# Fundamental Skills
# IUD Placement Training

# Learning Objectives

- Identify reasons for use of a tenaculum during IUD placement
- Describe correct use of uterine sound during IUD placement
- Demonstrate the hand skills necessary for placement of the copper IUD and the levonorgestrel IUDs

# Learning Objectives

- Explain the differences between the 5 IUDs currently on the market in the US
- Summarize the U.S. MEC category 3 and 4 recommendations regarding levonorgestrel and copper IUDs


- This presentation includes “off-label” discussion of products.
- When the speakers mentions use of medications for purposes other than what is included in their FDA label they will be identified as such.

# Characteristics of IUD's

- Highly effective
- Highest continuation rates
- Highest patient satisfaction
- Immediate return to fertility
- Safe
- Long-term protection
- Cost saving
- Prevent uterine CA
- Non-contraceptive benefits

(Soini, Hurskainen et al. 2016)

# HOW WELL DOES BIRTH CONTROL WORK?

## Really, really well

The Implant

Works, hassle-free, for up to... 4 years

Hormonal IUDs

Works, hassle-free, for up to... 3-6 years

Non-hormonal IUD

Works, hassle-free, for up to... 12 years

Sterilization, for men and women

Works, hassle-free, for up to... Forever

## Pretty well

The Pill

For it to work best, use it... Every. Single. Day.

The Patch

For it to work best, use it... Every week

The Ring

For it to work best, use it... Every month

The Shot

For it to work best, use it... Every 3 months

## Not as well

Withdrawal

Fertility Awareness

Use a condom with any other method for STI protection.

Internal Condom

Condom

For each of these methods to work, you or your partner have to use it every single time you have sex.

## What is your chance of getting pregnant?

Less than 1 in 100 women

6-9 in 100 women, depending on method

12-24 in 100 women, depending on method

FYI, without birth control, over 90 in 100 young women get pregnant in a year.

BEDSIDER
Bedsider.org

Bixby Center for Global Reproductive Health

# What is in a name?

- Intrauterine Device (IUD)
- Intrauterine Contraception (IUC)
  - Generic term for the method or any of the devices
- Terms can be used interchangeably

# Names for the Copper IUD

- Cu IUD
- Copper IUD
- Cu IUC
- Cu-T380A
- Paragard®
- Can’t call it an IUS

# Names for Levonorgestrel IUDs

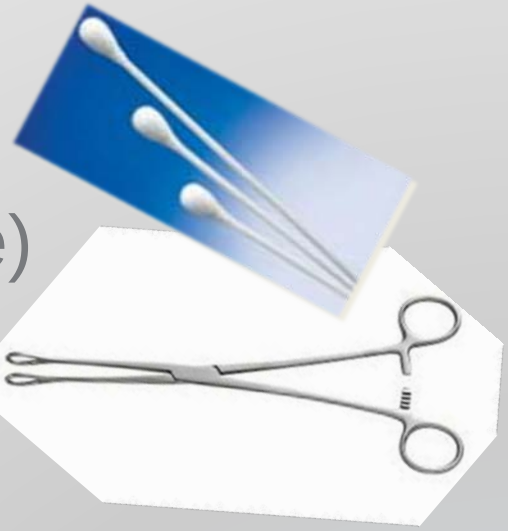
- LNG IUD, IUC, or IUS (Intrauterine System)
- LNG 52 IUD (Mirena) (Liletta)
  - LNG 20 or 18.5 (Mirena) (Liletta)
- LNG 19.5 IUD (Kyleena)
- LNG 13.5 IUD (Skyla)

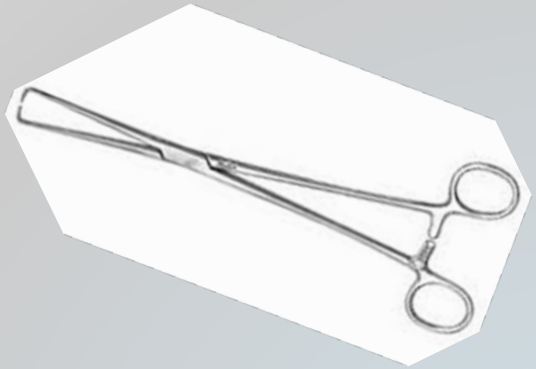
# Take Home the Demo Unit “IUDs”

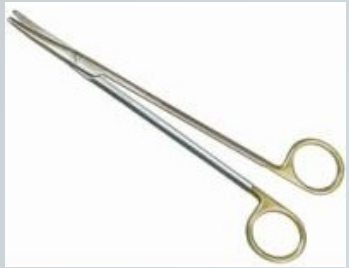
- Give them to your patient to hold, feel and play with while discussing the method
- Show patient:
  - how to feel the threads with it
  - what the plastic feels like if it is expelling
  - Keep them handy! In your lab coat, in each room

# IUD Placement in a Kit…

1. Antiseptic
2. Gauze (4” x 4”) or cotton balls) (sterile)
3. Ring forceps (non-sterile ok)
4. Single-toothed tenaculum (sterile)
5. Uterine sound;(sterile)
6. Scissors (non-sterile ok)



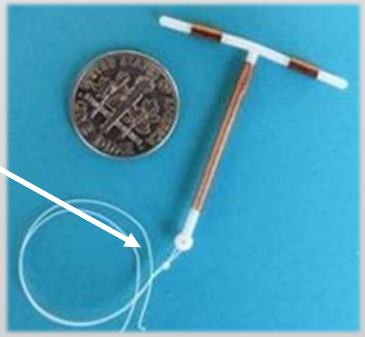




# Physical IUD Differences

Copper: Paragard

32mm horizontally x 36mm vertically



White threads

Levonorgestrel: LNG 52:

Mirena

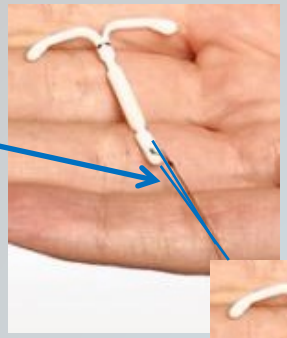
32mm x 32mm

Brown threads

Liletta

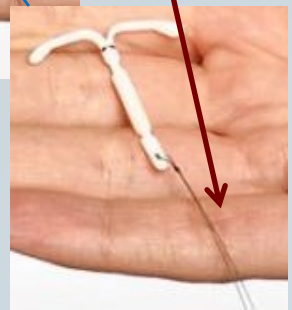
32mm x 32mm

Blue threads



Levonorgestrel: LNG 19.5: Kyleena

28mm horizontally x 30mm vertically



Levonorgestrel: LNG 13.5: Skyla

28mm horizontally x 30mm vertically

# Length of use: “UP TO”

Copper: Paragard

10 years (probably ≥ 12)

Levonorgestrel (LNG 52)

5 (probably ≥7 years)

