





# 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:1

## **Brand name Paragard®**

Will be referred to as Copper 380 mm2 IUD in this document.

Other names include Copper IUD, Cu-T 380A, Cu-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).

## **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).

#### 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 20 IUD, LNG 20 IUS.

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

Note: The copper IUD Miudella® has been recently FDA-approved although it is not yet available on the market at the time of this publication. We will refer to it as the Copper 175 mm2 IUD.

# **Duration of Action**

#### Copper 380 mm2 IUD (ParaGard®) can be used for up to 12 years.

The Copper 380 mm2 IUD (ParaGard) FDA-approved duration of action is for up to 10 years, with evidence supporting effectiveness for 12-20 years, and many national protocols recommending up to 12 years of use.<sup>2, 3</sup>

LNG IUD 52 mg (Mirena®, Liletta®): FDA-approved and evidence-based duration of use for up to 8 years.<sup>4, 5</sup>

LNG IUD 19.5 mg (Kyleena®): FDA-approved and evidence-based duration of use for up to 5 years.

LNG IUD 13.5 mg (Skyla®): FDA-approved and evidence-based duration of use for up to 3 years.

Copper 175 mm2 IUD (Miudella®) is FDA-approved for use for up to 3 years.

# Contraindications to Placement of IUDs

Use of intrauterine contraception is appropriate for people with pregnancy potential\*, of any age and parity, for whom no medical contraindication exists. The CDC Medical Eligibility Criteria for Contraceptive Use (MEC) is the U.S. guideline that provides recommendations about how safe each contraceptive method is when used by people with a variety of medical conditions and personal characteristics. The guideline has been updated in 2024 and may be available as a free smartphone app (search "CDC Contraception"), as a hard copy summary chart, on the <a href="CDC website">CDC website</a>, and on Beyond the Pill's resource page.

# **Absolute Contraindications**

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

- Allergy to any component of the product
- Pregnancy
- Current IUD in situ
- Cervical cancer (Category 4 for initiation; Category 2 for continuation)
- Endometrial cancer (Category 4 for initiation; Category 2 for continuation)
  - Note: LNG-IUD may be used to treat endometrial hyperplasia for those wishing to maintain fertility or for those avoiding surgical treatment.
- Gestational trophoblastic disease with persistently elevated β-hCG levels or malignant disease with evidence or suspicion of intrauterine disease (Category 4 for initiation; Category 2 for continuation)
- 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 a serious condition. Rule out pregnancy, malignancy, and infection.
- Current known chlamydia or gonorrhea infection or mucopurulent cervicitis. Wait at least 1 week after treatment initiation and ensure no signs or symptoms of infection before placement.
- Current PID, endometritis, salpingitis, pelvic tuberculosis, pelvic actinomycosis, puerperal sepsis, post septic abortion. Wait at least 4 weeks after treatment initiation and ensure no signs or symptoms of infection before placement.

Absolute contraindications to placement of a Copper 380 mm2 IUD (CDC MEC 4):

- Wilson's disease
- Copper allergy
- Bleeding disorder with impaired coagulation. Of note, anticoagulation and antiplatelet therapy can be continued at the time of IUD insertion.<sup>6</sup>

<sup>\*</sup>Note: throughout the protocol, we will make an effort to offer gender-neutral phrasing as we recognize that not all patients with uterus and ovaries and the capacity to become pregnant may identify as female. To retain the integrity of studies and accurately reflect study findings, the term "woman" or "women" may be used in some instances.

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

Breast cancer < 5 years since diagnosis</li>

Contraindications to placement of a Copper 175 mm2 IUD (Prescribing Information):<sup>7</sup>

- For use as post-coital emergency contraception
- Wilson's disease
- Hypersensitivity to any component of Miudella<sup>®</sup> including copper, trace elements present in copper components, or nitinol

# **Relative Contraindications**

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

- Reason to believe the patient was exposed to gonorrhea or chlamydia
- Complicated solid organ transplantation with graft failure (acute or chronic), rejection, cardiac allograft vasculopathy

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

Pelvic tuberculosis

Relative contraindication to placement of a Copper 380 mm2 IUD:

Severe thrombocytopenia

Relative contraindication to placement of an 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 LNG IUD if the following conditions are diagnosed during use:

Ischemic heart disease

# Prior to Placement

Follow person-centered counseling based on the patient's priorities and preferences for method characteristics. Encourage questions and offer information on potential bleeding changes, mode of administration, effectiveness, disadvantages and side effects, advantages and non-contraceptive benefits, and mechanism of action. Appropriate counseling, selection, and follow-up supports patient satisfaction with the method.<sup>8</sup>

In preparation for an IUD placement:

- Apply principles of person-centered and trauma-responsive care (more information in the section on Person Centered and Trauma-Informed Care During IUD Placement).
- Use plain language when providing information.
- Use visual aids, diagrams, and anatomy charts:
  - o To demonstrate where the IUD goes in the body (uterus).
  - To discuss possible side effects, including how it may affect their bleeding patterns and their use of menstrual hygiene products.
  - To review the IUD placement process.
- Have physical models available that patients can interact with as tactile aids to support contraceptive education and patient understanding.<sup>9</sup> Demonstrate demo unit in clenched palm to show strings coming out of cervix and allow for the patient to feel the strings.
- Offer options for staff to care for accompanying children.
- Discuss removal of the IUD and how they can follow-up with questions or concerns.
- Emphasize that the IUD will not affect future fertility. For example, "Your ability to get pregnant goes back to what is normal for you, immediately after the IUD is removed."
- Emphasize that they are not required that they keep an IUD for the maximum duration of time by always including "up to" when discussing potential length of use. For example, "The Skyla® IUD can be used up to 3 years."
- Ask about and address concerns regarding pain and anxiety with placement, offering available pain management modalities (see <u>Pain Management Options for IUD Placement</u>).
- Address any patient concerns about access to IUD placement, removal, and affordability.
  - Examples include suggestions of what a patient can do to ease procedural anxiety, the option of self-removal, and discussions around insurance coverage for placement, the device, and removal.

Review possible bleeding changes for any IUD being considered:

- LNG IUD 52 mg
  - Some people experience frequent bleeding and/or spotting in the first 3-6 months, which usually resolves by 6 months.<sup>10</sup>
  - Some people have little or no bleeding as soon as it is placed.
  - Many people notice their periods get lighter and lighter with time.
  - o By 12 months, 50% of people will have very light menses or no bleeding.

#### LNG IUD 19.5 mg

- o Some people experience frequent light bleeding or spotting in the first 3-6 months.
- Some people experience spotting or bleeding frequently or intermittently throughout use.
- Many people notice their periods get lighter and lighter with time and with this low dose of hormone, most users will continue to have regular light menses.
- By 12 months, 12% of users have no bleeding.

#### LNG IUD 13.5 mg

- o Some people experience frequent light bleeding or spotting in the first 3-6 months.
- Some people experience unscheduled spotting or bleeding throughout use.
- Many people notice their periods get lighter and lighter with time and with this low dose of hormone, most users continue to have regular light menses.
- By 12 months, 10% of users have no bleeding.

## Copper 380 mm2 IUD

- Some people experience spotting in the first several weeks.
- Users continue to menstruate at the same frequency as they would otherwise because the Copper 380 mm2 IUD contains no hormones.
- Many people have heavier, longer or crampier periods.
  - The anti-prostaglandin effect of high-dose Non-Steroidal Anti-inflammatory Drugs (NSAIDs) can significantly reduce menstrual blood loss and dysmenorrhea.
  - Consider pre-emptive use for first 3 cycles.
  - Patients can start 1-2 days prior to onset of menses and continue either the first 2 days of menses or throughout, as needed.

#### Copper 175 mm2 IUD

 Menstrual bleeding may be altered, and patients may experience heavier, longer bleeding patterns with spotting.

# **Telehealth Considerations and Strategies**

Counseling, education, screening for contraindications, informed consent, and payment can be done via telehealth.<sup>11</sup>

Initiate bridging methods as needed via telehealth or in-person, including advance provision of emergency contraception pills.<sup>12</sup>

Expedite access to in-person services for requests for IUD placements and removals, which are essential services and are time-sensitive when placing IUDs for emergency contraception.

