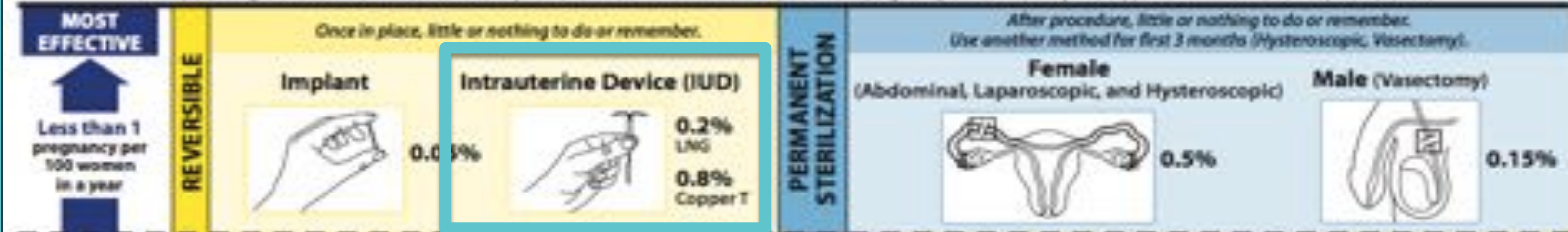
BURNS 3.4.15

Learning Objectives

- Describe the mechanism and effectiveness of contraceptive procedures
- Counsel patients about the benefits, risks and use for each contraceptive method
- Describe barriers to effective contraceptive use and to the reduction of unintended pregnancy
- Describe common outpatient and inpatient gynecologic procedures with their indications and possible complications: contraceptive implants
- Prerequisites:
  - NONE
- See also – for closely related topics
  - FLAME LECTURES 149A-C – Combined Hormonal Contraceptives
  - FLAME LECTURE 150 – Barrier contraceptive methods
  - FLAME LECTURE 152 – Nexplanon
  - FLAME LECTURE 153 – Mirena IUD for contraception
  - FLAME LECTURE 154 – Paragard for contraception
  - FLAME LECTURE 149A2 – The Contraceptive Counseling Visit

Mirena: General Info

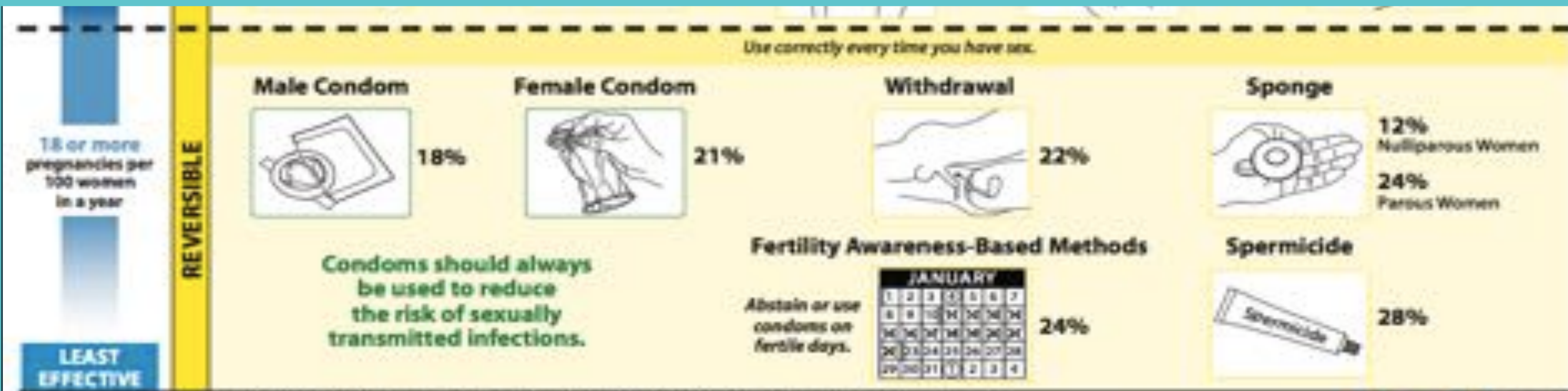
- Known as one of the four types of long-acting reversible contraceptives (LARCs)
- T-shaped intrauterine device (IUD) that is progestin-only
  - Releases 20 mcg/day levonorgestrel (falls to 14mcg/day after 5 years)
  - Hormone locally absorbed in uterine cavity; however small amount enters blood
- Mechanism(s) of action:
  - Thickens cervical mucous, blocking sperm entry
  - Slows tubal motility, blocking sperm migration
  - Alters endometrium to be unfavorable for implantation
  - Has minor anovulatory effects
  - Is a smooth-muscle relaxant in that it inhibits formation of cellular gap junctions leading to less uterine contractility (aka. decreased cramping)

