

# Insertion Procedure

**Avibela<sup>®</sup>**  
(levonorgestrel-releasing intrauterine system) **52 mg**

# Planning for AVIBELA® Insertion

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- 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 & social history that might influence the selection of AVIBELA
- Exclude pregnancy and confirm that there are no contraindications to using AVIBELA
- Ensure that the woman understands the contents of the Patient Information Booklet and obtain consent
- Check the expiration date on the box before opening it. Do not insert AVIBELA after the expiration date
- Avibela is supplied sterile, having been sterilized with ethylene oxide. Do not re-sterilize.

# Planning for AVIBELA® Insertion

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- Complete the pelvic examination, speculum placement, tenaculum placement, and sounding of the uterus before opening the AVIBELA pouch
- Do not open the pouch to insert AVIBELA if the cervix is unable to be properly visualized, if the uterus cannot be adequately instrumented (during sounding), or if the uterus sounds to less than 5.5 cm
- 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

# Timing of AVIBELA® Insertion

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

- AVIBELA can be inserted any time
  - Rule out pregnancy and possibility of ovulation and conception before insertion
  - 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

# Timing of AVIBELA® Insertion

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*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 6 weeks or until uterus is fully involuted
  - Rule out pregnancy and possibility of ovulation and conception before insertion
  - 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

# Timing of AVIBELA® Insertion

## Switching to AVIBELA from other contraceptives

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

# Items for Insertion

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- ✓ Gloves
- ✓ Speculum
- ✓ Sterile uterine sound
- ✓ Sterile tenaculum
- ✓ Antiseptic solution
- ✓ AVIBELA®  
with inserter  
in sealed pouch
- ✓ 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

# Preparation for Insertion

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- After opening the box, visually inspect the sealed pouch 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
- Use aseptic technique during the entire insertion procedure.
  - Loading and inserting AVIBELA does not require sterile gloves.
  - If not using sterile gloves, complete all steps for loading the IUD inside the pouch. Do not touch AVIBELA or parts of any sterile instrument that will pierce tissue (e.g., a tenaculum on the cervix) or go into the uterine cavity.
- Follow the insertion instructions exactly as described in order to ensure proper insertion

# Preparation for Insertion

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- 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
- Place 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

# Sounding the Uterus

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## Carefully sound the uterus to measure its depth

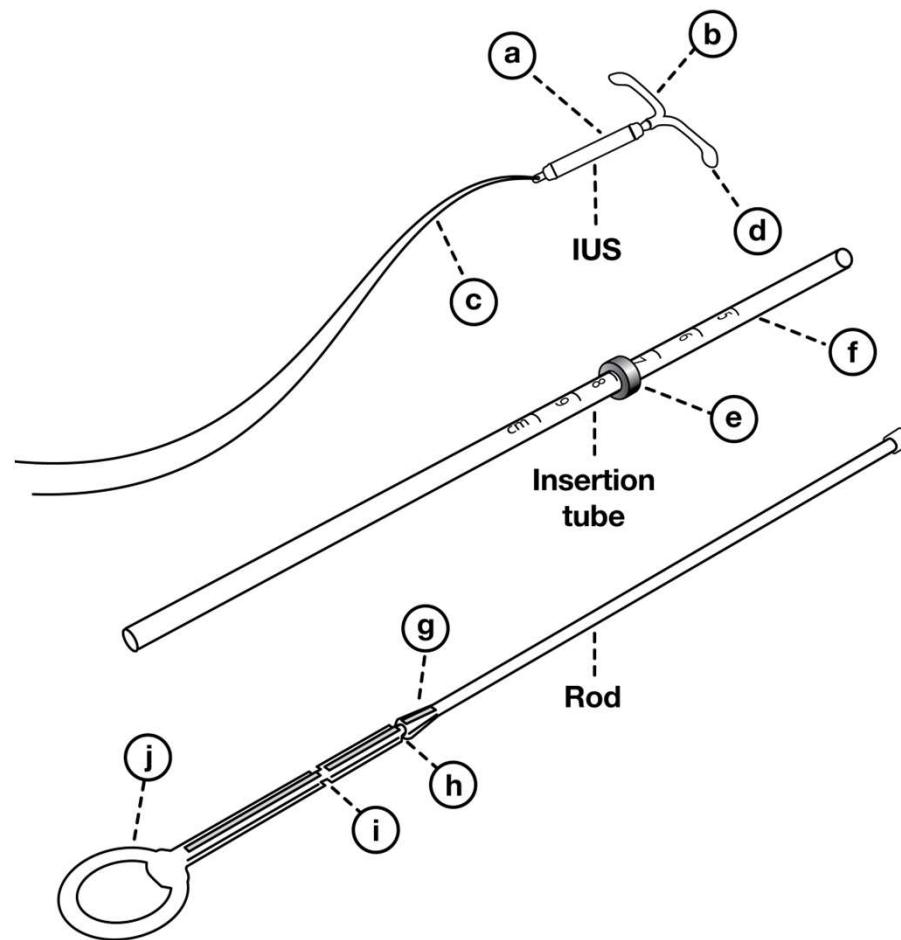
- The uterus should sound to a depth of at least **5.5 cm**. Insertion of AVIBELA® into a uterine cavity that sounds to less than 5.5 cm may increase the incidence of expulsion, bleeding, pain, perforation, and possibly pregnancy. AVIBELA should not be inserted if the uterus sounds to less than 5.5 cm.
- 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
- Open the pouch containing AVIBELA only after ascertaining that the patient is appropriate for AVIBELA