Levonorgestrel (LNG 19.5): Kyleena

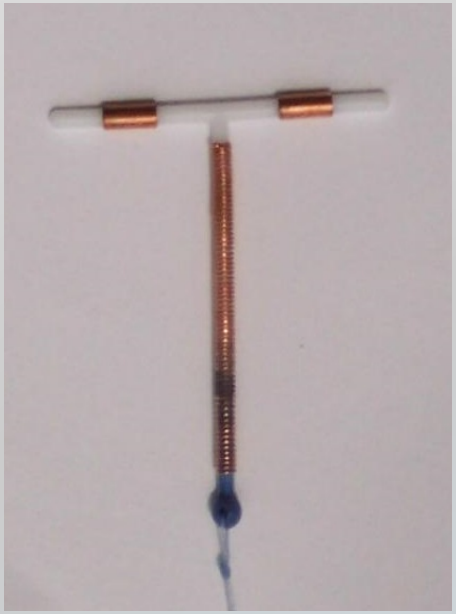
5 years

Levonorgestrel (LNG 13.5): Skyla

3 years

# Cu IUD: Mechanism of Action

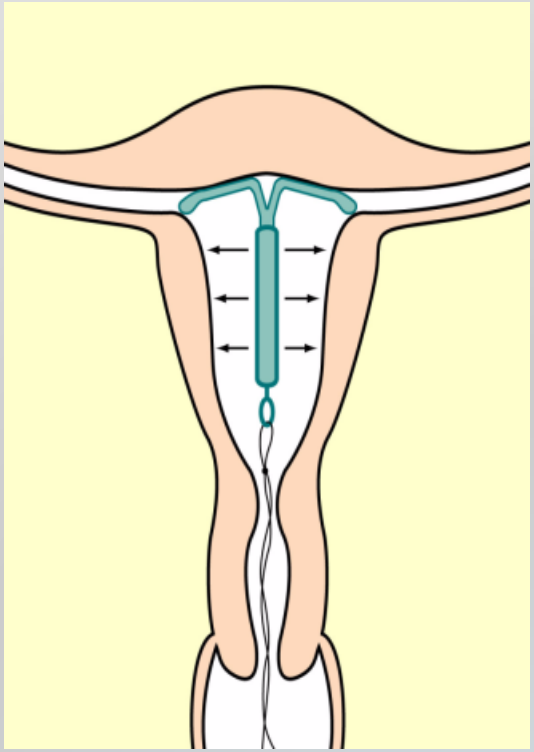
- Primary mechanism is prevention of fertilization
  - Reduce motility and viability of sperm
  - Inhibit development of ova
- Possible secondary mechanism inhibition of implantation



(Alvarez, Brache et al. 1988; Ortiz, Croxatto 2007; Rivera, Yacobson et al. 1999; Segal, Alvarez-Sanchez et al. 1985)

# LNG IUDs: Mechanism of Action

- Cervical mucus thickened
- Sperm motility and function inhibited
- Possible secondary mechanisms of action
  - Endometrium suppressed
  - Alterations in ovulation



(Jonsson, Landgren et al. 1991; Lewis, Taylor et al. 2010; Natavio, Taylor et al. 2013; Ortiz, Croxatto 2007; Rivera, Yacobson et al. 1999; Stanford, Mikolajczyk 2002; Videla-Rivero et al. 1987)

# Levonorgestrel 52 IUDs: Ovulatory Effects

- 93% of the cycles were ovulatory but just 58% of these 'ovulatory' cycles showed normal follicular growth and rupture.
- Ovulation 63% of amenorrhea group; 58% in regularly menstruating group

(Barbosa, Olsson et al. 1995; Nilsson, Lahteenmaki et al. 1984)

# Menstrual Effects: Cu IUD

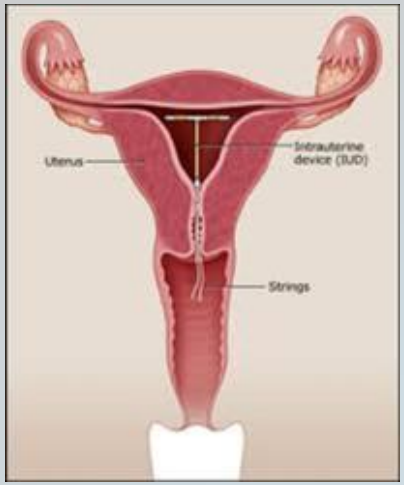
- No hormonal effect so have their usual “cycles”
- Menses often heavier or longer or dysmenorrhea
- May have irregular spotting and sometimes bleeding in the first few weeks

(Hubacher, Chen et al. 2009)

# Copper IUC: Decrease Bleeding (& Cramping)

NSAIDs prophylactically WITH FOOD

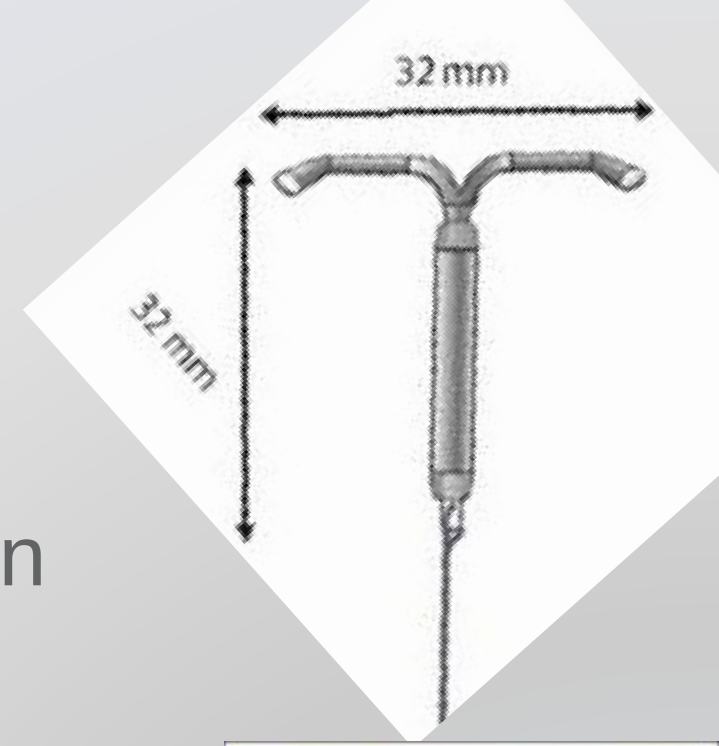

- Pre-emptive use for 1st 3 cycles
- Start before onset of menses for anti-prostaglan effect
- OTC Naproxen sodium 220mg x2 BID (max 1100mg/day) (If Rx-Anaprox DS)
- Ibuprofen 600-800mg TID (max 2400mg/day)

