



Protocol for Provision of Intrauterine Contraception

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IUD Devices

Nomenclature

Each intrauterine contraceptive device (IUD) may be called by a variety of names, including:

Brand name ParaGard®

Will be referred to as Cu-U IUD in this document.

Other names include: Cu- T 380A, Cu IUD, Copper IUD (intrauterine device), Copper IUD, Copper T

Brand name Skyla®

Will be referred to as LNG IUD 13.5 mg in this document.

Other names include: LNG 13.5 IUD, LNG 13.5 IUS (Intrauterine System), LNG 13.5 IUS, LNG 13.5 IUD

Brand name Kyleena®

Will be referred to as LNG IUD 19.5 mg in this document.

Other names include: LNG 19.5 IUD, LNG 19.5 IUS (Intrauterine System), LNG 19.5 IUS, LNG 19.5 IUD

Brand names Mirena® and Liletta®

Will be referred to as LNG IUD 52 mg in this document.

Other names include: LNG 52 IUD, LNG 52 IUS (Intrauterine System), LNG 52 IUD, LNG 20 IUD, LNG 20 IUS, LNG 20 IUD

LNG IUD in this document refers to any of the four levonorgestrel-releasing IUDs.

Candidates for use of an IUD

Use of intrauterine contraception is appropriate for any woman of childbearing age for whom no medical contraindication exists. This recommendation is for women of any age and parity. Adolescents and nulliparous women are excellent candidates for use of an IUD as are older women and parous women.

Duration of action

CU IUD (ParaGard) can be used for up to 12 years.

The CU IUD (ParaGard) Cu 380A is FDA approved for up to 10 years; however data indicate that it is effective for up to 20 years. Many national protocols allow for 12 years of use.

LNG IUD 52 mg (Mirena) can be used for up to 7 years.

LNG IUD 52 mg (Mirena) is FDA approved for up to 5 years of use; however there are data that indicate it is effective for up to 7 years of use. Many national protocols allow for 7 years of use.

LNG IUD 52 mg (Liletta) can be used for up to 7 years.

LNG IUD 52 mg Liletta is currently FDA approved for up to 4 years of use. However, the clinical trial that was submitted for FDA approval of Liletta is ongoing and designed for 10 years. Additional data support a longer duration of action including LNG release rates at 5 years comparable to Mirena.

LNG IUD 19.5 mg (Kyleena) can be used for up to 5 years.

LNG IUD 13.5 mg (Skyla) can be used for up to 3 years.

Contraindications to placement of IUDs

Absolute contraindications

Absolute contraindications to placement of any type of IUD (CDC MEC 4)

- Allergy to any component of the product
- Pregnancy
- Current IUD in situ
- Cervical cancer
- Endometrial cancer
- Gestational trophoblastic disease with persistently elevated β -hCG levels or malignant disease
- Any congenital or acquired uterine abnormality distorting the uterine cavity in a manner that is incompatible with placement of an IUD
- Unexplained vaginal bleeding with suspicion for serious condition. Rule out pregnancy, malignancy and infection.
- Mucopurulent cervicitis
- Current known chlamydia or gonorrhea infection
- Current PID, endometritis, salpingitis, pelvic tuberculosis, pelvic actinomycosis, puerperal sepsis, postseptic abortion. Consider waiting 3 months post-infection before placement.

Absolute contraindications to placement of a CU IUD (CDC MEC 4)

- Wilson's disease
- Copper allergy
- Bleeding disorder with impaired coagulation

Absolute contraindication to placement of an LNG IUD (CDC MEC 4)

- Breast cancer < 5 years since diagnosis

Relative contraindications

Use caution when these conditions exist prior to placing an IUD (CDC MEC 3, unless noted otherwise):

- Gestational trophoblastic disease with decreasing or undetectable β -hCG levels
- A very high individual likelihood of exposure to gonorrhea or chlamydial infection
- Complicated solid organ transplantation with graft failure (acute or chronic), rejection, cardiac allograft vasculopathy
- AIDS in a woman who is not clinically well

Use caution regarding continued use of any IUD if the following condition is diagnosed during use:

- Pelvic tuberculosis

Relative contraindication to placement of a CU IUD

- Hct < 30 % or Hgb < 10 gm/dl (CDC MEC 2; Concern exists about an increased risk for blood loss with CU IUDs.)
- Severe thrombocytopenia

Relative contraindication to placement of a LNG IUD

- Breast cancer > 5 years since diagnosis with no evidence of disease
- Systemic lupus erythematosus (SLE) — when antiphospholipid antibodies are positive or unknown (higher risk of thrombosis)
- Severe decompensated cirrhosis, malignant liver tumors, hepatocellular adenoma

Use caution regarding continued use of a LNG IUD if the following conditions are diagnosed during use:

- Ischemic heart disease
- Migraine with aura



Counseling prior to placement

Discuss the IUD using a sample “demo unit”

- Have patient hold the IUD demo
- Demonstrate demo unit in clenched palm to demonstrate strings coming out of cervix and for patient to feel what strings are.

Review possible bleeding changes for particular IUD she is considering

- LNG IUD 52 mg
 - Some women experience irregular bleeding and/or spotting in the first 3-5 months which will resolve by 5 months in the vast majority of cases
 - Some women have little or no bleeding as soon as it is placed
 - By 12 months 20-50% of women have very light menses or no bleeding
- LNG IUD 19.5 mg
 - Some women experience irregular bleeding in the first 3-5 months
 - Some women experience irregular spotting or bleeding throughout use
 - Many women continue to have regular light menses
 - By 12 months 12% of women have no bleeding
- LNG IUD 13.5 mg
 - Some women experience irregular bleeding in the first 3-5 months
 - Some women experience irregular spotting or bleeding throughout use
 - Many women continue to have regular light menses
 - By 12 months 10% of women have no bleeding
- CU IUD:
 - Some women experience spotting in the first several weeks
 - Women continue to menstruate as the CU IUD contains no hormones
 - Many women have heavier, longer or crampier periods
 - Non-Steroidal Anti-inflammatory Drugs 1 day prior to onset of menses, continuing through menses reduces MBL and dysmenorrhea

Informed consent prior to placement

A written consent form should be reviewed and signed with a witness. All patient questions should be addressed. Prior to placement, a woman should also be verbally informed of:

- The risk of:
 - Perforation
 - Expulsion
 - Infection
- Method failure/pregnancy
- What signs and symptoms to watch for
- What signs or symptoms should prompt her to return

The following can be used to guide informed consent conversations prior to placement:

- Perforation:
 - 1:1000 – most are simple and have no serious sequelae. If complete IUD perforation and translocation occurs, laparoscopy can be used to retrieve.
- Expulsion:
 - 2-5:100
 - Watch for and report:
 - Pregnancy symptoms
 - Sudden cramping or pain
 - Bleeding pattern returns to “pre-placement”
 - If patient unable to palpate strings or has symptoms
 - Use back up contraception
 - Call clinic for advice or RTC asap
 - Get pregnancy test
 - Infection:
 - Slight increased risk within first 3 weeks due to introduction of bacteria during placement
 - RTC for antibiotics with any signs or symptoms
 - Method failure/pregnancy
 - <1:100
 - If pregnancy symptoms, get a pregnancy test
 - if HCG positive counsel re: r/o ectopic

Testing prior to placement

There are no routine tests that must be done prior to placement of IUD. All of the following are only **as indicated** and can be done on the day of placement.

- Pregnancy test or reasonable certainty that patient is not pregnant (see Box 1)
- Hgb or hct
 - If history or suspicion of anemia prior to CU IUD placement
- CT/ GC: IUD can be placed the same day as testing and prior to receipt of test results
 - Patient is due for screening (<25 years and has not had screening in the past year)
 - Patient or partner has a new sex partner in the preceding 90 days or has multiple partners
 - Patient had recent CT or GC and has not been re-screened

Box 2. How To Be Reasonably Certain that a Woman Is Not Pregnant

A health-care provider can be reasonably certain that a woman is pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- Is ≤ 7 days after the start of normal menses
- Has not had sexual intercourse since the start of last normal menses
- Has been correctly and consistently using a reliable method of contraception
- Is ≤ 7 days after spontaneous or induced abortion
- Is within 4 weeks postpartum
- Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [$\geq 85\%$] of feeds are breastfeeds),* amenorrheic, and <6 months postpartum

U.S. Selected Practice Recommendations for Contraceptive Use, 2016 (US SPR).

Stanback J, Yacobson I, Harber L. Proposed clinical guidance for excluding pregnancy prior to contraceptive initiation. Contraception. 2017 Apr;95(4):326-330.

Initiation of IUDs

- An IUD can be placed at any time during the menstrual cycle (not necessary to be on period).
- If there are no contraindications, an IUD can be placed at any time if it is reasonably certain that the woman is not pregnant (See Box 2).
- If it is **not** reasonably certain that the woman is not pregnant, she should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant

Following birth

An IUD can be placed immediately after delivery of the placenta (ideally within 10 minutes) or within 72 hours after either a vaginal or cesarean birth, or wait until full involution of the uterus which is not sooner than 4-6 weeks postpartum.

Following aspiration for an abortion

- Immediately or any time thereafter if it is reasonably certain she is not pregnant

Following medication abortion or early pregnancy loss

- Once it is confirmed that client is no longer pregnant or any time thereafter if it is reasonably certain she is not pregnant

Following unprotected sex

The CU IUD is the most effective form of emergency contraceptive (nearly 100%), and remains this effective in cases where EC pills lose effectiveness (overweight, obesity, or repeat episodes of unprotected intercourse).

- The CU-IUD can be placed within 5 days of the first act of unprotected sexual intercourse as an emergency contraceptive.
- If the day of ovulation can be estimated, the CU-IUD can be placed >5 days after sexual intercourse as long as placement does not occur >5 days after ovulation.

Consider providing ECPs at the time of LNG-IUD placement if all of the following are true:

- She had unprotected sexual intercourse since the start of her last menstrual cycle
- It has been >5 days since menstrual bleeding started
- The first act of intercourse occurred within the last five days
- A pregnancy test is negative

Obtain a pregnancy test 3 weeks after placement. Use of ECPs also applies when switching to an LNG-IUD from a CU IUD.

Back-up contraception

CU IUD

- No additional contraceptive protection (aka no back up) is needed after placement of a CU IUD.

LNG IUD

- If a LNG-IUD is placed within the first 7 days since menstrual bleeding started, no back up is needed.
- If a LNG-IUD is placed >7days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
- When switching to an LNG-IUD from a hormonal or barrier method, consider continuing her previous method for 7 days after LNG-IUD placement.
- If a woman took a levonorgestrel ECP within 24 hours of LNG IUD placement, back up for 7 days.
- If a woman took ulipristal acetate (UPA) ECP within 24 hours of LNG IUD placement, back up for 14 days.
- If < 21 days postpartum, no backup needed.
- If \geq 21 days postpartum and menses has not resumed, backup for 7 days.
- If <7 days post-aspiration for abortion or for early pregnancy loss, no back up needed.
- If >7 days post-aspiration for abortion or for early pregnancy loss, backup for 7 days.
- If <7 days post medication abortion or post early pregnancy loss without a procedure, no back up needed.
- If >7 days post medication abortion or post early pregnancy loss without a procedure, backup for 7 days.



IUD placement

Instruments and supplies

- Exam gloves- non sterile
 - Sterile gloves are not necessary unless:
 - The provider wants to load Paragard with their hands instead of in the package or
 - The provider wants to bend the end of the metal sound with gloved hands rather than through the packaging for the sound.
- Non-sterile speculum:
 - Plastic or metal
 - The shortest size that allows visualization is best. A wider/shorter speculum allows more mobility and straightening of the uterus with a tenaculum.
 - Short and wider is better than longer.
- Lubricant for a pelvic exam
 - Use minimal amounts if planning to do cervical testing prior to placement.
- Cotton ball, or OB swab (scopette, drumstick swab) or 4x4 gauze pad
 - For applying antiseptic to the cervix prior to placement
 - Swab can also be used to demarcate correct place on the sound as it is withdrawn from the uterus in order to “read” the sound more easily.
- Antiseptic solution (4% chlorhexidine gluconate or povidone-iodine)
 - If using chlorhexidine, choose soap format containing 4% chlorhexidine gluconate and 4% isopropyl alcohol, not format containing 70% isopropyl alcohol in the vagina.
- Tenaculum:

Any of the following types of tenacula will work well. Providers may have particular preferences:

 - Single tooth with rounded or squared edges
 - Atraumatic (especially for multiparous cervixes)
 - Metal
 - Plastic
- Uterine sound:

Any of the following types of uterine sounds will work well. Most uterine sounds are 3- 4mm in diameter. Providers may have particular preferences:

 - Metal
 - Plastic
 - An endometrial sampler (for performing EMB), can be used, has a smaller diameter (3mm) than most uterine sounds and is disposable.

