

CENTER FOR FACULTY AND
PROFESSIONAL DEVELOPMENT

Continuing Education



Geisinger
College of
Health Sciences

GCHS Department of Family Medicine

presents

**Family Medicine
Outpatient Procedural
Training Day**

April 11, 2026

Geisinger Commonwealth
School of Medicine
Scranton, PA

OUTPATIENT PROCEDURE TRAINING DAY

TIME	ACTIVITY	LOCATION
9:00 AM - 9:30 AM	REGISTRATION & WELCOME	GCSOM LOBBY/AUDITORIUM
9:30 AM - 10:15 AM	STATION 1 BIRTH CONTROL IMPLANT <i>Jason Woloski, MD</i> <i>Michelle, Pacyna, DO</i>	TBD
10:20 AM - 11:05 AM	STATION 2 TOENAIL REMOVAL <i>Sumaira Khan, MD</i> <i>Thomas Brouse, MD</i>	TBD
11:10 AM - 11:55 AM	STATION 3 SHAVE/PUNCH BIOPSIES <i>Chelsea Harrison, MD</i> <i>Fnu Sanjna, MBBS</i>	TBD
12:00 PM - 12:45 PM - BREAK FOR LUNCH		
12:45 PM - 1:30 PM	STATION 4 IUDS <i>Bu Kim, MD</i> <i>Jade Evenstad, MD</i> <i>Hamda Memon, MD</i>	TBD
1:35 PM - 2:20 PM	STATION 5 SHOULDER / TRIGGER POINT <i>Anja Landis, MD</i> <i>Daniel Kruglyak, DO</i>	TBD
2:25 PM - 3:10 PM	STATION 6 KNEE INJECTION / TRIGGER FINGER <i>Ayesha Shah, DO</i> <i>Kevin Mathews, DO</i> <i>Ryan Ulibarri, MD</i>	TBD
3:10 - 3:30 PM	CLOSING REMARKS	AUDITORIUM
EVENING CELEBRATION		
4:00 - 7:00 PM	KEYNOTE SPEAKER <i>Dr. Wanda Filer</i>	AUDITORIUM

Thank you for attending the **Family Medicine Outpatient Procedural Training Day**. To receive credit for your participation, please complete the online evaluation form using the link below. A copy of the form will also be emailed to you following the activity. Completion of the evaluation is required for all participants.

Thank you.

<https://cce.geisinger.edu/content/learner-evaluation-4820>

In approximately two months, you will receive a follow-up evaluation survey related to this conference. This survey is designed to gather feedback on any changes or improvements you have made to your professional practice as a result of attending.

Any difficulties or questions, please contact the Continuing Education Program at 570-271-6692 or email at cce@geisinger.edu.

Birth Control Implant

Nexplanon[®]

(etonogestrel implant) 68mg Radiopaque

Clinical Training Program

Slide Booklet

NEXPLANON® (etonogestrel implant) 68 mg Radiopaque

Background

3



Overview of section contents

- Indications and use
- Product description and mechanism of action
- Data review, including:
 - Efficacy
 - Pharmacokinetics
 - Contraindications
 - Warnings and precautions
 - Adverse reactions
 - Drug interactions
 - Use in specific populations

4

Clinical Training Program

4

Clinical Training Program

Indications and use

5

NEXPLANON is a progestin-only implant indicated for use by women to prevent pregnancy

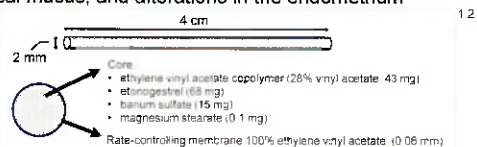
Clinical Training Program

5

Product description and mechanism of action

6

- NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive method. The implant must be removed by the end of the third year and may be replaced by a new implant at the time of removal, if continued contraceptive protection is desired
- Single-rod, progestin-only subdermal implant
 - Inserted subdermally just under the skin at the inner side of the non-dominant arm
- The contraceptive effect of NEXPLANON is achieved by suppression of ovulation, increased viscosity of the cervical mucus, and alterations in the endometrium



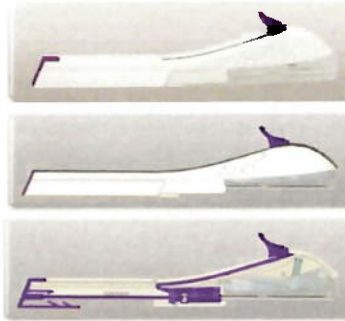
1. Funk S, Miller M, Mishel D, et al for IMPLANON US Study Group. *Contraception*. 2005; 71(5):319-326. 2. Guillebaud J. *Contraception: Your Questions Answered*. 5th ed. Churchill Livingstone; 2008.

Clinical Training Program

6

Applicator for NEXPLANON¹

- The applicator is designed to facilitate insertion of the implant subdermally just under the skin
- Applicator design elements:
 - Cap-blocking mechanism with cap/lever
 - Implant retained in needle before insertion
 - Single-handed movement with slider
 - Needle visible from the side



1. Mansour D. et al. *Contraception* 2010 82(3): 243-249

7

Clinical Training Program

7

Implant insertion and removal characteristics

- In a clinical study, after insertion, 300 (99.7%) of 301 NEXPLANON implants were palpable. The single non-palpable implant was not inserted according to the instructions
- In 112 (98.2%) of 114 women in 2 clinical trials for whom insertion and removal data were available, NEXPLANON implants were clearly visible with the use of 2-dimensional X-ray after insertion
 - The 2 implants that were not clearly visible after insertion were clearly visible with 2-dimensional X-ray before removal

8

Clinical Training Program

8

Clinical Training Program

Recommended timing of insertion

9

- **IMPORTANT: Rule out pregnancy before inserting the implant**

Previous contraceptive method	Timing of insertion
None	Between Days 1 and 5 of cycle even if the woman is still bleeding
Combined hormonal contraceptive	Preferably on the day after the last active tablet or day of removal of the vaginal ring or transdermal patch, at latest on the day following the usual tablet-free, ring-free, patch-free, or placebo tablet interval
Mircipill (progestin-only)	Any day of the month, within 24 hours of last tablet
Implant/intrauterine system (progestin-only)	Same day as removal
Injectable progestin-only	On the day the next injection is due
First-trimester termination of pregnancy	Within 5 days following abortion or miscarriage
Second-trimester termination of pregnancy	Between 21 to 28 days following abortion or miscarriage
Postpartum	Breastfeeding Not inserted until after 4 th postpartum week Not breastfeeding Between 21 and 28 days postpartum

- If inserted as recommended above, backup contraception is not necessary. If deviating from the recommended timing of insertion, rule out pregnancy and use backup barrier method of contraception for 7 days after insertion of NEXPLANON

Clinical Training Program

9

Data review

10

 ORGANON

Clinical trial data: Efficacy

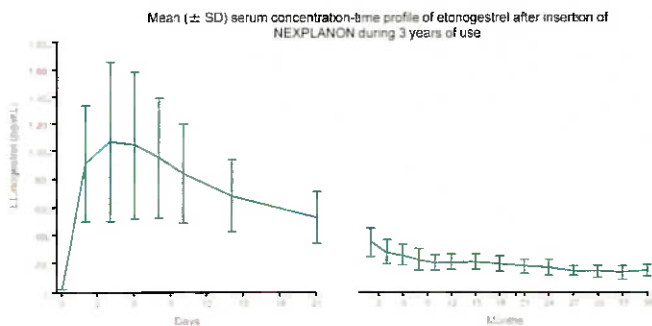
- The efficacy of IMPLANON® (etonogestrel implant) non-radiopaque was established in clinical trials of up to 3 years' duration that involved 923 subjects and 1,756 women-years of use
- Results:
 - In the subgroup of women, 18–35 years of age at entry, 6 pregnancies during 20,648 cycles of IMPLANON use were reported. Two pregnancies occurred in each of years 1, 2, and 3. Each conception was likely to have occurred shortly before or within 2 weeks after removal of the non-radiopaque etonogestrel implant
 - With these 6 pregnancies, the cumulative Pearl Index was 0.38 pregnancies per 100 women-years of use
- The clinical trials excluded women who weighed more than 130% of their ideal body weight and/or who were chronically taking medications that induce liver enzymes

11

Clinical Training Program

11

NEXPLANON: Pharmacokinetic profile



12

Clinical Training Program

12

Clinical Training Program

Contraindications

13

NEXPLANON should not be used in women who have:

- Known or suspected pregnancy
- Current or past history of thrombosis or thromboembolic disorders
- Liver tumors, benign or malignant, or active liver disease
- Undiagnosed abnormal genital bleeding
- Known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past
- Allergic reaction to any of the components of NEXPLANON

Clinical Training Program

13

Warnings and Precautions

14

Complications of Insertion/Removal

- NEXPLANON should be inserted subdermally so it will be palpable after insertion
- Palpate immediately after insertion
- Undetected failure to insert the implant may lead to an unintended pregnancy
- Complications related to insertion and removal procedures may occur, for example:
 - Pain
 - Paresthesia
 - Bleeding
 - Hematoma
 - Scarring
 - Infection

Clinical Training Program

14

Warnings and Precautions (*continued*)

Complications of Insertion/Removal (*continued*)

- If NEXPLANON is inserted deeply (intramuscular or intrafascial), neural or vascular injury may occur
 - To reduce the risk of deep insertions, it is important that you follow the insertion procedures discussed today and set forth in the Prescribing Information
- Deep insertions of NEXPLANON have been associated with paresthesia (due to neural injury), migration of the implant (due to intramuscular or fascial insertion), and intravascular insertion. If infection develops at the insertion site, start suitable treatment. If the infection persists, the implant should be removed
- Incomplete insertions or infections may lead to expulsion

15

Clinical Training Program

15

Warnings and Precautions (*continued*)

Complications of insertion/Removal (*continued*)

- Implant removal may be difficult or impossible if the implant:
 - Is not inserted correctly
 - Is inserted too deeply
 - Is not palpable
 - Is encased in fibrous tissue
 - Has migrated
- Reports of implant migration within the arm may have been related to deep insertion
- Postmarketing reports of implants located within the vessels of the arm and the pulmonary artery also may have been related to deep insertions or intravascular insertions
- Some cases of implants found within the pulmonary artery were associated with chest pain and/or respiratory disorders (such as dyspnea, cough, or hemoptysis); others were asymptomatic
- In cases where the implant has migrated to the pulmonary artery, endovascular or surgical procedures may be needed for removal

16

Clinical Training Program

16

Warnings and Precautions (*continued*)

17

Complications of Insertion/Removal (*continued*)

- If at any time the implant cannot be palpated, it should be localized and removal is recommended
- When an implant is removed, it is important to remove it in its entirety
- Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged
- Removal of deeply inserted implants should be conducted with caution in order to prevent injury to deeper neural or vascular structures in the arm and be performed by healthcare professionals familiar with the anatomy of the arm
- If the implant is located in the chest, healthcare professionals familiar with the anatomy of the chest should be consulted
- Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event

Clinical Training Program

17

Warnings and Precautions (*continued*)

18

Broken/Bent Implants

- Cases of breakage or bending of implants while inserted within a patient's arm have been reported. Cases of migration of a broken implant fragment within the arm have also occurred. These cases may be related to external forces, e.g., manipulation of the implant or contact sports. The release rate of etonogestrel may be slightly increased in a broken or bent implant, based on *in vitro* data. When an implant is removed, it is important to remove it in its entirety

Clinical Training Program

18

Warnings and Precautions (continued)

Changes in Menstrual Bleeding Patterns

- After starting NEXPLANON, women are likely to have a change from their normal menstrual bleeding pattern. These may include changes in bleeding frequency (absent, less, more frequent, or continuous), intensity (reduced or increased), or duration
- In clinical trials of IMPLANON® (etonogestrel implant) non-radiopaque, bleeding patterns ranged from:
 - Amenorrhea (1 in 5 women) to
 - Frequent and/or prolonged bleeding (1 in 5 women)
- The bleeding pattern experienced in the first 3 months of NEXPLANON use is broadly predictive of the future pattern
- Women should be counseled regarding the bleeding changes they may experience
- Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy

19

Clinical Training Program

19

Warnings and Precautions (continued)

Bleeding Irregularities and Discontinuation Rates

Bleeding irregularity	Discontinuation rate
All irregularities	11.1%
Irregular bleeding	10.8%
Amenorrhea	0.3%

