

- 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 AVIBELA, examine the system to ensure that it is intact
 - The hormone cylinder may slide over and cover the horizontal arms, giving the appearance of missing arms
 - This does not require further intervention if the system is verified to be intact.
- Breakage, embedment in the myometrium, or perforation of AVIBELA can make removal difficult
- IUD breakage may be associated with removal
- Analgesia, paracervical anesthesia, cervical dilation, alligator forceps or other grasping instrument, or hysteroscopy may assist in removal

Removal procedure

- With the patient comfortably in lithotomy position, place a speculum and visualize the cervix
- When the threads are visible:
 - Remove AVIBELA by applying gentle traction on the threads with forceps
 - If the IUD cannot be removed with gentle traction on the threads, perform an ultrasound to confirm the location of the IUD
 - If the IUD is in the uterus, use long, narrow forceps to grasp AVIBELA
 - 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



Removal procedure, continued

- If the threads of AVIBELA are not visible:
 - Determine location of the IUD and exclude embedment or perforation by ultrasound examination
 - If the IUD is in the uterine cavity, thoroughly cleanse the cervix and vagina with antiseptic solution
 - Use a thread retriever to capture the threads or a long, narrow forceps (e.g., Alligator forceps) to grasp AVIBELA
 - Consider use of a tenaculum, cervical anesthesia, cervical dilators, and/or ultrasound guidance as needed
- If AVIBELA cannot be removed using the above techniques, consider hysteroscopic evaluation for removal
- If the IUD is not in the uterine cavity, consider an abdominal x-ray or CT scan to evaluate if the IUD is in the abdominal cavity
 - Consider laparoscopic evaluation for removal, as clinically indicated
- After removal, examine the system to ensure it is intact

Continuation of contraception after removal

- If a patient wishes to continue using AVIBELA or another intrauterine contraceptive:
 - Insertion can occur immediately after removal
- Women with regular cycles who want to start a different birth control method:
 - Either remove AVIBELA 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 AVIBELA removal
- Women with irregular cycles or amenorrhea who want to start a different birth control method:
 - Start the new method at least 7 days before AVIBELA removal
- If AVIBELA is removed but no other contraceptive method has already been started, the new method can be started on the day AVIBELA is removed
- A new contraceptive method can be started on the day AVIBELA is removed. However, to prevent pregnancy, the patient should:
 - Use a backup barrier method of contraception (e.g., condoms), OR
 - Abstain from vaginal intercourse for 7 days

Important Safety Information

- Please refer to the approved AVIBELA labeling in your country for complete Important Safety Information

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(levonorgestrel-releasing intrauterine system) **52 mg**



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