# AVIBELA® Insertion Video

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- Insertion Video

# AVIBELA® IUD and Inserter



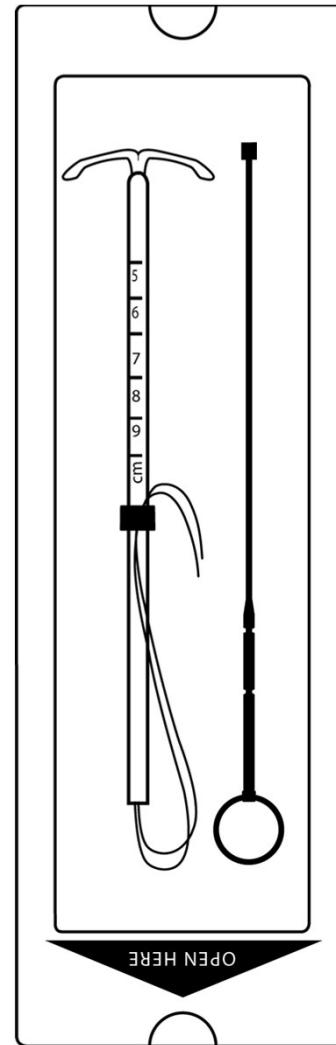
- (a) Levonorgestrel reservoir with membrane
- (b) Lateral arms
- (c) Blue removal threads
- (d) Knobs
- (e) Flange
- (f) Centimeter markings
- (g) Thickened mark
- (h) First indent
- (i) Second indent
- (j) Ring

# Loading the IUD Into the Inserter

Step 1: Place the AVIBELA® pouch on a flat surface and open from the bottom

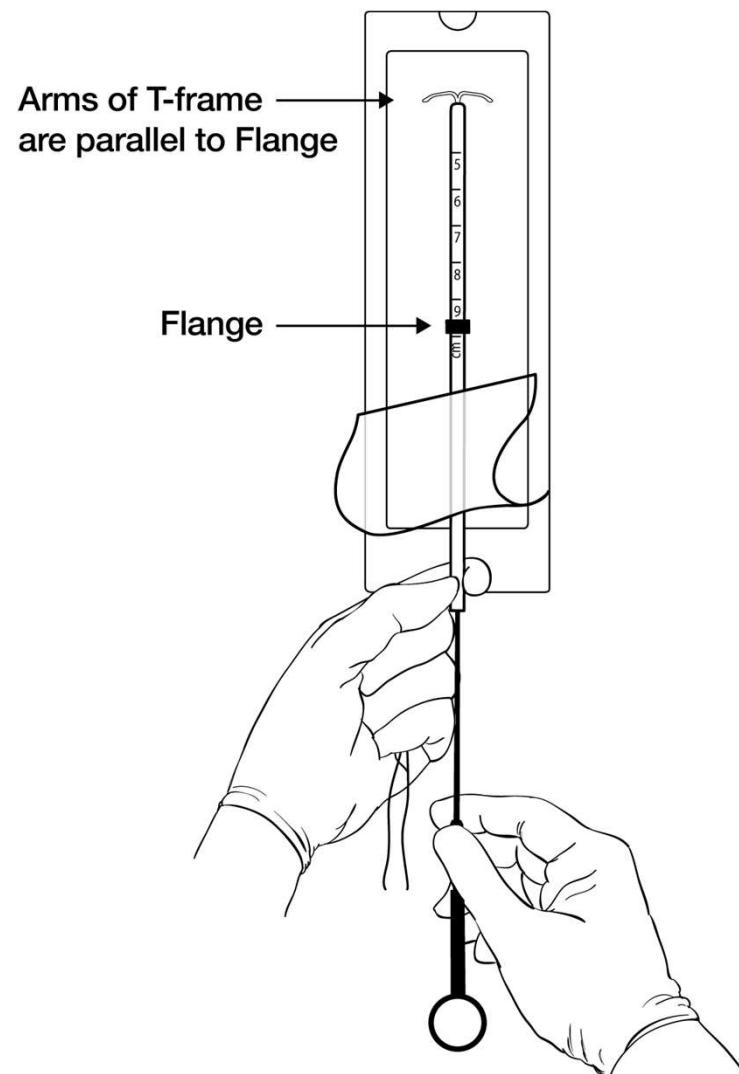
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- Open the sterile AVIBELA pouch from the bottom, folding the plastic up 1/3 of the way until the lower end of the IUD threads, rod, and insertion tube are exposed