- Ring forceps
 - If needed to hold cotton balls or 4X4 for cleansing the cervix
 - If needed to remove the IUD
 - If needed to retrieve strings or cotton balls from the vaginal vault
 - Long (Kelly) straight or curved forceps are an acceptable substitute (10 inches)
- Long curved scissors
 - It is important that the scissors be sharp so as to avoid incomplete cutting of the strings, with possible displacement.
- The IUD device
 - It is helpful to have 2 devices in the room in case the first device is contaminated for some reason before the placement is completed.
- Sanitary napkin

Have available (not needed for most placements)

- Os finders and/or small metal or plastic dilators (i.e. French 13/15)
- Monsels or silver nitrate sticks
- A ruler/measuring tape or OB tape with centimeter markings (helpful to “read” sounds with worn off markings)
- Sterile gloves
- Supplies for administering a paracervical block:
 - Local anesthetic
 - 10-20 cc Syringe
 - 22 gauge needle and needle extender (or spinal needle without needle extender)

Procedure for IUD placement

1) Perform a bimanual exam:

- Determine uterine axis / position
 - Anteverted/flexed
 - Midposition
 - Retroverted/flexed
- Assess for signs that contraindicate or complicate placement
 - Active mucopurulent cervicitis, untreated STI, or suspected PID
 - Anatomic abnormalities, enlarged uterus; irregular uterus, myomatous uterus – consider ultrasound assessment prior to placement as indicated if abnormal.

2) Place speculum

- Place speculum fully to cervix before opening, to avoid getting stuck in fore tissue.
- For obese patients consider:
 - Using a larger/wider speculum
 - Placing a condom around the speculum
 - Raising the patients hips by trying any of the following:
 - Have the patient place her hands beneath her buttocks.
 - Raise the bottom or lower the head of the table.
 - Have the patient flex her hips and grasp in front of her knees with her hands and raise her buttocks with her legs elevated.
- Assess for abnormal discharge: If mucopurulent discharge is seen coming from the os (or suspect upper genital tract infection) do not place an IUD that day. If vaginitis (BV, yeast or trichomoniasis), it can be treated and does not contraindicate IUD placement that day.
- Take any indicated samples for testing (chlamydia, gonorrhea, or wet mount) a Pap or HPV test. No need for any routine testing.

3) Prepare the cervix:

- Cleanse the cervix with povidone-iodine or 4% chlorhexidine gluconate.
 - Soak a scopette, cotton ball or folded 4x4 gauze grasped with a ring forceps into the antiseptic solution.
 - Place the antiseptic soaked cotton tip at the cervical os and draw a spiral outward to the outer edge of the cervix.
- If you are going to place a paracervical block, this would be the time.

4) Place tenaculum

Reasons to use a tenaculum:

- Straightens the cervical canal to enable the uterine sound and the IUD inserter to pass through the os more easily
- Aligns the uterine body so that curves from anteflexion or retroflexion are straightened out to avoid perforation at the point of flexion
- Stabilizes the cervix and holds it in place so that pressure from the sound or the IUD applicator doesn't push the cervix and uterus away from the instrument

How to hold a tenaculum when placing it on the cervix:

- Grasp with the dominant hand, holding the palm up and place the thumb through one ring and the middle or ring finger through the other ring. Use the index finger between the other two fingers as a brace and to stabilize. The preferred hand position is with palm up for placement in order to see where the tenaculum will grasp the cervical tissue.

- Open and place the open tenaculum teeth on the surface of the cervix. Once in contact with the cervix, with the tips 1 - 2 cm apart, squeeze together slowly to imbed teeth in the cervical tissue. Grasp 1-2 cm width of cervical tissue in a bite that is 1-2 cm deep. Do not take too shallow of a bite. Grasping an adequate amount of tissue prevents the tenaculum from pulling through the cervical epithelium, when applying traction upon it during sounding and IUD placement.

Where to position the tenaculum on the cervix:

- Position it horizontally 1-2 cm above or below the external os, or position it vertically. Position it so as not to occlude the opening.
- It is often the convention to grasp the anterior lip in an anteflexed uterus or the posterior lip in a retroflexed uterus but this is not evidence-based.
- It may be more feasible to consider cervical visibility rather than uterine flexion. In this case, grasp the visible lip of the cervix and bring os into view with traction.

Close the locking ratchet so it clicks into place (1-2 clicks is adequate) and is held securely.

- Place the ratchet into position by clicking down silently so it is inaudible to the patient.
- Gently lay the tenaculum down to rest on the posterior blade of the speculum in order to pick up the sound or IUD.
- Use the non-dominant to apply good traction with the tenaculum during sounding and when placing the IUD to assure the sound or IUD inserter is at the fundus (vs. back wall of a flexed uterus).

Clinical Pearl

Here are some techniques that may minimize the possible discomfort with tenaculum placement:

- Apply pressure against the cervix with the tenaculum before closing it.
- Close the tenaculum very slowly.
- Cough technique: Place the tenaculum more quickly as client coughs firmly to obscure the discomfort. Be sure to stabilize the speculum to prevent dislodging it.
- Instill 1cc of local anesthetic at tenaculum site prior to placing the tenaculum.
- When the tenaculum is not being used, avoid moving it inadvertently.

5) Sound the uterus

Reasons to sound the uterus:

- Sounding allows for documentation of uterine depth.
- Successful sounding indicates:
 - the ability to pass through the os, thus not wasting an IUD if unable
 - no notable anatomical distortions in the uterus
 - appropriate depth for placement of the IUD and consistent with size noted on bimanual.
 - the “pathway” through the internal os to the fundus, which informs the hand motions for subsequent IUD placement.
- Open the IUD package after successfully sounding the uterus. Once the IUD package is opened, if the IUD is not placed that day, it is contaminated and can't be used.