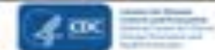


MIRENA IUD

Perfect use: 0.1- 0.2% failure in 1st year

Typical use: 0.1% failure in 1st year, 0.7% in 5 yrs, 1.1% in 7 yrs





ADVANTAGES

- Has very high efficacy
- Menses generally get lighter and lighter → amenorrhea in majority of women; thus can also treat abnormally heavy menses (menorrhagia)
- Convenient
- High continuation rate in clinical trials
- Helps prevent endometrial hyperplasia/cancer
- Reduces symptoms of endometriosis and bleeding 2/2 fibroids
- Safe contraceptive for women at increased risk for DVT or PE

DISADVANTAGES

- Spotting/bleeding may increase initially but decreases after first few months
- May cause cramping following initial insertion, especially in nulliparous patients
- Does not protect against STI's
- Side effects: Headache, weight gain, acne, breast tenderness, emotional lability (much less than other methods given low-dose, local absorption)
- Associated with slight increase ovarian cysts though these resolve without treatment
- Limitations in access:
  - Expensive (financial assistance is available if uninsured or whose insurance doesn't cover Mirena)
  - Requires access to physician properly trained in insertion & removal

Complications:

- Risk of PID briefly increased after insertion for first few weeks
- Potential for perforation of uterus at time of insertion (risk is < 1/1000)
- Can fall out without patient knowing, and then she is not protected

Mirena/Skyla vs. Paragard

Mirena (Hormonal IUD)	Paragard (Copper IUD)
Effective for at least 5 yrs	Effective for at least 12 yrs
Lighter to no periods	Heavier periods and/or more cramping
Irregular bleeding common in first few months; hormonal side effects	No intermenstrual spotting; no hormones/ hormonal side effects
Treats menorrhagia / dysmennorhea	Can be used as emergency contraceptive

*What about **Skyla**?*

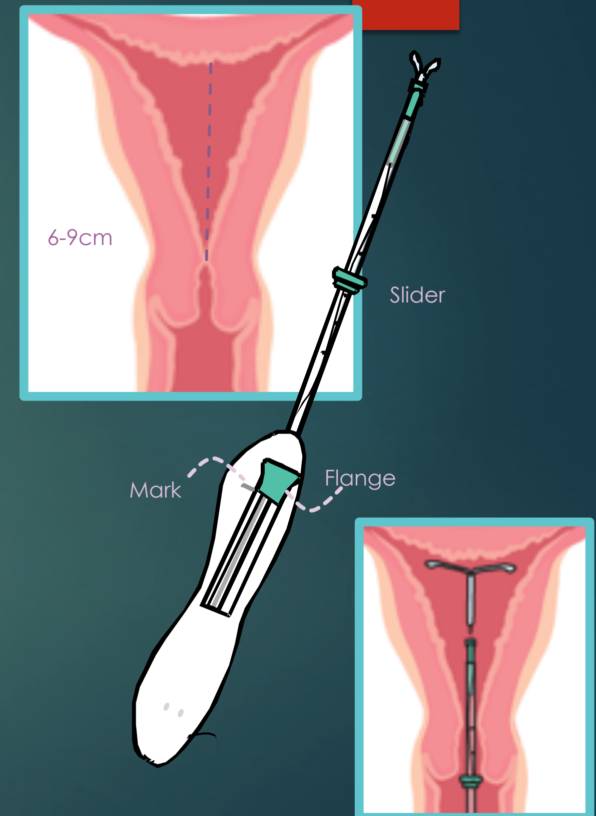
- Skyla is a hormonal IUD that releases levonorgestrel, just like the Mirena
- However, the dose is lower (13.5 mcg/day vs. 20 mcg/day) which may to less hormonal side effects (but also last a shorter amount of time; only 3 years)
- Lower rates of amenorrhea (one in 8 at one year, vs. one in three for Mirena)
- Skyla frame and inserter are smaller, easier and more comfortable to insert
- FDA-approved for use in nulliparous women (vs. considered safe but off-label for Mirena)

