PARAGARD IUD

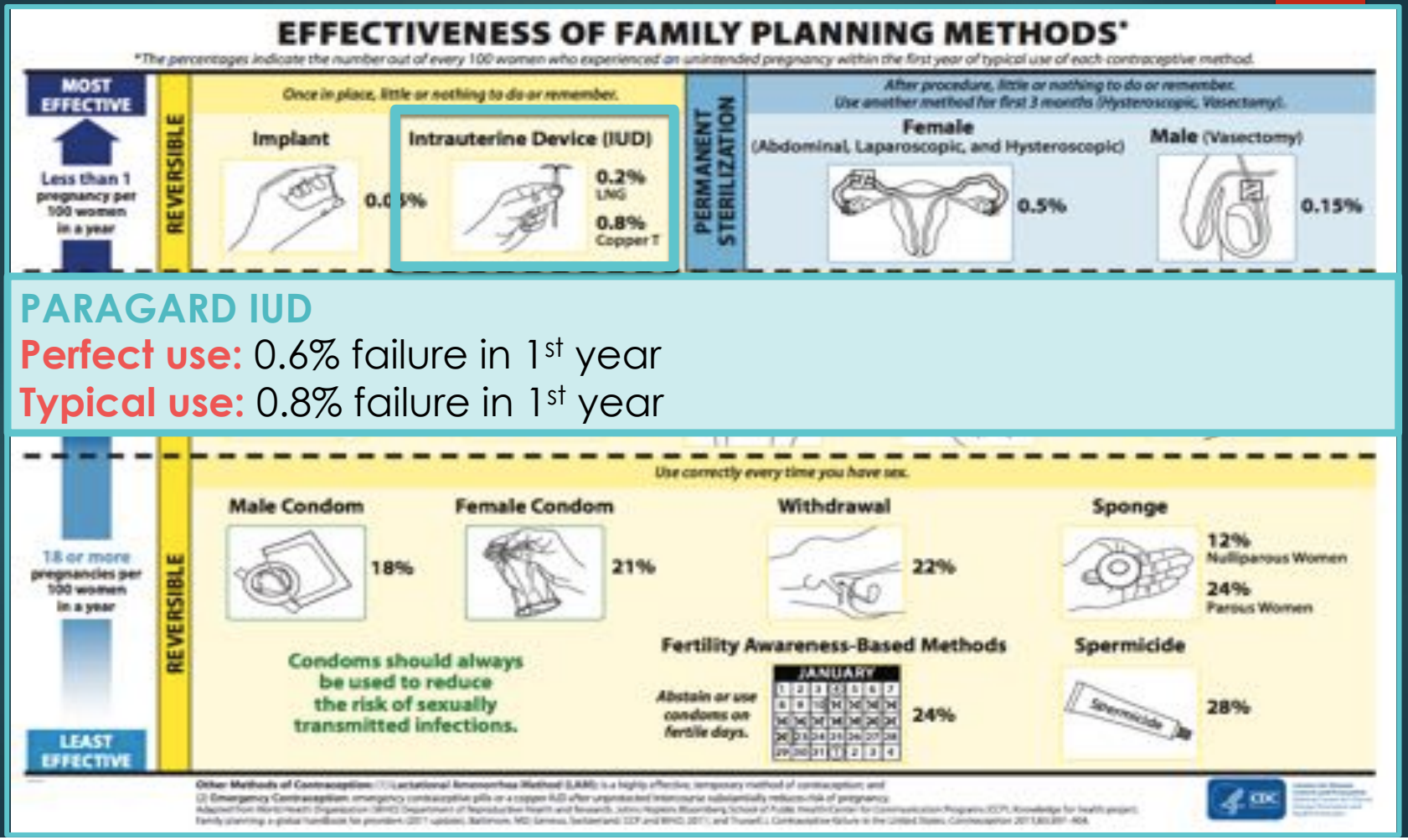
BURNS 3.24.15

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
  - FLAME LECTURE 154B – Emergency Contraception