- In clinical studies of the non-radiopaque etonogestrel implant, reports of changes in bleeding pattern were the most common reason for stopping treatment (11.1%). Irregular bleeding (10.8%) was the single most common reason women stopped treatment, while amenorrhea (0.3%) was cited less frequently. In these studies, women had an average of 17.7 days of bleeding or spotting every 90 days (based on 3,315 intervals of 90 days recorded by 780 patients)

20

Clinical Training Program

20

Clinical Training Program

Warnings and Precautions (*continued*)

21

Ectopic Pregnancies

- As with all progestin-only contraceptive products, be alert to the possibility of an ectopic pregnancy among women using NEXPLANON who become pregnant or complain of lower abdominal pain. Although ectopic pregnancies are uncommon among women using NEXPLANON, a pregnancy that occurs in a woman using NEXPLANON may be more likely to be ectopic than a pregnancy occurring in a woman using no contraception

Clinical Training Program

21

Warnings and Precautions (*continued*)

22

Thrombotic and Other Vascular Events

- The use of combination hormonal contraceptives (progestin plus estrogen) increases the risk of vascular events, including arterial events (strokes and myocardial infarctions) or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis, retinal vein thrombosis, and pulmonary embolism)
- NEXPLANON is a progestin-only contraceptive. It is unknown whether this increased risk is applicable to etonogestrel alone. It is recommended, however, that women with risk factors known to increase the risk of venous and arterial thromboembolism be carefully assessed
- There have been postmarketing reports of serious arterial thrombotic and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and strokes, in women using etonogestrel implants. NEXPLANON should be removed in the event of a thrombosis

Clinical Training Program

22

Warnings and Precautions (*continued*)

Thrombotic and Other Vascular Events (*continued*)

- Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum. Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence
- Evaluate for retinal vein thrombosis immediately if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions
- Consider removal of the NEXPLANON implant in case of long-term immobilization due to surgery or illness

Ovarian Cysts

- If follicular development occurs, atresia of the follicle is sometimes delayed, and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally, these enlarged follicles disappear spontaneously. On rare occasion, surgery may be required

23

Clinical Training Program

23

Warnings and Precautions (*continued*)

Carcinoma of the Breast and Reproductive Organs

- Women who currently have or have had breast cancer should not use hormonal contraception because breast cancer may be hormonally sensitive. Some studies suggest that the use of combination hormonal contraceptives might increase the incidence of breast cancer, however, other studies have not confirmed such findings
- Some studies suggest that the use of combination hormonal contraceptives is associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings are due to differences in sexual behavior and other factors
- Women with a family history of breast cancer or who develop breast nodules should be carefully monitored

24

Clinical Training Program

24

Warnings and Precautions (*continued*)

25

Liver Disease

- Disturbances of liver function may necessitate the discontinuation of hormonal contraceptive use until markers of liver function return to normal. Remove NEXPLANON if jaundice develops
- Hepatic adenomas are associated with combination hormonal contraceptives use. An estimate of the attributable risk is 3.3 cases per 100,000 for combination hormonal contraceptives users. It is not known whether a similar risk exists with progestin-only methods like NEXPLANON
- The progestin in NEXPLANON may be poorly metabolized in women with liver impairment. Use of NEXPLANON in women with active liver disease or liver cancer is contraindicated

Clinical Training Program

25

Warnings and Precautions (*continued*)

26

Weight Gain

- In clinical studies, mean weight gain in U.S. non-radiopaque etonogestrel implant (IMPLANON®) users was 2.8 pounds after 1 year and 3.7 pounds after 2 years. How much of the weight gain was related to the non-radiopaque etonogestrel implant is unknown. In clinical studies, 2.3% of the users reported weight gain as the reason for having the non-radiopaque etonogestrel implant removed

Elevated Blood Pressure

- Women with a history of hypertension-related diseases or renal disease should be discouraged from using hormonal contraception. For women with well-controlled hypertension, the use of NEXPLANON can be considered. Women with hypertension using NEXPLANON should be closely monitored. If sustained hypertension develops during the use of NEXPLANON, or if a significant increase in blood pressure does not respond adequately to antihypertensive therapy, NEXPLANON should be removed

Clinical Training Program

26

Warnings and Precautions (continued)

Gallbladder Disease

- Studies suggest a small increased relative risk of developing gallbladder disease among combination hormonal contraceptive users. It is not known whether a similar risk exists with progestin-only methods such as NEXPLANON

Carbohydrate and Lipid Metabolic Effects

- Use of NEXPLANON may induce mild insulin resistance and small changes in glucose concentrations of unknown clinical significance. Carefully monitor prediabetic and diabetic women using NEXPLANON
- Women who are being treated for hyperlipidemia should be followed closely if they elect to use NEXPLANON. Some progestins may elevate LDL levels and may render the control of hyperlipidemia more difficult

LDL = low-density lipoprotein

27

Warnings and Precautions (continued)

Depressed Mood

- Women with a history of depressed mood should be carefully observed. Consideration should be given to removing NEXPLANON in patients who become significantly depressed

Return to Ovulation

- In clinical trials with the non-radiopaque etonogestrel implant (IMPLANON®), the etonogestrel levels in blood decreased below sensitivity of the assay by 1 week after removal of the implant. In addition, pregnancies were observed to occur as early as 7–14 days after removal. Therefore, a woman should re-start contraception immediately after removal of the implant if continued contraceptive protection is desired

28

Clinical Training Program

Warnings and Precautions (*continued*)

29

Fluid Retention

- Hormonal contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions that might be aggravated by fluid retention. It is unknown if NEXPLANON causes fluid retention

Contact Lenses

- Contact lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist

Monitoring

- A woman who is using NEXPLANON should have a yearly visit with her healthcare professional for a blood pressure check and for other indicated health care

Clinical Training Program

29

Warnings and Precautions (*continued*)

30

Drug-Laboratory Test Interactions

- Sex hormone-binding globulin concentrations may be decreased for the first 6 months after NEXPLANON insertion followed by gradual recovery. Thyroxine concentrations may initially be slightly decreased followed by a gradual recovery to baseline

Clinical Training Program

30

Adverse Reactions

Adverse Reactions Leading to Treatment Discontinuation

- In clinical studies of IMPLANON® (etonogestrel implant) involving 942 women, change in menstrual bleeding pattern (irregular menses) was the most common adverse reaction causing discontinuation of use of the non-radiopaque etonogestrel implant (IMPLANON)

Adverse Reactions Leading to Discontinuation of Treatment in 1% or More of Subjects in Clinical Trials of the Non-Radiopaque Etonogestrel Implant (IMPLANON)

Adverse reactions	All studies (N=942)
Bleeding irregularities ^a	11.1%
Emotional lability ^b	2.3%
Weight increase	2.3%
Headache	1.6%
Acne	1.3%
Depression ^c	1.0%

^a Includes "frequent", "heavy", "prolonged", "spotting", and other patterns of bleeding irregularity
^b Among US subjects (N=330), 6.1% experienced emotional lability that led to discontinuation
^c Among US subjects (N=330), 2.4% experienced depression that led to discontinuation

31

Clinical Training Program

31

Adverse Reactions (continued)

Adverse Reactions

- Other adverse reactions that were reported by at least 5% of subjects of the non-radiopaque etonogestrel implant clinical trials are listed below:

Adverse reactions	All studies (N=942)	Adverse reactions	All studies (N=942)
Headache	24.9%	Dysmenorrhea	7.2%
Vaginitis	14.5%	Back pain	6.8%
Weight increase	13.7%	Emotional lability	6.5%
Acne	13.5%	Nausea	6.4%
Breast pain	12.8%	Pain	6.6%
Abdominal pain	10.9%	Nervousness	5.6%
Pharyngitis	10.5%	Depression	5.5%
Leukorrhea	9.6%	Hypersensitivity	5.4%
Influenza-like symptoms	7.6%	Insertion site pain	5.2%
Dizziness	7.2%		

32

Clinical Training Program

32

Adverse Reactions *(continued)*

33

Implant Site Reactions

- In a clinical trial of NEXPLANON, in which investigators were asked to examine the implant site after insertion, the following implant site reactions were reported in 8.6% of women:

Reaction	Incidence
Erythema	3.3%
Hematoma	3.0%
Bruising	2.0%
Pain	1.0%
Swelling	0.7%

Clinical Training Program

33

Postmarketing experience for NEXPLANON: Nexplanon Observational Risk Assessment Study (NORA)

34

- A postmarketing prospective active surveillance study was conducted among patients (N=7,364) in the United States to characterize the frequency of insertion-, localization-, and removal-related events

Incorrect Insertion Types and Incidence Reported by Healthcare Professionals

Type of Incorrect Insertion Event	Number of Events	Incidence per 1,000 Insertions (95% CI)
(Initially) Unrecognized Non-insertions	1	0.1 (0.0-0.8)
Partial Insertions	27	3.7 (2.4-5.3)
Deep Insertions	65	8.8 (6.8-11.2)
Injury to nerve or blood vessel	1	0.1 (0.0-0.8)
Implant located within muscle	2	0.3 (0.0-1.0)
Implant located adjacent to fascial tissue	56	7.6 (5.8-9.9)
Implant not palpable	6	0.8 (0.3-1.8)

Clinical Training Program

34

Postmarketing experience for NEXPLANON:
Nexplanon Observational Risk Assessment Study (NORA) (continued)

- Implant removal information from both healthcare professionals and patients was collected for 5,159 patients (70% of the study population). Of these patients, data were available from healthcare professionals regarding 4,373 removal procedures. Healthcare professionals reported removal-related difficulties or complications in 1.5% of removal procedures, which are summarized in the following table:

Removal-related Events Reported by Healthcare Professionals

Removal Related Events	Number of Events	Incidence per 1,000 Removals (95% CI)
Any Event [†]	60	13.7 (10.5-17.6)
Encased in Fibrotic Tissue	29	6.6 (4.4-9.5)
Implant Too Deep	11	2.5 (1.3-4.5)
Implant Migrated [‡]	6	1.4 (0.5-3.0)
Multiple Attempts Required	13	3.0 (1.8-5.1)
Other [§]	14	3.2 (1.8-5.4)

[†]Limited to one event per removal procedure.

[‡]Only local migrations within the arm reported.

[§]Other included fragmented or bent implants, patient related issues, wound care required, two incisions required, and difficulty identifying end of device.

35

Clinical Training Program

35

Postmarketing experience for NEXPLANON:
Nexplanon Observational Risk Assessment Study (NORA) (continued)

Adverse Reactions Reported by Patients at Implant Insertion and after Removal

Patient Reported Adverse Reactions	At Insertion		After Removal	
	N=7,384	Incidence per 1,000 insertions (95% CI)	N=7,384	Incidence per 1,000 insertions (95% CI)
Any Event [†]	49	6.7 (4.9-8.8)	42 [‡]	5.7 (4.1-7.7)
Pins and Needles/Numbness (arm/hand/fingers)	17	2.3 (1.4-3.7)	24	3.3 (2.1-4.9)
Severe Pain	10	1.4 (0.7-2.5)	11	1.5 (0.8-2.7)
Altered Strength/Movement	3	0.4 (0.1-1.2)	6	1.1 (0.5-2.1)
Injury to Blood Vessels or Blood Clots in Arm [§]	2	0.3 (0-1.0)	--	--
Other [¶]	22	3.0 (1.9-4.5)	18	2.4 (1.5-3.9)

[†]Limited to one event per woman.

[‡]Based on 3,447 questionnaires.

[§]No blood clots were observed during the study.

[¶]Other included lookback or insertion site pain, soreness, tenderness, dermatological changes, itching, bruising, and infection; local migrations within the arm, and physical damage to the implant (e.g., fractured or bent implant).