# **Considerations for People with Disabilities**

Providers often make incorrect assumptions that people with disabilities are not sexually active; <sup>13</sup> as a result, patients with disabilities are less likely to receive family planning services than those without.

Conversations about contraception should be offered to people with disabilities, including those with physical, intellectual, and developmental disabilities. 14-16

People with disabilities are at high risk of sexual coercion, assault, and of contracting HIV and can face significant barriers in accessing needed services. This stems from a lack of provider training, provider bias, harmful stereotypes, and health care facilities without accessibility accommodations or appropriate equipment.<sup>13</sup>

Most patients with disabilities can provide informed consent.<sup>13</sup> To support the autonomy of patients and avoid biased care, assume competence, and address your patient directly rather than looking to and asking a caregiver or support person, unless the patient indicates otherwise. Ask your patient what their priorities and preferences are and what accommodation requests they may (or may not) have prior to any exam or procedure. Offer anesthesia that is adequate for the individual's needs.

For patients with intellectual and/or developmental disability (IDD), you can support comprehension by utilizing the teach-back method to assess understanding of the appointment at hand and any information reviewed. To one way you can say this is, "I just went over a lot of information. To make sure I did my job right, can you tell me what you heard?" It may be appropriate to facilitate supported autonomous decision making in these cases, an alternative to guardianship which allows patients to choose someone they trust to assist with making decisions regarding specific topics. See the section on Person-Centered and Trauma-Informed Care During IUD Placement for more suggestions.

# **Considerations for People Identifying as Transgender and Gender Expansive**

All methods of contraception, including IUDs, can be used by transgender and gender expansive patients who were assigned female at birth (AFAB), including patients using testosterone therapy.<sup>19</sup> It is a common misconception among both patients and providers that testosterone is a contraceptive. Anyone with a uterus and ovaries who is having vaginal sex with a partner who produces sperm is at risk of pregnancy, regardless of whether or not they are using testosterone, and even if they have stopped menstruating.<sup>20</sup>

Some transgender and gender expansive patients may choose an IUD, including an LNG IUD, for menstrual suppression, which can be a desirable non-contraceptive benefit for all patients.<sup>21</sup>

Patients who are using testosterone may experience vaginal and cervical atrophy. While uterine atrophy can occur after long-term testosterone administration, there is no evidence of an increase in uterine perforation for IUD placement. Clinicians can offer 2-6 weeks of vaginal estrogen prior to speculum exam or IUD placement.

# **Considerations for Adolescents**

IUDs are safe for adolescents and young adults, and can be used without restriction, barring any medical contraindications. Adolescents and young adults have identified preprocedural anxiety and fear of a painful procedure as a primary barrier to using an IUD.<sup>22</sup> We recommend following many of the best practices already outlined when working with adolescent patients.

#### **Informed Consent**

Prior to signing a written consent form, elicit patient questions and review risks, warning signs, side effects, precautions, and how the patient can contact the clinic if any questions or concerns arise.

The following can be used to guide informed consent conversations about risks and warning signs prior to placement.<sup>10</sup>

- Pain with placement
  - o Pain varies between patients, <sup>23</sup> may be strong, but is generally short term.
  - Evidence highlights that providers underestimate patients' pain during placement.<sup>23</sup>
  - Fear of IUD placement pain, pre-procedure anxiety and negative perceptions of IUDs may lead patients to anticipate or feel a higher level of pain.<sup>24</sup>
  - Patient education to lower pre-procedure anxiety can be helpful.

#### Infection

- Slight increased risk (1/100) for pelvic inflammatory disease (PID) within first 3 weeks due to introduction of bacteria into the uterus during placement.
- o After the first 3 weeks, PID risk is the same as the general population (1-2/1000).
- Return to clinic for assessment of any warning signs or symptoms (fever, pain, abnormal vaginal discharge).
- Method failure/ pregnancy
  - o LNG IUDs: 4/1000
  - o Copper 380mm2 IUD: 8/1000
    - Copper 380 mm2 IUD has a slightly higher risk of method failure than LNG IUDs, but absolute risk is still low.
  - If pregnancy symptoms, take a urine pregnancy test.
  - Ectopic pregnancy risk: IUD users experience less risk of ectopic pregnancy, because of the IUD's efficacy at preventing pregnancy overall.<sup>25</sup> But if a patient has reason to think they may be pregnant or have had a positive pregnancy test, they need to be evaluated with ultrasound immediately to confirm the location of the pregnancy.
    - If an LNG IUD user becomes pregnant, there is an increased risk of the pregnancy being ectopic.<sup>26</sup>

#### Expulsion

- Approximately 5/100
- Watch for and report:
  - Pregnancy symptoms
  - Sudden cramping or pain
  - Bleeding pattern returns to "pre-placement" levels
  - Feeling hard plastic of IUD at cervix or markedly longer IUD strings
- o If patient unable to palpate strings or has symptoms of expulsion:
  - Use backup contraception and/or consider use of emergency contraception.
  - Take a urine pregnancy test.
  - Call clinic for advice or return to clinic ASAP.

#### Perforation:

- $\circ$  1/1000<sup>27</sup> most are simple and have no serious complications.
- If complete IUD perforation and translocation occurs, a procedure called laparoscopy can be used to retrieve the IUD.

# **Testing**

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

- Pregnancy test if there is possibility of pregnancy or it is not reasonably certain that patient is not pregnant (see Box 1 below).
- IUD can be placed during the same visit as STI testing and prior to receipt of test results.
  - o HPV &/or Pap (cytology) if due for cervical cancer screening.
  - CT/GC screening when:
    - Patient is due for screening (< 25 years and has not had screening in the past year).
    - Patient or partner has had a new sex partner or multiple partners in the preceding 90 days.
    - Patient had CT or GC  $\geq$  3 months ago and has not been re-screened for reinfection.

# Box 1. How to Be Reasonably Certain that Patient Is Not Pregnant

A healthcare provider can be reasonably certain that a patient is pregnant if they have no symptoms or signs of pregnancy and meet any one of the following criteria:

- Is ≤ 7 days after the start of normal menses.
- Has not had vaginal-penile 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 chest- or breastfeeding (exclusively chest- or breastfeeding to ≥ 85% of the time), amenorrheic, and < 6 months postpartum.</p>

Adapted from the U.S. Selected Practice Recommendations for Contraceptive Use, 2024 (US SPR).

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

# Initiation of IUDs

An IUD can be placed at any time during the menstrual cycle (it is unnecessary for the patient to be menstruating).

If there are no contraindications, an IUD can be placed at any time it is reasonably certain the patient is not pregnant or with a negative urine pregnancy test.

For post-abortion, early pregnancy loss, or postpartum patients, an IUD may be placed with a positive pregnancy test if there is relative certainty a patient is not pregnant, using criteria in Box 1 above, clinical judgment, and history.

 See "Following Birth," "Following a Uterine Aspiration for Abortion or Early Pregnancy Loss", and "Following Medication Regimens for Abortion or Early Pregnancy Loss" below.

A backup method in no longer required for the Copper 380 mm2 IUD and LNG IUD 52 mg.<sup>28</sup>

# **IUD as Emergency Contraception (EC)**

The Copper 380 mm2 IUD is the most effective form of emergency contraceptive (EC; nearly 100%). The LNG IUD 52 mg has been shown to be non-inferior to the Copper 380 mm2 IUD for EC and may be preferred by some patients. IUDs remain highly effective as EC in cases where EC pills have been shown to be less effective (BMI of 25 or greater, and/ or repeat episodes of unprotected intercourse).

- Whether for EC or for ongoing contraception, a Copper 380 mm2 IUD or an LNG IUD 52 mg can be placed at any time during the menstrual cycle, with a negative urine pregnancy test.<sup>29</sup> While data is still limited on LNG IUD 52 mg as EC, some providers may choose to offer simultaneous LNG EC pills until further data on mechanism and efficacy are available.
- If no menses occurs within 3 weeks of IUD placement for EC, or the patient is experiencing other symptoms of pregnancy, repeat a pregnancy test.