The manufacturer's instructions suggest the uterus should measure:

- 6-9 cm for ParaGard
- 6-10 cm for Mirena
- No less than 5.5cm and no upper limit for Liletta
- Not specified for Skyla or Kyleena

Note: Clinical judgment may apply, and many providers place devices if the uterus sounds ≥ 5.5 cm with no upper limit. If the uterus sounds >10 - 11 cm, correlate with bimanual exam and clinical circumstance (post aspiration, postpartum, fibroids, etc.) and consider perforation.

Sounding technique:

- A metal sound may require straightening after autoclaving prior to use, or conversely may benefit from bending the distal few cm to mimic the uterine flexion. To maintain sterility, only touch the end that will be entering the patient's uterus through sterile packaging or with sterile gloves.
- Hold the sound like a pencil, or like throwing a dart. Use wrist and finger action, not elbow action.
- Hold at fulcrum with a light grip so it can transmit information to the hand about the internal cervical and uterine flexion.
- If difficulty is encountered when attempting to pass through the internal os, try positioning the sound at various angles in the os to find the direction of the pathway
- Place the pinky finger on the speculum or the patient's inner thigh to stabilize the dominant hand while advancing sound.
- Immediately after successfully passing through the internal os, pause for a moment and then intentionally and slowly proceed to the fundus, to reduce risk of perforation from momentum.
- Minimize repeated tapping of the fundus, for patient comfort.

- Note the depth sounded in centimeters by looking for the “line of glistening” where blood, mucous or betadine is visible. Most sounds have centimeter markings on them, or may be held up to a measuring tape. Alternately use the following technique.
 - Once the sound is positioned at the fundus, pick up a long scopette and hold it at the fat, drumstick end. Place the other end right alongside the sound at the external os. Remove the sound and swab together and bring them into view. Where the swab rests on the sound marks the uterine sound measurement.
- Note sound depth (cm) in medical record.

6a) Placement of CU IUD

1. Sterile loading of device into insertion tube
 - Avoid loading the IUD arms in inserter > 2-5 minutes before uterine placement.
 - Use either the no-touch technique by loading the IUD in the package or by using sterile gloves.
 - Fold the two horizontal arms down and tuck the tips of the arms into the insertion tube. The copper collars will be outside the tube.
 - Slide the solid white stabilizing rod into the insertion tube until it is touching the bottom of the IUD within the tube.
2. Set flange
 - The wide aspect of the flange is designed to be in the same plane as the arms of the IUD which is also the same plane as the arms of the patient.
 - Set the flange to the sound depth measured either through the sterile packaging or with sterile gloves.
3. Pass through internal os
 - Apply traction to the tenaculum with the non-dominant hand.
 - Hold onto the insertion tube with the dominant hand and advance the tube gently to the fundus.
 - Stop advancing when fundal resistance is met.
4. Let go of the tenaculum and let it rest on the speculum.
5. Hold onto the white solid rod with the non-dominant hand and keep it immobile. It functions as a stabilizer to hold the IUD in place (the white rod is never used as plunger).
6. Pull the insertion tube back until it touches the ring of the rod to release the arms of the CU IUD at the fundal position.
7. Re-advance insertion tube to fundus to “re-seat” the IUD and ensure high fundal placement.
8. Remove solid rod before removing the insertion tube.
 - This to prevent inadvertently pulling the IUD down into the lower uterine segment or even expelling the IUD.

Note: This step (removing the white rod) can occur prior to re-advancing the insertion tube to the fundus.

9. Remove the insertion tube.
10. Cut the strings to 3-4 cm.

6b) Placement of LNG IUDs: Mirena, Kyleena, and Skyla

1. Sterile loading of device into inserter
 - Avoid loading the IUD arms in inserter > 2-5 minutes before uterine placement.
 - Push the slider completely forward in the direction of the arrow to load IUD into the inserter.
 - The tips of the arms will meet to form a rounded end extending slightly beyond the insertion tube.
 - Keep pressure with your thumb or forefinger on slider at all times, and in fully forward-most position.
 - DO NOT move the slider back at this time as this may prematurely release the IUD. Once the slider is moved below the mark, the IUD cannot be reloaded.
2. Set flange
 - Use one of the notches in the sterile packaging to set the upper edge of the flange to correspond to the uterine depth (in centimeters) measured during sounding.
3. Apply traction to the tenaculum with the non-dominant hand.
4. Pass the inserter through internal os.
5. Either:
 - Advance the loaded inserter until the flange is 1.5 to 2 cm from the external os, OR
 - Advance loaded inserter to fundus and then retract down until the flange is 1.5 to 2 cm from the external os.
6. Retract the slider down to the “first mark.”
7. Wait 10-15 seconds in this position.
 - This step ensures that the arms have fully opened before advancing, and helps prevent perforation.
8. Advance the inserter to the fundus. When the inserter is at the fundus, the flange will be touching or close to the cervix.
 - Once you encounter fundal resistance, stop, as the IUD is now in the fundal position.
9. Holding the inserter firmly in place, release the IUD by moving the slider all the way down.
10. Continue to hold the slider all the way down while gently withdrawing the inserter from the uterus.

Clinical Pearl: Keep thumb or forefinger on slider at all times to avoid displacement.

6c) Placement of LNG IUD: Liletta (Note: Single handed inserter for Liletta became available in 2016; these instructions represented here)

1) Sterile loading of device into insertion tube

- Avoid loading the IUD arms in inserter > 2-5 minutes before uterine placement.
- Use either the no-touch technique by loading it in the package or by using sterile gloves.

2) Completely open the sterile lid by peeling the lid back from the handle end toward the inserter tip.

3) Loading the inserter

- Remove the inserter from the tray, grasping the handle below the sliders and twist gently; not by pulling on the tube.
- Ensure both sliders are pushed **fully forward** and aligned with their respective markings.
- Grip the handle, keeping your thumb or finger in the groove of the BLUE slider (over the number 1), and apply **forward pressure** while ensuring both sliders are **fully forward**
- To load into the inserter, ensure the IUD arms are horizontal; adjust the IUD rotation as needed using the flat, sterile surface of the tray – While maintaining **forward pressure** on the blue slider, pull both threads evenly, **straight** back without excessive force until you feel a hard stop.
- Once you feel the hard stop, pull—and **lock**—the threads into the cleft by cleating them at the bottom of the handle to prevent the IUD from moving out of the top of the insertion tube.
- After the IUD is loaded, continue to maintain **forward pressure** on the BLUE slider
- 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. If the IUD is not correctly loaded, **do not attempt placement**. Liletta can be re-loaded if this occurs.
- Adjust the flange to the measured uterine depth based on sounding completed in Step 1. To adjust, place the flat side of the flange in the tray notch or against a sterile edge inside of 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
- If an adjustment to the curvature of the insertion tube is required to accommodate the anatomical orientation of the uterus, you may gently bend or straighten the insertion tube, **but do not touch above the flange unless using sterile gloves**.