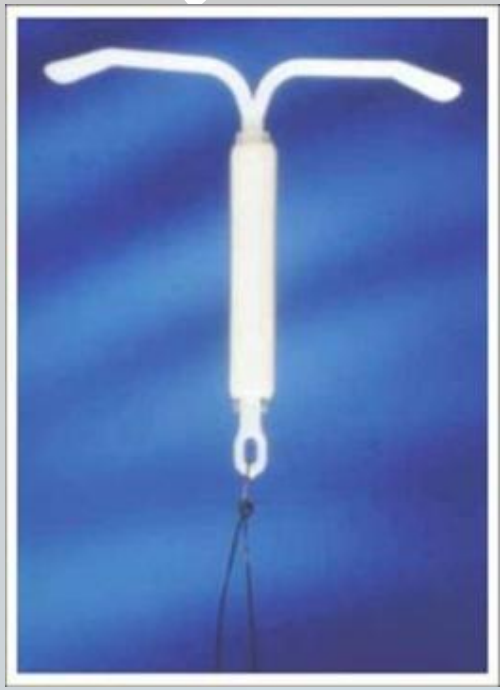



(Godfrey, Folger et al. 2013; Grimes, Hubacher et al. 2006)

# Levonorgestrel IUC 52

- Brand names Mirena® and Liletta®
- Levonorgestrel - 52mg in reservoir
- 19.5-20 mcg levonorgestrel/day
- Insertion tube 4.4 (Mirena®) 4.8mm (Liletta®)



(Liletta Prescribing Information 2017; Mirena Prescribing Information 2017)

# Levonorgestrel IUD 19.5

- Brand name Kyleena®
- 19.5 mg in reservoir
- 17.5 mcg/day after 24 days--declines to 7.4 mcg/day
- Silver ring at top
- Insertion tube 3.8mm

(Kyleena Prescribing Information 2016)

# Levonorgestrel IUD 13.5

- Brand name Skyla®
- Levonorgestrel - 13.5 mg in reservoir
- 14 mcg/day after 24 days -- declines to 5 mcg/day after 3 years
- Silver ring at top
- Insertion tube 3.8mm

(Skyla Prescribing Information 2017)

# LNG 52 IUDs: Menstrual Effects

- Initially some women have frequent spotting and irregular bleeding
- Usually settles down after 4-6 months
- Usually menses become increasingly light
- Amenorrhea 20-80%

(Bachmann, Korner 2009; Backman, Huhtala et al. 2002; Gemzell-Danielsson, Schellschmidt et al. 2012; Hidalgo, bahamondes et al. 2002; Mansour, 2012)

# Treatment for Bleeding with LNG IUD in the First 90 days

- Naproxen may work
- Transdermal E2 and tranexamic acid likely not to work

(Madden, Proehl et al. 2012;Sordal, Inki et al. 2013; Varma, Sinha et al. 2016)

# It Just Gets Better and Better…

Decreased bleeding with placement of subsequent IUS

(Heikinheimo, Inki et al. 2014)

# Levonorgestrel 19.5 and 13.5 IUDs: Menstrual Effects

- Less data about bleeding profile
- Initially some users have frequent spotting and irregular bleeding
- Usually have light, regular menses that become increasingly light
- Less amenorrhea than LNG 52

(Gemzell-Danielsson, Schellschmidt et al. 2012; Nelson, Apter et al. 2013)

# LNG 52 IUD
# Other Side Effects

- Weight gain comparable to users of CU T
- Acne rarely reported
- Uncommon: headaches, nausea, breast tenderness, mood changes, ovarian cyst formation, hair loss

(Ilse, Greenberg et al. 2008; Modesto, de Nazare Silva dos Santos et al. 2015; Vickery, Madden et al. 2013)

# LNG 52
# Non-contraceptive Benefits

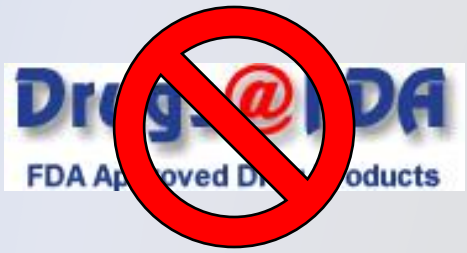
- Decreased
  - Menstrual blood loss
  - Dysmenorrhea
  - Iron deficiency anemia
  - Long term risk of endometrial cancer


- Can be left in place during and after transition to menopause for use with ET

(Sitruk-Ware, 2007)

# LNG 52 IUD
# Additional Therapeutic Uses

- Endometrial hyperplasia
- Symptomatic endometriosis, adenomyosis
- Decreased bleeding from symptomatic fibroids




(ACOG Practice Bulletin 2014; Bragheto, Caserta et al. 2007; Chan, Tam et al. 2007; Cho, Nam et al. 2008; Fraser 2013; Haimovich, Checa et al. 2008; Heikinheimo and Gemzell-Danielsson 2012; Kaunitz 2007; Kaunitz, Bissonnette et al. 2012; Matteson, Rahn et al. 2013; Soysal, Soysal 2005; Sturdee 2006; Varila, Wahlstrom et al. 2001; Varma, Sinha et al. 2006; Varma, Soneja et al. 2008; Wildemeersch 2016; Wong, Chan et al. 2013)

# Extended + Off Label Use

- Mirena
- Liletta
- Paragard as EC

# Mirena Levonorgestrel-releasing Intrauterine System 52 Mg

# 7 Year Data


- Mirena FDA approved for up to 5 years
- Data show that it is highly effective for at least 2 additional years of use
- $6^{th}$ year failure rate 0.25
- $7^{th}$ year failure rate 0.43
- Another trial showed 7-year pregnancy rate of 0.5 per

(McNicholas 2017; Rowe, Farley et al. 2016)

# 52-mg LNG-IUD Data Suggest

- Efficacy as long as 15 years.
- Healthcare professionals, policy makers and stakeholders could take advantage of the present information to decide to maintain the same device at least up to seven years.
- Furthermore, amenorrhea could be a good indicator of contraceptive effect.

(Bahamondes, Fernandes et al. 2017)

| Months (years) after IUS placement | | | | | |
|---|---|---|---|---|---|
| **Bleeding pattern** | 61–84 (5-7) | 85–108 (7-9) | 109–132 (9-11) | 133–156 (11-13) | 157–180 (13-15) |
| No bleeding | 55.1 | 62.5 | 61.3 | 70.6 | 75.0 |
| Spotting | 26.7 | 20.8 | 25.8 | 18.6 | 1.7 |
| Irregular | 1.2 | 0 | 0 | 0 | 0 |
| Heavier | 2.3 | 2 | 0 | 0 | 0 |
| Regular | 8.8 | 5.2 | 0 | 0 | 0 |
| # Starting period | 776 | 107 | 58 | 30 | 23 |

(Bahamondes, Fernandes et al. 2017)

# Reason for Discontinuation

| | Months (years) after IUS placement | | | | |
|---|---|---|---|---|---|
| | 61–84 (5-7) | 85–108 (7-9) | 109–132 (9-11) | 133–156 (11-13) | 157–180 (13-15) |
| Pregnancy | 0 | 0 | 0 | 0 | 0 |
| Expulsion | 0.3% | 0.6% | 0 | 1.1% | 2.1% |
| Planning pregnancy | 1.3% | 2.0% | 0 | 0 | 7.1% |
| Bleeding pain | 0.2% | 2.3% | 0 | 0 | 0 |