# **Following Birth**

In the postpartum period, many patients may be motivated to avoid repeat pregnancy. Initiating contraception early can help patients to obtain healthy birth spacing.<sup>30</sup> Offering immediate provision prior to discharge from the hospital is evidence based and can give patients full access to a range of contraceptive options, allowing patients to decide about the timing and type of pregnancy prevention that suits them. Delaying access to contraception until the first comprehensive postpartum visit, traditionally at around six weeks postpartum, may put some postpartum people at risk of pregnancy, either due to loss to follow-up or because they have had already had sexual intercourse prior to the postpartum visit.

A systematic review found that although IUD expulsion rates vary by timing of placement, type, and mode of delivery, IUD insertion can take place at any time.<sup>31</sup> An IUD can be placed:

- Immediately after delivery the placenta after either a vaginal or cesarean birth.
- Early interval placement, between 10 minutes to 4 weeks postpartum (which may better coincide with early postpartum clinic visits).
- Interval placement, by waiting until full involution of the uterus, which generally occurs by 4-6 weeks postpartum.

Insertion of IUDs among postpartum patients is safe and does not appear to increase health risks associated with IUD use such as infection.<sup>32</sup> Although randomized controlled trials found conflicting results on breastfeeding outcomes when LNG-IUDs were initiated immediately postpartum compared with 6–8 weeks postpartum, initiation of LNG-IUDs immediately postpartum had no other harmful effect on infant health, growth, or development.<sup>33-36</sup> There are no significant differences in lactogenesis, breastfeeding continuation, and infant growth parameters between immediate postpartum and delayed insertion of LNG IUDs, or between LNG and Copper 380 mm2 IUDs in most studies. Breastfeeding patients using IUDs do not have an increased risk for certain IUD-related adverse events including expulsion, infection, pain, or bleeding compared with those not breastfeeding.

Early compared to delayed interval IUD placement may better coincide with early postpartum or well-baby visits. IUD placement at 2-4 weeks postpartum compared with 6-8 weeks postpartum was found to be noninferior in a randomized trial, except for higher rates of partial but not complete expulsion.<sup>31</sup> Even so, the benefits of immediate and early IUD insertion may outweigh this risk if uptake, continuation or satisfaction are improved with earlier insertion. Counseling about the risk of expulsion at these time points may help patients make informed choices about the optimal timing of IUD placement.

CDC  Medical Eligibility for Initiating Postpartum IUD			
Condition		LNG-IUS	Copper IUD
Postpartum	<10 minutes after delivery of placenta	2	2
	>10 minutes to <4 weeks	2	2
	≥4 weeks	1	1
	Puerperal sepsis	4	4

Source: CDC MEC, 2024

# Following a Uterine Aspiration for Abortion or Early Pregnancy Loss

Immediately or any time thereafter if it is reasonably certain patient is not pregnant, using criteria in the table above, clinical judgment, and other history such as declining serial quantitative beta hCG.

# Following Medication Regimens for Abortion or Early Pregnancy Loss

Once it is confirmed that the patient is no longer pregnant or any time thereafter if it is reasonably certain patient is not pregnant, using criteria in Box 1, clinical judgment, and history, such as declining serial quantitative beta hCGs.

Studies demonstrate safety, acceptability, and high continuation rates when IUDs are placed soon after medication abortion, without increased incidence of expulsions or complications.<sup>37, 38</sup> Patients were more likely to return for the IUD placement if scheduled early after the medication abortion, and less likely to have had unprotected intercourse prior to placement.<sup>39</sup>

# **Backup Contraception**<sup>40</sup>

Copper 380 mm2 or LNG IUD 52 mg	No additional contraceptive protection (aka no backup) is needed after placement.	
LNG IUD 13.5 or 19.5 mg	<ul> <li>If placed within the first 7 days since start of LNMP, no backup is needed.</li> </ul>	
	<ul> <li>If placed &gt; 7days since start of LNMP, it is recommended to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.</li> </ul>	
	<ul> <li>When switching to an LNG IUD 13.5 or 19.5 mg from a hormonal or barrier method, consider continuing the previous method for 7 days after placement.</li> </ul>	
	■ If < 21 days postpartum, no backup needed.	
	<ul> <li>If ≥ 21 days postpartum and menses has not resumed, backup for 7 days.</li> </ul>	
	<ul> <li>If &lt; 7 days post aspiration for abortion or for early pregnancy loss, no backup needed.</li> </ul>	
	<ul> <li>If &lt; 7 days post medication abortion or post early pregnancy loss without a procedure, no back up needed.</li> </ul>	
	<ul> <li>If &gt; 7 days post medication abortion or post early pregnancy loss without a procedure, backup for 7 days.</li> </ul>	
	<ul> <li>Note: Urine pregnancy test may be positive for up to 4-6 weeks after abortion or pregnancy loss.<sup>41</sup></li> </ul>	
	<ul> <li>If &gt; 7 days post aspiration for abortion or for early pregnancy loss, backup for 7 days.</li> </ul>	
	<ul> <li>Note: Urine pregnancy test may be positive for up to 4-6 weeks after abortion or pregnancy loss.<sup>41</sup></li> </ul>	
Copper 175 mm2	Per the manufacturer, there is no current guidance on back-up contraception. Pending further data or recommendations, providers can counsel patients on use of a back-up method similar to the 13.5 or 19.5 LNG IUD.	

# Pain Management Options for IUD Placement

Increasing attention has focused on the need for clinicians to address IUD pain in a patient-centered way.<sup>40</sup> Evidence highlights that providers underestimate patients' pain during placement.<sup>23</sup>

Pre-procedure fear, anxiety, and negative perceptions of IUDs were significant predictors of pain during IUD placement. Taking patient concerns seriously and offering education to lower pre-procedure anxiety are suggested strategies, as is routine practice of trauma-informed care. Continued high-quality research on non-pharmacological pain and anxiety management strategies is warranted.<sup>42</sup>

# **NSAIDS**

Multiple non-steroidal anti-inflammatory drug (NSAID) formulations have been studied with mixed results. Meta-analyses suggest that effectiveness is greater for ketorolac, followed by naproxen, followed by ibuprofen – and more so for post-insertion cramping than for the IUD placement itself.<sup>40, 43, 44</sup> Offering NSAIDs can be part of a multi-modal pain management strategy.

# **Topical Anesthetics**

There is evidence that lidocaine as a topical gel, cream, or spray can reduce patient pain; while results are mixed, offering these options can be part of a multi-modal pain management strategy. Many studies have evaluated a range of topical anesthetics to reduce pain. Studies have shown pain reduction with topical anesthetics during both tenaculum placement and IUD placement, as well as in post-insertion pain scores. In a meta-analysis, no evidence of side effects was found. Renerally, 10% topical lidocaine reduced pain more than the 2-4% concentrations widely available in the U.S. All the use of topical lidocaine does not improve placement success, patient satisfaction, or provider ease of placement, nor does it reduce the need for adjunctive placement measures (e.g., cervical dilation) or reduce adverse events. Studies also demonstrated that patients were willing to extend the visit time to gain pain control.

#### **Paracervical Block**

Paracervical lidocaine was effective in producing lower VAS pain scores related to tenaculum placement (mean difference [MD]: - 20.54) and IUD insertion (MD: - 28.99) in the same meta-analysis of 13 studies.<sup>45</sup>

Recent data suggest that only 5% of providers currently offer paracervical block and is a topic that deserves more training focus.<sup>55</sup>

Although there are many styles of paracervical block, a common approach is to inject 1-2 ml at 12 o'clock for the tenaculum, and then up to 20 ml total at two or more sites at the cervico-vaginal junction to target paracervical innervation. Controlled trials show less procedural pain, except at time of injection, and pain scores improve with buffered lidocaine, deep injections (1.5-3 cm), and 4 vs. 2-site block. Some use a cough technique to distract during injection, but one study showed this is ineffective.

Pressure on nerves provides much of the analgesic effect, with studies showing that saline is only slightly less effective than lidocaine.<sup>58</sup> No evidence suggests one anesthetic is superior.

Neither the slow method (closure of tenaculum over a 5-second period) versus the 'cough' method (closure of tenaculum at the time of patient's cough) was superior for pain reduction or provider satisfaction.<sup>59</sup>

See tips for paracervical block below. In addition to hands-on training programs, instructional materials include the Ipas video on How to do a Paracervical Block.

