Copper T380A (Paraguard) IUD
- Clinical efficacy to 12 years (though labeling says 10)
- Mechanism of action:
  - Increase in uterine and tubal fluids containing copper ions, enzymes, prostaglandins and macrophages that impair sperm function and prevent fertilization.
- Failure rate:
  - 0.7 per 100 women in the first year of use.
  - Cumulative 5-7 year failure rates between .7 and 1.4 pregnancies per 100 women.
  - For comparison, the overall 10 year failure rate for tubal sterilization in the US is 1.9 per 100 women.

Levonorgstrel (Mirena) IUD
- Releases levonorgstrel into the endometrial cavity at 20 mcg per day initially. The rate declines to 14 mcg per day after 5 years.
- Clinical efficacy to 7 years (though labeling says 5)
- Mechanism of action:
  - Thickening of cervical mucus, inhibiting sperm transport and survival, suppressing the endometrium, producing a foreign body reaction, and in some cases preventing ovulation.
- Failure rate:
  - First year cumulative failure rate 0.14 per 100 women and cumulative 5 year failure rate 0.71 per 100 women.

Benefits of Intrauterine contraception
- High efficacy
- Protective against ectopic pregnancy
- Duration of effect
- Convenience
- Low risk of side effects
- Cost effectiveness
- Additional medical benefits of levonorgstrel IUD
  - Progesterone effects on the uterine cavity include reduced blood loss with menses and about 20% rate of amenorrhea. Can be used to treat menorrhagia.
- Cancer protection
  - Several studies have demonstrated reduced risk of endometrial cancer in IUD users.

Side effects, Risks of IUD
- Menstrual changes
  - Copper IUD: heavier menses as well as irregular bleeding during the first few months of use. In the first year of using the copper IUD, 12% of women will discontinue it because of menstrual changes, compared with 50% who discontinue oral contraceptives within the first year.
  - Levonorgstrel IUD: light bleeding or spotting irregularly in the first month of use and thereafter decreased bleeding although it may remain irregular. 20% will experience amenorrhea in first year (more with continued use).
- Cramping and pain
  - At the time of insertion, discomfort and cramping for 10-15 minutes.
• Expulsion
  o 2-10% of IUD users expel their IUD within the first year. Women with heavy menses and severe dysmenorrhea are more likely to have expulsion of the copper IUD.

• Perforation
  o Can occur at the time of insertion. Most important determinate of risk is the skill of the provider performing the insertion. In the hands of a skilled operator the risk is less than 1 per 1000 insertions.

• Upper genital tract infection
  o Rigorous randomized control trials with current devices have established that the risk of infection and infertility among IUD users is extremely low. There is an increased risk of PID for 4 weeks after insertion due to the risk of undetected cervicitis, but after this, the risk the risk of PID is the same or lower than that in patients without IUDs. There is no increase in risk of upper tract infection (PID) with an existing IUD if patient acquires cervicitis after insertion.

Contraindications to IUD insertion:
• Acute pelvic inflammatory disease
• Mucopurulent cervicitis
• Postpartum endometritis in the past three months
• Suspected uterine or cervical cancer
• Current pregnancy
• Wilson’s disease (Copper IUD)

The current labeling for the Paraguard IUD does not list nulliparity or history of pelvic inflammatory disease or sexually transmitted infection as contraindications to insertion. The expulsion rate for a nulliparous woman is 5-7% and for a multiparous woman is 3-5%.

Relative contraindications (weigh against risk of unwanted pregnancy)
• Current high risk sexual behavior (multiple partners without condom use)
• Unresolved abnormal pap smear (rationale: if LEEP is required, may need to remove IUD, resulting in poor resource utilization)

Pre-Insertion visit (not always necessary if recent pap/cultures and lower risk):
  1. Counsel the patient about benefits, risks and menstrual changes with each IUD.
  2. Complete a general procedure consent form
  3. Explain follow up plan and monitoring
  4. Assess by history whether the patient could be pregnant or at risk for pregnancy
  5. Perform a pelvic exam including a Pap smear if this has not been done recently and cervical cultures for gonorrhea and chlamydia.
  6. Perform a bimanual exam to assess size and position of the uterus, and to detect anatomic abnormalities that could distort the uterine cavity (bicornuate uterus, submucous fibroids)
  7. Arrange a 30 minute visit for insertion and counsel the patient on pre-medication with an NSAID and to avoid unprotected sex until the IUD has been inserted.
  8. Tests such as HIV, Hepatitis B, RPR, wet prep and hemoglobin and hematocrit may be done as indicated but are not required.
  9. Provide patient info about Paraguard or Mirena and speak with the team nurse to insure that an IUD will be available on the day of insertion.
Insertion timing:

IUD insertion can be done at any time during the menstrual cycle if it is reasonably certain that the patient is not pregnant at the time of insertion. For example, she has not had unprotected sex since her last period and she has a negative urine pregnancy test on the day of insertion. Clinical history is as important as a negative pregnancy test!

Procedure set up:

- Nonsterile tray:
  - K-Y jelly, nonsterile gloves
  - Betadine and large swabs
  - +/-Sterile gloves (should use “no-touch” technique- anything going inside the uterus is sterile)
  - Speculum
  - Tenaculum
  - plastic sound
  - IUD
  - Scissors

Insertion Instructions:

Before the patient arrives, review the insertion procedure carefully. Be sure to practice with the model if you have not performed an insertion recently. Videos and handbooks are available from the manufacturer to assist with insertion techniques.

1. Perform a careful bimanual examination to identify the position of the uterus. An unrecognized retroflexed uterus may increase the possibility of uterine perforation or improper placement of the IUD.
2. Insert a warmed speculum
3. Swab cervix and vagina with antibacterial solution (betadine, or phisohex if shellfish allergy)
4. Use No-Touch Technique throughout the procedure: any instruments, or parts of instruments, that enter the uterus must be sterile
5. A paracervical block may be used if a difficult insertion is anticipated.
6. Grasp the anterior lip of the cervix horizontally (at 12:00) with the tenaculum about 1 centimeter from the os. Close the tenaculum slowly to minimize discomfort. One click should be sufficient.
7. Before sounding the uterus, place tension on the tenaculum (using non-dominant hand) to straighten the axis of the uterus.
8. Gently insert plastic sound until resistance is felt at the fundus. Note the depth in centimeters at the external os. The uterus should sound to 6-9 centimeters for successful IUD use. A shorter length will increase the risk of expulsion and longer depth may reduce effectiveness. If you meet resistance at 4cm, you may be at the internal os of the cervix (remember normal cervical length from OB).

Copper IUD (Paraguard) insertion technique:

1. Prior to inserting the speculum, but no more than 5 minutes before insertion, use sterile gloves to fold the arms down into the inserter. Then insert the solid rod into the insertion tube from the bottom alongside the thread until it touches the bottom of the IUD.
2. After sounding the uterus, hold the sound next to the inserter and move the flange to the sounding depth (from the tip of the IUD to the flange). Also make sure that the arms of the IUD and the long access of the flange lie in the same plane.
3. Again holding traction on the tenaculum, insert the IUD until the resistance is felt at the uterine fundus. At this point, the flange should be at the external os.
4. Stabilize the white solid rod with one hand and withdraw the inserter tube 1/2 inch to release the arms. (you will need to let go of the tenaculum at this step)
5. Gently push the insertion tube up to the fundus to ensure fundal placement of the IUD.
6. Holding the inserter tube stable, remove the white rod.
7. Remove the inserter tube.

**Levonorgstrel/Mirena Insertion Technique:**
1. After sounding the uterus, pick up the inserter and release the threads from the handle.
2. Check that the slider is in the position farthest away from you.
3. Align the arms of the IUD so that they are horizontal using a sterile surface (such as the inside of the package) or sterile gloved fingers.
4. Pull on both threads to draw the IUD into the insertion tube and note that the knobs at the end of the arms now cover the open end.
5. Fix the threads tightly while holding the slider in position.
6. Position the flange to the depth measured by the sound.
7. Again placing tension on the tenaculum, insert the inserter into the cervical canal and advance until the flange is 1½ to 2 centimeters from the external os.
8. Hold the inserter steady and pull back the slider to the mark. This releases the arms of the IUD.
9. Advance the inserter until the flange is at the cervix.
10. Holding the handle steady, pull the slider all the way back to release the threads
11. Withdraw the inserter.