(Bahamondes, Fernandes et al. 2017)

# Liletta* Levonorgestrel-releasing Intrauterine System 52 Mg

*The 340B price for Liletta is $50

# LILETTA


- Now FDA approved for up to 5 years
- This new indication is part of an ongoing 10 year clinical trial
- LNG content though 5 years supports functional equivalence to Mirena

(Creinin, Jansen et al. 2016)

# How to Choose IUD Type

## Copper T IUD

- Doesn't want, can't use or can't tolerate hormonal contraception
- Wants regular periods
- Seeking the "longest-acting" method possible

## LNG IUS

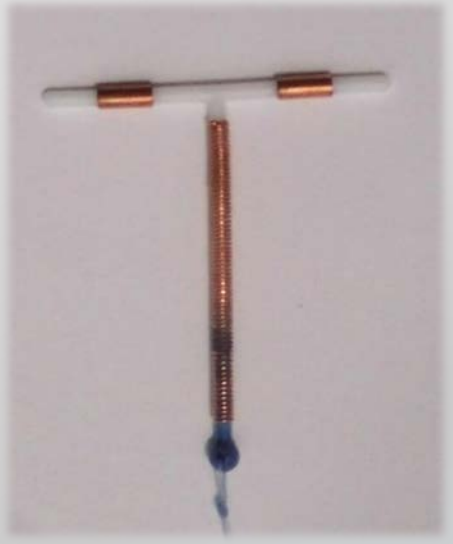
- Wants less menstrual blood flow
- Seeks a non-contraceptive benefit
- Wants to treat dysmenorrhea

# Copper T: The Most Effective Emergency Contraceptive

- Obese users have > failure rates with oral EC - both LNG and ulipristal (ella)
- 1,963 patients CU T IUD for EC -- pregnancy rate was 0.23%
- High continuation rates
- Should be offered routinely for EC

(Cheng, Che et al. 2012; Cleland, Zhu et al. 2012; ACOG Practice Bulletin 2015; Turok, Godfrey et al. 2013; Wu, Godfrey et al. 2010)

# No Decrease in Efficacy Due to Weight



Off- label Use


# Dispelling Myths

# IUDs:

- Do NOT cause ectopic pregnancy
- Do NOT cause pelvic infection
- Do NOT cause infertility
- Do NOT need to be removed:
  - for PID treatment
  - if inflammatory changes or actinomyces are noted on a Pap test

(Forrest 1996; Lippes 1999; Westhoff 2007)

- **IUDs are not** abortifacients
- **IUDS CAN** be used by:
  - those who have had an ectopic pregnancy
  - nulliparous patients
  - teens

(Forrest 1996)

# More Difficult in Nullips or Teens??

- N= 1,177 aged 13–24 years old
- 59% nulliparous
- First-attempt success rate of 95.5%
- 86% of placements done by advanced practice clinicians
- Complications were rare
- No perforations were reported

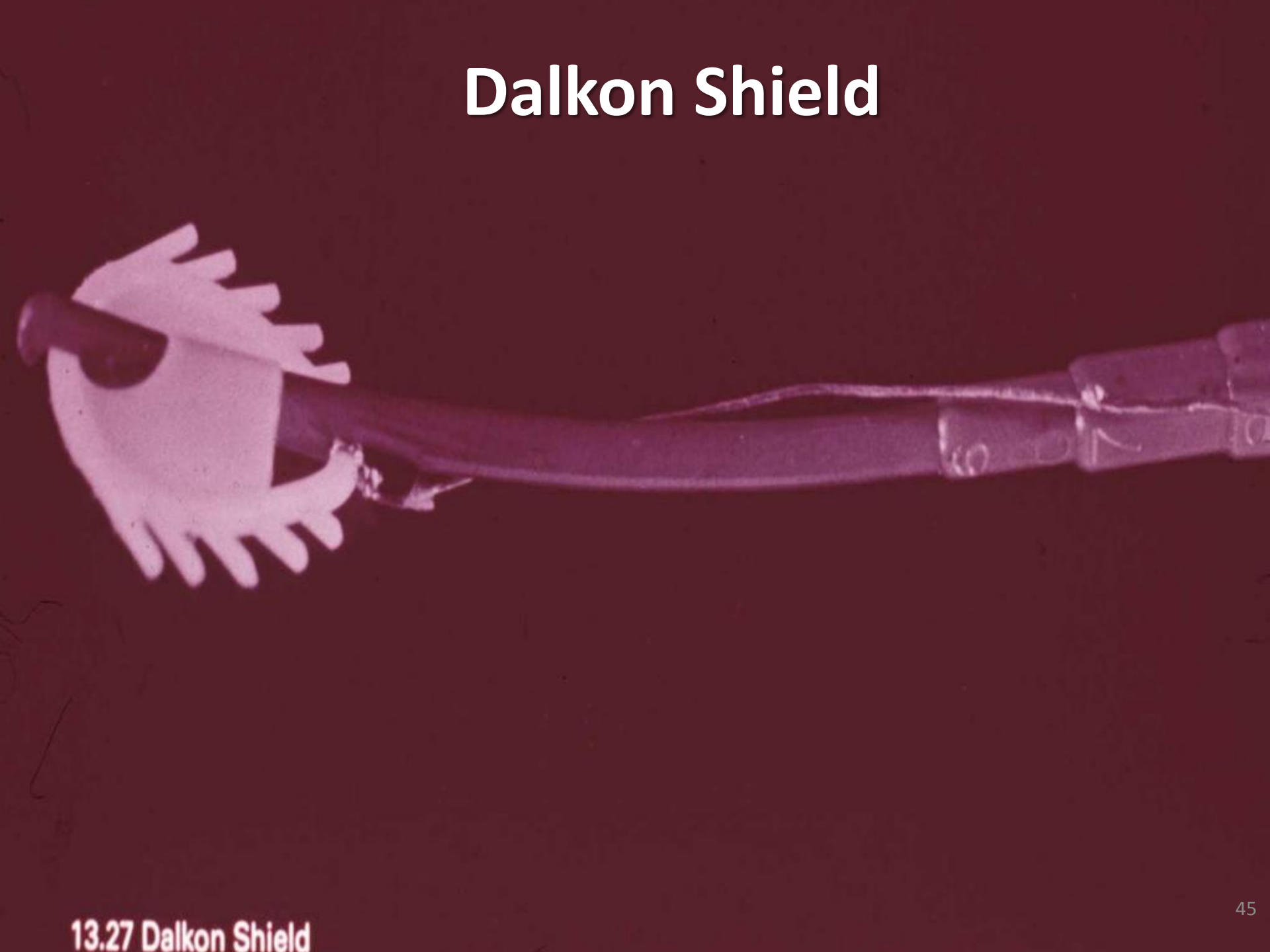
(Teal, Romer et al. 2015)

