

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

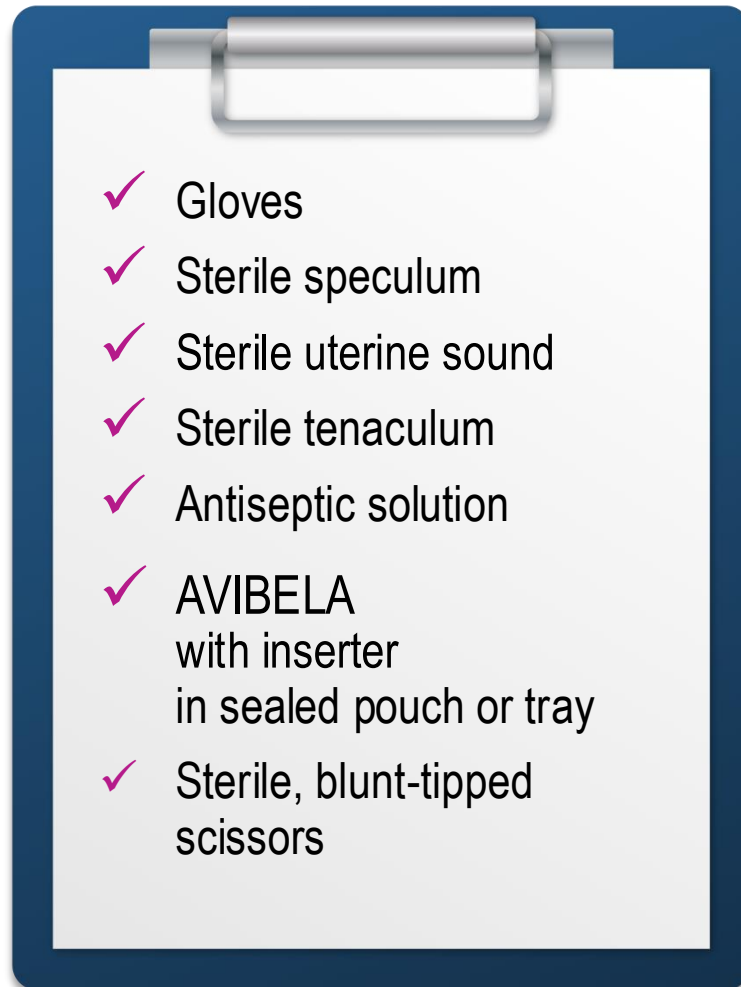
Timing of AVIBELA insertion after first trimester abortion and miscarriage:

- 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

Insertion procedure

Step 2: Opening the sterile AVIBELA packaging

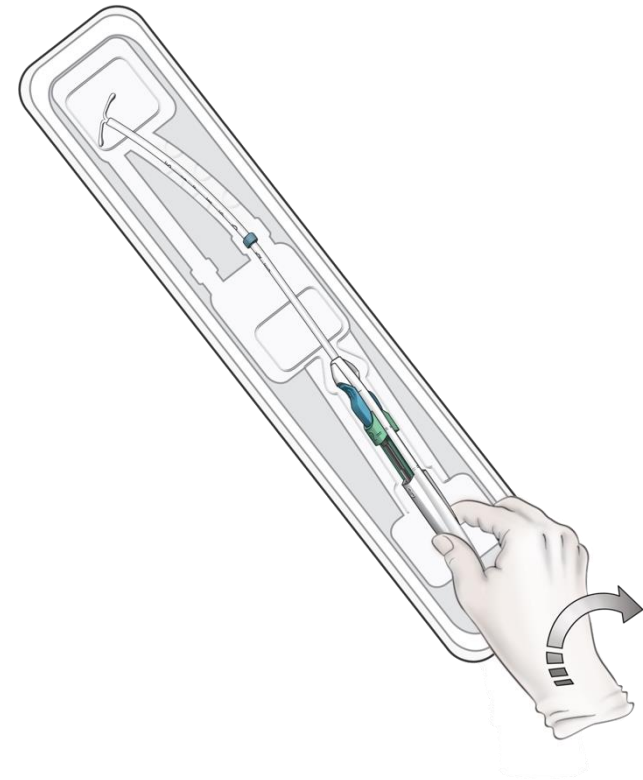
- Remove the sealed tray containing AVIBELA from the unit carton
- Inspect the sealed tray and do not use the product if the packaging, inserter, or IUD is damaged
- Lay the tray on a flat surface with the sealed peel-off lid side up
- Remove the peel-off lid