36

Clinical Training Program

36

Adverse Reactions From Postmarketing Spontaneous Reports

37

Note: It is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure because these reactions are reported voluntarily from a population of uncertain size

The following additional adverse reactions were identified during the post-approval use of IMPLANON® (etonogestrel implant) and NEXPLANON

- *Gastrointestinal disorders:* constipation, diarrhea, flatulence, vomiting
- *General disorders and administration site conditions:* edema, fatigue, implant site reaction, pyrexia
- *Immune system disorders:* anaphylactic reactions
- *Infections and infestations:* rhinitis, urinary tract infection
- *Investigations:* clinically relevant rise in blood pressure, weight decreased
- *Metabolism and nutrition disorders:* increased appetite
- *Musculoskeletal and connective tissue disorders:* arthralgia, musculoskeletal pain, myalgia
- *Nervous system disorders:* convulsions, migraine, somnolence
- *Pregnancy, puerperium and perinatal conditions:* ectopic pregnancy
- *Psychiatric disorders:* anxiety, insomnia, decreased libido
- *Renal and urinary disorders:* dysuria
- *Reproductive system and breast disorders:* breast discharge, breast enlargement, ovarian cyst, pruritus genital, vulvovaginal discomfort
- *Skin and subcutaneous tissue disorders, angioedema:* aggravation of angioedema and/or aggravation of hereditary angioedema, alopecia, chloasma, hypertichosis, pruritus, rash, seborrhea, urticaria
- *Vascular disorders:* hot flush

Clinical Training Program

37

Adverse Reactions From Postmarketing Spontaneous Reports (continued)

38

Reported complications related to insertion or removal of the etonogestrel implants include vasovagal reactions (e.g., hypotension, dizziness, or syncope), bruising, slight local irritation, pain, itching, fibrosis at the implant site, paresthesia or paresthesia-like events, scarring, and abscesses. Implant expulsions and migrations also have been reported. In some cases, implants have migrated to the chest wall or into the vasculature, including the pulmonary artery. Some cases of implants migrating to the pulmonary artery presented with symptoms of chest pain and/or respiratory disorders (e.g., dyspnea, cough, or hemoptysis); other cases have been reported as asymptomatic. In-patient surgical interventions might be necessary when removing implants associated with complications

Clinical Training Program

38

Drug Interactions

- **Substances decreasing the plasma concentrations of hormonal contraceptives (HCs) and potentially diminishing the efficacy of HCs:** Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the plasma concentrations of HCs and potentially diminish the effectiveness of HCs or increase breakthrough bleeding
- Interactions between HCs and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Counsel women to use an alternative non-hormonal method of contraception or a back-up method when enzyme inducers are used with HCs, and to continue back-up non-hormonal contraception for 28 days after discontinuing the enzyme inducer to ensure contraceptive reliability
- **Substances increasing the plasma concentrations of HCs:** Co-administration of certain HCs and strong or moderate CYP3A4 inhibitors such as itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase the serum concentrations of progestins, including etonogestrel

39

Drug Interactions (*continued*)

Selection of drugs or products that may decrease the effectiveness of NEXPLANON or increase breakthrough bleeding

Efavirenz	Bosentan	Rifampicin	Aprepitant
Phenytoin	Felbamate	Topiramate	St. John's wort
Barbiturates	Griseofulvin	Rifabutin	
Carbamazepine	Oxcarbazepine	Rufinamide	

Selection of drugs whose plasma concentrations may change because of NEXPLANON

Cyclosporine (increased)	Lamotrigine (decreased)		
--------------------------	-------------------------	--	--

40

Drug Interactions (*continued*)

41

HIV/HCV protease inhibitors and non-nucleoside reverse transcriptase inhibitors

- Significant changes (increase or decrease) in the plasma levels of progestin have been noted in some cases of co-administration with:
 - HIV protease inhibitors:
 - Decrease e.g. nelfinavir, nintonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, and tipranavir/ritonavir
 - Increase e.g. indinavir and atazanavir/ritonavir
 - HCV protease inhibitors
 - Decrease e.g. boceprevir and telaprevir
 - Non-nucleoside reverse transcriptase inhibitors
 - Decrease e.g. nevirapine, efavirenz
 - Increase e.g. etravirine
- These changes may be clinically relevant in some cases. Consult the Prescribing Information of anti-viral and anti-retroviral concomitant medications to identify potential interactions

HIV = human immunodeficiency virus; HCV = hepatitis C virus

Clinical Training Program

41

Use in Specific Populations

42

Exposure to NEXPLANON during pregnancy

- NEXPLANON is contraindicated during pregnancy because there is no need for pregnancy prevention in a woman who is already pregnant
- Epidemiologic studies and meta-analyses have not shown an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb-reduction defects) following maternal exposure to low dose combined hormonal contraceptives (CHCs) prior to conception or during early pregnancy
- No adverse development outcomes were observed in pregnant rats and rabbits with the administration of etonogestrel during organogenesis at doses of 315 or 781 times the anticipated human dose (60 µg/day)
- NEXPLANON should be removed if maintaining a pregnancy

Clinical Training Program

42

Use in Specific Populations (continued)

Exposure to NEXPLANON during lactation

- Small amounts of contraceptive steroids and/or metabolites, including etonogestrel are present in human milk
- No significant adverse effects have been observed in the production or quality of breast milk, or on the physical and psychomotor development of breastfed infants
- Hormonal contraceptives, including etonogestrel, can reduce milk production in breastfeeding mothers. This is less likely to occur once breastfeeding is well-established; however, it can occur at any time in some women
- When possible, advise the nursing mother about both hormonal and non-hormonal contraceptive options, as steroids may not be the initial choice for these patients. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NEXPLANON and any potential adverse effects on the breastfed child from NEXPLANON or from the underlying maternal condition

43

Use in Specific Populations (continued)

Pediatric Use

- Safety and efficacy of NEXPLANON have been established in women of reproductive age. Safety and efficacy of NEXPLANON are expected to be the same for postpubertal adolescents. However, no clinical studies have been conducted in women less than 18 years of age. Use of this product before menarche is not indicated

Geriatric Use

- This product has not been studied in women over 65 years of age and is not indicated in this population

Hepatic Impairment

- No studies were conducted to evaluate the effect of hepatic disease on the disposition of NEXPLANON. The use of NEXPLANON in women with active liver disease is contraindicated

44

Clinical Training Program

Use in Specific Populations (*continued*)

45

Overweight Women

- The effectiveness of the etonogestrel implant in women who weighed more than 130% of their ideal body weight has not been defined because such women were not studied in clinical trials
- Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion
- Therefore, it is possible that NEXPLANON may be less effective in overweight women, especially in the presence of other factors that decrease serum etonogestrel concentrations, such as the concomitant use of hepatic enzyme inducers

Clinical Training Program

45

NEXPLANON® (etonogestrel implant) 68 mg Radiopaque

46

Insertion, localization, removal, and reinsertion

 ORGANON

Overview of section contents

- Insertion of NEXPLANON
- Localization of NEXPLANON
- Removal and reinsertion of NEXPLANON

47

Clinical Training Program

47

NEXPLANON® (etonogestrel implant) 68 mg Radiopaque

Insertion

48

 ORGANON

Clinical Training Program

Before insertion of NEXPLANON

49

- The healthcare professional should confirm the following:
 - The woman's medical history has been obtained and a physical examination, including a gynecologic examination, has been performed
 - The woman is not pregnant and has no other contraindication to NEXPLANON
 - The woman understands the benefits and risks of NEXPLANON
 - The woman has received a copy of the Patient Labeling included in the packaging
 - The woman does not have allergies to the antiseptic and/or anesthetic to be used during insertion

Clinical Training Program

49

Equipment needed to insert NEXPLANON

50

- Insert NEXPLANON under aseptic conditions
- The following equipment is needed for the implant insertion:
 - An examination table for the woman to lie on
 - Sterile surgical drapes
 - Sterile gloves
 - Antiseptic solution
 - Surgical marker
 - Local anesthetic
 - Needles and syringe
 - Sterile gauze
 - Adhesive bandage
 - Pressure bandage



Image supplied for display purposes.

Clinical Training Program

50

Position woman prior to insertion



Have the woman lie on her back on the examination table with her non-dominant arm flexed at the elbow and externally rotated so that her hand is underneath her head (or as close as possible)

To help make sure the implant is inserted just under the skin, the healthcare professional should be positioned to see the advancement of the needle by viewing the applicator from the side and not from above the arm. From the side view, the insertion site and the movement of the needle just under the skin can be clearly visualized

51

Clinical Training Program

51

Identify the insertion site

- Identify the insertion site, which is at the inner side of the non-dominant upper arm. The insertion site is overlying the triceps muscle about 8-10 cm from the medial epicondyle of the humerus and 3-5 cm posterior to (below) the sulcus (groove) between the biceps and triceps muscles
- This location is intended to avoid the large blood vessels and nerves lying within and surrounding the sulcus. If it is not possible to insert the implant in this location (e.g., in women with thin arms), it should be inserted as far posterior from the sulcus as possible

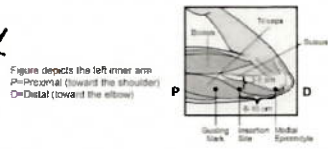
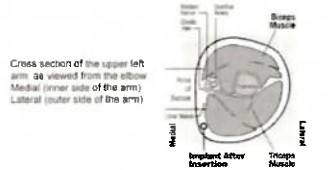


Figure depicts the left inner arm. P=Proximal (toward the shoulder) D=Distal (toward the elbow)



Cross section of the upper left arm viewed from the elbow. Medial (inner side of the arm) Lateral (outer side of the arm)

52

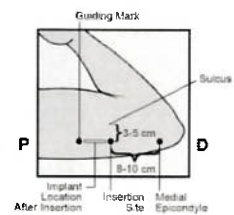
Clinical Training Program

52

Mark the insertion site

53

- Make two marks with a surgical marker:
 - First, mark the spot where the etonogestrel implant will be inserted
 - Second, mark a spot at 5 cm proximal (toward the shoulder) to the first mark
 - This second mark (guiding mark) will later serve as a direction guide during insertion
 - After marking the arm, confirm the site is in the correct location on the inner side of the non-dominant arm



For illustrative purposes
Figure depicts the left inner arm
P=Proximal (toward the shoulder)
D=Distal (toward the elbow)

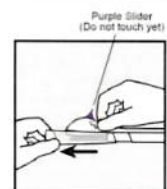
Clinical Training Program

53

Inserting NEXPLANON

54

- To begin the insertion procedure, clean the skin from the insertion site to the guiding mark with an antiseptic solution
- Anesthetize the insertion area (for example, with anesthetic spray or by injecting 2 mL of 1% lidocaine just under the skin along the planned insertion tunnel)
- Remove the sterile preloaded disposable NEXPLANON applicator containing the implant from its blister packaging. Prior to use, visually inspect the packaging for breaches of integrity or damage (e.g., torn, punctured, etc.). If the packaging has any visual damage that could compromise sterility, do not use the product
- Hold the applicator just above the needle at the textured surface area and remove the transparent protection cap by sliding it horizontally in the direction of the arrow away from the needle. If the cap does not come off easily, the applicator should not be used
- You should see the white colored implant by looking into the tip of the needle
- **Do not touch the purple slider until you have fully inserted the needle subdermally, as doing so will retract the needle and prematurely release the implant from the applicator**
- If the purple slider is released prematurely, restart the procedure with a new applicator

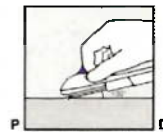
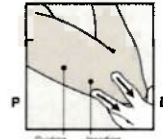


Clinical Training Program

54

Inserting NEXPLANON (continued)

- With your free hand, stretch the skin around the insertion site towards the elbow
- The implant should be inserted subdermally just under the skin
- To help make sure the implant is inserted just under the skin, you should position yourself to see the advancement of the needle by viewing the applicator from the side and not from above the arm. From the side view, you can clearly see the insertion site and the movement of the needle just under the skin
- Puncture the skin with the tip of the needle slightly angled less than 30°



For illustrative purposes.
Figures depict the left inner arm.
P=Proximal (toward the shoulder)
D=Distal (toward the elbow)

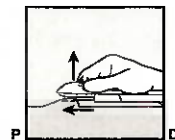
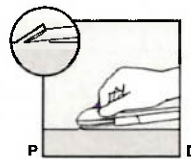
55

Clinical Training Program

55

Inserting NEXPLANON (continued)

- Insert the needle until the bevel (slanted opening of the tip) is just under the skin (and no further). If you inserted the needle deeper than the bevel, withdraw the needle until only the bevel is beneath the skin
- Lower the applicator to a nearly horizontal position
- To facilitate subdermal placement, lift the skin with the needle while sliding the needle to its full length
- You may feel slight resistance but do not exert excessive force
- If the needle is not inserted to its full length, the implant will not be inserted properly
- If the needle tip emerges from the skin before needle insertion is complete, the needle should be pulled back and be readjusted to subdermal position before completing the insertion procedure



For illustrative purposes.
Figures depict the left inner arm.
P=Proximal (toward the shoulder)
D=Distal (toward the elbow)

56

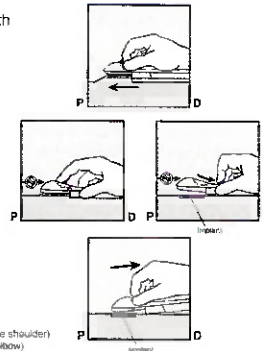
Clinical Training Program

56

Inserting NEXPLANON (continued)

57

- Keep the applicator in the same position with the needle inserted to its full length. If needed, you may use your free hand to stabilize the applicator.
- Unlock the purple slider by pushing it slightly down.
- Move the slider fully back until it stops.
- **Do not move** (↔) **the applicator while moving the purple slider**.
- The implant is now in its final subdermal position, and the needle is locked inside the body of the applicator.
- The applicator can now be removed.
- **If the applicator is not kept in the same position during this procedure or if the purple slider is not moved fully back until it stops, the implant will not be inserted properly and may protrude from the insertion site.**
- If the implant is protruding from the insertion site, remove the implant and perform a new procedure at the same insertion site using a new applicator. **Do not push the protruding implant back into the incision.**



P=Proximal (toward the shoulder)
D=Distal (toward the elbow)

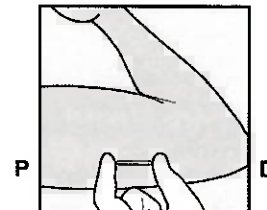
Clinical Training Program

57

Verify the presence of the implant

58

- Apply a small adhesive bandage over the insertion site.
- **Always verify the presence of the implant in the woman's arm immediately after insertion by palpation.**
- By palpating both ends of the implant, you should be able to confirm the presence of the 4-cm rod.