# PID

- The risk of infection after IUD placement is low
- Studies demonstrate no increased risk of PID in nulliparous IUD users
- No evidence that IUD use is associated with subsequent infertility

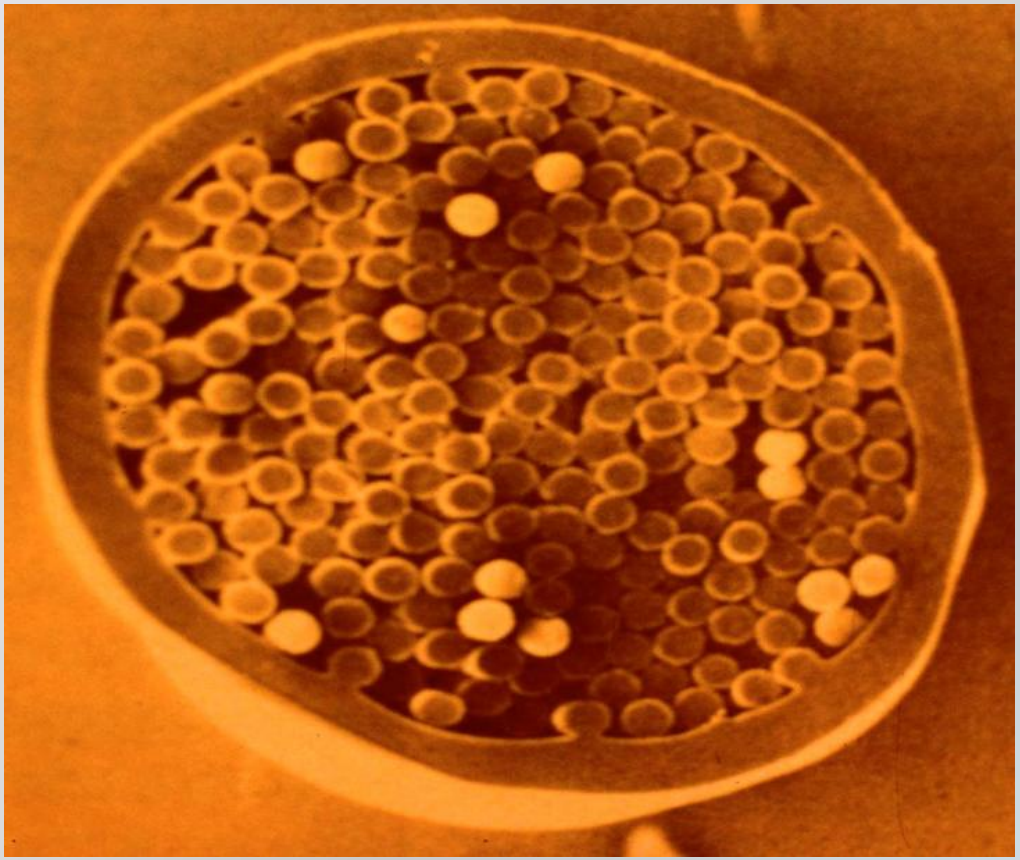
(Birgisson, Zhao et al. 2015; Hubacher, Lara-Ricalde et al. 2001; Steenland, Zapata et al. 2013)

# Dalkon Shield

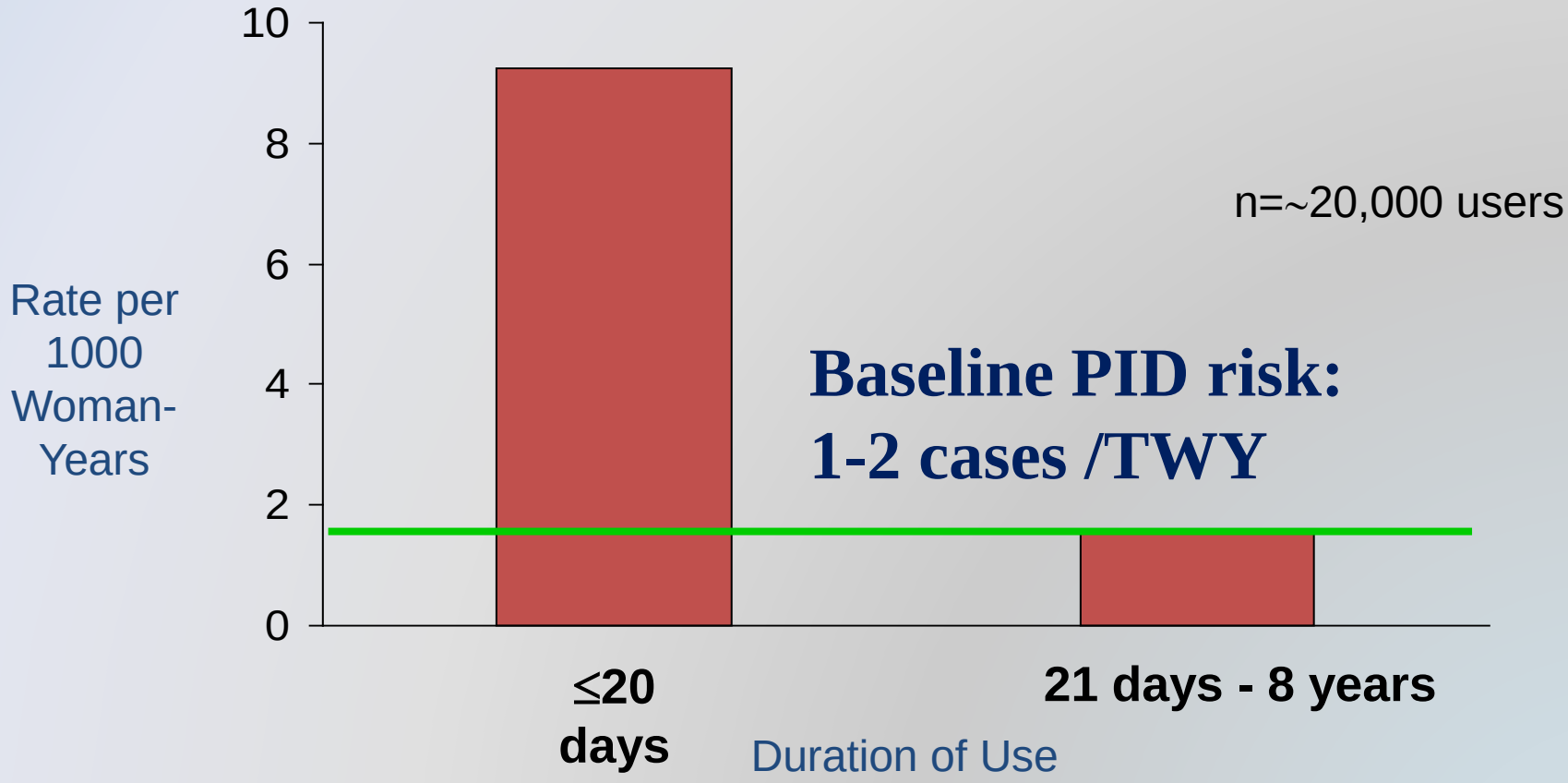


13.27 Dalkon Shield

# Dalkon Shield: Multi-filament String



# Rate of PID by Duration of IUC Use: *Bacterial contamination of the endometrial cavity not the IUD*




(Farley, Rowe et al. 1992)