# **Future Inserter Types**

A novel <u>inserter</u> (Crossglide® technology) is being evaluated for future use, and could provide an alternative to tenaculum use in the future.

The Copper 175mm2 IUD, commercially known as Miudella<sup>®</sup>, will also feature a novel inserter that will have some similarities and some differences to other IUD inserters. The Miudella<sup>®</sup> inserter will come pre-loaded and with a pre-cut thread and is under a Risk Evaluation and Mitigation Strategy at the time of this publication.<sup>60, 61</sup>

## **Conscious Sedation and General Anesthesia**

Some patients may disclose trauma history, and regardless of trauma history, some people may have difficulty with pelvic exams and/or procedures and may benefit from discussion of sedation options. Offer both conscious sedation and general anesthesia or refer to providers who offer these services, including possible placement in the operating room, may be appropriate.

# **Ineffective Means of IUD Pain Management**

Neither misoprostol cervical preparation nor intrauterine lidocaine infusion were found to be effective at reducing pain. Misoprostol produced higher VAS pain scores post-insertion (MD: 2.83) and caused side effects such as nausea and cramping and was not found to be helpful in subgroups such as adolescents.<sup>45</sup> Use of intrauterine lidocaine (2%) infused through an endometrial aspirator did not significantly reduce IUD insertion pain scores.<sup>62</sup>

# **IUD Placement**

# Person-Centered and Trauma-Informed Care During IUD Placement

For patients with a history of trauma, maintaining control over their body and person is paramount. Supporting a patient's self-efficacy and bodily autonomy is best practice, regardless of the person's trauma history. Applying principles of trauma-care universally during IUD counseling, placement, management, and removal is patient-centered. The LARC Doula Toolkit, a free clinic training resource that demonstrates how to integrate patient support staff during IUD and implant procedures, can be downloaded for additional guidance and training of staff.

- Allow for more time on the schedule for the placement visit.
- Utilize a spacious exam room, and set up all appropriate equipment: antiseptic solution, tenaculum, sound, os finders or dilators, swabs/cotton/or 4x4s, IUD in package (with another readily available in case of compromised sterility).
- Ensure the exam table is accessible. Ideal table characteristics include:
  - Lowering to 20 inches for easy transfer.
  - Side rails for support.
  - Adjustable padded boots rather than footrests.
- Cover intimidating-looking instruments and solutions.
- Insure an adequate light source.
- Prioritize patient comfort (temperature in room, minimize use of cold instruments, offer a pillow, heating pad, lavender oil).
- Offer a pre-procedure anxiolytic or sedation as needed. This may support those who experience discomfort or gender dysphoria with pelvic exams.<sup>65</sup>
- Use gentle, unhurried movements and touch throughout procedure.
- Position and drape to minimize exposure of intimate body parts in a vulnerable situation.
- Patient removes only clothing that is strictly necessary.
- Patient adjusts clothes, drape, and gown for their comfort.
- Provider is eye level or below the patient's eye level.
- Consider raising the head of the table if the patient prefers greater visibility.
- Offer options for alternative exam positioning. See <u>quide for no-stirrup pelvic exams</u>.
- Prior to beginning the exam, offer to describe what parts of the body will be involved.
- Normalize that some patients may experience involuntary movements during exam and procedure. Discuss possible movements and plans if they were to occur.
- Let the patient know: "If you want me to stop, you only have to say stop, and I will stop immediately"
- Offer self-placement of speculum.
- Use smaller (shorter is best for IUD placement) speculum size.

- Ask the patient their preference for how much information they receive during the placement. Offer to describe all steps of the procedure vs. not discussing the steps at all during the procedure vs. keeping the patient informed about what they will feel next. For example:
  - o "You may hear clicks when the speculum is opened." or
  - "The lubrication on the speculum will feel cool."
- For each step of the procedure, check for ongoing consent.
- Ask "What might help reduce stress/discomfort during the exam (make you more comfortable)?"
   Ask what has worked for them in the past. Consider offering multiple non-pharmacological modalities, including:
  - Distraction (with their phone or device or support person)
  - Deep diaphragmatic breathing
  - o Imagery techniques
  - Stress ball or fidget toy to hold
  - Aroma- or music therapy
- Encourage presence of a support person or doula for support.
- Consider alternate forms of pelvic exam (i.e. feet on table without foot holders).
- Consider offering anesthesia with deep sedation for patients who may be unlikely to tolerate placement.
- Offer pre-procedure anxiolytics as needed.
- Offer a cervical block.
- Consider pre-procedure topical estrogen (i.e. intra-vaginal cream, tablets, or ring) for 2-6 weeks for postmenopausal patients getting an IUD for uterine protection and for transgender patients on testosterone.<sup>66</sup>
- Have tissues or wipes ready for after exam.

Here are some phrases to avoid and suggestions for language that may be less triggering for survivors of trauma.

Instead of:	Consider:
"Open your legs."	"Let your knees move out to the side as much as is comfortable for you."
"Relax"	"Think about your muscles being heavy."
or	or
"Relax, it won't as much the more still you are."	"Some people say it helps to imagine your head/shoulders dropping into the headrest and to think of sinking your hips into the table."

For more information on how to support patients, during IUD and implant appointments, check out the <u>LARC Doula Toolkit</u> and/or review the <u>Clinician Guide for Trauma-Informed Care document</u>, which includes a handy pre-, during, and post-pelvic exam checklist.<sup>64, 67</sup>

# **Instruments and Supplies**

See this checklist created by Beyond the Pill for a clinic-friendly version.<sup>68</sup>

- Non-sterile exam gloves
  - Using no-touch technique so the working portions of the instruments (part going through the cervix or into tissue) are kept sterile.
  - Consider keeping sterile gloves on hand in case the provider needs:
    - To fold the Copper 380 mm2 IUD arms against the stem within its package (while the single-handed inserter should not require this, our experience is that occasionally it is needed), or
    - To bend the end of the metal sound with gloved hands rather than through the packaging.
- Non-sterile speculum
  - Plastic or metal
  - A shorter speculum allows more mobility and uterine straightening with a tenaculum. If more visibility is needed, use a wider rather than a longer speculum.
- Lubricant for exam
  - Obtain any needed cervical testing prior to using lubricant.
- Cotton ball, gauze, or OB swab (scopette, drumstick swab)
  - 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 solution containing 4% chlorhexidine gluconate and 4% isopropyl alcohol, not containing 70% isopropyl alcohol.
- Tenaculum
  - Providers may have preferences, but any of the following types of tenacula will work well:
    - Single tooth with rounded or squared edges
    - Atraumatic (especially for multiparous cervices)
    - Metal
    - Plastic
    - An alternative to tenaculum is a suction cervical stabilizer
- Uterine sound
  - Any of the following types of uterine sounds will work well, and having access to alternative types may be helpful. Most uterine sounds are 3- 4mm in diameter. Providers often have preferences:
    - Metal (including sound or dilators)

- Plastic
- An endometrial sampler (for performing EMB), can be used, has a smaller diameter (3mm) than most uterine sounds and is disposable.
- Ring forceps
  - To hold cotton balls or 4X4 for cleansing the cervix.
  - To remove the IUD.
  - o 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
  - Ideally sharp to avoid incomplete cutting of the strings, which could lead to possible displacement.
- The IUD
  - o Do not open the IUD package until you have successfully sounded the uterus.
- Sanitary napkin
- Tissue or wet wipe for the patient (for post-procedure)

# Supplies to have Available (Not Needed for Most Placements)

- Os finders and/or small metal or plastic dilators (i.e. French 13/15)
- Monsel's or silver nitrate sticks
- Ruler/measuring tape or OB tape with centimeter markings (helpful to "read" sounds with worn off markings)
- Sterile gloves
- Supplies for administering cervical block:
  - Local anesthetic (typically 1% lidocaine with or without epinephrine)
  - o 10-20 cc Syringe
  - 22-gauge needle with backup needle extender (or spinal needle without needle extender)

# **Training for IUD Placement**

Clinicians need hands-on training to place IUDs. After initial training, additional hands-on practice usually necessitates 3-10 IUD insertions with a proctor and may vary by experience. Training can be streamlined with additional IUD model and simulator practice.