For illustrative purposes, Figure depicts the left inner arm.
P=Proximal (toward the shoulder)
D=Distal (toward the elbow)

Clinical Training Program

58

After implant insertion

- Request that the woman palpate the implant
- Apply a pressure bandage with sterile gauze to minimize bruising
- The woman may remove the pressure bandage in 24 hours and the small adhesive bandage over the insertion site after 3 to 5 days
- Complete the PATIENT CHART LABEL and affix it to the woman's medical record
- The applicator is for single use only and should be disposed in accordance with the Centers for Disease Control and Prevention guidelines for handling of hazardous waste

59

Clinical Training Program

59

If the implant is not palpable after insertion

- **If you cannot feel the implant or are in doubt of its presence, the implant may not have been inserted or it may have been inserted deeply:**
 - Check the applicator. The needle should be fully retracted and only the purple tip of the obturator should be visible
 - Use other methods to confirm the presence of the implant. Given the radiopaque nature of the implant, suitable methods for localization are
 - 2-dimensional X-ray
 - X-ray computerized tomography (CT scan)
 - Ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater)
 - Magnetic resonance imaging (MRI)
- If these methods fail, call the Organon Service Center at 1-844-674-3200 for information on the procedure for measuring etonogestrel blood levels which can be used for verification of the presence of the implant
- **Until the presence of the implant has been verified, the woman should be advised to use a non-hormonal contraceptive method, such as condoms**
- Deeply-placed implants should be localized and removed as soon as possible to avoid the potential for distant migration

60

Clinical Training Program

60

Localization is essential

- A non-palpable implant should always be located prior to attempting removal
- Localization begins with palpation
- If the implant is not palpable after insertion, confirm its presence in the arm with imaging techniques. Regardless of chosen technique for confirmation of presence, removal of implants with ultrasound guidance is recommended:
 - 2-dimensional X-ray
 - Ultrasound scanning with a high-frequency linear array transducer (10 MHz or greater)
 - X-ray CT scan
 - Magnetic resonance imaging

63

CT = computed tomography

Clinical Training Program

63

Localization is essential *(continued)*

- Reports of implant migration within the arm may have been related to deep insertion. Postmarketing reports of implants located within the vessels of the arm and the pulmonary artery also may have been related to deep insertions or intravascular insertions
- Inserting an implant more deeply than subdermally (a deep insertion) may preclude palpation and localization, making removal difficult or impossible

64

Clinical Training Program

64

Localization is essential *(continued)*

65

- If the implant cannot be found in the arm after comprehensive localization attempts, consider applying imaging techniques to the chest as events of migration to the pulmonary vasculature have been reported. If the implant is located in the chest, surgical or endovascular procedures may be needed for removal; healthcare professionals familiar with the anatomy of the chest should be consulted
- If at any time these imaging methods fail to locate the implant, etonogestrel blood level determination can be used for verification of the presence of the implant. For details on etonogestrel blood level determination, call 1-844-674-3200 for further instructions
- If the woman is ever unsure about whether the implant is present (she is unable to palpate the implant), she should contact her healthcare professional immediately and use a non-hormonal birth control method (such as condoms) until the healthcare professional confirms that the implant is in place

Clinical Training Program

65

Radiopaque implant X-ray visualization

66



Adapted with permission from Mansour D et al.
1. Mansour D et al. *Contraception*. 2010;82(3):243-249

© Organon group of companies. All rights reserved.

Clinical Training Program

66

Ultrasound localization

- **Ultrasound**
 - Should be performed by a healthcare professional with proper equipment and who is familiar with implant localization procedures¹
 - High frequency linear array transducer¹
 - ≥ 10 MHz²
 - Set ultrasound focus at a superficial level (increases visibility of shadow)^{1,2}
 - With correct technique and transducer, most implants can be located¹
- **Ultrasound characteristics^{3,4}**
 - Sharp acoustic shadow below the implant in the transverse position
 - Implant is a small echogenic spot (2 mm) when viewed in transverse position

1. Shulman LP et al. *Contraception*. 2008;73(4):325-330. 2. Welling M. *J Fam Plann Reprod Health Care*. 2005;31(4):320-321. 3. Merki-Feld GS et al. *Contraception*. 2001;63(6):325-328. 4. Westerway SC et al. *Aust N Z J Obstet Gynaecol*. 2003;43(5):346-350.

67

Clinical Training Program

67

Implants localized by ultrasound



1. Shulman LP et al. *Contraception*. 2008;73(4):325-330.

68

Clinical Training Program

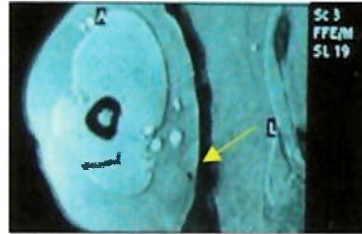
68

Clinical Training Program

Implant localized by MRI

69

- On MRI, the properly placed radiopaque implant appears as a hypointense area
 - Important to differentiate from blood vessels¹



Adapted with permission from Shulman LP, Gabnel H¹

MRI = magnetic resonance imaging

1. Merki-Feld GS, et al. *Contraception* 2001;63(6):325-328; 2. Shulman LP, Gabnel H. *Contraception* 2006;73(4):325-330

Clinical Training Program

69

Implant localized by MRI (continued)¹

70

- Improperly placed implant
 - Deep placement into biceps muscle



Adapted with permission from Shulman LP, Gabnel H¹

MRI = magnetic resonance imaging

1. Shulman LP, Gabnel H. *Contraception* 2006;73(4):325-330

Clinical Training Program

70

If imaging methods fail to locate the implant

- A serum etonogestrel assay can be requested to confirm presence of NEXPLANON but not its location
- For details on etonogestrel blood level determination, call 1-844-674-3200 for further instructions

71

Clinical Training Program

71

NEXPLANON® (etonogestrel implant) 68 mg Radiopaque

Removal and reinsertion

72

 ORGANON

Preparation

73

- Removal of the implant should only be performed under aseptic conditions by a healthcare professional who is familiar with the removal technique. **If you are unfamiliar with the removal technique, call 1-844-674-3200 for further information**
- Before initiating the removal procedure, the healthcare professional should assess the location of the implant and carefully read the instructions for removal
- The exact location of the implant in the arm should be verified by palpation
- If the implant is not palpable, consult the medical record and, if not available, ask the woman to verify the arm which contains the implant
- If the implant cannot be palpated, it may be deeply located or have migrated. Consider that it may lie close to vessels and nerves
- Removal of non-palpable implants should only be performed by a healthcare professional experienced in removing deeply placed implants and familiar with localizing the implant and the anatomy of the arm. Call 1-844-674-3200 for further information

Clinical Training Program

73

Equipment needed to remove NEXPLANON

74

- The following equipment is needed for removal of the implant:
 - An examination table for the woman to lie on
 - Sterile surgical drapes
 - Sterile gloves
 - Antiseptic solution
 - Surgical marker
 - Local anesthetic
 - Needles and syringe
 - Sterile scalpel
 - Forceps (straight and curved mosquito)
 - Skin closure
 - Sterile gauze
 - Pressure bandage



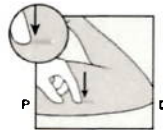
Image supplied by Organon, Inc. 0013

Clinical Training Program

74

Removing NEXPLANON

- Confirm that the woman does not have allergies to the antiseptic or anesthetic to be used
- Have the woman lie on her back on the table. The arm should be positioned with the elbow flexed and the hand underneath the head (or as close as possible)
- Locate the implant by palpation. Push down the end of the implant closest to the shoulder to stabilize it; a bulge should appear indicating the tip of the implant that is closest to the elbow
- **If the tip does not pop up, removal of the implant may be more challenging and should be performed by professionals experienced with removing deeper implants. Call 1-844-674-3200 for further information**
- Mark the distal end (end closest to the elbow), for example, with a surgical marker



For illustrative purposes, Figure depicts the left inner arm.
P=Proximal (toward the shoulder)
D=Distal (toward the elbow)

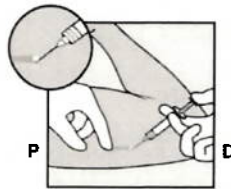
75

Clinical Training Program

75

Removing NEXPLANON (continued)

- Clean the site with an antiseptic solution
- Anesthetize the site, for example, with 0.5 to 1 mL 1% lidocaine, where the incision will be made
 - Be sure to inject the local anesthetic **under** the implant to keep the implant close to the skin surface
 - Injection of local anesthetic **over** the implant may make removal more difficult



For illustrative purposes, Figure depicts the left inner arm.
P=Proximal (toward the shoulder)
D=Distal (toward the elbow)

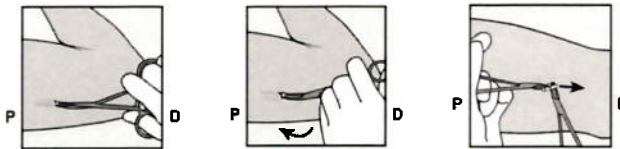
76

Clinical Training Program

76

Removing NEXPLANON (continued)

- If the tip of the implant does not become visible in the incision, insert forceps (preferably curved mosquito forceps, with the tips pointed up) superficially into the incision
- Gently grasp the implant and then flip the forceps over into your other hand. With a second pair of forceps carefully dissect the tissue around the implant and grasp the implant
- The implant can then be removed
- **If the implant cannot be grasped, stop the procedure and refer the woman to a healthcare professional experienced with complex removals or call 1-844-674-3200**



For illustrative purposes.
Figures depict the left lower arm.
P=Proximal (toward the shoulder)
D=Distal (toward the elbow)

79

Clinical Training Program

79

Removing NEXPLANON (continued)

- Confirm that the entire implant, which is 4 cm long, has been removed by measuring its length
- There have been reports of broken implants while in the patient's arm
- In some cases, difficult removal of the broken implant has been reported
- If a partial implant (less than 4 cm) is removed, the remaining piece should be removed
- If the woman would like to continue using NEXPLANON, the new implant may be inserted in the same arm and through the same incision from which the previous implant was removed if the site is in the correct location

80

Clinical Training Program

80

Clinical Training Program

After removing the implant

81

- Close the incision with a sterile adhesive wound closure
- Apply a pressure bandage with sterile gauze to minimize bruising
 - The woman may remove the pressure bandage in 24 hours and the sterile adhesive wound closure in 3 to 5 days
- The woman should restart contraception immediately after removal of the implant if continued contraceptive protection is desired

Clinical Training Program

81

Removal video

82

Removal Procedure of Palpable
NEXPLANON® (etonogestrel implant) 68 mg Radiopaque

Clinical Training Program

82

Removal of a non-palpable implant

Implant removal may be difficult or impossible if:

- Implant is not inserted correctly
- Implant is inserted too deeply
- Implant not palpable
- Implant encased in fibrous tissue
- Implant has migrated
- A non-palpable implant should always be located prior to attempting removal
- Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged
- Once the implant has been localized in the arm, the implant should be removed by a healthcare professional experienced in removing deeply placed implants and familiar with the anatomy of the arm, and the use of ultrasound guidance during the removal should be considered

83

Clinical Training Program

83

Removal of a non-palpable implant (*continued*)

- If the implant cannot be found in the arm after comprehensive localization attempts, consider applying imaging techniques to the chest as events of migration to the pulmonary vasculature have been reported
- If the implant is located in the chest, surgical or endovascular procedures may be needed for removal; healthcare professionals familiar with the anatomy of the chest should be consulted
- If the implant migrates within the arm, removal may require a minor surgical procedure with a larger incision or a surgical procedure in an operating room
- Removal of deeply inserted implants should be conducted with caution to help prevent injury to deeper neural or vascular structures in the arm and be performed by healthcare professionals familiar with the anatomy of the arm and removal of deeply inserted implants
- If you are unfamiliar or uncomfortable with the removal of deeply inserted implants, please call 1-844-674-3200 for further information

84

Clinical Training Program

84

Clinical Training Program

Replacing NEXPLANON

85

- Immediate replacement can be done after removal of the previous implant and is similar to the insertion procedure described in the insertion instructions
- The new implant may be inserted in the same arm, and through the same incision from which the previous implant was removed if the site is in the correct location; i.e., 8-10 cm from the medial epicondyle of the humerus and 3-5 cm posterior to (below) the sulcus, as described in the insertion instructions
- If the same incision is being used to insert a new implant, anesthetize the insertion site [e.g., 2 mL lidocaine (1%)] applying it just under the skin commencing at the removal incision along the 'insertion canal' and follow the subsequent steps in the insertion instructions

Clinical Training Program

85

Thank you

86

Before prescribing NEXPLANON® (etonogestrel implant) 68 mg Radiopaque, please read the Prescribing Information included in your Clinical Training Program Kit.