# US Medical Eligibility Criteria 2016

| Category | Definition | Recommendation |
|---|---|---|
| 1 | No restriction in contraceptive use | Use the method |
| 2 | Advantages generally outweigh theoretical or proven risks | More than usual follow-up needed |
| 3 | Theoretical or proven risks outweigh advantages of the method | Clinical judgment that this patient can safely use |
| 4 | The condition represents an unacceptable health risk if the method is used | Do not use the method |

# *Any* IUD US MEC 2016

| Category 4 | Category 3 |
| --- | --- |
| ▪ Pregnancy<br>▪ Distorted uterine cavity<br>▪ Post-partum sepsis<br>▪ Postseptic abortion<br>▪ Current GC/CT/purulent cervicitis/PID<br>  ▪ Initiate: 4 Continue: 2<br>▪ Pelvic TB<br>  ▪ Initiate: 4 Continue: 3<br>▪ Malignant GTD<br>▪ Cervical/endometrial cancer<br>  ▪ Initiate: 4 Continue: 2 | ▪ Postpartum (48h-4 wk)<br>▪ Complicated: graft failure<br>  ▪ Initiate: 3 Continue: 2 |

# CU IUD US MEC 2016

| Category 4 | Category 3 |
| --- | --- |
| ▪ Copper allergy<br>▪ Wilson's disease | ▪ Severe thrombocytopenia |

# LNG IUD US MEC 2016

| Category 4 | Category 3 |
| --- | --- |
| ▪ Breast cancer | ▪ Severe decompensated cirrhosis<br>▪ Hepatocellular adenoma<br>▪ Malignant (hepatoma)<br>▪ Positive (or unknown) antiphospholipid antibodies<br>▪ Current and history of ischemic heart disease (continuation)<br>▪ Breast cancer >5 years |

# 3 Buckets



# Timing of IUD Placement

- Can be placed anytime in cycle- as long as patient is not pregnant
- No benefit to placement during menses
  - No impact on pain/discomfort
- Immediate post-partum (after placenta)
- Immediate post-abortion

(Grimes, Lopez et al. 2010;
US Selected Practice Recommendations 2016)

# Timing of Cu T IUD Placement for EC

- Within 5 days of the first act of unprotected sexual intercourse
- When the day of ovulation can be estimated it can be placed beyond 5 days after sexual intercourse, as long as placement does not occur >5 days after ovulation



(Grimes, Lopez et al. 2010;
US Selected Practice Recommendations 2016)

# How Long to Wait After Treatment for Cervical Infection?

- The *optimal* time for IUD placement after treatment is unclear


- Delay IUD placement until:
  - treatment is complete
  - symptoms have resolved
  - the cervical examination appears normal
  - no masses or tenderness on bimanual exam

(ACOG Practice Bulletin 2017)

# Pre-IUD Placement Screening

- Must do a pelvic exam
- Otherwise, no *routine* tests
  - Any indicated screening test can be performed at time of IUD placement
- Baseline Hgb-may be helpful for later management

(Grentzer, Peipert et al. 2015; Secura, Allsworth et al. 2010; Sufrin, Postlethwaite et al. 2010; Sufrin, Postlethwaite et al. 2012; US Selected Practice Recommendations 2016)

# Pre-IUD Placement Screening

- CT/GC:
  - If age <25 and due for annual screening
  - Or if high risk for STI
  - Can be done on day of placement
- Cervical cancer screening only if due
- Pregnancy test if indicated

(Birgisson, Zhao 2015; Faundes, Telles et al. 1998; Martinez, Lopez-Arregui 2009; Turok, Eisenberg et al. 2016)

# Pre-IUD Placement Medication

- NSAIDs 30-60 minutes before placement: may help insertional pain, helps post placement
- Consider cervical block, topical
- Prophylactic Misoprostol: increase side effects and no benefit
- Prophylactic antibiotics; no value for routine administration

(Lopez, Bernholc et al. 2015; Matthews 2016; Walsh, Grimes et al.; Zapata, Jatlaoui et al. 2016)

# Counseling and Informed Consent

- Discuss menstrual changes
- Perforation, infection, expulsion, method failure
- Return if:
  - String cannot be located
  - Symptoms of pregnancy/infection
  - Sudden unexplained pelvic pain occurs
  - Excessively heavy bleeding

# Know resources in your area

- For mentorship/proctoring
- To discuss challenging cases
- To manage complications

# Helpful Resources

- App US MEC and SPR Guidelines: cdc.gov/mmwr
- Nat'l Clinical Training Center for Family Planning: www.ctcfp.org
- LARC Practice Resources: acog.org/goto/larc
- Paragard®: paragard.com
- Mirena®: mirena-us.com
- Skyla®: skyla-us.com
- Kyleena®: kyleena-us.com
- Liletta®: lilettahcp.com/

# Take Home the Demo Unit "IUDs"

- Give them to your patient to hold, feel and play with while discussing
- Show patient:
  - how to feel the threads with it
  - what the plastic feels like if it is expelling
- Keep them handy!! In your lab coat, in each room

# IUD Placement Practicum

# Steps for IUD Placement

- Perform bimanual pelvic exam to determine uterine position and r/o contraindication
- Visualize cervix with (SHORTEST) speculum
  - Collect CT/GC, pap as indicated
- Inspect cervix for mucopurulent discharge

# Steps for IUD Placement

- Cleanse cervix with antiseptic
  - Povidone iodine
  - Chlorhexidine gluconate
- Use of sterile gloves vs. “no-touch” technique

# Tenaculum Purpose

- Stabilize the cervix to allow passage of sound and IUD through the os
- Straighten any irregularities in the cervical canal
- Straighten uterine curvatures or flexion

# To Place Tenaculum

- Dominant hand in “palm-up” position to allow one to see above the hand
- Thumb in one ring
- Middle or ring finger in the other ring


Palm Up Middle Finger


Palm Up Ring Finger

# Tenaculum
# Choose Site for Placement

- Anterior lip
- Posterior lip
- Typically a horizontal bite,
  some prefer vertical

**Do not occlude os!**

# Tenaculum: Size of Bite


- 1-1.5 cm wide
- 1 cm deep
- Not too shallow- may tear through
- Not too deep- unnecessary

**Do not occlude os!**

# Tenaculum: Closing Ratchet

- Once the teeth are in contact with the cervix, press into the tissue
- Close the ratchet only 1-2 clicks
- Close the ratchet silently
- Once the ratchet is closed, test your application gently to be sure it is secure


1-2 Clicks
Palm Up

# Tenaculum Pain Reduction

- Squeeze teeth together EXCEEDINGLY slowly
- Have patient cough at application (hold onto speculum!)
- 1cc local anesthetic to tenaculum site

