### INTRAUTERINE DEVICE (IUD): IDENTIFICATION OF CANDIDATE

#### DEFINITION
The U.S. Medical Eligibility Criteria (US MEC), are used as a basis for recommendations for this protocol, not the product labeling. There are three types of intrauterine contraceptive devices available in the US. The Copper T380A IUD (ParaGard®) is effective for at least 10 years.* In typical use, the copper IUD has a first year failure rate of 0.8%; its 10 year cumulative failure rate is 2.7%. The levonorgestrel-releasing IUS-20 mcg/24 hr (Mirena®) is effective for 5 years and has a first year and 5 year failure rate in typical use of less than 1%. Mirena offers many noncontraceptive health benefits related to menstrual suppression. The LNG IUS-13.5 mg (Skyla®) is approved for up to 3 years of use. First year failure rate is 0.41%. IUDs may be used by nulliparous women and may be placed immediately following delivery or following pregnancy loss at any gestational age.  

* Literature supports 12 to 20 years of use.

#### SUBJECTIVE
Must include:
1. LNMP and PMP.
2. Document any unprotected coitus in last 5 days.

Must exclude:
1. Any US MEC Category 4 condition for her desired IUD.
2. Any US MEC Category 3 condition for her desired IUD, until MD approves use.

#### OBJECTIVE
Must include:
1. Normal pelvic exam (bimanual and speculum exams).
2. Complete uterine involution is needed following pregnancy, unless placing immediately following pregnancy loss or placing immediately post-partum.
   a. If placing IUD immediately following pregnancy loss, must have uterus evacuated of all products of conception, no signs of infection and no excessive, ongoing bleeding.
3. If placing routinely, must have uterine size on bimanual exam consistent with uterine depth of:
   b. Mirena: 6.0-10 cm.
   c. Skyla®: large enough to accommodate IUD.

Must exclude:
1. Any US MEC Category 4 conditions for her desired IUD.
2. Any US MEC Category 3 conditions for her desired IUD, until MD approves use.

#### LABORATORY
Must include:
1. Hgb/Hct if recent history of excessive menstrual blood loss or anemia.
2. Patient does not need any testing done to qualify for IUD if she has no signs or symptoms of infection. If indicated by age, screening guidelines, sexual history or symptoms, perform needed tests to rule out GC or chlamydial cervicitis or trichomonias vaginitis. It is not necessary to delay IUD placement until results are available. Prompt (within 7 days) treatment will prevent PID if the woman does have a cervical infection at the time of IUD placement.
3. Negative urine pregnancy test if patient has had any unprotected intercourse at any time in her cycle that could result in pregnancy, or if she has had any irregular menses recently or any symptoms of pregnancy.

Must exclude:
1. Any US MEC Category 4 condition for her desired IUD.
2. Any US MEC Category 3 conditions for her desired IUD, until MD approves IUD use.