4) Placing Liletta into the Uterus

- Apply gentle traction on the tenaculum as needed while advancing the loaded insertion tube through the os. Advance the tube until the upper edge of the flange is 1.5 cm to 2.0 cm from the external cervical os.
- Maintain **forward pressure** on the BLUE slider throughout the placement process
- Using your thumb or finger, gently bring only the BLUE slider back until you feel the thumb groove deepen as the blue slider aligns with the green slider.
- The BLUE and GREEN sliders will merge together to form a common thumb recess but do not move the green slider down at all during this step.
- DO NOT move the BLUE slider any more than is necessary to create the recess
- Maintain the GREEN slider so that the double line markings on the slider and the insertion handle remain aligned. This will allow the IUD arms to open in the lower uterine segment

5) Releasing Liletta and completing the procedure

- Wait 10 –15 seconds to allow for the arms of the Liletta to fully open
- While maintaining a firm hold on both sliders so they remain in the correct position, advance the inserter until the flange touches the cervix. If fundal resistance is encountered, do not continue to advance. The IUD is now in the fundal position.
- While holding the inserter steady and maintaining its position relative to the cervix, move **both** sliders (BLUE and GREEN) together down the handle, until **two** clicks are heard which indicates that both of the sliders have been brought fully down to the correct final position. In addition, check the bottom to be sure the GREEN indicator is visible in the cleft at the bottom of the handle (near the removal threads) which indicates that the threads are released from the handle.
- Look at the cleft to ensure the threads were properly released; if not released, or if a click is not heard, grasp the threads and gently pull the threads out of the cleft.

6) Remove the inserter from the uterus

7) Cut strings

- Use the insertion tube as a guide to hold and cut the strings, before removing tube from vagina.
- Cut strings at 3-4 cm to allow the strings to wrap around the posterior lip of the cervix.
- Cut straight across strings to minimize sharply pointed tips that may poke the partner.
- Use sharp scissors to avoid IUD displacement with multiple cutting attempts.
- Trimming strings inside the cervical canal can be considered for women experiencing reproductive or sexual coercion and who wish to conceal IUD use from a partner.
- Document length of strings in chart.

In case of difficulty passing through the internal os/cervical stenosis

1. Hold gentle firm pressure with the sound for several seconds until the os opens.
2. Change the angle of the sound in the os to find the direction of the pathway.
3. Adjust the curvature of the sound; either increase the curvature or make the sound straighter.
4. Add traction on tenaculum in a different way; for example pulling down, up or to the side.
5. Consider re-positioning the tenaculum.
6. Use os finders or a small cervical dilator to initially pass through the internal os, followed by sounding.
7. Consider using a smaller diameter sounding device like a plastic sound or an endometrial sampler.
8. Consider ultrasound guidance.
9. Consider the assistance of another provider.

Follow up after IUD placement

- No routine follow-up visit is required.
- Adolescents, women with relevant medical conditions or with multiple medical problems may benefit from a follow up visit after placement.
- Best timing for such a visit is 4-8 weeks, to support her adjustment to any changes with menses.
- Encourage a woman to call or return at any time to discuss side effects, concerns, desired removal, or need for IUD replacement.
- At other routine visits, providers who see IUD users should:
 - Assess the woman's satisfaction with her IUD and if she has any concerns.
 - Consider performing an examination to check for presence of the IUD strings.