# **Procedure for IUD Placement**

#### 1) Perform a bimanual exam

Determine uterine axis/position:

- Anteverted or flexed
- Misposition
- Retroverted or flexed
- Assess for signs that may make placement challenging or contraindicated:
  - Pelvic/uterine tenderness, anatomic abnormalities; enlarged uterus; irregular uterus; myomatous uterus – consider ultrasound guidance as indicated if abnormal and available.
  - Active mucopurulent cervicitis, untreated STI, or suspected PID.

# 2) Place speculum

- Place speculum fully to cervix before opening, to avoid getting stuck in fore tissue.
- If viewing is challenging, due to positioning or habitus, consider:
  - Raise the bottom or lower the head of the table.
  - Have the patient place their hands beneath their buttocks.
  - Hyper flexion of the legs (McRobert's Position).
  - Using a wider speculum when necessary.
  - Placing a condom (or finger of a glove) with tip cut off around the speculum if view obstructed by vaginal tissue. Alternatively, consider using a vaginal side-wall retractor.



Image source: Beyond the Pill

- Assess for abnormal discharge. If mucopurulent discharge at os (or suspect upper genital tract infection) do not place an IUD that day, and initiate treatment. If vaginitis (BV, yeast or trichomoniasis), treatment and IUD placement are appropriate that day.
- Obtain any indicated samples for testing (chlamydia, gonorrhea, or wet mount), Pap or HPV test.

# 3) Prepare the cervix

- Cleanse the cervix with 4% chlorhexidine gluconate as needed.
  - Scopette (OB swab, drumstick) cotton ball or folded 4x4 gauze grasped with a ring forceps with antiseptic solution, placed at cervical os and spiraled outward to the outer cervical edge.
- If you are going to place a cervical block, place now. For more information see: <a href="https://www.innovating-education.org/2018/05/larc-insertion-managing-pain-with-iud-insertion/">https://www.innovating-education.org/2018/05/larc-insertion-managing-pain-with-iud-insertion/</a>

# 4) Optional cervical block

- Although injection can be painful, a cervical block significantly reduces pain with tenaculum, IUD placement and pain post-placement.<sup>69</sup>
- Cervical blocks should be offered routinely and may be particularly helpful for patients requiring more cervical manipulation or for patients experiencing anxiety.
- Injection locations and techniques for para and intra-cervical blocks vary by provider (i.e. while 4 and 6 o'clock sites are shown in image below, 10 and 2 o'clock sites are also common).
- Local anesthetics block nerve impulses, and volume causes tissue distention, providing some analgesic effect.
- No evidence suggests one anesthetic is superior; saline has somewhat less effect than lidocaine.<sup>58</sup>

Below are images of position of injections in a paracervical block.

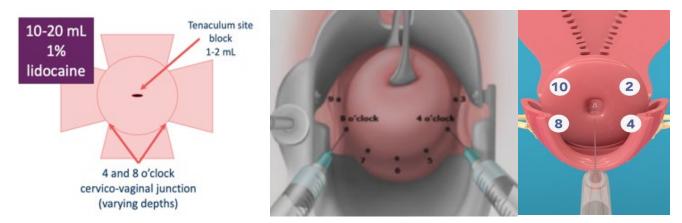


Image sources: PICKK presentation, UpToDate Vidaeff 2024, and Innovating Education Pain Management Video.

#### 5) Place tenaculum

Tenaculum use assists to:

- Straighten the cervical canal to enable instruments to pass through the os more easily, avoiding perforation at flexion point.
- Stabilize the cervix and provide countertraction so instruments can pass.

Placing a tenaculum on the cervix:

- Grasp with dominant hand, holding palm up and placing thumb through one ring and middle or ring finger through the other. Use the index finger in between as a brace and to stabilize.
- Place the open tenaculum teeth on the cervical surface, and with tips 1-2 cm apart, squeeze together slowly to imbed teeth in a 1-2 cm deep bite. If the grasped cervical tissue becomes attenuated or the tenaculum becomes dislodged, regrasp a somewhat larger bite to prevent pulling through.
- One can position the tenaculum horizontally 1-2 cm above or below the external os. Or alternatively, some providers prefer vertical placements, finding fewer tears and less sidewall resistance at removal.
- It is conventional to grasp the anterior lip in an anteflexed uterus or the posterior lip in a retroflexed uterus, but this is not evidence-based.
- After speculum placement, if the entire cervix is not visualized it is acceptable to grasp the visible lip of the cervix and bring the os into view with traction.
- Close the locking ratchet (1-2 clicks is adequate), hold securely with non-dominant hand to apply traction during sounding and IUD placement at the fundus (rather than the back wall of a flexed uterus).
- One can lay the tenaculum down to rest (on speculum) in order to pick up the sound or IUD.

## 6) Sound the uterus

Reasons to sound the uterus:

- Sounding allows for documentation of uterine depth, and indicates:
  - o The ability to pass through the cervical 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 successful uterine sounding. 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 the following (although clinical judgement may apply, i.e. with fibroids, post-abortion, or postpartum placement):

- 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®

#### Sounding technique:

With traction on the tenaculum, gently pass the sound into the cervical canal, holding the sound loosely with pencil-grasp, allowing it to rotate within canal (which should have a snug, smooth, mucosal feel). Hold at fulcrum with a light grip so it can transmit information to the hand about the internal cervical and uterine flexion. You may feel the internal os "give way" to gentle, steady pressure at a depth of 3-4 cm.

- Metal sounds can be bent at the distal few cm to mimic the uterine flexion and may require reshaping after autoclaving prior to use. To maintain sterility, only touch the uterine end through sterile packaging or with sterile gloves.
- Plastic sounds are considered slightly safer and are disposable (do not require autoclave).<sup>27</sup> Plastic sounds cannot be bent to maintain a curve that mimics uterine flexion, but once a plastic sound is removed from the uterus it may look curved mirroring the uterine curvature.

To reduce risk of perforation and increase comfort:

- Move slowly and intentionally avoiding momentum.
- Consider placing pinky finger on the speculum 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.

#### Measuring with the sound:

- Note the depth sounded in centimeters by looking for the "fluid line" or "line of glistening" where blood, mucous or cleansing solution is visible. Most sounds have centimeter markings or may be held up to a measuring tape.
- Alternately, once the sound is at the fundus, pick up scopette and hold it at the fat, drumstick end. Place the other end 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.

## 7) Place the IUD

## Placement of Copper 380 mm2 IUD (Single-handed inserter; new in 2024)

1) Open the Sterile Package

Place the package containing IUD (face-up) on a flat sterile field Open the pouch from the handle end where the arrow on the Placement Guide says "OPEN". Remove the clear cover from the tray. Confirm that the top of the button is located at the starting line on the handle prior to loading. The inserter should remain in the tray until T-Arms are loaded. Do not slide the button on the handle before folding the arms in the tray. Do not repeatedly slide the button forward and back as this may cause slack in the threads and may result in an unsuccessful placement.

2) Load Paragard into the Inserter

With gloves, place one hand on the distal end of the tray and the other on the inserter handle. Slide the handle completely forward so that the IUD advances into the Loading Tip folding the IUD T-Arms against the stem. Once the T-Arms are folded against the stem, slide the button on the handle completely forward to advance the insertion tube over the tips of the T-Arms. Only the tips of the T-Arms should be in the insertion tube. Do not advance beyond the copper collars. IMPORTANT: Do not leave the T-Arms of Paragard bent for more than 5 minutes, as the arms may not open properly.

3) Adjust the Flange

Once the IUD is in the insertion tube, adjust the blue flange. The tray is marked with centimeters and can be used to set the flange to the correct depth. Adjust the flange so the distance from the top of Paragard (where it protrudes from the inserter) to the top of the flange is equal to the pre- measured uterine depth.

## 4) Remove Inserter from Tray

Ensure the button remains in the forward position. To remove the inserter from the tray, gently lift the handle out of the tray, then gently slide the inserter back and lift out of the tray. Upon removal from the tray, verify and rotate the blue flange as needed so that the horizontal arms of Paragard and the long axis of the blue flange and handle lie in the same horizontal plane to ensure the arms open in the proper direction. Confirm that both T-Arms are captured within the insertion tube.