TIMING OF INSERTION

- QUICK START METHOD ("LMP" = FIRST day of bleeding):
  - If LMP < 5 days ago → PLACE IT
  - If LMP 5-8 days ago → Upreg neg → Plan B + PLACE IT (Plan B works for up to 3 days)
  - If LMP 5-10 days ago → Upreg neg → Ella + PLACE IT (Ella works for 5 days, but more costly than Plan B)
  - If LMP was > 10 days ago → Upreg neg → if abstinence OR perfect contraceptive use → PLACE IT + Back method x 1 week
  - If LMP was > 10 days ago → Upreg neg → if imperfect contraceptive use → DO NOT PLACE → Give alt form + Upreg in 3 weeks
- Post-delivery/Post-abortion: May be inserted immediately following delivery/abortion, or 4-8 weeks following

INSERTION[3]

1. Most women don't need anesthetic, but a NSAIDs or a paracervical block can be performed, especially in nulliparous women
2. Check position, size, and mobility of uterus with bimanual exam
3. Insert speculum and place tenaculum to stabilize cervix
4. Assess (sound) intrauterine length by gently placing a sound or the device itself up to the fundus to ensure uterus is between 6-9 cm
5. Arrange to slider to the distance sounded (see image on right), and push flange up to load IUD into the tube thus tucking the arms
6. Gently insert tube into cervical canal, holding the flange with thumb to prevent prematurely releasing the IUD. Stop when reaching the fundus or when the slider reaches the cervical os
7. Pull entire device back 2-3 cm
8. While holding inserter steady, pull flange back to first click to release arms. Wait 10 secs, then gently push inserter back to the fundus
9. Once in fundus, then pull flange all the way down to fully release Mirena
10. Gently withdraw inserter completely out, and cut the threads 2-3 cm long outside cervix



FOLLOW-UP & PROBLEM MANAGEMENT[1,3]

- Patient should return 4-6 weeks after insertion to verify IUD is still in place and that no problems have occurred
- Patient should also be instructed on how to check for strings so they can self-check monthly (usually after every period if not experiencing amenorrhea)
- Expulsion/Partial Expulsion:
  - Rates: 3-5% following routine placement, 5-8% immediate post-abortion, 25% immediate post-delivery
  - May present with bleeding or pain but can often be expelled without patient noticing
  - If expulsion suspected: Confirm expulsion using pelvic ultrasound
  - If expulsion confirmed: Rule out pregnancy, then can replace with new IUD
- Missing strings
  - It is not a problem to have missing strings, unless the IUD needs to come out
  - If missing, use U/S or AXR to check for extra-uterine IUD and test for pregnancy. If both negative, then can reinsert new IUD
  - If IUD needs to be removed, you can use a cytobrush or special graspers to remove under U/S guidance

FOLLOW-UP & PROBLEM MANAGEMENT[1,3]

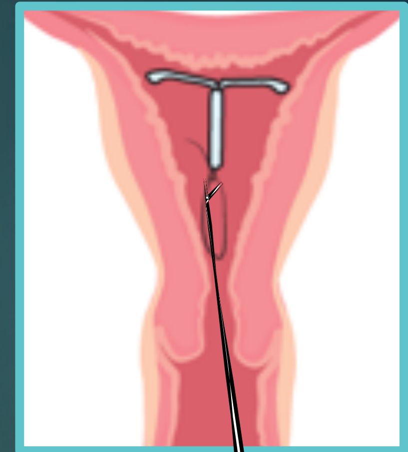
- Embedment: IUD embedded in myometrium, reducing effectiveness and causing discomfort; occurs very rarely
  - If diagnosed on U/S, can remove IUD and replace with new one
- Uterine perforation:
  - Signs: pain, loss of resistance to advancing instrument
  - Perforation during uterine sounding: remove sound, give antibiotics and observe
    - Patient stable: send home with alternate contraception
    - If pain persists or vital signs change, needs immediate laparoscopic evaluation
  - Perforation during IUD placement: remove IUD if possible, if not then do ultrasound and send for immediate laparoscopic evaluation
  - Asymptomatic perforation found later: arrange for elective laparoscopic removal
  - Not a contraindication for future IUD use