# Loading the IUD Into the Inserter

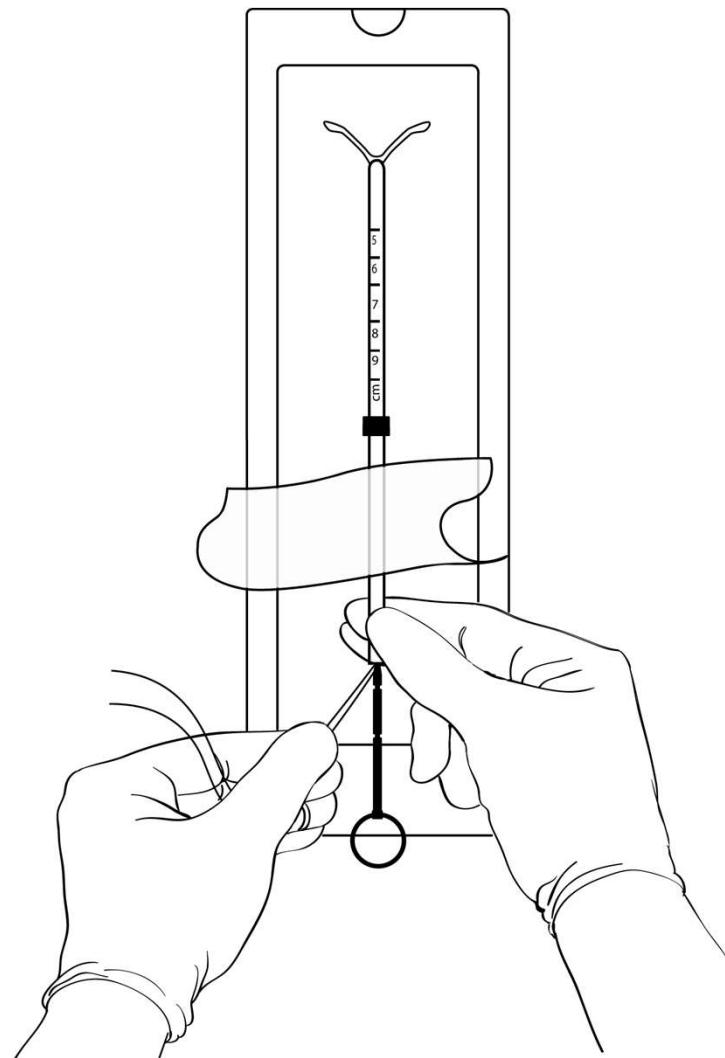
Steps 2 and 3: Release the threads from the flange and insert the rod



# Loading the IUD Into the Inserter

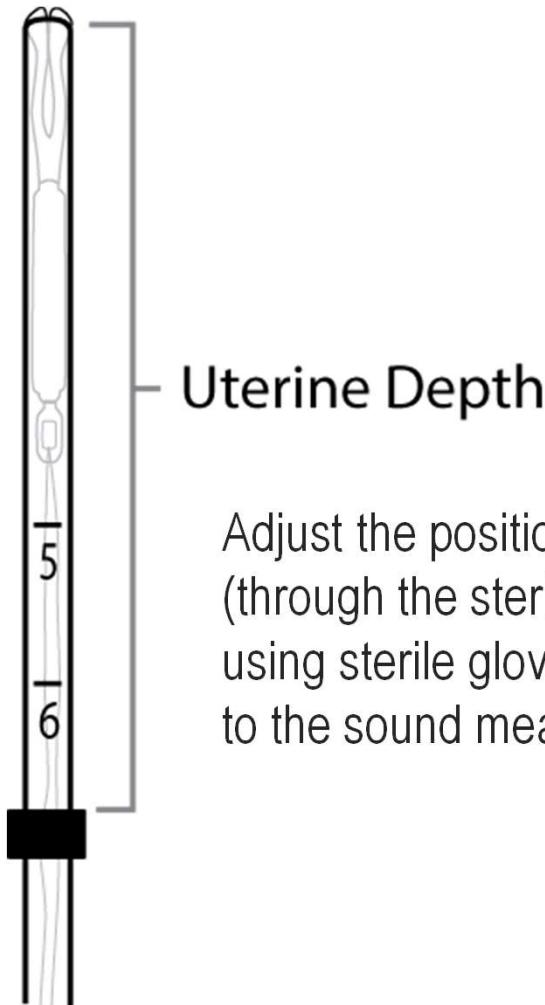
## Step 4: Load the IUD into the inserter