Paragard

- Known as one of the four types of long-acting reversible contraceptives (LARCs)
- T-shaped intrauterine device (IUD) that is hormone-free because it is made a plastic T surrounded by a copper coil
- Mechanism(s) of action:
  - Copper is spermicidal, inhibits sperm motility, inhibits acrosomal enzymes so sperm can't fertilize egg, and facilitates endometrial phagocytosis of sperm
  - The Paragard does not interfere with fertilized egg, thus not an abortificant
- Approved for 10 years, but effective up to 12 years


EFFECTIVENESS OF FAMILY PLANNING METHODS*
*The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.
MOST EFFECTIVE
Less than 1 pregnancy per 100 women in a year
REVERSIBLE
Once in place, little or nothing to do or remember.
Implant
Intrauterine Device (IUD)
0.2% LNG
0.8% Copper T
PERMANENT STERILIZATION
After procedure, little or nothing to do or remember.
Use another method for first 3 months (Hysteroscopic, Vasectomy).
Female (Abdominal, Laparoscopic, and Hysteroscopic)
0.5%
Male (Vasectomy)
0.15%
PARAGARD IUD
Perfect use: 0.6% failure in 1st year
Typical use: 0.8% failure in 1st year
18 or more pregnancies per 100 women in a year
LEAST EFFECTIVE
REVERSIBLE
Use correctly every time you have sex.
Male Condom
18%
Female Condom
21%
Withdrawal
22%
Sponge
12% Nulliparous Women
24% Parous Women
Condoms should always be used to reduce the risk of sexually transmitted infections.
Fertility Awareness-Based Methods
Abstain or use condoms on fertile days.
JANUARY
24%
Spermicide
28%

ADVANTAGES

- Very high efficacy
- Convenient, requires no action at time of intercourse
- High continuation rate in clinical trials
- Effective option for women who don't want/cannot use hormonal methods
- Fewer prescribing precautions than Mirena IUD & other hormonal options
- Possible protection against endometrial cancer and cervical cancer
- Rapid return to fertility when desired
- Cost effective – without any assistance ~ $475 over 10-12 years (=$40-47/year)
- Safe contraceptive for women at increased risk for DVT or PE or with thrombogenic mutations
- Can be used as emergency contraceptive

DISADVANTAGES

- Increased menstrual bleeding (up to 50% increase)
- May cause cramping following insertion, , especially in nulliparous patients
- No protection against STI's
- Some women can experience spontaneous expulsion (likelihood decreases over time)
- If strings too short or cut improperly can cause partner discomfort during sex
- Limitations in access:
  - Requires access to physician properly trained in insertion & removal
- Prescribing precautions
  - Pregnancy
  - Uterus < 6cm or > 9cm
  - Severe anemia
  - Active STI or PID
  - Wilson's disease / Copper allergy
  - Uterine anatomical abnormality
  - Known/suspected uterine / cervical CA