# Tenaculum: Use When Sounding

- Change hands; hold the tenaculum with the non-dominant hand while sounding and for IUD placement
- OK to let tenaculum lay on speculum when picking up the sound or IUD

# Tenaculum Hand Position While Sounding and for IUD Placement

- Thumb on one side of ratchet and fingers on the other
- Avoid the rings
- Avoid inadvertent movements

USE the tenaculum


Fingers NOT in rings


Can “Choke up”

# Uterine Sound Purpose

- Insure that you can pass through the internal os
- Informs the direction and pathway through the os up to the fundus

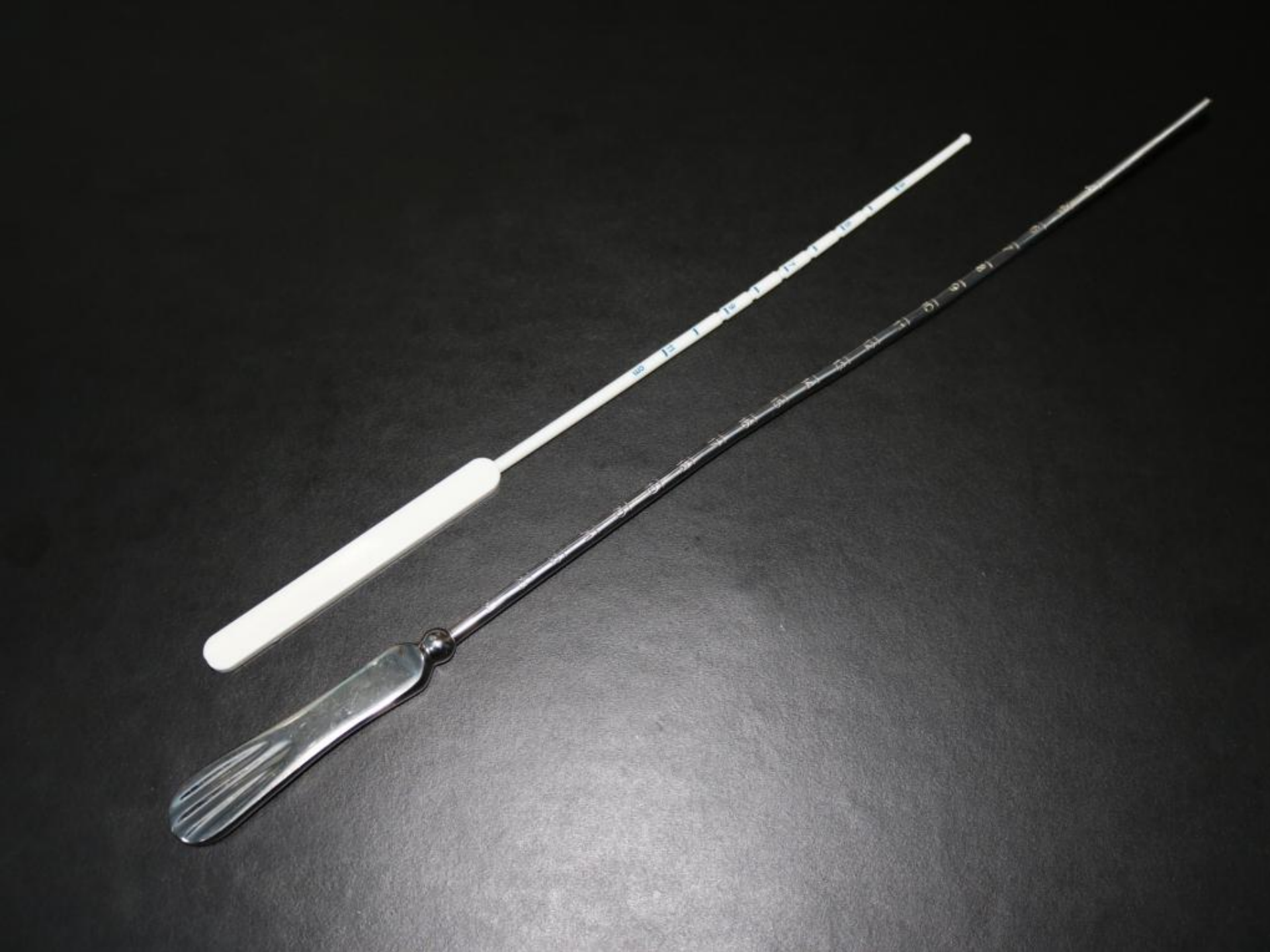
# Uterine Sound Purpose

Measures the depth/distance from the external os to the fundus

- Appropriate for IUD placement not <5.5 cm
- 10 cm or more in some cases
- Tells you where to set the flange
- So you don’t waste the IUD

# Sound Which One?

- Usually 4mm (occasionally 3mm)
- Metal sound
  - Can be bent to mimic uterine flexion
- Plastic sound
  - May be less likely to perforate
- Endometrial sampler
  - Thinner diameter