© 2024 Organon group of companies. All rights reserved.
ORGANON and the ORGANON Logo are trademarks of the Organon group of companies.
US-XPL-116999 02/24

 ORGANON

Toenail Removal

INGROWN TOENAILS

Madelyn Pollock

Ingrown toenails usually present with pain, redness, swelling, and sometimes discharge. It is not uncommon for patients to have attempted self-remedies. Often, the irritation is long-standing enough to cause granulation tissue to form. The great toe is virtually the only toe involved, and either the medial or lateral border of the nail may be affected.

Figure 29-1 is an algorithm for the suggested treatment of an ingrown toenail.

Removal of the toenail, either partial or total, remains the definitive treatment for bothersome ingrown nails. For recurrent episodes, ablation of the germinal matrix tissue can be used to prevent regrowth of the nail. Permanent destruction can be effected using chemicals or radiofrequency energy.

ANATOMY

Figure 29-2 illustrates the nail bed anatomy.

INDICATIONS

- Onychocryptosis (ingrown nail)
- Onychomycosis (fungal infection of the nail) with significant pain; without medical treatment, however, the fungus will recur
- Chronic, recurrent paronychia (inflammation of the nail fold)
- Onychogryposis (deformed, curved nail)

For a first occurrence, it is reasonable to remove only the offending portion of the nail and allow regrowth while educating the patient to correct all offending practices such as overtrimming nails and wearing tight-fitting shoes. If an ingrown nail recurs, permanent ablation of the portion of nail matrix causing the problem is indicated.

CONTRAINDICATIONS

- Allergy to local anesthetics (see Chapter 5, Local and Topical Anesthetic Complications).
- Bleeding diathesis.
- Diabetes mellitus and peripheral vascular disease are relative contraindications and should be considered on a case-by-case basis.
- Pregnant patients should not have phenol ablation.

EQUIPMENT AND SUPPLIES

- 5- or 10-mL syringe with long (1½-inch) needle (25 or 27 gauge).
- Local anesthetic generally *without* epinephrine (e.g., 2% lidocaine with or without sodium bicarbonate buffer to decrease the sting; see Chapter 4, Local Anesthesia). Recent research does not confirm the previous concerns that epinephrine might cause excess vasoconstriction in the digits. However, with patients at high risk, such as those with long-standing diabetes or severe peripheral vascular disease, it might be best to avoid it.
- Narrow Locke periosteal elevator (nail elevator; Fig. 29-3).

- Sterile scissors with straight blades (or an English nail splitter [Fig. 29-4] or miniblade with wedge tip).
- Wide rubber band, small Penrose drain, donut digital tourniquet (Ellman Corp.; Fig. 29-5), or a portable blood pressure cuff (tourniquets are optional but very helpful).
- Two straight hemostats.
- Silver nitrate sticks for cautery of granulation tissue (optional). Best to curette this tissue off with a reusable dermal curette.
- Alcohol swabs.
- Povidone-iodine (Betadine) solution.

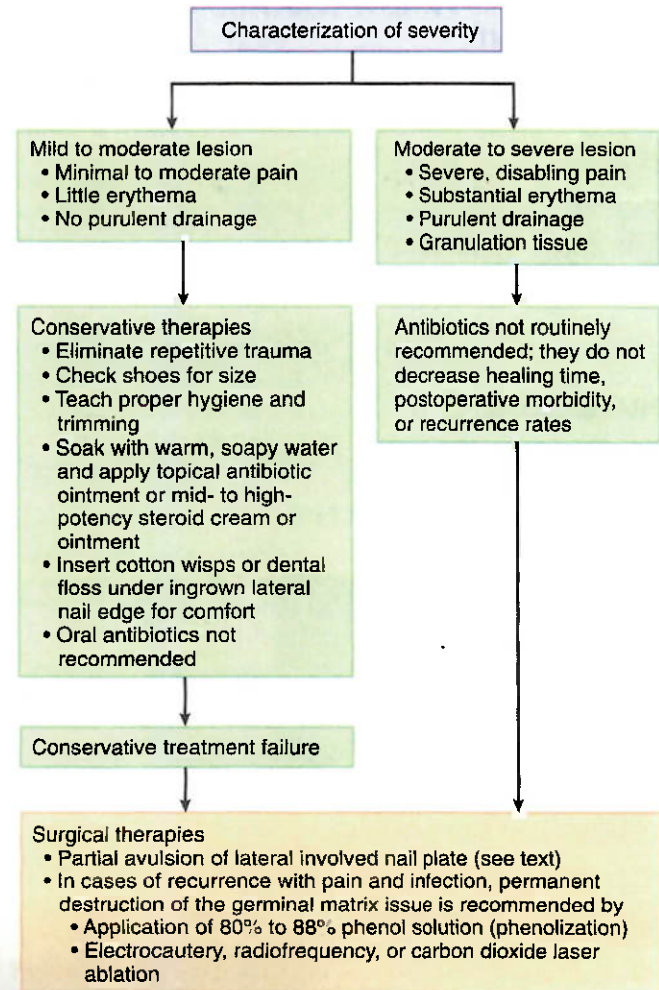


Figure 29-1 Algorithm for a suggested approach to the patient with an ingrown toenail. (Modified from Heidelbaugh JJ, Lee H: Management of the ingrown toenail. *Am Fam Physician* 79:303–308, 2009.)

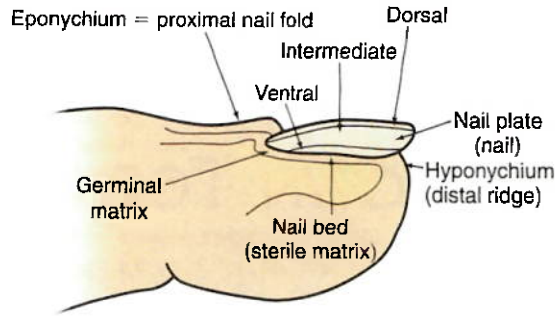


Figure 29-2 Nail bed anatomy and terminology. Also see more details in Chapter 27, Nail Bed Repair.

- Monsel's solution to control any possible bleeding after the tourniquet is removed.
- Sterile gauze and tubular gauze dressing.
- Antibiotic ointment (Polysporin or Bacitracin).
- Phenol solution (88%) and isopropyl alcohol for permanent ablation of the nail, if desired.
- As an alternative to phenol, the Ellman Surgitron (radiofrequency unit) with specially designed, Teflon-insulated matrix ablation tips (less inflammation and excellent results; see Chapter 30, Radiofrequency Surgery [Modern Electrosurgery]).

PREPROCEDURE PATIENT EDUCATION AND CONSENT

See the patient education form online at www.expertconsult.com. A signed consent is not mandatory but the patient must be well informed of the procedures and the intended outcome. A patient education handout that explains the nature of ingrown nails is helpful. Before beginning the procedure, be sure the patient understands that providing anesthesia is uncomfortable, but after that there should be no pain. There is no guarantee that removing the portion of ingrown nail will resolve the problem, but generally it will if the nails are cared for properly afterward. The major benefit to removing the toenail (or a portion of it) is pain relief, with the secondary benefit of allowing the body to heal the inflamed area.

PROCEDURE

NOTE: Nonsterile gloves may be used in this procedure.

Removal of Partial or Full Nail

1. With the patient in the supine position, *prepare* the toe with Betadine. If the patient has significant discomfort, anesthesia (step 2) can precede this step for patient comfort.



Figure 29-3 Locke periosteal elevator. **A**, Front view. **B**, Side view. **C**, Miniblade with wedge tip. (Courtesy of John L. Pfenninger, MD, The Medical Procedures Center, PC, Midland, Mich.)

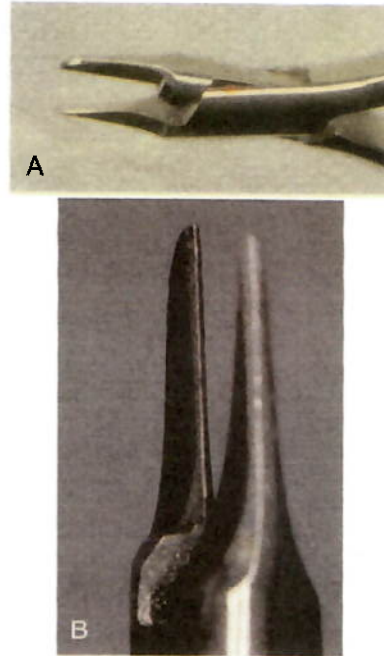


Figure 29-4 Nail splitter. **A**, Flat jaw on bottom. **B**, Beveled jaw on top. (Courtesy of John L. Pfenninger, MD, The Medical Procedures Center, PC, Midland, Mich.)

2. Administer a digital block as described in Chapter 8, Peripheral Nerve Blocks and Field Blocks.
3. Apply a tourniquet if desired. Options include the following:
 - Use a straight hemostat to firmly secure a wide rubber band or Penrose drain around the base of the toe.
 - Apply a blood pressure cuff at the calf so it will not affect the operative field. To use this method, place the cuff around the calf, elevate the foot to about a 45-degree angle at the hip, and, after 1 to 2 minutes of elevation, raise the cuff pressure to above systolic, lock the cuff so it stays inflated, and then lower the foot to the operative field. Maintain the pressure until the procedure is completed.
 - The Ellman donut tourniquets (see Fig. 29-5) are disposable and come in various sizes. After the procedure, simply cut them with scissors to remove them.
4. Identify the portion of the nail to be removed, which is at least 20% to 25% of the nail.
5. When anesthesia is achieved (5 to 10 minutes), *loosen and lift the nail to be removed* from the nail bed by using the flat, rounded blade of the scissors, a single jaw of a straight hemostat, or a narrow periosteal elevator. The elevator works best to decrease the likelihood of injury to the nail bed (see Fig. 29-3). Introduce



Figure 29-5 The Ellman digital tourniquet. (Courtesy of John L. Pfenninger, MD, The Medical Procedures Center, PC, Midland, Mich.)

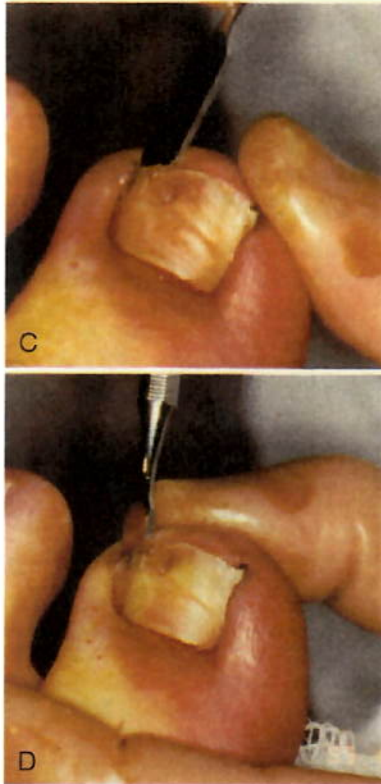
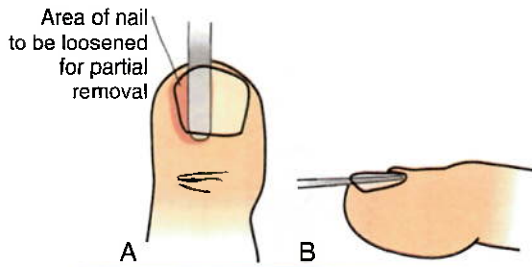


Figure 29-6 **A**, Periosteal elevator advanced all the way under the proximal nail fold. **B**, Lateral view. Advance with upward pressure on the nail with forward motion until more pressure is felt under the nail fold. **C**, Inserting the elevator. **D**, The instrument has been fully inserted, freeing the lateral portion of the nail from the nail bed. (C and D, Courtesy of John L. Pfenninger, MD, The Medical Procedures Center, PC, Midland, Mich.)

and advance the instrument with continued upward pressure against the nail plate and away from the nail bed to minimize injury and bleeding (Fig. 29-6). It is important to completely free the proximal nail at its base under the nail fold to allow removal and to expose the germinal tissue of the nail bed. Push forward gently—the elevator moves easily when under the nail. Resistance will be felt when the proximal end of the nail plate has been loosened sufficiently. Release the entire nail plate in this fashion if the entire nail is to be removed.