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**?*

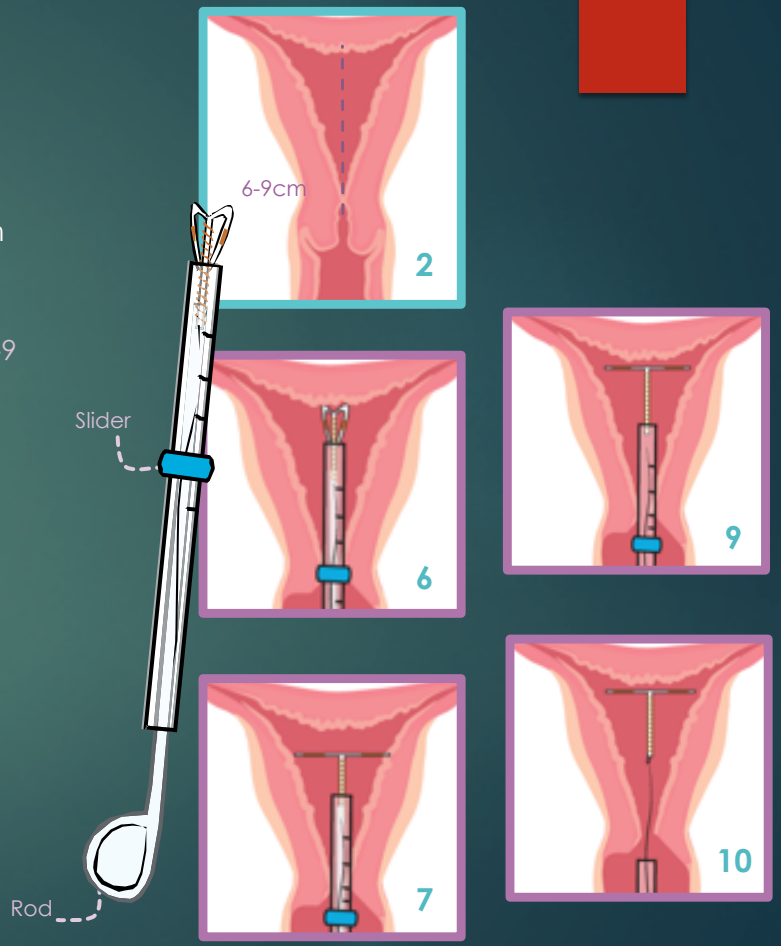
- Skyla is a hormonal IUD that releases levonorgestrel just like the Mirena
- However, the dose is lower (13.5 mcg/day vs. 20 mcg/day) which may to less hormonal side effects (but also last a shorter amount of time; only 3 years)
- Skyla frame and inserter are smaller, easier and more comfortable to insert
- FDA-approved in nulliparous women (also true of Paragard)

TIMING OF INSERTION

- QUICK START METHOD ("LMP" = FIRST day of bleeding):
  - If LMP < 5 days ago → PLACE IT
  - If LMP 5-10 days ago → Upreg neg → PLACE IT (If pregnancy not desired in that it may function as emergency contraception)
  - If LMP was > 10 days ago → Upreg neg → if abstinence OR perfect contraceptive use → PLACE IT
  - 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[2]

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. Load IUD into insertion tube by bending arms
6. 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
7. 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
8. Pull the inserter tube back ~1 cm while holding the white rod steady so that IUD arms are released
9. Gently push the inserter tube back into uterus so that the IUD is placed against the fundus
10. Pull back the white rod from inserter tube
11. Withdraw inserter tube and cut the threads, leaving 2-3 cm visible 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)
- 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]

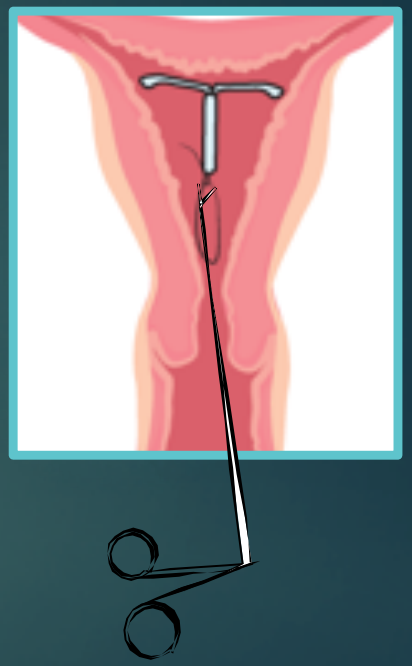
- Embedment: IUD embedded in myometrium, reducing effectiveness and causing discomfort; occurs very rarely
  - If diagnosed on U/S, can remove IUD and replace with new one
- Uterine perforation:
  - Signs: pain, loss of resistance to advancing instrument
  - Perforation during uterine sounding: remove 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***
- Paragard IUDs should be replaced after 10-12 years
- 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 Paragard to ensure it is intact



Paragard as Emergency Contraception[1]