Evaluation / Management

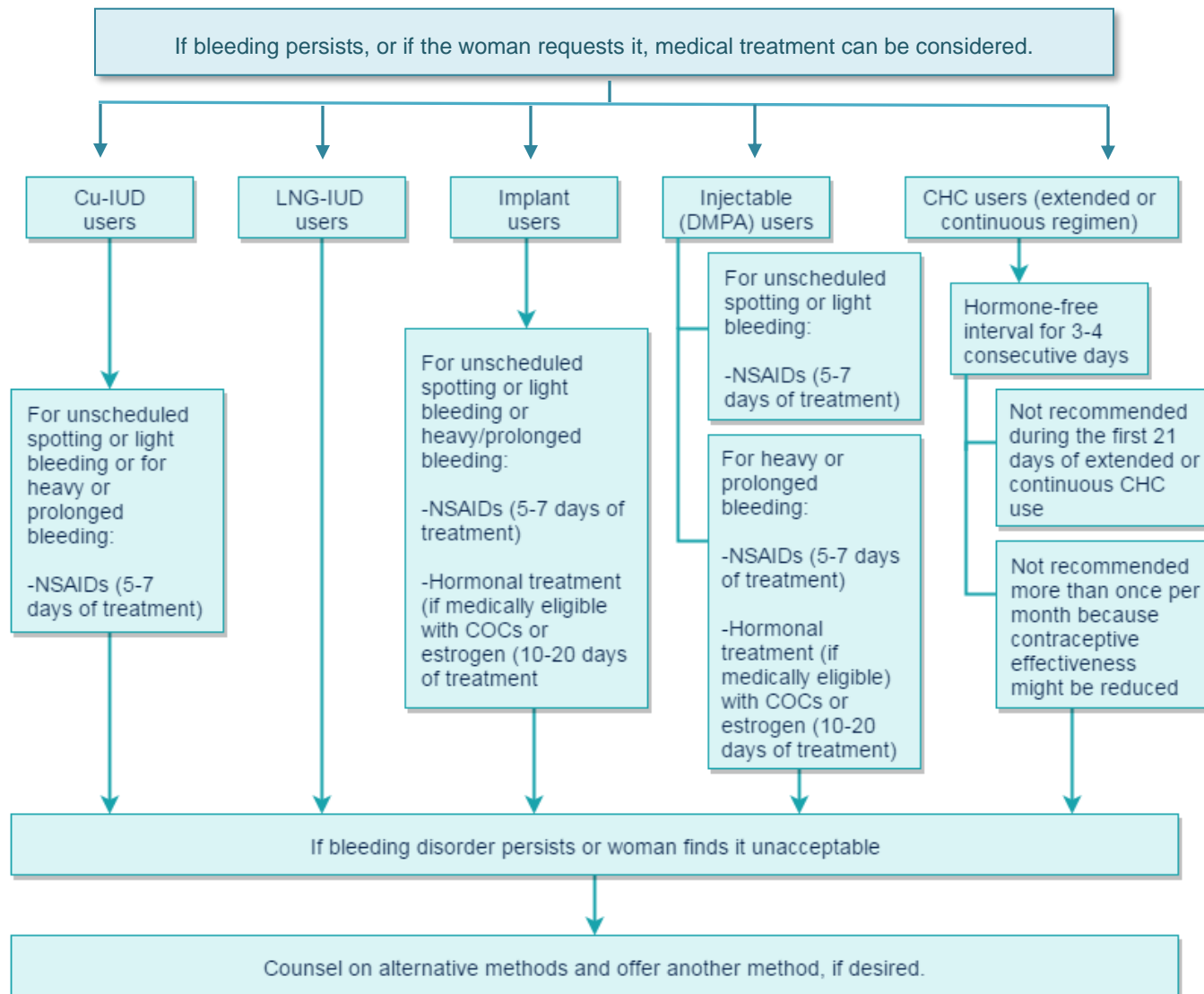
Amenorrhea with LNG IUD in place

- History: Check for signs or symptoms of pregnancy
- Labs: pregnancy test
- Exam: as needed if pregnancy test is positive
- If not pregnant, reassure as normal
- If not acceptable, counsel on other IUDs or other methods

Bleeding irregularities with IUD in place

- History: Signs or symptoms of pregnancy, infection, lesion, malignancy, fibroids
- Labs as indicated: pregnancy test, CT/GC, hgb, pap/HPV, ultrasound
 - Note: more training required for LNG IUD ultrasound localization.
- Exam: rule out pregnancy, cervical neoplasm, polyps, infection, fibroids, IUD displacement
- If IUD in situ and no lesion, infection or pregnancy, reassure
- LNG IUD: Advise bleeding is likely to abate after 3-5 months
- CU IUD: offer NSAIDS starting 24 hours before menses and continuing for 5-7 days
- If not acceptable, counsel on other methods.

Bleeding irregularities with IUD in place



Source: CDC US SPR 2016 Appendix E

Pregnancy with IUD in place

If any significant pain, bleeding or hemodynamic instability, refer immediately to ER / hospital.

- History: Signs or symptoms of ectopic pregnancy; bleeding, pain
- Exam: rule out ectopic pregnancy, blood pressure, pulse, speculum exam, bimanual exam
- Labs and testing as indicated: pregnancy test, quantitative hCG, ultrasound
- Management:
 - IUD in situ; confirmed intrauterine pregnancy, patient plans to terminate pregnancy:
 - May advise patient it is best to remove IUD while awaiting termination or may await termination and remove IUD at that time
 - IUD perforated or translocated; confirmed intrauterine pregnancy, patient plans to terminate pregnancy:
 - Arrange timely follow-up to extract IUD with appropriate procedure based on location of IUD.
 - IUD in situ; confirmed intrauterine pregnancy, patient plans to continue pregnancy:
 - Advise patient to seek prenatal care immediately.
 - Advise her of increased risk of spontaneous abortion, septic abortion, premature rupture of membranes, preterm delivery and chorioamnionitis if IUD left in situ.
 - If strings are visible advise her that while there is a risk of spontaneous abortion if IUD is removed, the risk is lower than if the IUD is left in place.
 - If strings are visible, it is strongly advised to remove IUD immediately once informed consent is obtained.
 - Advise her to see a provider immediately if any bleeding, cramping, pain, fever or abnormal vaginal discharge develops.
 - Confirmed ectopic pregnancy: manage ectopic pregnancy as per usual
 - If IUD in situ, may leave in place or may replace
 - If IUD expelled, may replace once ectopic is resolved.
 - If IUD displaced or perforated manage as appropriate to IUD location.

Diagnosis of STD or Vaginitis with an IUD in place

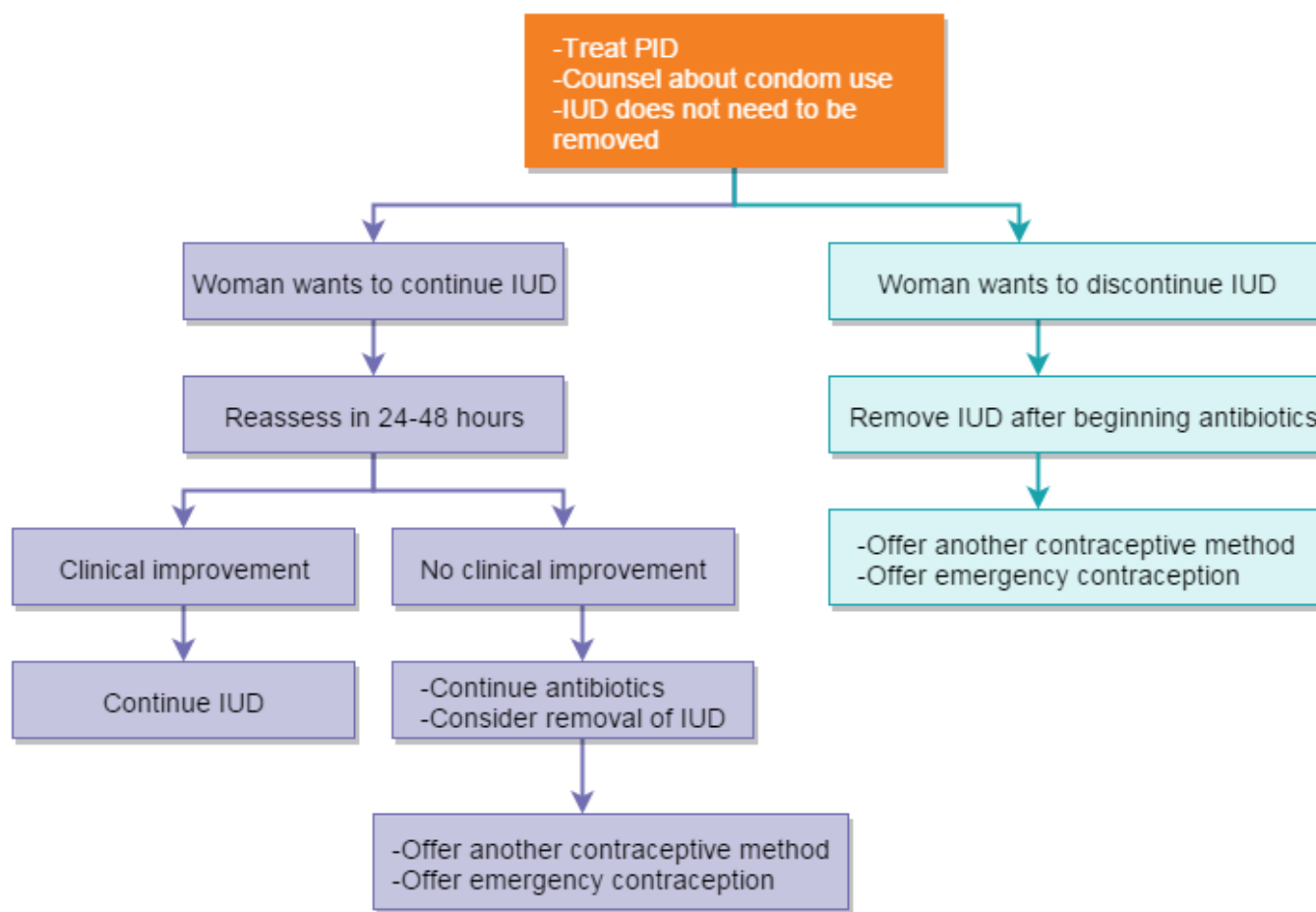
- Treat the infection per CDC 2015 STD treatment guidelines and leave the IUD in place.
- If diagnosing an STD, counsel patient on condom use.