Insertion procedure

Step 3 : Loading AVIBELA into the inserter

- To remove the inserter from the tray, grasp the handle below the sliders and twist gently
- Do not attempt to remove the inserter by pulling on the tube

Removing inserter from tray

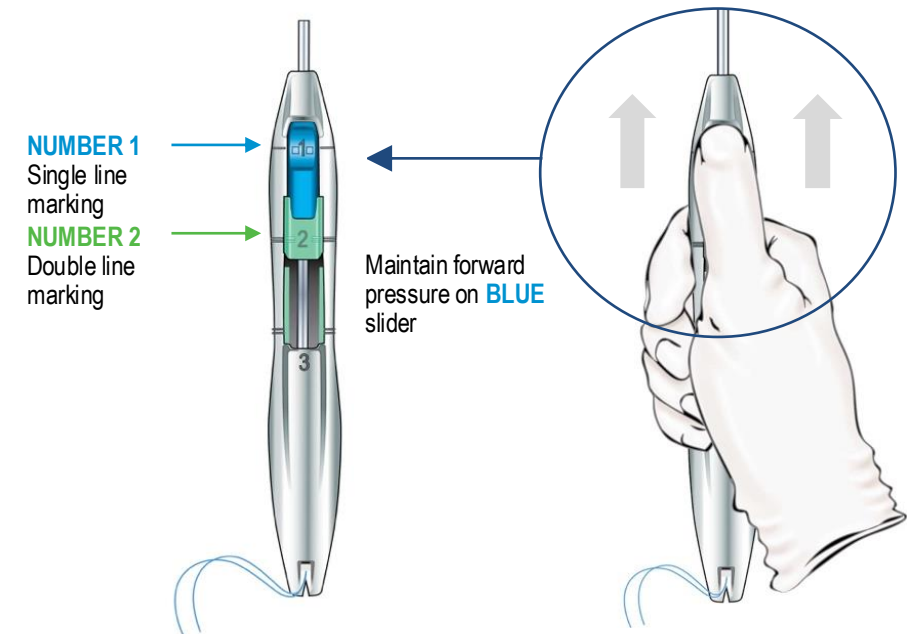


Insertion procedure

Step 3: Loading AVIBELA into the inserter

- Ensure both sliders (labeled 1 and 2) are **fully forward**
 - The BLUE slider (labeled with the number 1) has a single line marking that will align with the handle's single line marking
 - The GREEN slider (labeled with the number 2) has a double line marking that will align with the handle's double-line marking
- 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**