**Post Insertion:**
1. Cut the strings to 2-3 centimeters and note the length of the threads in the patient record.
2. Let the patient touch the cut ends so she knows what she will feel when doing string checks.
3. Schedule a follow-up visit 6-8 weeks after insertion
4. Review signs of infection, expulsion and pregnancy.
5. Review common symptoms:
   - Cramping in the first few weeks can be managed with NSAIDs. If severe cramping occurs or lasts longer than 3 weeks, the patient should be instructed to call.
   - Frequent spotting can be expected in the first 3-6 months. Levonorgstrel IUD users can expect decreased bleeding after 6 months of use.
   - Systemic progesterone side effects are rare.

**Sample Procedure Note: IUD Insertion**
Risks and benefits of the procedure were explained to the patient, including infection, perforation and failure. All questions were answered. Procedure consent was signed by the patient. She is currently using condoms consistently and had a negative urine pregnancy test on the day of insertion. LMP was 3 weeks ago. Cervical cultures were negative for GC and Chlamydia two months ago and the patient has had no new sexual partners. Bimanual exam showed a small anteverted uterus. **Uterus was sounded to 8 centimeters.** Para Guard IUD (Lot #     ) was inserted in the usual fashion without difficulty. The strings were cut to 2.5 centimeters. The patient was advised to follow up in 6-8 weeks and signs of infection, expulsion, and pregnancy were reviewed. The patient tolerated the procedure well.

**Troubleshooting:**
- Problems with insertion
  - The IUD falls on the floor or is otherwise contaminated.
    - The manufacturer will replace contaminated IUDs. Notify your team nurse to call for replacement (you don’t need to turn in the device itself)
  - The uterus sounds to less than 6 centimeters.
    - Remove the speculum and reassess the position of the uterus. Is it retroflexed or very anteverted so that the fundus is not being reached? If the true sounding depth is less than 6 centimeters, the patient is not a candidate for the IUD. If you are unable to pass the sound
beyond the internal os (~4cm), a dilator may be needed (find an experienced preceptor to assist you). If this is not available, patient can reschedule and premedicate with misoprostol which softens the cervix (400mcg per vagina 2 hours prior to insertion). You must be certain that the patient is not pregnant prior to giving misoprostol.

- **Excessive bleeding**
  Patients that have excessive bleeding with the copper IUD can use NSAIDS. Other causes of bleeding should be considered, and persistent abnormal bleeding requires clinical evaluation. Endometrial biopsy may be performed with the IUD in place.

- **Pain and cramping**
  NSAIDS may be used to manage cramping and pain. Pain that develops after insertion may reflect threatened expulsion, dislodgement, infection or a complicated pregnancy.

- **Expulsion**
  Symptoms of expulsion include absence or lengthening of the IUD string, cramping or pain, unusual vaginal discharge, post coital bleeding or dispareunia, or presence of the IUD at the cervical os or in the vagina. If a woman is not pregnant, another IUD can be inserted immediately. The manufacturers will often replace an IUD that is expelled in the first several months so notify your team nurse if this occurs.

- **Perforation**
  Rare event, usually occurs at the time of insertion (although it may not become apparent until later). Copper IUDs found to be outside the endometrial cavity should be removed by laparoscopy because of the risk of inducing adhesion formation. Levorgstrel IUDs do not induce such adhesions, and there is no medical indication for removal if the patient is asymptomatic.

- **Missing strings**
  Differential diagnosis includes perforation, expulsion, migration of the IUD towards the fundus, pregnancy, and strings in the endocervical canal. If the patient is not pregnant, the endocervical canal can be gently explored with a cotton swab or cytobrush to locate the strings. If this is not successful, ultrasound should be obtained to assess the location of the IUD.

- **Pregnancy**
  If a pregnancy occurs with an IUD in place, confirm that the pregnancy is in the uterus rather than ectopic. Remove the IUD promptly in the earliest stages of pregnancy to reduce the risk of spontaneous miscarriage and preterm delivery.

- **Pelvic Inflammatory disease**
  PID in the presence of an IUD should be treated according to published recommendations, including broad spectrum antibiotics and partner treatment. There is no evidence to support the practice of IUD removal during treatment of PID.

*Summarized from Contraceptive Technology IUD Chapter, Mirena and Paraguard manufacturers’ information*