Diagnosis of pelvic inflammatory disease (PID) with IUD in place

Treat according to CDC's 2015 STD Treatment Guidelines (available at <http://www.cdc.gov/std/treatment>).

CDC SPR algorithm for management of PID with an IUD in place

- Treat the PID according to the CDC Sexually Transmitted Diseases Treatment Guidelines.
- Provide comprehensive management for STDs, including counseling about condom use.
- The IUD does not need to be removed if the woman needs ongoing contraception.
- Reassess the woman in 48–72 hours. If no clinical improvement occurs, continue antibiotics and consider removal of the IUD.
- If the woman wants to discontinue use, remove the IUD sometime after antibiotics have been started to avoid the potential risk for bacterial spread resulting from removal.
- If the IUD is removed, consider ECPs if appropriate. Counsel the woman on alternative contraceptive methods, and offer another method if it is desired.



Source: CDC US SPR 2016 Appendix F

Actinomyces report on Pap test

Actinomyces are anaerobic bacteria capable of causing a pelvic actinomycosis which is a rare, but severe, pelvic infection. Pelvic actinomycosis is associated with IUD use, however most infections are seen in malnourished women over 35, who are long term IUD users. The large majority of Pap test results that read actinomyces or “actinomyces like organisms” reflect asymptomatic colonization, not infection, and the result is not diagnostic or predictive of disease.

- History: Signs or symptoms of PID; fever, abnormal discharge, pelvic or abdominal pain, deep dyspareunia, intermenstrual spotting or bleeding
- Labs: none needed unless signs or symptoms of PID. If suspicious for PID work up per CDC STD 2015 treatment guidelines
- Exam: pain, pelvic mass
- Management: asymptomatic colonization does not require antibiotic therapy or removal of the IUD.

No visible strings

Possibilities:

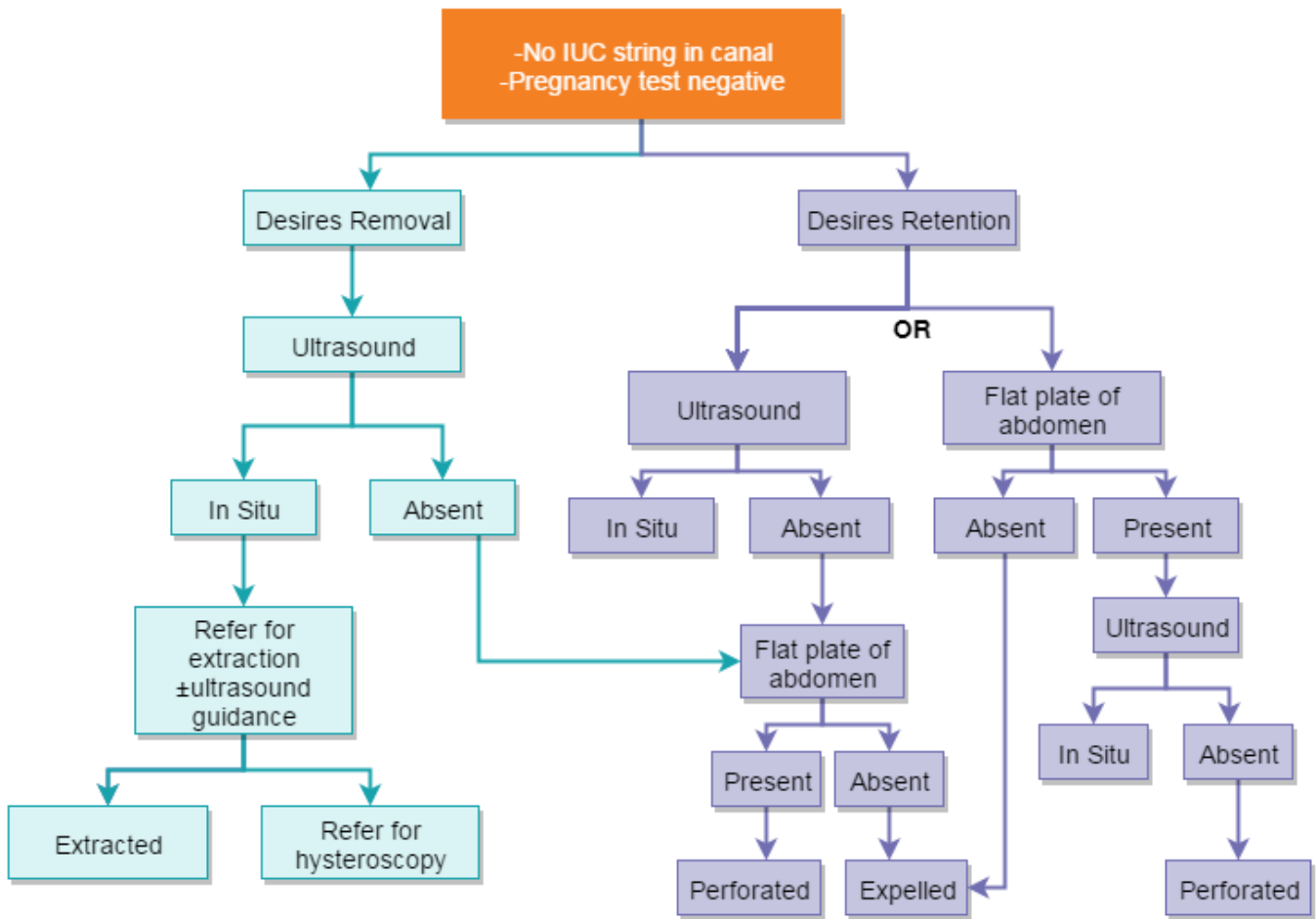
- Strings present but not visible because they are in canal or uterus
- Expulsion
- Pregnancy with IUD in situ and strings pulled into uterus
- Embedment, later partial perforation
- Translocation after perforation