Sliders completely forward for loading IUD

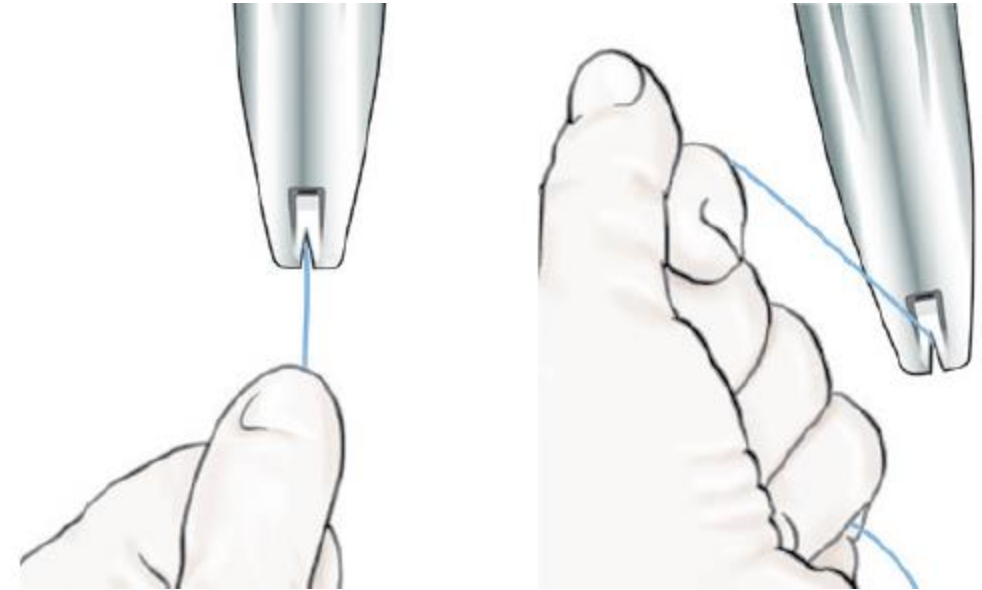


Insertion procedure

Step 3: Loading AVIBELA into the inserter

- Ensure the arms of the IUD are horizontal
 - Adjust the rotation of the IUD as needed using the flat sterile surface of the tray
- While maintaining **forward pressure** on the BLUE slider, gently pull the threads **straight** back to load AVIBELA into the insertion tube
- Pull the threads upward or downward to lock the threads into the cleft at the bottom end of the handle
 - You must **lock the threads** in the cleft to prevent the IUD from moving out of the top of the insertion tube
- Once the threads are locked into the cleft, **stop holding the threads**

Locking threads in cleft



Reminder: It's important to ensure even tension is applied to both threads when pulling

Insertion procedure

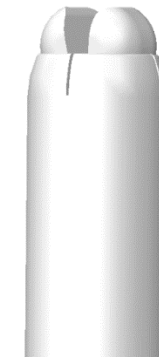
Step 3: Loading AVIBELA into the inserter

- After the IUD is loaded, continue to sustain **forward pressure** on the BLUE slider to maintain a hemispherical dome with the tips of the IUD
- If the IUD is not correctly loaded, **do not attempt insertion**

The AVIBELA inserter can be reloaded if needed. To re-load:

- 1) Pull the BLUE slider back with your thumb until the groove becomes aligned with the GREEN slider to release the IUD
- 2) Manually pull the threads out of the cleft
- 3) Return the blue slider to the forward position and repeat the loading steps

Close-up of hemispherical dome at tip of tube



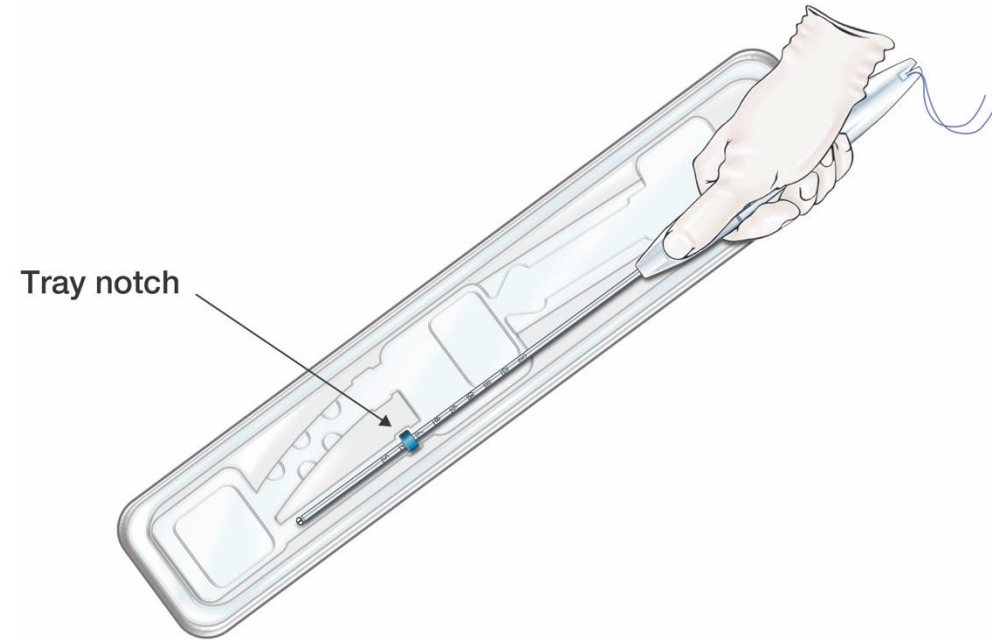
When correctly loaded, the IUD is completely within the insertion tube with the tips of the arms forming a hemispherical dome at the top of the tube