	Paragard IUD	Plan B / POP EC
Timing after intercourse	Up to 8 days after ovulation, usually within 5 days of unprotected intercourse	ASAP but can be used up to 5 days after unprotected intercourse (Sooner is more effective)
Dose	Non-hormonal copper IUD	2 doses of . 75mg levonogestrel 12 hrs apart or single 1.5mg dose
Pregnancy / 100 women	.1-.2 %	<12hr: .4% 1-3 days: 2.7% (Avg: 1.1%)
Advantages	Effective long-term contraception	Available over-the-counter
Disadvantages	More expensive, requires physicians visit and insertion procedure, more prescribing precautions	Less effective, requires more immediate action
Side Effects	Pain, bleeding, expulsion	Spotting, hormonal side effects (nasuea, vomitting, moodiness)

CDC Guideline - Paragard

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.

		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		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		1
Hypertension	Adequately controlled	1
	Systolic 140-159 or Diastolic 90-99	1
	Systolic ≥ 160 or Diastolic ≥ 100	1
Vascular disease		1
History of high blood pressure during pregnancy		1
Deep Vein Thrombosis / Pulmonary Embolism	History of DVT/PE, not on anticoagulant therapy	1
	Acute DVT/PE	2
	Established DVT/PE, on anticoagulant therapy for at least 3 mo	2
	Family history	1
Major surgery	With prolonged immobilization	1
	Without prolonged immobilization	1

		Initiation | Continuation
Known thrombogenic mutations		1
Superficial venous thrombosis	a. Varicose veins	1
	b. Superficial thrombophlebitis	1
Current and history of ischemic heart disease		1
Stroke (history of cerebrovascular accident)		1
Known hyperlipidemias		1
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	1
	b. Severe thrombocytopenia	3 | 2
	c. Immunosuppressive treatment	2 | 1
	d. None of the above	1 | 1
Rheumatoid arthritis	a. On immunosuppressive therapy	2 | 1
	b. Not on immunosuppressive therapy	1
Neurologic conditions		
Headaches		
a. Non-migrainous (mild or severe)		1
b. Migraine	i. Without aura / <35 years	1
	Without aura / ≥35 years	1
	With aura	1
Epilepsy		1
Depressive disorders		
Depressive disorders		1
Reproductive tract infections and disorders		
Vaginal bleeding patterns	a. Irregular pattern without heavy bleeding	1
	b. Heavy or prolonged bleeding (includes regular and irregular patterns)	2
Unexplained vaginal bleeding (suspicious for serious condition, before evaluation)		4 | 2
Endometriosis		2
Benign ovarian tumors (including cysts)		1
Severe dysmenorrhea		2
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		1
Cervical cancer (awaiting treatment)		4 | 2
Breast disease	a. Undiagnosed mass	1
	b. Benign breast disease	1
	c. Family history of cancer	1
	d. Breast cancer (current)	1
	e. Breast cancer (past / no evidence of current for 5 yrs	1

		Continuation
Endometrial hyperplasia		1
Endometrial cancer		4 | 2
Ovarian cancer		1
Uterine fibroids		2
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)	1
	c. Nephropathy/retinopathy/ neuropathy	1
	d. Other vascular disease or diabetes of >20 yrs'	1
Thyroid disorders	a. Simple goiter	1
	b. Hyperthyroid	1
	c. Hypothyroid	1
Gastrointestinal conditions		
Inflammatory bowel disease (IBD)		1
Gallbladder disease	a. Symptomatic	1
	b. Asymptomatic	1
History of cholestasis	a. Pregnancy-related	1
	b. Past COC-related	1
Viral hepatitis	a. Acute or flare	1
	b. Carrier	1
	c. Chronic	1
Cirrhosis	a. Mild (compensated)	1
	b. Severe (decompensated)	1
Liver tumors		
a. Benign	i. Focal nodular hyperplasia	1
	ii. Hepatocellular adenoma	1
b. Malignant (hepatoma)		1
Anemias		2
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. Paipert et al. Continuation and satisfaction of reversible contraception. Obstet Gynecol. 2011;117(5):1105-13. doi: 10.1097/AOG.0b013e31821188ad

OTHER REFERENCES