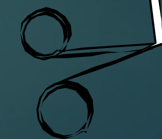
FOLLOW-UP & PROBLEM MANAGEMENT[1,3]

- Cramping and/or pain:
  - Cramping after insertion lasts up to 2 weeks
  - If cramping persists, rule out pregnancy, infection, and expulsion and consider alternative contraceptive
- Infection
  - *BV / Candidiasis*: treat routinely
  - *Trichomoniasis*: treat routinely and discuss condom use/STI protection
  - *Cervicitis / PID*: Give first dose of antibiotics before consider removing IUD. If patient shows improvement after first dose, may not need IUD removal. If patient does not improve, remove IUD. Either way continue standard treatment.
  - *Actinomycosis*: ~7% of IUD users are colonizers of Actinomyces (often noted on pap)
    - If no signs of infection, continue to observe with annual pap smears
    - If sign of PID, treat with penicillin G (2 wks), doxycycline (2 wks), or tetracycline (1 month) AND remove IUD because the bacteria bind to this foreign body, repeat Pap smear, and reinsert a new IUD once infection is cleared

DISCONTINUATION[2]

- ***Fertility returns immediately after discontinuation***
- Mirena IUDs should be replaced after 5 years (though failure rate is still 1.1% at 7 years overall)
- Remove by gently pulling on strings with forceps
  - If no strings are visible, can remove using alligator forceps
- Removal may some cause pain and/or bleeding
- Examine removed Mirena to ensure it is intact





CDC Guideline - Mirena

1 = No restriction for the use of the contraceptive method.
2 = Advantages of using the method generally outweigh the theoretical or proven risks.
3 = Theoretical or proven risks usually outweigh the advantages of using the method.
4 = Unacceptable health risk if the contraceptive method is used.

Condition			Initiation | Continuation
Age			Menarche to <20 years =2
			≥20 years =1
Parity			
Nulliparous			2
Parous			1
Postpartum (breastfeeding or nonbreastfeeding)			
<10 min after delivery of placenta			2
10 min after delivery of placenta to <4weeks			2
≥4 weeks			1
Peurperal sepsis (endometritis)			4
Postabortion			
First trimester			1
Second trimester			2
Immediate post-septic abortion			4
Past ectopic pregnancy			1
Smoking			
Age <35 years			1
Age >35 years	<15 Cig/day		1
	≥15 Cig/day		1
Obesity			
BMI >30			1
Menarche to <18 years + BMI≥30			1
History of Bariatric surgery that limits absorption of nutrients			1
Cardiovascular disease			
Multiple risk factors for arterial CV disease			2
Hypertension	Adequately controlled		1
	Systolic 140-159 or Diastolic 90-99		1
	Systolic ≥ 160 or Diastolic ≥ 100		2
Vascular disease			2
History of high blood pressure during pregnancy			1
DVT / Pulmonary Embolism	History of DVT/PE, not on anticoagulant therapy		2
	Acute DVT/PE		2
	Established DVT/PE, on anticoagulant therapy for at least 3 mo		2
	Family history		1