Insertion procedure

Step 3: Loading AVIBELA into the inserter

- Adjust the flange to the measured uterine depth based on sounding
 - Place the flat side of the flange in the tray notch or against a sterile edge inside the tray
 - Slide the insertion tube as necessary to move the flange to the correct measurement
 - Ensure the flat sides of the flange are in the same horizontal plane as the handle

Adjusting the flange



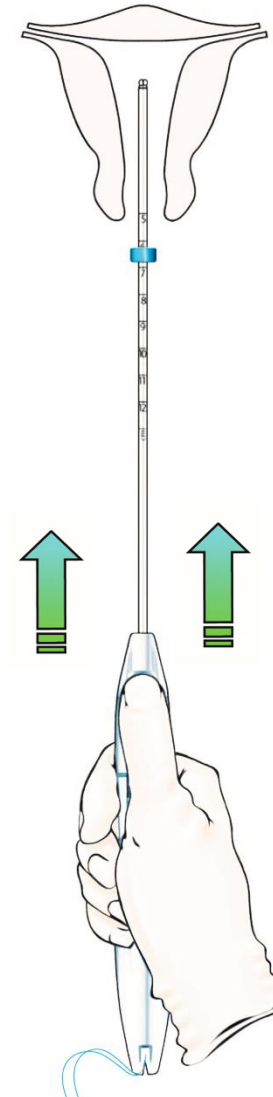
Reminder: When bending the tube, be careful to avoid sharp bends to prevent kinking

Insertion procedure

Step 4: Inserting AVIBELA into the uterus

- Apply gentle traction on the tenaculum and continue to apply **forward pressure** on the BLUE slider while inserting the loaded insertion tube through the cervical os
- Advance the tube until the upper edge of the flange is 1.5 – 2 cm from the external cervical os
- Maintain forward pressure on the BLUE slider throughout the insertion process