6. For a partial nail removal, scissors or a nail splitter (see Fig. 29-4) should be used to completely split the nail 5 to 6 mm in from the lateral or medial margin in a longitudinal direction (Fig. 29-7). A miniblade with a wedge at the tip also works well. Include the base of the nail. This requires introducing your cutting instrument beneath the proximal nail fold. Take care to protect the nail fold from damage when making this part of the incision.
7. Grasp that portion of the nail to be removed lengthwise with a straight hemostat and remove it, using a steady pulling motion with a simultaneous upward twist of the hand toward the affected side (Fig. 29-8). This twisting action ensures that the nail will be



Figure 29-7 Using the nail splitter to “cut” through the nail. Flat jaw is down, beveled side is up. (Courtesy of John L. Pfenninger, MD, The Medical Procedures Center, PC, Midland, Mich.)

rolled out from beneath the affected nail margin instead of rolling over it. If the entire nail is to be removed, the nail may be removed in two halves or in its entirety after a thorough loosening and lifting of the nail. In removing the entire nail, the forceps should apply lift and distal traction on the nail as it separates from the nail bed. Indications for total removal include onychomycosis that can cause painful pincer nails or perhaps having both the medial and lateral aspects of the nail ingrown (Fig. 29-9).

8. Remove all granulation tissue by grasping with hemostats and pulling. Light curettage with a reusable dermal curette (not as sharp as the disposables) removes any residual tissue from the nail groove. Without a tourniquet there will be significant bleeding during this portion of the procedure, especially if there is significant granulation tissue. Application of silver nitrate or Monsel's solution to the exposed nail bed will control bleeding and, with silver nitrate, discourage persistence of granulation tissue.
9. If ablation is to be performed, complete that portion at this step before the tourniquet is removed and the wound dressed (see later discussion).
10. Remove any tourniquet used.
11. Observe the area for hemostasis, using pressure as necessary. When hemostasis is obtained, dress with antibiotic ointment, non-adherent gauze pad, and tube gauze (Fig. 29-10).

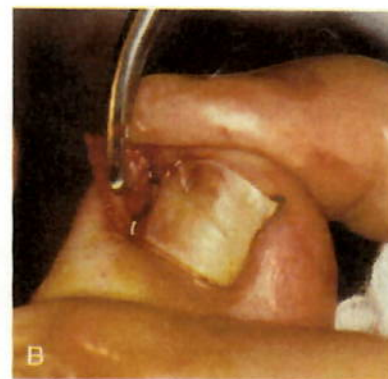
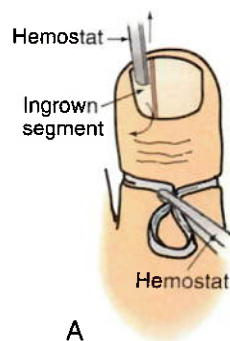


Figure 29-8 Technique for nail removal after nail has been elevated and split. **A** and **B**, Grasp that portion of the nail to be removed lengthwise with a straight hemostat, and remove it using a steady pulling motion with a simultaneous upward twist of the hand toward the affected side. (B, Courtesy of John L. Pfenninger, MD, The Medical Procedures Center, PC, Midland, Mich.)

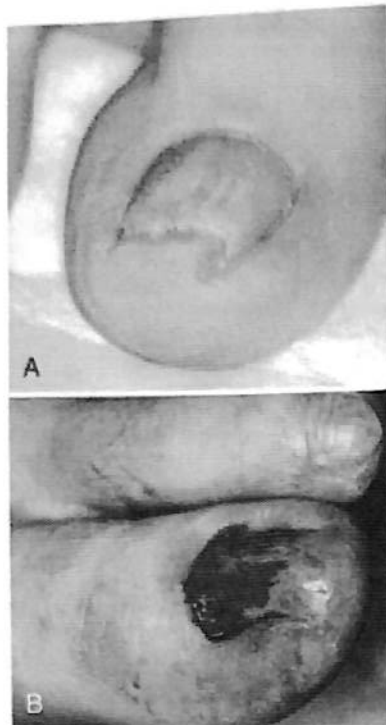


Figure 29-9 Complete removal of the toenail. **A**, Onychomycosis. **B**, Appearance after the nail has been removed. (Courtesy of John L. Pfenninger, MD, The Medical Procedures Center PC, Midland, Mich.)

Nail Bed Ablation (Matrixectomy)

If recurrent regrowth of the toenail with resulting pain or infection occurs, permanent ablation of the germinal tissue is recommended (matrixectomy).

Phenol Chemical Method

1. Remove total or partial nail as described previously. The area must be dry and not bleeding. Remove all granulation tissue.
2. Sponge the exposed nail bed dry with cotton swabs and then cauterize the germinal tissue, including that under the nail fold, by application of phenol on a cotton swab to the nail bed tissues (Fig. 29-11). It is important to achieve good hemostasis before this step so that the tissue is dry. Use caution to avoid phenol contact with normal skin. A skin hook can be helpful in elevating the skin fold from the nail matrix. Hold the phenol-dampened cotton swab in place for 3 minutes. Three separate 60-second applications with drying of the surface in between is also reported to be effective. The tissue will pale or "gray" at the area of application.



Figure 29-10 A compression dressing is applied after most toenail procedures. (Courtesy of John L. Pfenninger, MD, The Medical Procedures Center, PC, Midland, Mich.)

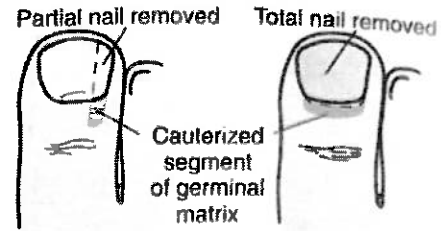


Figure 29-11 Area of nail bed to be cauterized in partial (left) and total permanent nail removal (matrixectomy) (right).

3. After 3 minutes, drip 70% isopropyl alcohol into the nail groove and swab the area to neutralize the phenol.

Radiofrequency Method

See Chapter 30, Radiofrequency Surgery (Modern Electrosurgery).

The radiofrequency method of ablation is quick and easy. Although formal studies have not been performed, it is thought that radiofrequency causes markedly less pain, swelling, and discharge than other methods. It is difficult to control liquid agents, and they tend to destroy more tissue than desired.

1. Remove whole or partial nail as described previously.
2. Place antenna lead under the heel of foot.
3. Turn unit to "Hemo-part rect" (hemostasis/coagulation setting) and set the power at 2 to 3.
4. Insert wide or narrow insulated matrixectomy tip over nail matrix, under the eponychium as far as it will go, insulated side up (Fig. 29-12). These electrodes are insulated with Teflon on one surface to prevent damage to the undersurface of the

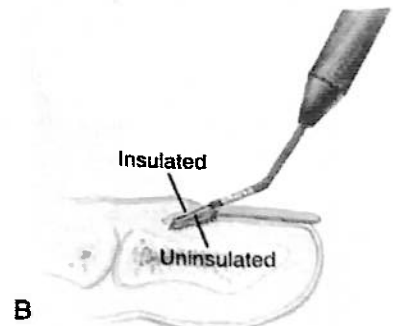
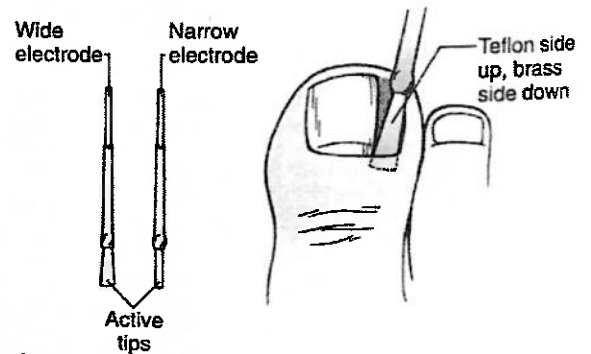


Figure 29-12 Application of nail matrixectomy electrode with Teflon-coated side up: top (A) and lateral (B) views. The lateral 25% of the nail has been removed.

proximal nail fold while ablating the nail matrix with the un-insulated surface beneath. A slight upward pressure should be exerted against the undersurface of the nail fold to ensure that no pressure is exerted on the underlying matrix. The field must be free of blood. For proper effect, there should be a slight gap between electrode and matrix.

5. Apply power and slowly withdraw the electrode pulling distally. Contact should last for only 1 to 2 seconds, and a sizzling sound should be heard. This step can be repeated once or twice over the same area after a 15-second cooling period. If the entire nail matrix is to be ablated, multiple applications are necessary with side-to-side placements of the electrode; slight overlapping should not be a problem. Caution: two to three passes (maximum) over the same tissue area are sufficient. Avoid overtreatment. The matrix is very thin and bone lies immediately beneath it. Overtreatment can cause burns with prolonged healing times of up to 6 to 8 weeks. It is often easier to use the narrower electrode because the power level can be set lower and it affords better control. Side-by-side applications may then be needed even for partial nail removal.

Other Methods

Sodium hydroxide (10% solution) and CO₂ laser are also described in the literature for use in matrixectomy. Sodium hydroxide is applied similarly to phenol and is thought by some to decrease postoperative drainage and speed healing compared with the phenol method. It is not as commonly used in the United States as phenol. The CO₂ laser requires special equipment and training and is usually operated by dermatologists or podiatrists.

When either partial or complete ablation is accomplished apply antibiotic ointment to the nail bed, cover with a sterile gauze pressure dressing, remove the tourniquet, and wrap with a tubular gauze dressing. Coban, CoFlex, and other similar self-adherent dressings provide a comfortable pressure wrap that holds the dressing in place.

SAMPLE OPERATIVE REPORT

Informed consent obtained: Yes _____ No _____
 Site (circle one): Left Right Medial Lateral great toe
 Anesthesia: Digital block _____% Lidocaine without epi _____mL
 Tourniquet used: Yes _____ No _____
 Nail removal (circle one): Complete Partial
 Granulation tissue removed: Yes _____ No _____ Cautery Y
 Chem/elect N
 Ablation performed: No _____ Yes _____ (Phenol radioablation
 [tip _____ wide _____ narrow, setting _____])
 Other _____

Hemostasis was obtained.

The wound was dressed with antibiotic ointment and covered with a sterile dressing. The patient was given oral and written instructions in postoperative management. The patient tolerated the procedure without complications.

COMMON ERRORS

- Inadequate anesthesia resulting in patient discomfort. Ensure full anesthesia before starting procedure. Anesthetizing the toe generally requires 6 to 10 mL of lidocaine.
- Prolonged use of tourniquet resulting in ischemia. This can be avoided by foregoing use of the tourniquet in patients with possible decreased circulation and limiting the time under tourniquet pressure for all cases.
- Laceration of nail bed during lifting or splitting of the nail. This can result in difficult-to-control bleeding at the nail edge and scarring, leading to deformity of the nail when it grows back. Position any cutting instrument used such that the nail bed is protected during the incision. Use of the miniblade (also called

Beaver or wedge blade), which has no sharp edge on the portion of the blade facing the nail bed, can help.

- Retained portion of nail results in persistent pain after procedure. Avoid this by careful examination of the nail fold and the removed portion of the nail after the procedure. A feathery edge of nail where it abuts the nail growth plate demonstrates that all the nail was removed. If necessary, explore the area and remove retained fragments.