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# Loading the IUD Into the Inserter

## Step 5: Adjust the flange to the uterine depth



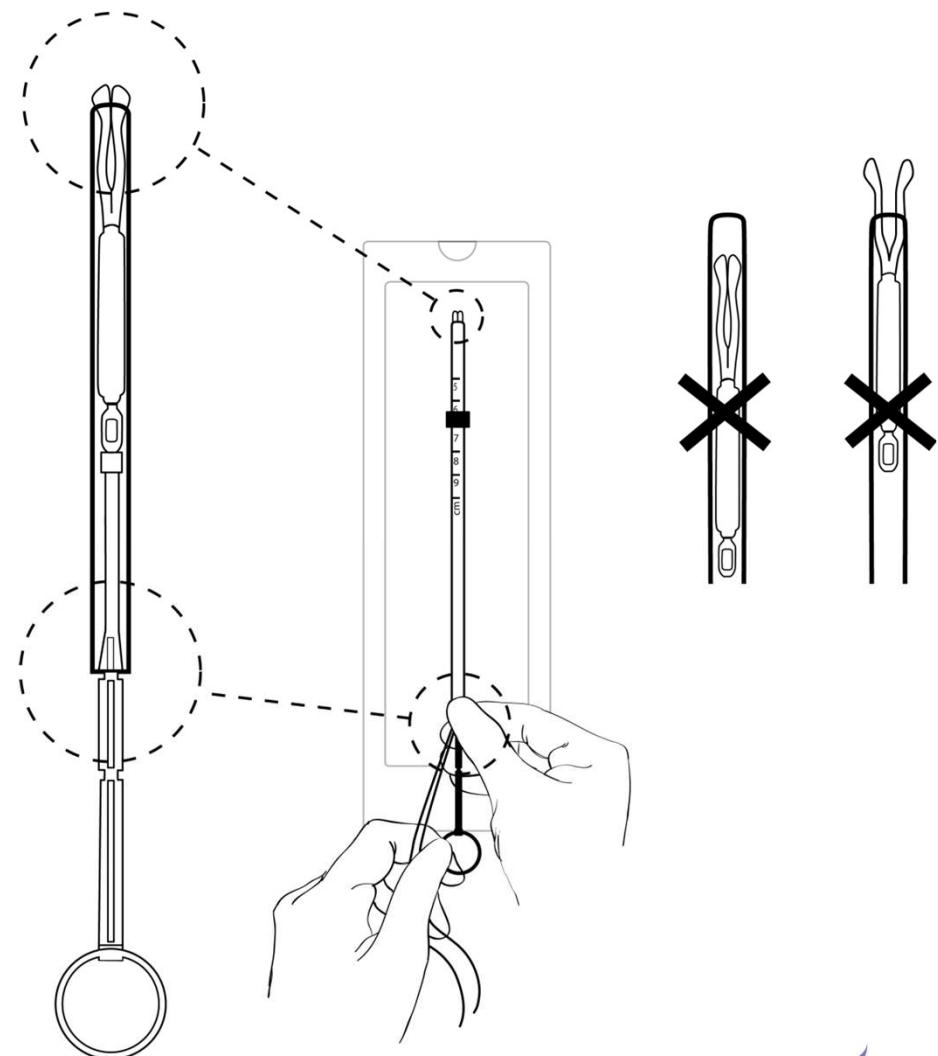
Adjust the position of the flange (through the sterile package if not using sterile gloves) to correspond to the sound measurement

# Loading the IUD Into the Inserter

## Step 6: Final IUD positioning

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, PINCH AND HOLD the bottom 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

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- ✓ 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

