C5.5 - COPPER T380-A INTRAUTERINE DEVICE (IUD)

Policy

The Copper T-380A Intrauterine Device (ParaGard®) is a small T-shaped device made of polyethylene with added barium sulfate for x-ray visibility. The T-shaped device has fine copper wire wound around the vertical stem. The horizontal arms of the T have a sleeve of copper around them. The bottom of the T has a white knotted loop of polyethylene string. Clients should be given information about the risks of insertion as part of the informed consent process. Clients should be adequately counseled about the bleeding and cramping expectations after placement of a copper IUD, which often increases menstrual bleeding and cramping by about 30%.

Procedure

Mode of Action

It is not known exactly how the Copper IUD works, however it is thought that the main mechanism of action is the prevention of fertilization through a cytotoxic inflammation that is spermicidal. Copper IUD is also thought to work via the following mechanisms:

- Local foreign body inflammatory response causing lysis of the blastocyst and/or prevention of implantation, although evidence suggests that fertilization occurs in less than 1% of cycles.
- Copper interferes with estrogen uptake and its intracellular effects on the endometrium.
- Copper concentration in cervical mucous is high. The copper inhibits sperm motility and is spermicidal.

Effectiveness

Theoretical and actual effectiveness is 99.0-99.4%.

Contraindications

Absolute Contraindications

Unacceptable Health Risk (method should not be used):

- Known or suspected pregnancy.
- Acute, active pelvic infections/STI, including immediate postpartum uterine infection.
- Gestational trophoblastic disease with persistently elevated beta HCG Levels or malignant disease with evidence or suspicion of intrauterine disease, uterine abnormalities (a distorted uterine cavity such as bicornuate uterus or fibroid distorting the cavity).
- Cervical cancer, awaiting treatment.
- Endometrial cancer.
- Severe dysmenorrhea (if has not tolerated the Copper IUD previously).
- Immediately post-septic abortion.
- Pelvic tuberculosis.
- Unexplained vaginal bleeding.
- Current pregnancy (unless being used as EC) or inability to rule out pregnancy.

Strong Relative Contraindications

Theoretical or proven risks usually outweigh the advantages:

- Complicated solid organ transplantation.

Other Considerations

The advantages of using the IUD generally outweigh the theoretical or proven risk.
Refer to the Appendix for the CDC Medical Eligibility Criteria Summary Chart

Advantages

- No action is required for contraception
- The Copper IUD should not be noticeable during intercourse.
- It is always there when needed.
- It contains no hormones.
- Its duration of action is 10-12 years.
- Users should continue to have a regular menstrual cycle.

Disadvantages

- Must be changed periodically as indicated by manufacturer (10 years).
- May make menses heavier and more painful.
- May be expelled without the client's knowledge.
- Does not protect against STIs.

Side Effects

- Increased dysmenorrhea.
- Heavier menstrual flow.
- Mid-cycle bleeding (may be a symptom of infection).
- Spotting (not unusual in the first 3 months).

Warning Signs

- A late or missed period and/or feelings of pregnancy.
- Abdominal pain, pelvic pain or pain with intercourse (suggests perforation or infection).
- Fever/Chills (suggests infection).
- Foul vaginal discharge (suggests infection).
- Missing or change in length of IUD strings (suggests expulsion or displacement).
- Severe or prolonged vaginal bleeding (suggests dislocation or perforation).

Potential Complications Associated with Paragard®

- Uterine perforation, although this is rare. Difficulty removing the Copper IUD.
- Infection secondary to placement (this risk only is present for the first 21 days after placement).
- Expulsion of device (rate of expulsion may be increased with nulliparous women).
- Intra-uterine infection risk is increased in the first 3 weeks after IUD placement, but then returns to baseline.

Risk of STI's is not increased with IUD placement and STI can be treated with IUD in place.

- If a pregnancy occurs, there is a substantial risk of possible spontaneous abortion if intra-uterine conception occurs (chances are 25% risk if IUD removed, and 50% if IUD left in place).
- The FDA approved lifespan for each IUD is variable. The Copper T380-A is FDA approved for 10 years, but is efficacious for up to 12 years. Clinical providers should discuss the difference between FDA approved duration of action and evidence-based duration of action.
- IUD are very effective at preventing pregnancy, so there is an overall significant decreased risk of pregnancy. However, if a conception occurs, and in the unlikely event the fertilized egg implants and a pregnancy begins, it is more likely that the pregnancy is ectopic. Patients with an IUD and known or suspected pregnancy, should be encouraged to immediately seek care.

STI Testing

If a client has not been screened for STIs according to STI screening guidelines, screening must be performed at the time of insertion. STI can be treated after insertion, with the Copper IUD remaining in place.

Instructions to the Client

The only maintenance of the Copper IUD involves:

- Client checking IUD strings at end of each menses (if this is reassuring to the client, if not, it is not necessary).
- Client aware of danger signs.
    - i) A late or missed period. Periods should continue to be monthly/regular with a Copper IUD. Periods often are heavier and crampier with Copper IUD. If you miss a period, do a pregnancy test right away.
    - ii) Abdominal pain or pelvic pain or pain with intercourse (may suggest infection or abnormal location of the IUD). You see your IUD, because it has fallen out (expulsion)
    - iii) Fever/Chills (suggesting infection) accompanied by pelvic pain—especially if in the first month after insertion.
    - iv) Foul vaginal discharge (suggests infection) or new exposure to any sexually transmitted infection
    - v) Missing or change in length of strings
    - vi) Severe or prolonged vaginal bleeding
- Annual exam for preventative care, also able to assess problems and check position of the IUD.
- Client should be aware of type of IUD to insure timely replacement.
- Client should be aware of how to access removal services.
- Call the clinic with any problems related to method.

Fertility Return

Return to fertility after removal is typically rapid/immediate. Immediate use of an alternative contraceptive is recommended after removal if the client is not seeking pregnancy. Encourage prenatal vitamin initiation at time of removal if not switching to a different highly or moderately effective contraceptive method.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of

	Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)