#### 5) Insert Paragard to the Fundus

To orient the uterus in an axial position, apply gentle traction to the tenaculum. While holding the button forward, pass the loaded inserter through the cervical canal until the IUD reaches the fundus of the uterus. This will ensure IUD placement at the highest possible position within the uterus. The blue flange should be at the cervix in the horizontal plane. The button should remain in the forward position

## 6) Release Paragard and Withdrawing Inserter

Release the IUD arms by holding the handle steady and sliding the button all the way down (and you may feel a click). Do not stop at the starting line as it is not used for deployment.

This releases the threads and the IUD T-Arms high in the uterine fundus. Gently and slowly withdraw the inserter from the uterus and cervical canal. Only the threads should be visibly protruding from the cervix. Trim the threads so that 3 to 4 cm protrude into the vagina.

Measure and note the length of threads, date of placement and lot number. Discard the used inserter – do not attempt to re-use the inserter because it is a single use device.

If you suspect that Paragard is not in the correct position, check placement (with ultrasound, if necessary). If it is not positioned completely within the uterus, remove it and replace it with a new CuT IUD. Do not reinsert an expelled or partially expelled IUD.

#### Placement of Copper 380 mm<sup>2</sup> IUD (Older two-handed inserter)

- 1) After successful sounding, load the Copper 380 mm2 IUD into the insertion tube.
  - Use either <u>the no-touch technique</u> by loading the IUD in partially open package, or use sterile gloves.<sup>70</sup>
  - Fold the two horizontal arms down and tuck the tips of the arms slightly into the insertion tube. The copper collars will be outside the tube.
  - Avoid loading the IUD arms > 5 minutes before uterine placement.
  - 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 flange's wide aspect is designed to be in the same plane as the IUD arms.
- Set the flange to the sound depth measured either through the sterile packaging or with sterile gloves.

- 3) Remove the loaded insertion tube from the sterile packaging and check to be sure the white rod is touching the bottom of the IUD and the flange is in the same horizontal plane as the arms of the IUD.
- 4) Pass loaded IUD insertion tube gently through internal os. Once through the internal os, pause and then intentionally and slowly proceed to the fundus using dominant hand.
  - Apply traction to the tenaculum with the non-dominant hand.
  - Stop advancing when fundal resistance is met.
- 5) Allow the tenaculum to rest on the speculum.
- 6) Immobilize the white solid rod with the non-dominant hand. The rod functions as a stabilizer to hold the IUD in place. Never use it as plunger, to avoid perforation.
- 7) Pull the insertion tube back until it touches the ring of the rod to release the arms of the Copper 380 mm2 IUD at the fundal position.
- 8) Re-advance insertion tube to fundus to "re-seat" the IUD and ensure high fundal placement.
- 9) Remove solid rod before removing the insertion tube, to prevent inadvertent displacement or expulsion of the IUD.
- 10) Remove the insertion tube, using it as a guide to hold and cut the strings, before removing the insertion tube from vagina.
- 11) Cut the strings at 3-4 cm. Use sharp scissors to avoid IUD displacement and cut straight across strings to minimize sharply pointed tips that may poke the partner. Cutting strings on the longer side (> 3cm) may allow strings to wrap around the cervix, facilitate self-removal, help minimize a partner feeling the strings, or facilitate concealing IUD use from a partner.
- 12) Document length of strings in chart.
- 13) Remove instruments sequentially.

#### Placement of LNG IUDs: Mirena®, Kyleena®, and Skyla®

- 1) After successful sounding, open package and lift out inserter without touching the part that will go into the patient's uterus.
- Load of device into insertion tube.
  - Avoid loading the IUD arms into inserter > 5 minutes before uterine placement the less time the better.
  - Push the slider completely forward in the direction of the arrow to load the arms of the IUD into the inserter. The arms will fold up.
  - The tips of the arms will meet to form a rounded end extending slightly beyond the insertion tube.
  - o Maintain pressure, keeping thumb or forefinger on the slider at all times throughout the procedure, to avoid displacement.
  - 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.
- 3) Set flange.
  - Use notch in the sterile packaging to set the upper edge of the flange to correspond to the uterine depth (in centimeters) measured during sounding.

- 4) Apply traction to the tenaculum with the non-dominant hand.
- 5) Pass the inserter gently through internal cervical os (with pelvic curve of inserter aligned with suspected uterine position).
- 6) Once through the internal os, pause and then intentionally and slowly, advance the loaded inserter until the upper edge of the flange is 1.5 to 2 cm from the external os.
  - Alternatively advance loaded inserter to fundus and then retract down until the flange is 1.5 to 2 cm from the external os.
- 7) While holding the inserter steady and maintaining its position relative to the cervix, pull the slider down to the "first mark."
- 8) Wait 10-15 seconds in this position to ensure the arms have fully opened before advancing to prevent perforation.
- 9) Advance the inserter to the fundus (stopping in fundal position). When the inserter is at the fundus, the flange will be touching or close to the cervix.
- 10) Release the IUD by moving the slider all the way down (toward you) while holding the inserter securely in place, and gently withdraw the inserter from the uterus.
- 11) Cut the strings. Use the insertion tube as a guide to hold and cut the strings, before removing tube from vagina. Use sharp scissors to avoid IUD displacement and cut straight across strings to minimize sharply pointed tips that may poke the partner. Cut the strings to 3-4 cm, which allows strings to wrap around the cervix, may help facilitate self-removal, helps minimize a partner feeling the strings, or for patients who wish to conceal IUD use from a partner.
- 12) Document length of strings in chart.
- 13) Remove instruments sequentially.

Placement of LNG IUD: Liletta® (Note: Single handed inserter for Liletta® became available in 2016. The manufacturer updated the label in June 2023. Liletta® instructions are represented and adapted slightly here.)

- 1) Open sterile package.
  - Completely open the sterile lid by peeling the lid back from the handle end toward the inserter tip.
  - Avoid loading the IUD arms in inserter > 2-5 minutes before uterine placement.
- 2) Sterile loading of the inserter.
  - Remove the inserter from the tray, grasping the handle below the sliders and twist gently but not by pulling on the tube. Do not touch the part of the inserter that goes in the patient's uterus.
  - Ensure both BLUE and GREEN sliders (labeled 1 and 2 respectively) 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.

- The arms of the IUD do not come pre-aligned so to load them into the inserter, it is necessary to ensure the IUD arms are horizontal. See the flat, sterile surface of the tray to:
  - Adjust the IUD rotation as needed.
  - Hold the arms of the IUD securely against the packaging.
- While maintaining forward pressure on the blue slider and holding the arms in the horizontal position in the packaging, pull both threads evenly, straight back without excessive force until you feel a hard stop. The arms will fold up and be pulled into the insertion tube.
- Once feeling a hard stop, gently pull the threads into the cleft and lock them 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 arms of the IUD are loaded into the tube, continue to maintain forward pressure on the BLUE slider.
- When correctly loaded, the tips of the arms of the IUD form a hemispherical dome at the top of the tube.
- If the IUD is not correctly loaded, do not attempt placement. Liletta® can be reloaded if this occurs.
- Adjust the flange to the measured uterine depth based on sounding. To adjust:
  - Place the flat side of the flange in the tray notch or edge inside 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 arms of the IUD. This way, if the loaded IUD is not completely horizontal, the flange will mirror the position of the IUD within the uterus so the positioning of the handle can be adjusted such that the arms of the IUD are deployed in the correct horizontal plane.
- If an adjustment to the curvature of the insertion tube is required to accommodate the anatomical orientation of the uterus, you may turn it over (for a retroverted uterus), gently bend or straighten the insertion tube, but do not touch above the flange unless using sterile gloves.
- 3) Place Liletta® into the uterus.
  - Apply gentle traction on the tenaculum as needed while advancing the loaded insertion tube through the os.
  - Once through the internal os, pause and then intentionally and slowly advance the tube until the upper edge of the flange is 1.5 cm to 2.0 cm from the external cervical os.
    - Alternatively advance loaded inserter to fundus and then retract down until the flange is 1.5 to 2 cm from the external 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 merge 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.
- 4) Release 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 toward the number 3, until:
    - A click is heard, indicating both sliders have been brought fully down to the correct final position.
    - Check that the GREEN indicator is visible in the cleft at the bottom of the handle (near the removal threads).
    - Check that the threads have been released from the cleft.
  - If the threads are not released, or if a click is not heard, grasp the threads and gently pull the threads out of the cleft.
- 5) Remove the inserter from the uterus.
- 6) Cut the strings.
  - Use the insertion tube as a guide to hold and cut the strings, before removing tube from vagina. Use sharp scissors to avoid IUD displacement and cut straight across strings to minimize sharply pointed tips that may poke the partner.
  - Cut the strings to 3-4 cm, which allows strings to wrap around the cervix, may help facilitate self-removal, helps minimize a partner feeling the strings, or for patients who wish to conceal IUD use from a partner.
  - Document length of strings in chart.
  - Remove instruments sequentially.