COMPLICATIONS

- Infections (treat with soaking and appropriate antibiotics)
- Bleeding (generally controlled with pressure)
- Regrowth of nail and return of symptoms (regrowth rate after phenol cauterization is 4% to 25%; for radiofrequency, <5%)
- Excessive tissue destruction with radiofrequency unit, leading to prolonged healing time and possible osteomyelitis

POSTPROCEDURE PATIENT EDUCATION AND MANAGEMENT

The foot should be rested and preferably elevated during the first 12 to 24 hours. Because phenol ablates the nerve endings of the nail plate, pain should be absent when it is used. There is minimal pain with the radiofrequency unit. Nonsteroidal anti-inflammatory drugs or acetaminophen may be taken for discomfort.

The dressing should be changed in 12 to 24 hours, at which point ambulation can be encouraged; however, vigorous exercise should be avoided for 1 week. The toe should be washed with soap and water at least twice daily (depending on soiling) until healed. Topical antibiotic ointment should be applied and the area kept clean until healed. Tell the patient to expect a sterile exudate from the nail bed for several weeks. Explaining that the wound will "heal like a burn" can help patients understand that the exudate is not an indication of infection. Emphasize proper nail hygiene to prevent further recurrences (Fig. 29-13).

CPT/BILLING CODES

- 11730 Nail removal, partial or complete
 11732 Avulsion each additional nail
 11750 Permanent nail removal (matrixectomy), partial or complete

ICD-9-CM DIAGNOSTIC CODES

- 110.1 Onychomycosis
 703.0 Ingrown toenail
 703.8 Onychogryphosis

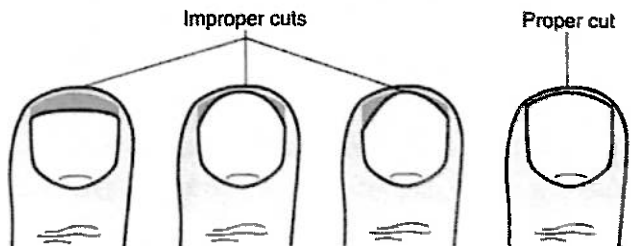
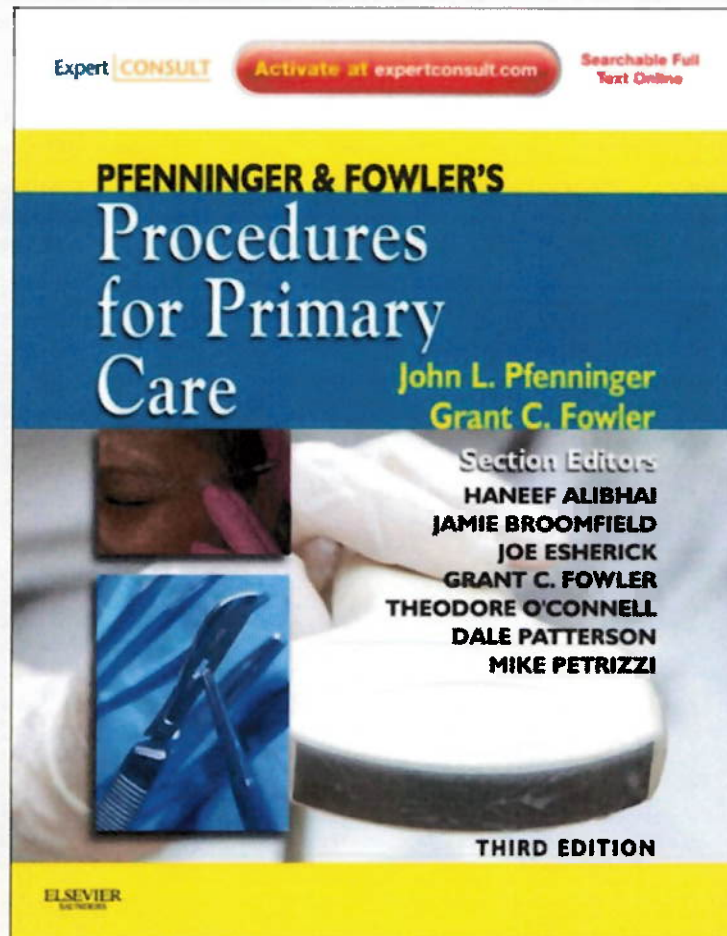


Figure 29-13 Examples of improper and proper nail care. Trim the nail flat and straight across and not too short. (Redrawn from Heideitsaun JJ, Lee H. Management of the ingrown toenail. *Ann Fam Physician* 79:303-308, 2009.)

Diagrams and Pictures Adapted from : Pfenninger JL, Fowler GC. *Pfenninger and Fowler's Procedures for Primary Care*. 3rd ed. Saunders; 2011



Shave/Punch Biopsies

Shave and Punch Biopsies

- Biopsy Indications
 - Diagnosis of rashes or blisters involving the dermis (drug reaction, cutaneous lymphoma, lupus, pemphigus) or processes involving the subcutis (erythema nodosum, panniculitis)
 - Diagnosis and treatment of atypical moles and pigmented lesions (dysplastic nevi, malignant melanoma)
- Choosing Shave
 - Flat, thin specimen
 - Appropriate for predominantly epidermal lesions
 - warts, papillomas, skin tags, superficial BCC or SCC, seborrheic or actinic keratosis
 - Not appropriate for suspicious pigmented lesions
 - Preferable to techniques that require sutures for the foot due to excessive tension
- Choosing Punch
 - Cylindrical specimen
 - May be used for lesions that require dermal or subcutaneous tissue for diagnosis
 - inflammatory/bullous lesions, dysplastic or complex nevi, panniculitis, scalp/hair follicle biopsies
 - Bullae – perilesional biopsy
 - Suspected neoplasm – thickest area of lesions that can be obtained with narrow margins
 - Limitations – may not provide wide enough sample in suspect pigmented lesions which can affect staging/prognosis
- Lesions suspicious for melanoma
 - ABCDE (EFG)
 - Glasgow 7 point checklist/ revised
 - Ugly duckling sign

TABLE 2

Clinical Tools for Identifying Cutaneous Malignant Melanoma

Tool	Criteria	Use
ABCDE (asymmetry, border, color, diameter, evolving) mnemonic	Half of the lesion is different than the other half Irregular or poorly defined border Varied color from one area to another; different shades of tan, brown, black, and sometimes red, white, or blue in the same lesion Larger than 6 mm (pencil eraser) Mole is changing size, shape, or color	Primarily a patient education tool; presence of any one element should prompt evaluation
EFG (elevated, firm, growing) mnemonic: add to ABCDE mnemonic to help identify nodular melanoma	New elevated or thickened lesion Firmness on palpation Lesion grows continuously over 1 month	If any positive findings, consider biopsy
Glasgow 7-point checklist	Change in size of lesion Irregular pigmentation Irregular border Inflammation Itch or altered sensation Larger than other lesions (diameter > 7 mm) Oozing or crusting of lesion	Used by primary care physicians; if three or more elements are present, refer or perform biopsy
Revised 7-point checklist	Major features (2 points each): Change in size of lesion Irregular pigmentation Irregular border Minor features (1 point each): Inflammation Itch or altered sensation Larger than other lesions (> 7 mm diameter) Oozing or crusting of the lesion	Used by primary care physicians to identify clinically significant lesions for biopsy; score of 3 or more warrants a referral or biopsy
Ugly duckling sign	Mole that does not follow the pattern of or look like the surrounding moles on a person's body	Used by patients or physicians to identify possible melanoma

Information from references 8-14.

Lauters R, Brown AD, Harrington KA. Melanoma: Diagnosis and Treatment. Am Fam Physician. 2024 Oct;110(4):367-377. PMID: 39418569.

TABLE 2

Clinical Tools for Identifying Cutaneous Malignant Melanoma

Tool	Criteria	Use
ABCDE (asymmetry, border, color, diameter, evolving) mnemonic	<p>Half of the lesion is different than the other half</p> <p>Irregular or poorly defined border</p> <p>Varied color from one area to another; different shades of tan, brown, black, and sometimes red, white, or blue in the same lesion</p> <p>Larger than 6 mm (pencil eraser)</p> <p>Mole is changing size, shape, or color</p>	Primarily a patient education tool; presence of any one element should prompt evaluation
EFG (elevated, firm, growing) mnemonic: add to ABCDE mnemonic to help identify nodular melanoma	<p>New elevated or thickened lesion</p> <p>Firmness on palpation</p> <p>Lesion grows continuously over 1 month</p>	If any positive findings, consider biopsy
Glasgow 7-point checklist	<p>Change in size of lesion</p> <p>Irregular pigmentation</p> <p>Irregular border</p> <p>Inflammation</p> <p>Itch or altered sensation</p> <p>Larger than other lesions (diameter > 7 mm)</p> <p>Oozing or crusting of lesion</p>	Used by primary care physicians; if three or more elements are present, refer or perform biopsy
Revised 7-point checklist	<p>Major features (2 points each):</p> <p>Change in size of lesion</p> <p>Irregular pigmentation</p> <p>Irregular border</p> <p>Minor features (1 point each):</p> <p>Inflammation</p> <p>Itch or altered sensation</p> <p>Larger than other lesions (> 7 mm diameter)</p> <p>Oozing or crusting of the lesion</p>	Used by primary care physicians to identify clinically significant lesions for biopsy; score of 3 or more warrants a referral or biopsy
Ugly duckling sign	Mole that does not follow the pattern of or look like the surrounding moles on a person's body	Used by patients or physicians to identify possible melanoma

Information from references 8-14.

Table 4. Materials for Punch and Shave Biopsies

Material	Comment
Skin preparation solution (e.g., povidone-iodine, chlorhexidine [Peridex])	—
Clean towel or drape	A Cochrane review showed that plastic adhesive drapes do not reduce the risk of surgical site infection, and may actually increase it. ²³
Local anesthesia (lidocaine [Xylocaine] 1 or 2%, with or without 1:100,000 epinephrine)	Two small prospective randomized controlled trials showed that lidocaine iontophoresis is a safe and effective topical anesthetic, ²⁴ and that lidocaine/tetracaine (Synera) patches may be beneficial for older patients undergoing skin procedures. ²⁵
3-mL syringe	—
21-gauge needle for drawing up anesthetic Smallest possible 25- to 30-gauge needle for injecting	Pain can be minimized using above referenced non-needle techniques, using slow (30-second) injection, and by mixing 1 mL of sodium bicarbonate with 9 mL of lidocaine. ^{16,26} These techniques may cut pain scores by more than 50 percent.
Skin punches (2, 3, 4, 6, and 8 mm) Flexible shave biopsy instrument (Dermablade), double-sided razor blades, or no. 15 scalpel blade Forceps Scissors Needle driver (punch) Gauze pads Nonabsorbable sutures or adhesive (Table 2) Nonsterile gloves Small adhesive bandages (circular or square) Enough 10% formalin containers for number of biopsies to be performed	—
White petrolatum on a swab	A randomized controlled trial showed that white petrolatum is a safe wound care ointment for ambulatory surgery and decreases the risk of allergic reactions and gram-negative bacterial superinfections. The authors estimate a savings of \$8 million to \$10 million per year in the United States if petrolatum was used instead of topical antibiotics. ²⁷
Hemostatic agents	Aluminum chloride 20% solution, Monsel solution (ferric subsulfate), silver nitrate sticks (75% silver nitrate/25% potassium nitrate).

Information from references 18, and 23 through 27.

- **Method - Shave**
 - Can be done with scalpel (15 blade), dermablade, double edged razor, or scissors
 - Hemostasis with aluminum chloride 20% solution
 - silver nitrate or ferric subsulfate (Monsel solution) may be used but can leave staining
 - Keep area covered and moist for at least 1 week may decrease scarring

Table 5. Performing a Shave Biopsy

Obtain consent.

Clean skin.

Anesthetize skin.

Superficial shave:

For macular or raised nonsuspicious lesions, hold blade parallel to the skin and shallowly remove a thin disk or the lesion itself, if raised (Figures 1 and 2).

Saucerization:

For pigmented lesions, measure a 1- to 3-mm margin before shaving^{1,4} (Figure 4A; also see <http://www.youtube.com/user/AFPJournal#p/a/u/1/R0yvX-ty9VM> [scoop shave biopsy—long version] and <http://www.youtube.com/user/AFPJournal#p/a/u/2/bCrRr1s3wCl> [scoop shave biopsy—short version]).

Anesthetize, creating a wheal to make the lesion easier to shave (Figure 4B), and squeeze skin between the thumb and forefinger of the nondominant hand to further elevate the lesion.^{1,4}

Hold blade at a 45-degree angle to the skin, bend or bow the blade depending on the width of lesion, and remove a disk of tissue well into the subcutaneous fat^{1,4} (Figure 5).

If a nidus of pigment remains after saucerization, a punch or elliptical biopsy must be performed, and the sample sent in the same specimen container (Figure 6).