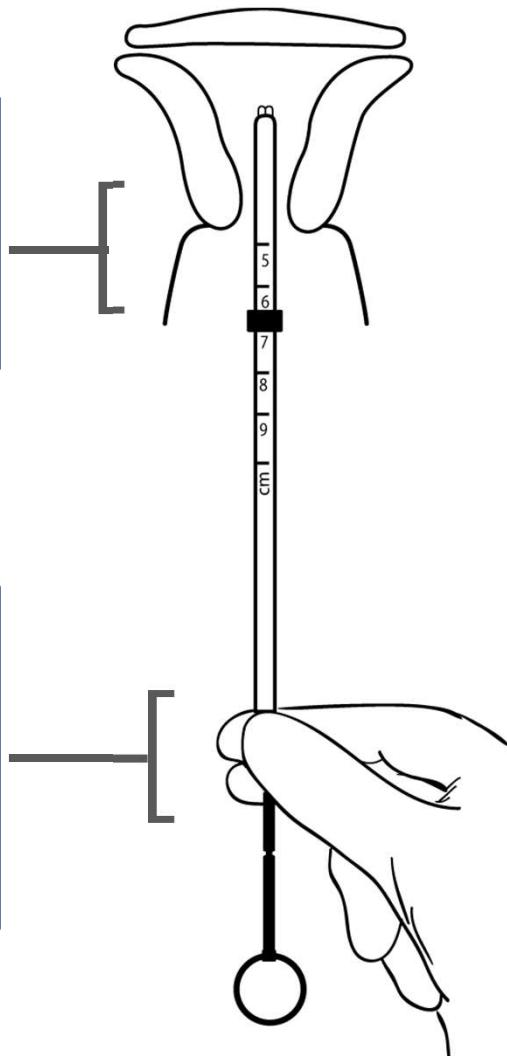
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- Remove the loaded IUD insertion tube from the pouch while holding the lower end of the tube firmly between your fingers and thumb.
- If not using sterile gloves, do not touch the flange and any part of the insertion tube above the flange during this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

# IUD Insertion Into the Uterus

## Step 1: Insert IUD into the uterus

STOP 1.5-2.0 cm prior to the cervix to allow the arms of AVIBELA® to open

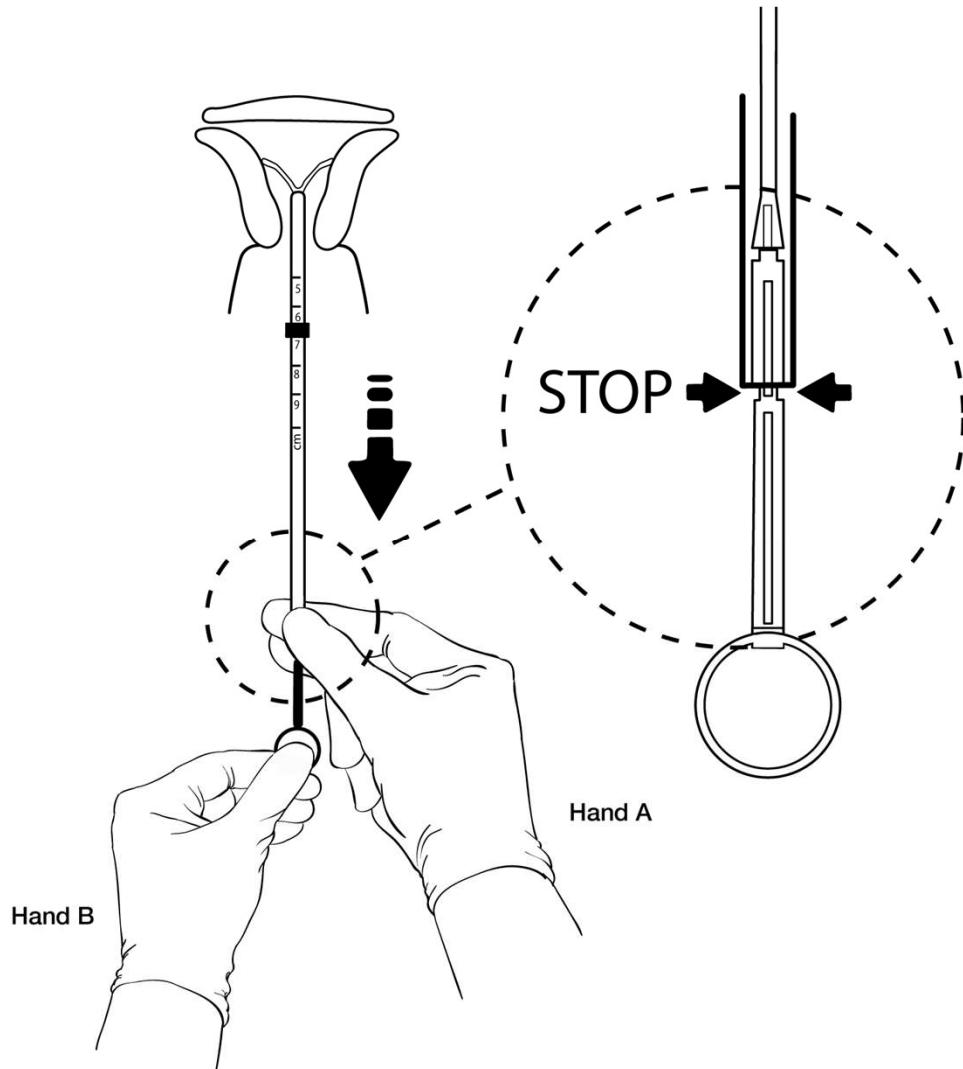


A FIRM PINCH of the tube and rod holds the hemispherical dome in place and prevents the rod from falling out of the tube