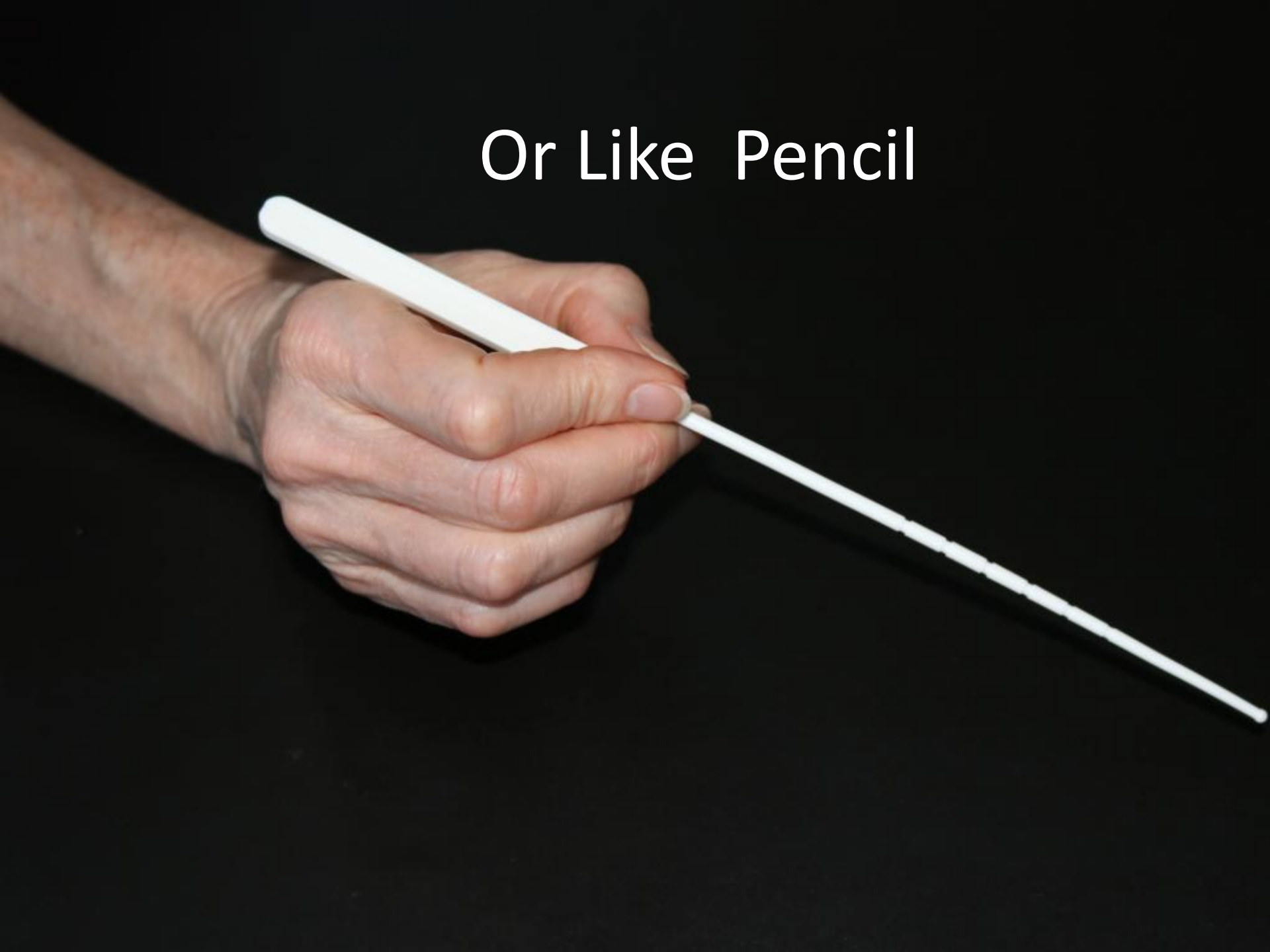


# Sound Hand Skills

- Avoid momentum
- Hold it like a pencil or dart
- Use *Wrist* action
  - Not elbow
  - Not shoulder
- Brace fingertips on speculum to achieve control of force while advancing the sound


Hold the Sound Like a Dart

# Or Like  Pencil



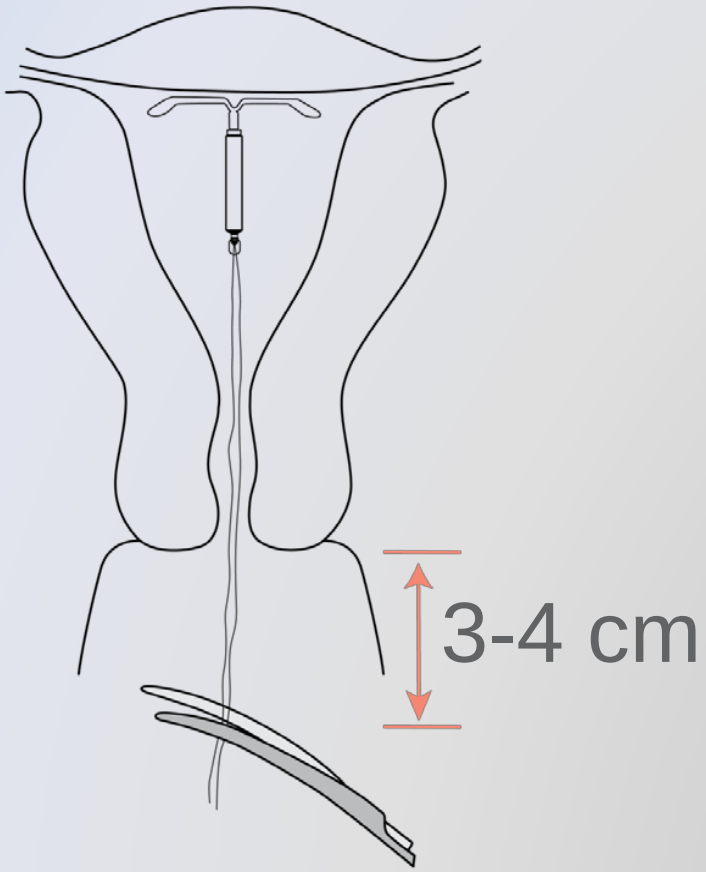
# Safety Tips

- Don’t push hard or use force at internal os
- *Slow* progression through the internal os

Once you have passed through the internal os, *Stop* and then…

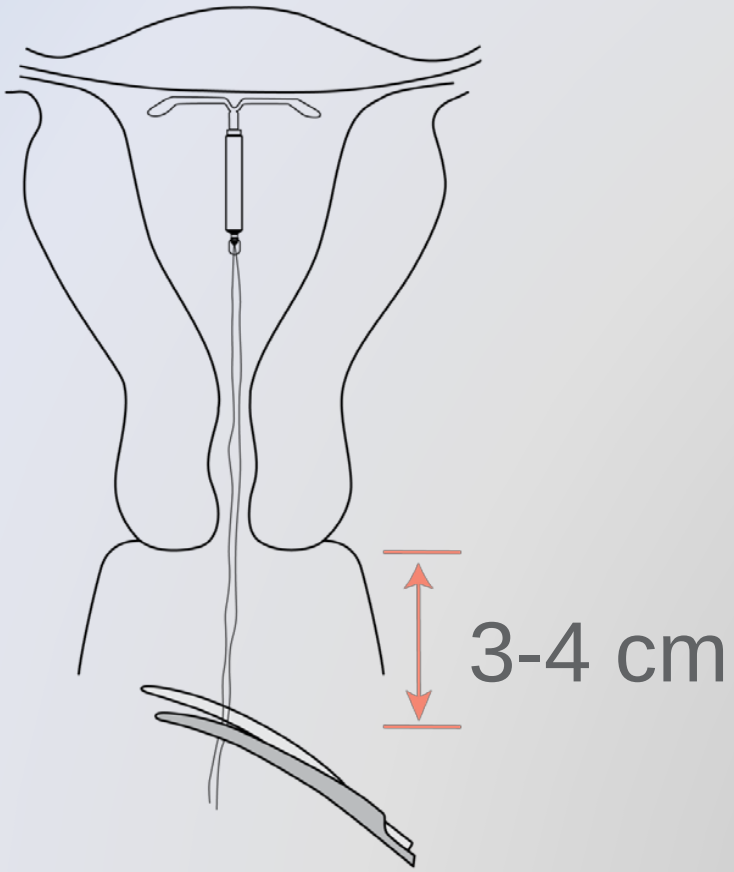
- Intentionally proceed to the fundus

# Cutting the threads




- Use scissors that are:
  - Sharp
  - Blunt-tipped
  - Long
  - Curved
- Leave 3-4 cm outside of the cervix

# Caution




- Cut the strings/ threads perpendicular to the thread length *(cutting threads at an angle may leave sharp ends)*
- Do not pull on the threads when cutting to prevent displacing the IUD