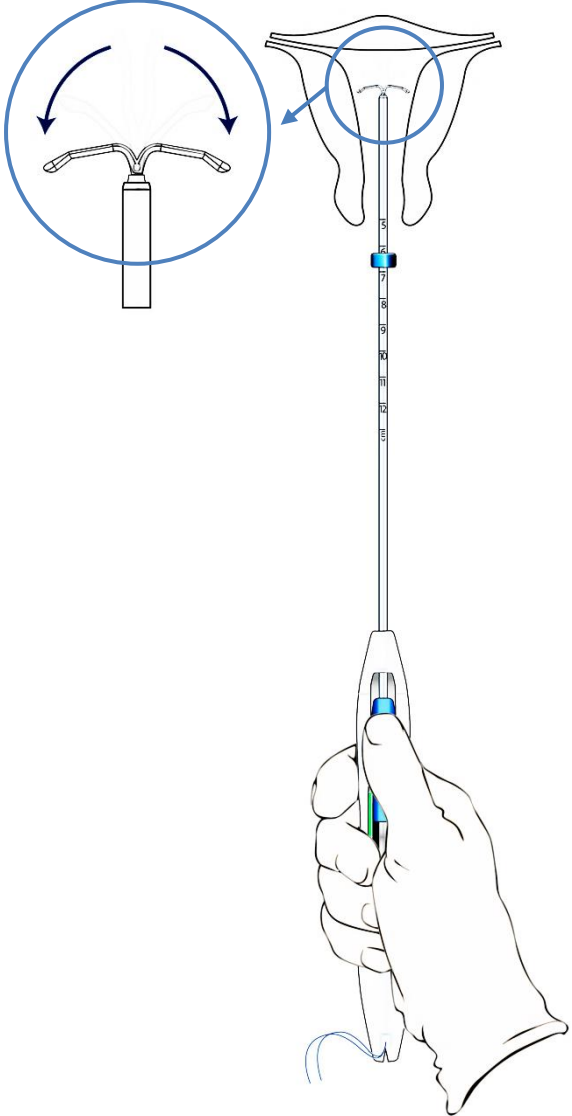
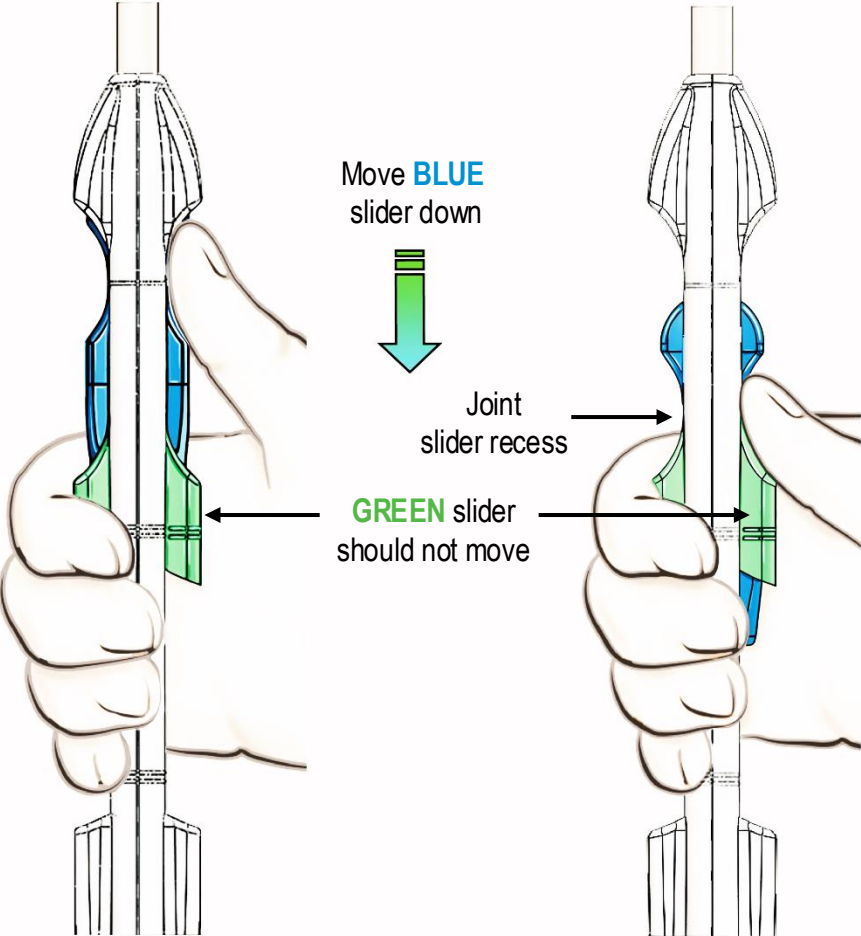
Advancing insertion tube until flange is 1.5 to 2 cm from the external cervix



Maintain forward pressure on the **BLUE** slider

Insertion procedure

Step 4 : Inserting AVIBELA into the uterus



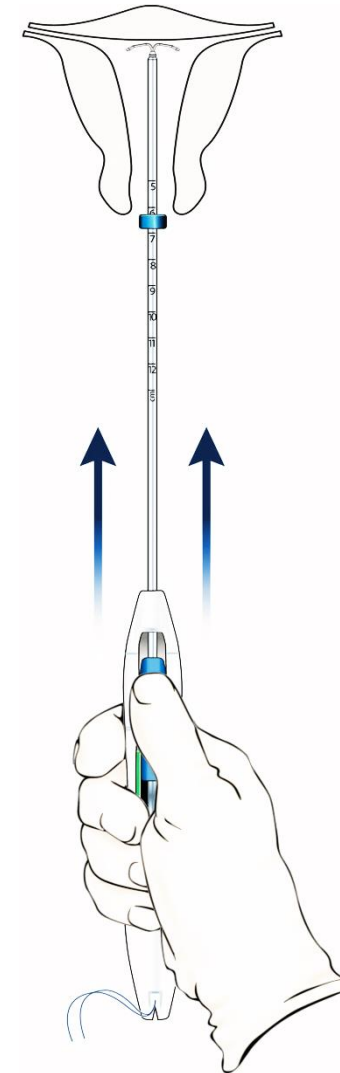
Insertion procedure

Step 4: Inserting AVIBELA into the uterus

- Without moving the sliders, advance the inserter until the flange touches the cervix
- If fundal resistance is encountered, do not continue to advance
- AVIBELA is now in the fundal position