- Apply gentle traction on the tenaculum to straighten the alignment of the cervical canal and uterine cavity
- 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

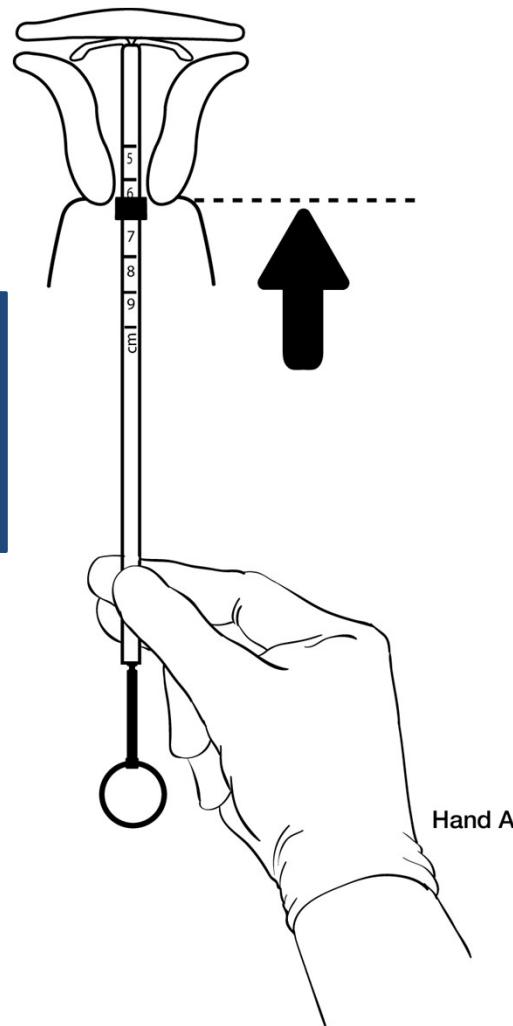


- Release hold on tenaculum
- Hold the insertion tube with the fingers of one hand (Hand A) and the rod with the fingers of other hand (Hand B)
- **HOLD THE ROD STILL** with Hand B
- Relax the firmness of the pinch on the tube, AND PULL THE INSERTION TUBE BACK with Hand A to the edge of the second (bottom) indent of 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

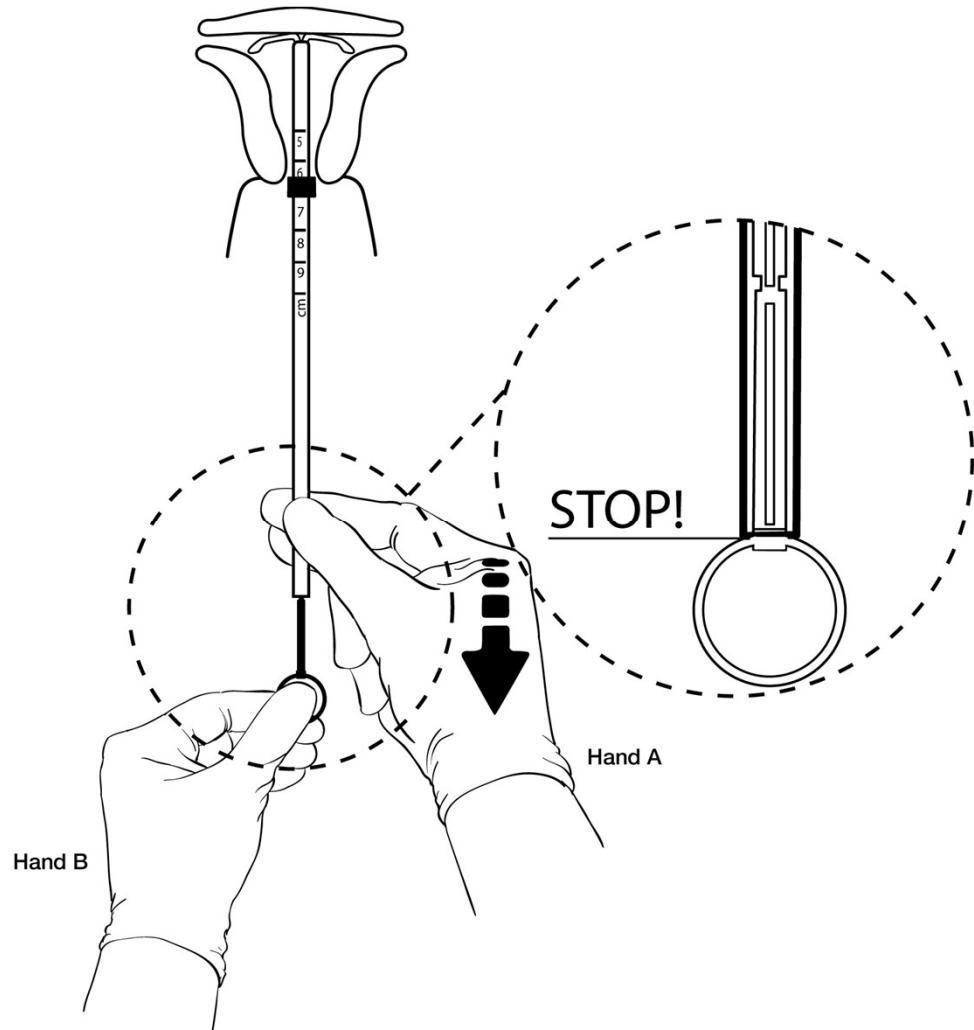
Fundal positioning is important to minimize risk of expulsion