#### ASSESSMENT
Candidate for IUD/IUS use.
### PLAN
1. Select IUD. If patient has copper allergy, Wilson’s disease, anemia (Hgb less than 10 g/dL), excessive menstrual bleeding or severe dysmenorrhea, she is a better candidate for a LNG-IUS rather than for the copper IUD. If she prefers monthly bleeding or does not want to use hormones, ParaGard® or perhaps Skyla® would be a better choice.
2. Instruct patient to read and answer all questions on patient product information brochure. Answer all of patient’s questions. Have her sign the manufacturer’s consent form and any clinic consent form required. See manufacturer’s website to get additional copies of the patient brochure and the consent forms in her language. Tell the woman who wants to use one of the LNG-IUSs that she will have to sign another copy of the consent form for her particular IUS after the procedure is done.
3. Consider advising patient to take a nonsteroidal anti-inflammatory agent 1 to 4 hours prior to IUD/IUS placement if not medically contraindicated. It will not reduce pain during IUD placement, but may reduce cramping and pain afterwards.
4. If possible, place the IUD at this visit (See IUD Placement protocol). If IUD not placed during this visit, insure she has an interim birth control method and tell patient when to return for placement according to the type of IUD she desires.
5. Schedule Copper IUD (ParaGard®) placement any time in the cycle when the woman is not pregnant.
   a. Placement after completion of menses may reduce early expulsion risk. If possible, avoid placing IUD during heavy menstrual flow days.
   b. Copper IUD is effective as post-coital emergency contraceptive for up to 7 days after exposure.
   c. May place a new IUD (copper or hormonal one) immediately after removing an existing IUD, if she is a candidate for her desired new IUD.
   d. Placement immediately following uncomplicated first trimester pregnancy loss is an option. Postpartum women and women who experience pregnancy loss in second or third trimester may be candidates for immediate placement, but such IUD placement requires different training, (See IUD Placement protocol). Most women will probably wait until uterine involution is complete (usually 6-8 weeks).
6. Schedule a levonorgestrel IUS (Mirena or Skyla®) placement according to the following instructions for on-label placement:
   a. Within first 7 days of cycle. To reduce early expulsion rates, try to avoid placement on heavy flow days.
   b. Women who are not cycling (e.g. due to breast-feeding or DMPA-induced amenorrhea) may have placement at any time they are not pregnant and have not had recent unprotected intercourse. Advise 7 days use of abstinence or back-up method after IUS placement.
   c. Women switching from OCs, advise completion of pill pack, especially if IUS placed during the last week of active pills.
   d. May place new IUS immediately after removal of existing IUS if she is still candidate. Removal is recommended on menses but if removed at other time in cycle, advise 7 days use of abstinence or use of a backup method following replacement. Consider EC if she has had recent intercourse. Neither LNG-IUS is a post coital contraceptive.
   e. Placement immediately following uncomplicated first trimester pregnancy loss is an option. Postpartum women and women who experience pregnancy loss in second or third trimester may be candidates for immediate IUS placement, but special training is needed for placement under these conditions, (See protocol IUD Placement). Most women will probably wait until uterine involution is complete (usually 6-8 weeks).
   f. If placement is desired at any other time in cycle or under different conditions, make sure the patient is not pregnant and have her use abstinence or a back-up method for 7 days following IUS placement.

### PATIENT EDUCATION
1. Reinforce IUD education as described in manufacturer’s brochure. Provide information about mechanisms of IUD/IUS action, stress the importance of safer sex practices, describe possible placement complications, and follow-up needed if problems arise after placement. Reassure patient that as an ongoing method, all IUDs work as contraceptives, by preventing fertilization.
2. Discuss risks of IUD/IUS if pregnancy occurs: ectopic pregnancy; preterm labor; need for IUD

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### PATIENT EDUCATION (Continued)

3. Inform patient that Mirena is the most effective medical treatment for heavy menstrual bleeding and can reduce symptoms of endometriosis and problems with anemia. By providing progestin, Mirena also helps reduce the risk of endometrial cancer and precancer, especially in women with anovulatory cycles.

4. Discuss the expected short term side effects following placement, including unscheduled bleeding and cramping. Advise that many of these symptoms may subside over time.

5. Discuss the intermediate and longer term effects of each IUD.
   a. ParaGard®: Monthly bleeding will increase by an average of 30-50%, but that increase can usually be reversed by the use of NSAIDs during menses. (See IUD Complications: Amenorrhea and Abnormal Bleeding protocol).
   b. Mirena:
      1) Unscheduled bleeding and spotting may be frequent in the first 4 months of use, but will diminish over time.
      2) Total blood loss will be significantly reduced with longer use of Mirena.
      3) 20% of women will have no spotting or bleeding at all by 12 months of use. By that time, most other women will have only 1-3 days of spotting a month.
      4) Some women experience headaches or breast tenderness, especially with early use, but usually the symptoms are only temporary or are due to other causes.
      5) Mirena is the most effective medical therapy for heavy or prolonged menstrual bleeding. It may also help reduce dysmenorrhea.
   c. Skyla®:
      1) Unscheduled bleeding and spotting may be frequent in the first 4 months of use, but will diminish over time.
      2) Total blood loss will be significantly reduced with longer use.
      3) 12% of women will have no spotting or bleeding at all by 3 years of use.
      4) Some women experience headaches or breast tenderness, especially with early use, but usually the symptoms are only temporary or are due to other causes.

6. Remind women that the pregnancy protection, non-contraceptive benefits and the side effects disappear almost immediately following IUD removal.

### REFERENCES


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