At the time of publication, placement instructions for the Copper IUD 175 mm2 (Miudella®) have not been published.

# Difficulty Passing Through the Internal Os or with Cervical Stenosis

- 1) Add traction on tenaculum in a different way; for example, pulling down, up or to the side.
- 2) Change the angle of the sound, dropping wrist and try positioning the sound at various angles in the os to find the direction of the pathway.
- 3) Hold gentle firm pressure with the sound for several seconds until the os opens.

- 4) Try switching from flexible plastic to rigid sound, dilator or os finder. A smaller diameter sounding device like a plastic sound or an endometrial sampler may pass more easily. Adjust the curvature of a rigid sound; either increase the curvature or make the sound straighter.
- 5) Consider re-positioning the tenaculum to another lip of cervix.
- 6) Consider shorter, wider (or Klopfer) speculum if available. Try widening blades.
- 7) Consider ultrasound guidance.
- 8) Consider the assistance of another provider.
- 9) Consider providing misoprostol (sublingual/vaginal/buccal) and reattempt on another clinical day.

# **Follow Up After IUD Placement**

- No routine follow-up visit is required.<sup>40</sup>
- People with additional medical or educational needs may benefit from a follow up 4-6 weeks later.
- Confirm your clinic's ability to accommodate patients who desire removal or IUD replacement, or who wish to discuss side effects or concerns whether by telehealth visit, phone call, or returning to clinic.
- At routine visits, providers who see IUD users should assess satisfaction with the IUD and if there are any concerns.

# **Evaluation and Management**

# **Vasovagal Reflex During Procedure**

- During a vasovagal reaction, patients may feel sweaty and nauseated, have an urgent need to urinate or defecate, and may "black out." This is almost always a vasovagal reflex, caused by stimulation of the parasympathetic nervous system that can occur with cervical procedures, anxiety, and other emotions.
- It begins with pooling of blood in the extremities which decreases peripheral vascular resistance, causing a sudden drop in blood returning to the heart. This triggers a reflex bradycardia—an abnormally slow heartbeat—along with a drop in blood pressure. This combination leads to reduced blood flow to the brain and syncope.<sup>72</sup>
- Symptoms include pallor, sweating, nausea/vomiting, syncope, and even pseudo seizure.
- A patient who is overheated, dehydrated, hypoglycemic, or over-medicated may be predisposed to syncope.
- To help prevent vasovagal reactions:
  - Isometric extremity contractions can be used.<sup>72</sup>
  - o Create a calming environment.
  - Encourage hydration and cooling if the patient is overheated.
- Giving the patient a heads up and showing them how to practice the isometric contractions ahead of time can help them stop the reaction themselves.
  - For example, you might say:
    - "Sometimes people having this done begin to feel dizzy and they can sometimes pass out. If that happens to you it doesn't mean anything is seriously wrong, but it can be scary. If you start to feel lightheaded, sweaty, or if you feel weird in anyway, it may be a sign that you're about to faint or pass out. You can prevent that from happening by intensely griping the muscles in your hands, arms, feet and legs while releasing the muscles of the belly, bottom, and chest. There is no need to move your arms or legs—just tense the muscles in place. Do you want to practice trying that now?" <sup>773</sup>
- Additional ways to manage a vasovagal include:
  - Apply ice or cool cloth on head or neck.
  - Have patient sniff an alcohol swab or ammonia capsule.
  - Keep the patient supine or in Trendelenburg, with head to side if vomiting.
- Although rarely needed, if vasovagal is prolonged, consider atropine, IV Fluids, oxygen, and evaluation for other potential causes.

#### 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, validate and offer reassurance.
- If not acceptable, offer removal and alternative contraceptive services, if desired.

# **Bleeding Irregularities with IUD In Place**

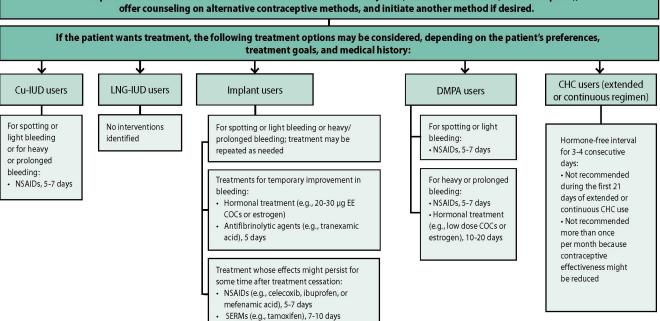
- **History:** Signs or symptoms of pregnancy, infection, lesion, malignancy, fibroids.
- Labs as indicated: Pregnancy test, CT/GC, Hgb, pap/HPV, ultrasound (refer our as needed).
- **Exam:** Rule out pregnancy, infection, cervical neoplasm, polyps, fibroids, IUD displacement.
- If IUD is in situ and no lesion, infection, or pregnancy, confirm and offer reassurance.
- LNG IUD: Advise bleeding may decrease after 3-6 months of use.
- Copper 380 mm2 IUD: Offer NSAIDS starting 24 hours before menses and continuing for 5-7 days.
- If not acceptable, offer removal and alternative contraceptive services, if desired.



# Management of Bleeding Irregularities While Using Contraception\*

Explore patient goals, including continued method use (with or without treatment for bleeding irregularities) or method discontinuation. If the patient wants to continue use, provide reassurance and advise the patient that they may contact their provider at any time to discuss bleeding irregularities or other side effects.

If the patient desires removal or discontinuation of the method at any time, remove the method (if IUD or implant), offer counseling on alternative contraceptive methods, and initiate another method if desired.



<sup>\*</sup> If clinically indicated, consider an underlying health condition, such as interactions with other medications, sexually transmitted infections, pregnancy, thyroid disorders, or new pathologic uterine conditions

Abbreviations: CHC = combined hormonal contraceptive; COC = combined oral contraceptive; CUC = combined oral contraceptiv LNG-IUD = levonorgestrel intrauterine device; NSAIDs = nonsteroidal anti-inflammatory drugs; SERM = selective estrogen receptor modulator

Source: For full recommendations and updates, see the U.S. Selected Practice Recommendations for Contraceptive Use webpage at https://www.cdc.gov/contraception/hcp/usspr/



Source: CDC US SPR, 2024

# **Pregnancy with IUD In Place**

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

- History: Signs or symptoms of ectopic pregnancy; bleeding, pain.
- Labs and tests as indicated: Pregnancy test, quantitative hCG, ultrasound (refer out as needed).
- **Exam:** Rule out ectopic pregnancy, blood pressure, pulse, speculum exam, bimanual exam.
- Management:
  - IUD in situ; confirmed intrauterine pregnancy (IUP), patient plans to terminate pregnancy.
    - May advise patient it is best to remove IUD while awaiting termination or may remove IUD at time of termination.
  - IUD in situ; confirmed IUP, patient plans to continue pregnancy.
    - Advise of increased risk of miscarriage, septic abortion, premature rupture of membranes, preterm delivery and chorioamnionitis if IUD left in situ.<sup>74</sup>
    - If strings are visible, advise that while there is a risk of bleeding and/or spontaneous abortion if IUD is removed, the risk is lower than if the IUD is left in place. Use shared decision-making to discuss risks and benefits of removal. Remove IUD immediately if informed consent is obtained.
    - Advise patient to seek timely prenatal care, and see a provider immediately if any bleeding, cramping, pain, fever, or abnormal vaginal discharge develops.
  - IUD perforated, and embedded or translocated; confirmed IUP, patient plans to terminate pregnancy.
    - Arrange timely follow-up to extract IUD with appropriate procedure based on location of IUD. Advanced imaging may be needed by referral site to determine best approach.
  - Confirmed ectopic pregnancy. Manage ectopic pregnancy as per standard care.
    - If IUD in situ, may leave in place or may replace.
    - If IUD expelled, may replace once ectopic is resolved.
    - If IUD displaced, perforated, and embedded or translocated: manage as appropriate to IUD location.