- Apply gentle traction with tenaculum before advancing 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

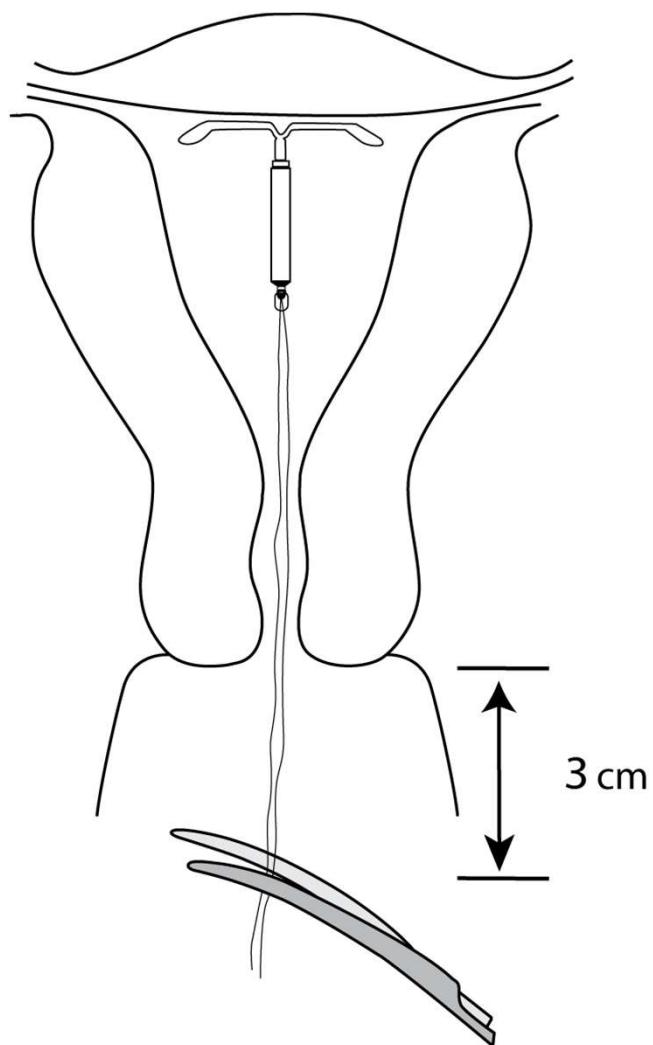


- Hold the rod still with Hand B while pulling the insertion tube back with Hand A to the ring of the rod
- While holding the inserter tube with Hand A, withdraw the rod from the insertion tube all of the way out to prevent the rod from catching on the knot at the lower end of the IUD
- Completely remove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

**Removing the rod first and then the tube prevents the IUD from being pulled out of the uterus**

# 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 to Consider During or After Insertion

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## 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 suspected, 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
- 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

# Continuation of Contraception After Removal

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- Women who desire to continue using AVIBELA®
  - A new system or another intrauterine contraceptive can be inserted immediately after removal at any time during the cycle
- Women with regular cycles who desire a different contraceptive:
  - 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 desire a different contraceptive:
  - Start the new method at least 7 days prior to AVIBELA removal

# Continuation of Contraception After Removal

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- A new contraceptive method can be started on the day AVIBELA® is removed. However, to prevent pregnancy either:
  - A backup barrier method of contraception should be used, OR
  - Abstain from vaginal intercourse for 7 days

# Timing of Removal of AVIBELA®

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- 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 if she has intercourse in the week prior to removal without use of a backup contraceptive method, she is at risk of pregnancy
- AVIBELA should be removed after 3 years. AVIBELA can be replaced at the time of removal with a new AVIBELA if continued contraceptive protection is desired