Initial management:

1. Pregnancy test if appropriate
2. Advise/prescribe back-up contraceptive method until intrauterine location is confirmed
3. Probe for strings in cervical canal:
4. Cytology brush to tease strings from canal.
5. Endocervical speculum, 10” Kelly, alligator, straight forceps to help open the external os sufficiently to see the strings if they are buried in the endocervical canal.
 - Endocervical speculum or forceps in a closed position into external os, open it once it is inside but do not advance it through the internal os. An excellent light and magnification (a colposcope) can assist in visualizing strings if they are there.
 - A “thread retriever” device (such as an Emmett’s) or an IUD “hook” can be used to attempt to bring the strings down from the cervical canal.
6. If attempts to visualize the strings are unsuccessful the location of the IUD must be determined utilizing the algorithm below.

If it is determined that the IUD is in situ (intrauterine) and the patient desires continuation:

- Leave in place for remainder of IUD lifespan



Source: Patty Cason, RN, MS, FNP-BC & Mike Policar, MD, MPH

IUD removal procedure

If beyond the first 5 days of the menstrual cycle, there is a theoretical risk of pregnancy so it is best to wait to remove the IUD until 5 days after last intercourse. If the woman chooses to have the IUD removed despite risk of pregnancy, offer ECP.

Uncomplicated removals

- Speculum exam to fully visualize cervical os with strings in view
- Clasp strings with ring forceps close to os
- Pull straight towards clinician with a steady direct movement

Complicated removals

Strings not visible after searching

- Best to determine if IUD is in the uterus (see management of missing strings) prior to attempting removal but also acceptable to attempt removal first
- Rule out pregnancy
- Bimanual exam to determine position (flexion) and size of uterus
- Place paracervical block (optional)
- Use “alligator” forceps (best with simultaneous real time pelvic ultrasound)
 - Cleanse os (as usual prior to IUD placement)
 - Apply tenaculum
 - Sound for angle of os and cavity and to determine if IUD tip can be palpated (optional).
 - Pass closed forceps through the internal os and advance 1 cm into endometrial cavity.
 - Feel for the lower tip of the IUD (the place where the strings attach at the bottom of the plastic T) with the thin jaws of the forceps.
 - Gently open and close the jaws of the forceps until the IUD or strings can be grasped. Each time, rotate the forceps about ¼ turn into a different position while remaining in the lower endometrial cavity.
 - Once there is a good purchase on the IUD or strings, close the forceps.
 - Holding the IUD or strings firmly with the forceps, use a steady even-paced motion and pull the IUD out through the os with the forceps.
- IUD hook is best for circular IUDs; it is less helpful with T-shaped IUDs however, if extraction with the forceps is unsuccessful and the IUD is in the cavity, extraction with the hook or use of a “thread retriever” device passed up to the fundus can be attempted.
 - While applying outward traction with a tenaculum, pass the hook through the internal os and advance the tip toward the fundus. First, sweep the hook down the anterior uterine wall toward the internal os and remove. If unsuccessful, repeat by sweeping the hook down the posterior uterine wall.

- If it is determined that the IUD is in the uterus, yet extraction with a forceps and hook is unsuccessful, extract via operative hysteroscopy.
- For settings without immediate access to hysteroscopy alternate management options include:
 - Attempting with a paracervical block prior to instrumentation
 - Using suction from an endometrial pipelle or MVA with a 5-6 mm curette to bring strings beyond external os
 - Attempting in clinic with moderate sedation

Strings visible but initial attempt at removal unsuccessful

- If strings break off, attempt extraction with alligator forceps with ultrasound guidance
- IUD embedded and unable to remove IUD by pulling strings or by extraction with forceps or hook, remove with hysteroscopic guidance

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CDC Medical Eligibility Criteria:

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2. Centers for Disease Control and Prevention, *Appendix J. Classifications for Emergency Contraception*, U.S. Medical Eligibility Criteria for Contraceptive Use, 2016, <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf>

CDC Selected Practice Recommendations:

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2. American College of Obstetricians and Gynecologists, *ACOG Committee Opinion #735: Adolescents and Long-Acting Reversible Contraception: Implants and Intrauterine Devices*, *Obstetrics & Gynecology*, 2018 May; 131(5):e130-e139.
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2. Prabhakaran S and Chuang A, *In-office retrieval of intrauterine contraceptive devices with missing strings*, *Contraception*, 83(2), 102-106, 2011.
3. Marchi NM, Castro S, Hidalgo MM, Hidalgo C, Monteiro-Dantas C, Villarroel M and Bahamondes L, *Management of missing strings in users of intrauterine contraceptives*, *Contraception*, 86(4), 354-358, 2012.
4. Creinin MD, Jansen R, Starr RM, Gobburu J, Gopalakrishnan M, Olariu A. Levonorgestrel release rates over 5 years with the Liletta® 52-mg intrauterine system. *Contraception.* 2016 Oct;94(4):353-6.