# Management of Sexually Transmitted Infection (STI) or Vaginitis with IUD In Place

- Treat the infection per <u>CDC 2021 STI Treatment Guidelines</u> and leave IUD in place, if patient desires.<sup>75</sup>
- If diagnosing an STI, counsel patient on condom use, partner treatment, and abstaining from sexual intercourse until treatment is complete.

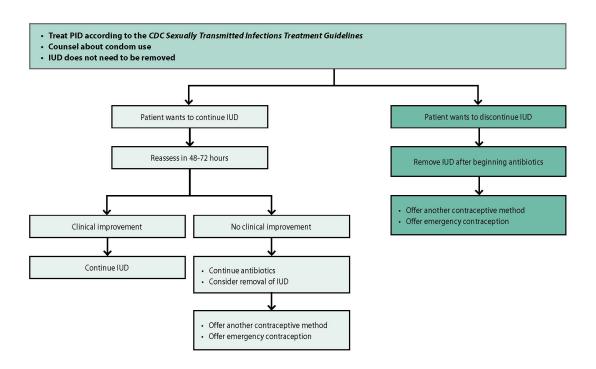
# Diagnosis of Pelvic Inflammatory Disease (PID) with IUD In Place

Treat according to CDC's 2021 STD Treatment Guidelines.

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

- Treat the PID according to the CDC STI Treatment Guidelines.
- Provide comprehensive management, including counseling about condom use, partner treatment, and/or abstaining from sexual intercourse until treatment is complete.
- The IUD does not need to be removed.
- Reassess in 48-72 hours. If no clinical improvement occurs, continue antibiotics, and consider removal of the IUD.
- If the patient wants to remove the IUD, it is best to wait until at least 24-48 hours of antibiotics.
- If the IUD is removed, consider ECPs if appropriate. Counsel on contraceptive options and offer another method if desired.

# Management of IUDs When Users are Found to Have Pelvic Inflammatory Disease\*



\*Refer to CDC Sexually Transmitted Infections Treatment Guidelines (https://www.cdc.gov/std/treatment-guidelines/default.htm) for information on PID diagnostic considerations and treatment regimens.

Abbreviations: IUD = intrauterine device; PID = pelvic inflammatory disease

Source: For full recommendations and updates, see the U.S. Selected Practice Recommendations for Contraceptive Use webpage at <a href="https://www.cdc.gov/contraception/hcp/usspr/">https://www.cdc.gov/contraception/hcp/usspr/</a>



Source: CDC US SPR, 2024

# **Actinomyces Report on Pap Test**

Actinomyces are anaerobic bacteria capable of asymptomatic colonization or causing a pelvic actinomycosis which is a rare, but severe, pelvic infection. Most 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. Pelvic actinomycosis is associated with IUD use, however most infections are seen in malnourished people over 35 who are long term IUD users.

- **History:** Signs or symptoms of PID include fever, abnormal discharge, pelvic or abdominal pain, deep dyspareunia, and intermenstrual spotting or bleeding.
- Labs: None needed unless signs or symptoms of PID. If suspicious for PID, work up per CDC STD 2021 treatment guidelines.
- Exam: Pain, pelvic mass.
- Management: Asymptomatic colonization does not require antibiotic therapy or removal of the IUD.
- Treat per CDC STD 2021 treatment guidelines.

# **No Visible Strings**

#### Possibilities:

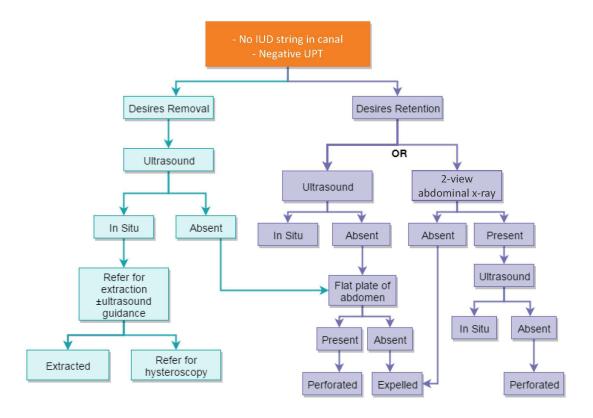
- Strings present but not visible because they are in canal or uterus
- Expulsion
- Pregnancy with IUD in situ and strings pulled into uterus
- Embedment, later partial perforation
- Translocation after perforation

#### Initial management:

- 1) Pregnancy test if appropriate.
- 2) Advise/prescribe back-up contraceptive method and/or EC until intrauterine location is confirmed.
- 3) Probe for strings in cervical canal using cytology brush or thread retriever to tease strings down.
- 4) Endocervical speculum, 10" Kelly, alligator, straight forceps to help open the external os sufficiently to see the strings if they are within the canal.
  - Endocervical speculum or forceps in a closed position into external os, open once inside but avoid advancing through internal os. Added light and magnification (via colposcope) can assist in visualizing strings if needed.
- 5) 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:

May leave in place for up to the remainder of the IUD lifespan.



Source: Cason, P and Policar, M.

# **IUD Removal**

Inform patient that "Your ability to get pregnant goes back to whatever is normal for you immediately" after IUD removal. If penile-vaginal intercourse has occurred within the past 5 days, there is a theoretical risk of pregnancy due to sperm's ability to survive in the vaginal canal. Use shared decision-making to consider waiting 5 days after last intercourse to remove the IUD, placing a Copper 380 mm2 IUD or LNG IUD 52 mg following current IUD removal (see IUD as EC), or offering ECP.

Patients report barriers to IUD removal, including provider resistance.<sup>76</sup> Given the importance of patient autonomy, addressing providers' concern about "hasty" removal through additional training can help providers be better able to support patients' decision making around contraceptive use.<sup>77</sup>

# **IUD Self-Removal**

IUD self-removal can be considered a safe alternative to office removal and may have a positive impact on reproductive autonomy, decision making, and satisfaction with the method. In one study, 30% of participants (35 out of 116) successfully removed their own IUDs. This study, participants were more likely to successfully remove their IUD in a non-clinical setting and would recommend the method to a friend or use the method with a future IUD. This IUD Self Removal factsheet can be offered to patients who are interested in learning more. The safe interested in learning more.

For patients who desire IUD removal in clinic, see below.

# **Uncomplicated Removals**

- 1) Place speculum to fully visualize cervical os with strings in view.
- 2) Clasp strings with ring forceps close to os.
- 3) 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 <u>No Strings Visible</u>) 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 speculum and optional paracervical block.
- 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.
  - o 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.
- Close the forceps to obtain a purchase on the IUD or strings, and remove, using a steady even-paced motion to pull the IUD out through the os.
- A "thread retriever" can be used to catch the strings in the cervical canal or uterus and bring them out of the external os.
  - O While applying outward traction with a tenaculum, pass the thread retriever through the external os and sweep the cervical canal to catch the strings. If this is not successful, pass the retriever through the internal os and advance the tip toward the fundus. Sweep the retriever down the anterior uterine wall through the os. If unsuccessful, repeat by sweeping the retriever down the posterior uterine wall.
- IUD hook is helpful for circular IUDs; it is less helpful with T-shaped IUDs however, if extraction with the alligator forceps and thread retriever is unsuccessful, consider extraction with a hook.
  - O 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 the hook has caught the IUD. 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, thread retriever, and hook is unsuccessful.
  - Attempt above using cervical block and / or moderate sedation.
  - o Use suction from an MVA with a 5-6 mm curette to bring strings beyond external os
  - Refer as needed to extract via operative hysteroscopy.

#### Strings visible but initial attempt at removal unsuccessful

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

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