# Items for Removal

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Ensure all needed items for AVIBELA® 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 (eg, Alligator forceps)

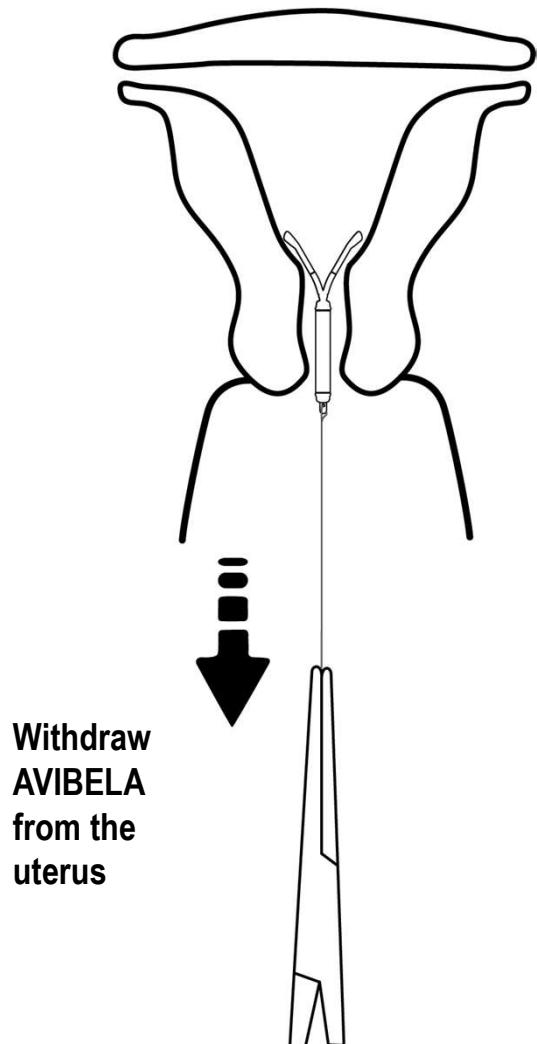


Packing forceps



Alligator forceps

# AVIBELA® Removal Process



- Remove AVIBELA by applying gentle traction on the threads with forceps
- If the threads of AVIBELA are not visible or if it cannot be removed with traction on the threads, perform an ultrasound examination to confirm location
- If the IUD is in the uterine cavity, use a long, narrow forceps (e.g. Alligator forceps) to grasp it.
  - Consider use of a tenaculum, cervical anesthesia, cervical dilators, and/or ultrasound guidance as needed
- If the IUD 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.

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# IMPORTANT SAFETY INFORMATION

# Who is not appropriate for AVIBELA®

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- Use of AVIBELA is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity; known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; known or suspected uterine or cervical neoplasia; acute liver disease or liver tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in the past 3 months; unexplained uterine bleeding; current IUS; acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of AVIBELA.

# Clinical considerations for use of AVIBELA®

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- Use AVIBELA 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 headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction.
- Insertion of AVIBELA 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. About 1/3 of women diagnosed with PID developed the infection within a week of AVIBELA insertion, while the remainder were diagnosed more than six months after insertion. PID is often associated with sexually transmitted infections (STIs); AVIBELA does not protect against STIs, including HIV. PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae. PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death.

# Pregnancy related risks with AVIBELA®

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- If pregnancy should occur with AVIBELA 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. The likelihood of a pregnancy being ectopic is increased with AVIBELA. Risks associated with ectopic pregnancy include loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

# Be aware of other serious complications & most common adverse reactions

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- Some serious complications with IUSs like AVIBELA® 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 AVIBELA is essential in order to minimize serious infections such as GAS.
- Perforation (total or partial, including penetration/embedment of AVIBELA 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 perforation occurs, locate and remove AVIBELA. Surgery may be required. Delayed detection or removal of AVIBELA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera.
- Partial or complete expulsion of AVIBELA may occur, resulting in the loss of contraceptive protection.
- Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent ovarian cysts.
- In the clinical trial of AVIBELA the most common adverse reactions ( $\geq 5\%$  users) were vaginal infections (13.6%), vulvovaginal infections (13.3%), acne (12.3%), headache or migraine (9.8%), nausea or vomiting (7.9%), dyspareunia (7.0%), abdominal pain or discomfort (6.8%), breast tenderness or pain (6.7%), pelvic discomfort or pain (6.1%), depression or depressed mood (5.4%), and mood changes (5.2%).

# AVIBELA® Manufacturing Information

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AVIBELA is manufactured by:

Odyssea Pharma, Belgium,  
an affiliated company of  
Allergan USA, Inc.  
Rue du Travail, 16  
B-4460  
Grâce-Hollogne, Belgium