Move AVIBELA into the fundal position

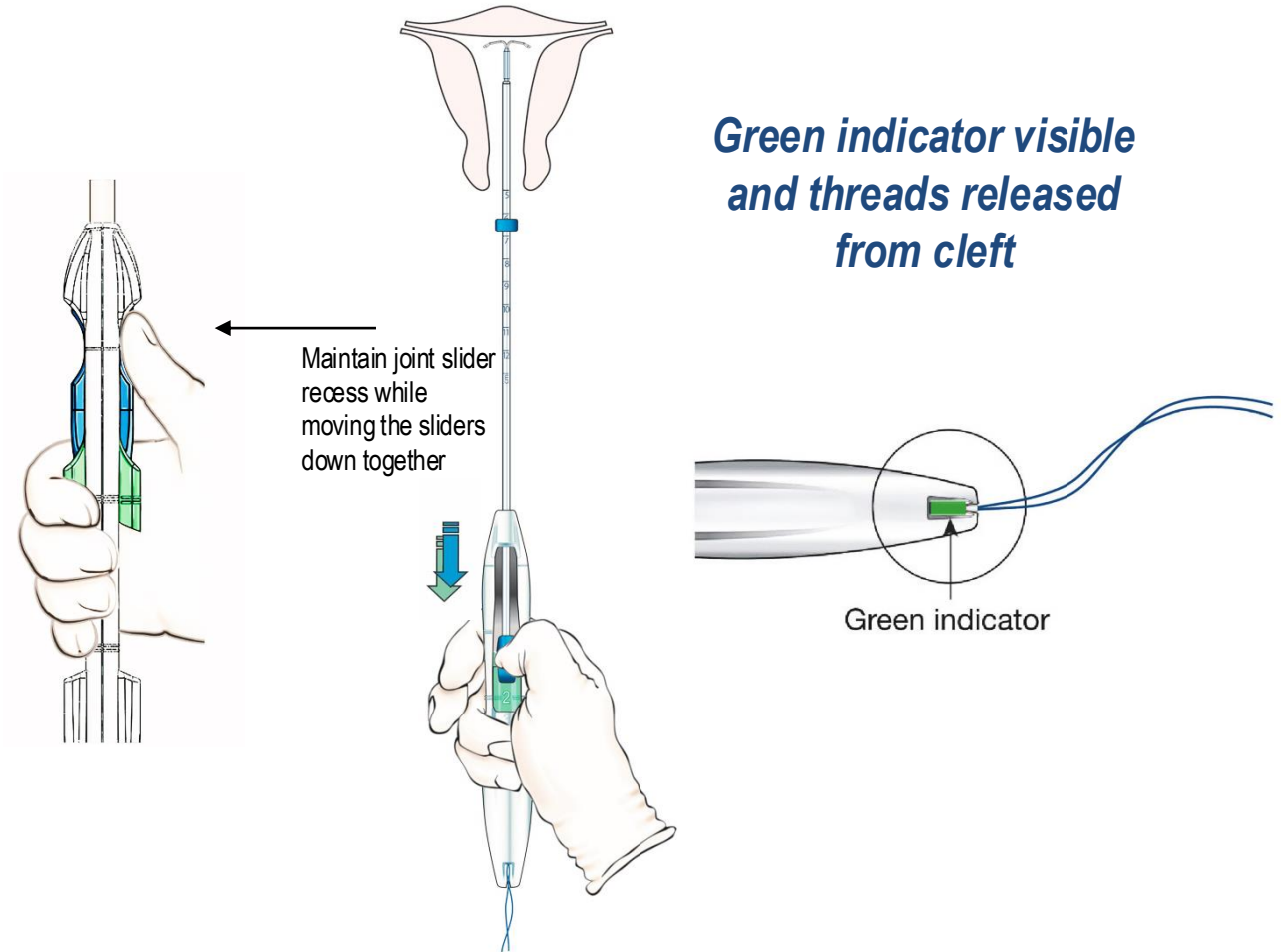
Reminder: Fundal position is important to prevent expulsions