Condition		Initiation | Continuation
Major surgery	With prolonged immobilization	2
	Without prolonged immobilization	1
Known thrombogenic mutations		2
Superficial venous thrombosis	a. Varicose veins	1
	b. Superficial thrombophlebitis	1
Current and history of ischemic heart disease		2 | 3
Stroke (history of cerebrovascular accident)		2
Known hyperlipidemias		2
Valvular heart disease	a. Uncomplicated	1
	b. Complicated§ (pulmonary hypertension, risk for atrial fibrillation, history of subacute bacterial endocarditis)	1
Peripartum Cardio-Myopathy	a. Normal or mildly impaired cardiac function (Patients with no limitation or slight/mild limitaiton of activities)	2
	b. Moderately or severely impaired cardiac function (Patients with marked limitation of activity or patients who should be at complete rest)	2
Rheumatic Diseases		
SLE	a. Positive (or unknown) antiphospholipid antibodies	3
	b. Severe thrombocytopenia	2
	c. Immunosuppressive treatment	2
	d. None of the above	2
Rheumatoid arthritis	a. On immunosuppressive therapy	2 | 1
	b. Not on immunosuppressive therapy	1
Neurologic conditions		
Headaches		
a. Non-migrainous (mild or severe)		1 | 1
b. Migraine	i. Without aura / <35 years	2 | 2
	Without aura / ≥35 years	2 | 2
	With aura	2 | 3
Epilepsy		1
Depressive disorders		
Depressive disorders		1
Reproductive tract infections and disorders		
Vaginal bleeding patterns	a. Irregular pattern without heavy bleeding	1 | 1
	b. Heavy or prolonged bleeding (includes regular and irregular patterns)	1 | 2
Unexplained vaginal bleeding (before evaluation)		4 | 2
Endometriosis		1
Benign ovarian tumors (including cysts)		1
Severe dysmenorrhea		1
Gestational trophoblastic disease	a. Decreasing or undetectable beta-hCG levels	3
	b. Persistently elevated beta-hCG levels or malignant disease	4
Cervical ectropion		1
Cervical intraepithelial neoplasia		2
Cervical cancer (awaiting treatment)		4 | 2
Breast disease	a. Undiagnosed mass	2
	b. Benign breast disease	1
	c. Family history of cancer	1
	d. Breast cancer (current)	4
	e. Breast cancer (past)	3

Condition		Initiation | Continuation
Endometrial hyperplasia		1
Endometrial cancer		4 | 2
Ovarian cancer		1
Uterine fibroids		1
Anatomical abnormalities	Distorted uterine cavity	4
	Other abnormalities not distorting uterine cavity	2
Pelvic inflammatory disease (PID)	a. Past PID without subsequent pregnancy	1 | 1
	b. Past PID with subsequent pregnancy	2 | 2
	b. Current PID	4 | 2
STIs	Current purulent cervicitis or chlamydia, or gonorrhea	4 | 2
	Other STI's or Vaginitis	2 | 2
HIV/AIDS	High risk for HIV	2 | 2
	HIV infection	2 | 2
	AIDS	3 | 2
Other infections	Schistosomiasis	1
	Tuberculosis (pelvic)	4 | 3
	Malaria	1
Endocrine Conditions		
Diabetes	a. History of gestational disease	1
	b. Nonvascular disease (Type I or Type II)	2
	c. Nephropathy/retinopathy/ neuropathy	2
	d. Other vascular disease or diabetes of >20 years' duration	2
Thyroid disorders	a. Simple goiter	1
	b. Hyperthyroid	1
	c. Hypothyroid	1
Gastrointestinal conditions		
Inflammatory bowel disease (IBD)		1
Gallbladder disease	a. Symptomatic	2
	b. Asymptomatic	2
History of cholestasis	a. Pregnancy-related	1
	b. Past COC-related	2
Viral hepatitis	a. Acute or flare	1
	b. Carrier	1
	c. Chronic	1
Cirrhosis	a. Mild (compensated)	1
	b. Severe (decompensated)	3
Liver tumors		
a. Benign	i. Focal nodular hyperplasia	2
	ii. Hepatocellular adenoma	3
b. Malignant (hepatoma)		3
Anemias		1
Solid organ transplantation	Complicated	3 | 2
	Uncomplicated	2
Drug Interactions		
Antiretroviral Therapy	NRTI's	2/3 | 2
	nNRTI's	2/3 | 2
	Ritonavir-boosted protease inhibitors	2/3 | 2
Anticonvulsant Therapy	Certain anticonvulsants	1
	Lamotrigine	1
Antimicrobial Therapy	Broadspectrum Antibiotics, Antifungals, Antiparasitics	1
	Rifampicin therapy	1

IMPORTANT LINKS / REFERENCES

- [CDC US Medical Eligibility Criteria for Contraceptive Use Chart]

1. Managing Contraception *2012-2014*
2. UpToDate "Insertion and removal of an intrauterine contraceptive device" February, 2015
3. UpToDate "Intrauterine contraception (IUD): Overview" February, 2015
4. UpToDate "Management of problems related to intrauterine contraception" February, 2015
5. Mirena "Education for Clinician" *2013* Bayer HealthCare