Insertion procedure

Step 5: Releasing AVIBELA and procedure completion

- While holding the inserter steady and maintaining its position relative to the cervix, move **both** sliders (BLUE and GREEN) together while maintaining the joint slider recess down toward the number 3 on the handle until a click is heard and the GREEN indicator at the bottom of the handle is visible, signifying deployment

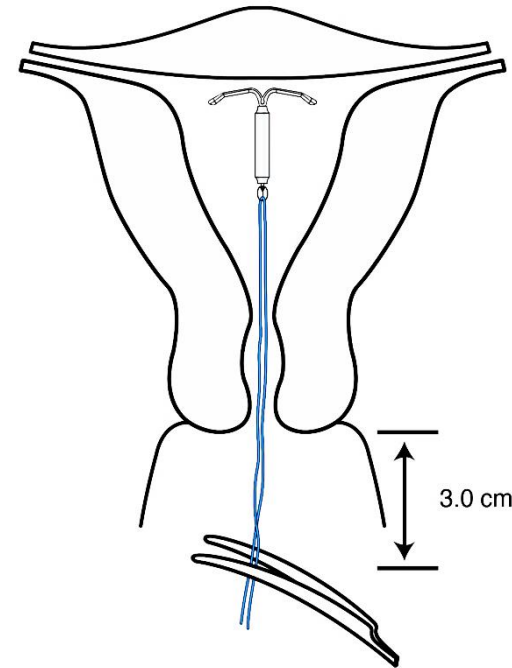


Insertion procedure

Step 5: Releasing AVIBELA and procedure completion

- Withdraw the inserter from the uterus
- Use blunt-tipped sharp scissors to cut the IUD threads perpendicular to the thread length, leaving about 3 cm outside of the cervix
 - Do not apply tension or pull on the threads when cutting to prevent displacing the IUD

**Cut the threads about
3 cm from the cervix**



**Reminder: Do not cut threads at
an angle as this may leave sharp
ends**

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



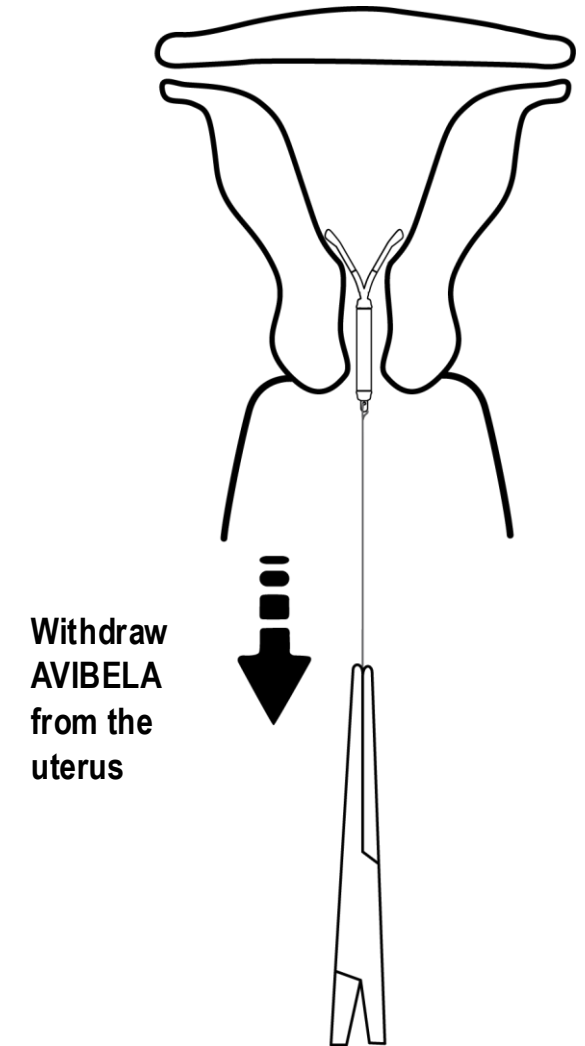
Alligator forceps

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

Avibela[®]

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

Medicines[®]
360 ♀



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