Use a hemostatic agent or electrocautery and wipe clean.

Dress with petrolatum and instruct the patient to keep the area moist and covered for at least one week to minimize scarring.

Information from references 1, 3, 4, 6, and 8.

- **Method - Punch**

- Close with simple interrupted or vertical mattress suture for best cosmetic result
- Secondary intention healing and suturing provide similar cosmetic result for 1-4mm diameter lesions (2.3.4 mm available to order)

Pickett H. Shave and punch biopsy for skin lesions. Am Fam Physician. 2011 Nov 1;84(9):995-1002. PMID: 22046939.

Table 6. Performing a Punch Biopsy

Obtain consent.

Determine skin lines of tension using Langer lines (Figure 7 and 8). Punching in one direction produces few lines and another produces numerous, pulling skin perpendicular to the numerous lines' punch; this will produce an oval that can be easily approximated (Figures 8, 9, and 10).

Determine the punch size with a 1- to 3-mm margin around the lesion. If area is too large for a punch biopsy, consider a larger surgical biopsy (Table 5).

Prepare skin.

Drape skin.

Anesthetize, creating a wheal (Figure 4B).

Place punch over lesion after pulling perpendicular to Langer lines, and firmly but gently rotate through skin until there is a decrease in tension on the tissue; this indicates a full-thickness sample.

Remove tissue gently with forceps or needle to minimize crush artifact (Figure 10).

If sample is 4 mm or less, may dab with aluminum chloride 20% solution or other hemostatic agent (Table 4) or close with one suture (Table 2), may also consider closing with surgical adhesive. A Cochrane review showed that tissue adhesives are as effective as traditional sutures for closure of general incisions without high tension.²⁸

Information from references 5, 6, and 28.

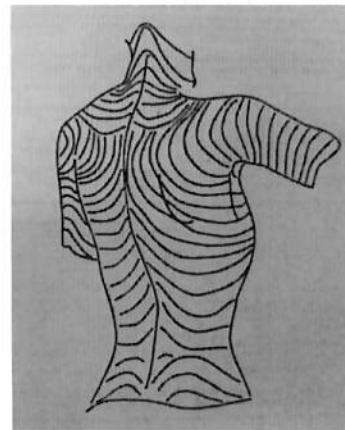
Dressing/care of site

Table 7. Dressing and Care of Biopsy Site

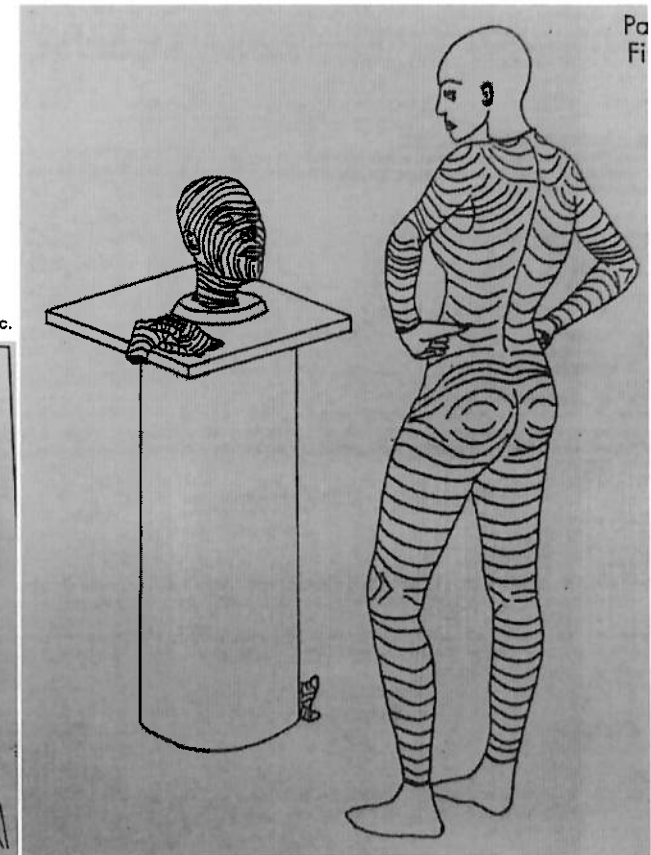
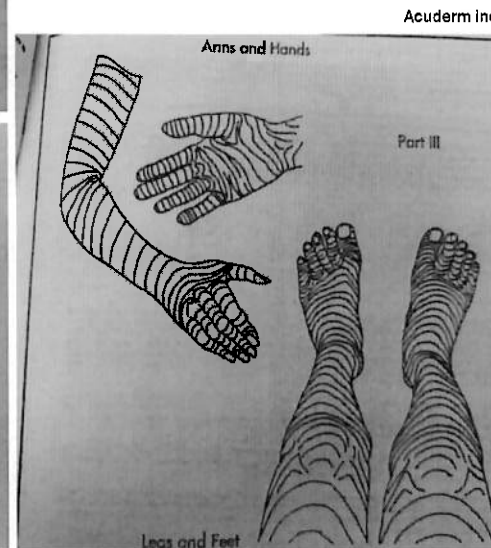
Clean area after hemostasis is achieved.
Cover with petrolatum and sterile dressing.
Send tissue to pathology in formalin; if specimen is large enough and there is high suspicion for malignancy, consider suture tagging an area for pathologist.
Give discharge instructions, keep area covered and dry for 24 hours (punch biopsies) or covered and moist for at least one week (shave biopsies).
Complications are rare, bleeding can be managed with pressure, suture, or cautery, if infection occurs, it usually appears within three days after biopsy and can be treated with suture removal or oral antibiotics.³⁸

Information from reference 18

Pickett H. Shave and punch biopsy for skin lesions. Am Fam Physician. 2011 Nov 1;84(9):995-1002. PMID: 22046939.



Langer lines



Sources:

Acuderm inc. Skin Tension lines. [Residency handout]. York: Wellspan Family Medicine Residency; (n.d.)

Lauters R, Brown AD, Harrington KA. Melanoma: Diagnosis and Treatment. Am Fam Physician. 2024 Oct;110(4):367-377. PMID: 39418569.

Pickett H. Shave and punch biopsy for skin lesions. Am Fam Physician. 2011 Nov 1;84(9):995-1002. PMID: 22046939.

Table 7. Dressing and Care of Biopsy Site

Clean area after hemostasis is achieved.

Cover with petrolatum and sterile dressing.

Send tissue to pathology in formalin; if specimen is large enough and there is high suspicion for malignancy, consider suture tagging an area for pathologist.

Give discharge instructions; keep area covered and dry for 24 hours (punch biopsies) or covered and moist for at least one week (shave biopsies).

Complications are rare; bleeding can be managed with pressure, suture, or cautery; if infection occurs, it usually appears within three days after biopsy and can be treated with suture removal or oral antibiotics.¹⁸

Information from reference 18.

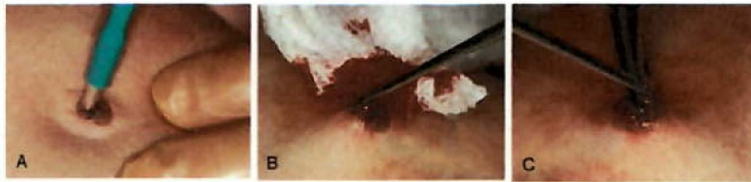


FIG. 26.5 (A) Applying the punch for a skin biopsy. (B) Excising the tissue freed by the punch. (C) Typical cylinder of tissue obtained from a 3-mm punch.

Courtesy The Medical Procedures Center, Midland, Michigan.

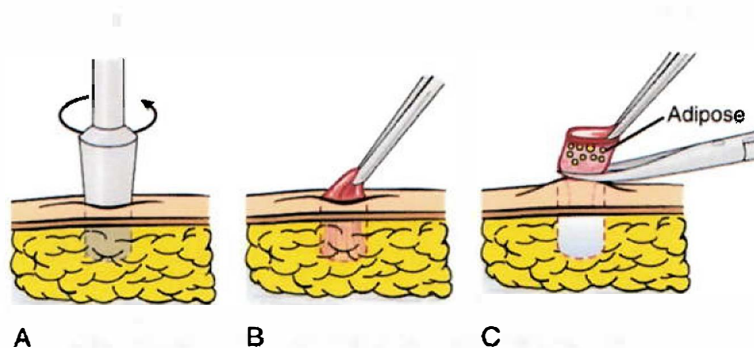


FIG. 26.6 Punch biopsy technique. (A) Twisting the punch with gentle pressure. (B) Picking up the loosened piece. (C) Cutting with scissors or a blade.



FIG. 26.7 Pressure dressing for a biopsy. (A) Components: gauze pad, antibiotic ointment, and adhesive bandage. (B) Gauze pad with antibiotic ointment. (C) Pressure dressing on finger.

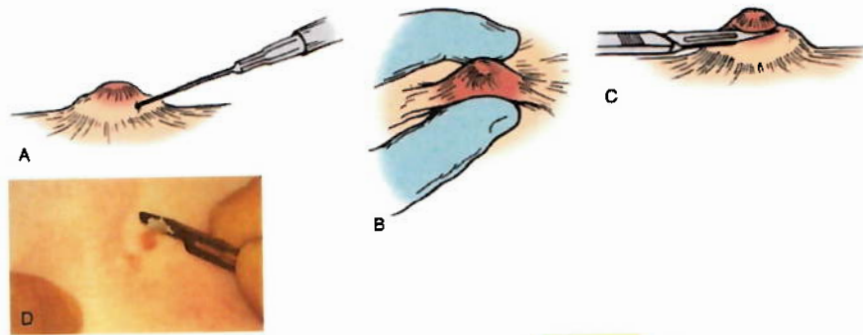
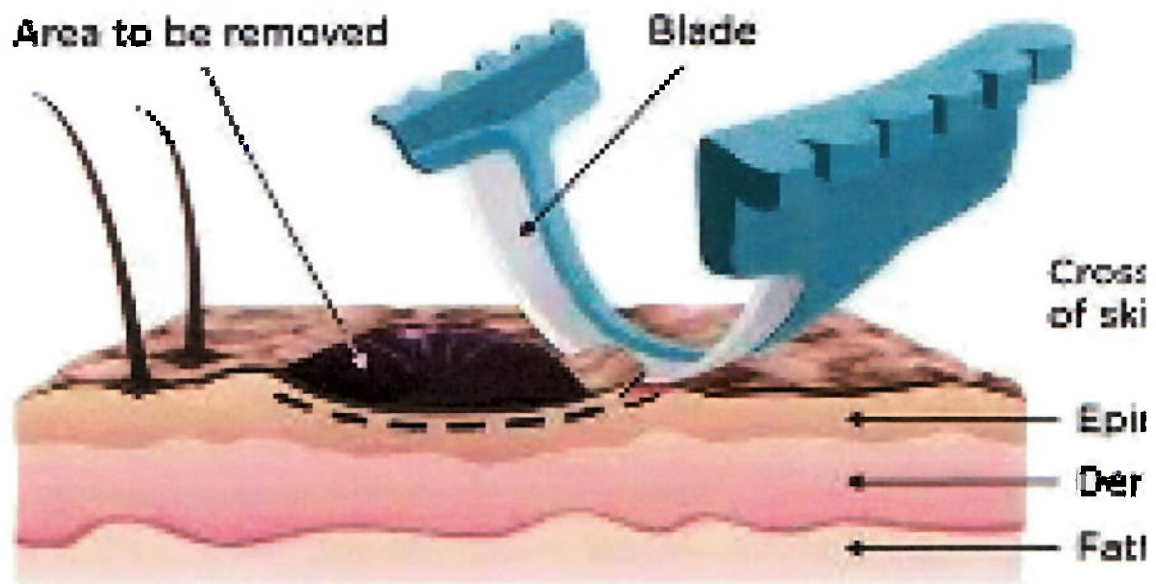


FIG. 26.9 One technique of shave biopsy. (A) Inject a local anesthetic to elevate the lesion. (B) Roll the skin between the thumb and forefinger to create a flat cutting surface and a tamponade effect on the surrounding blood vessels. (C) Holding a No. 15 blade parallel to the skin or at a slight downward angle, shave the lesion flush with or slightly below the surrounding skin. (D) Shave technique using a No. 15 blade. No scalpel handle is necessary.

A–C, Courtesy The Medical Procedures Center, Midland, Michigan.

Skin Shave Biopsy



IUDs



Bayer IUDs (Intrauterine Devices): An Overview for New Learners

Mirena[®] (levonorgestrel-releasing
intrauterine system) 52mg

Kyleena[®] (levonorgestrel-releasing
intrauterine system) 19.5mg

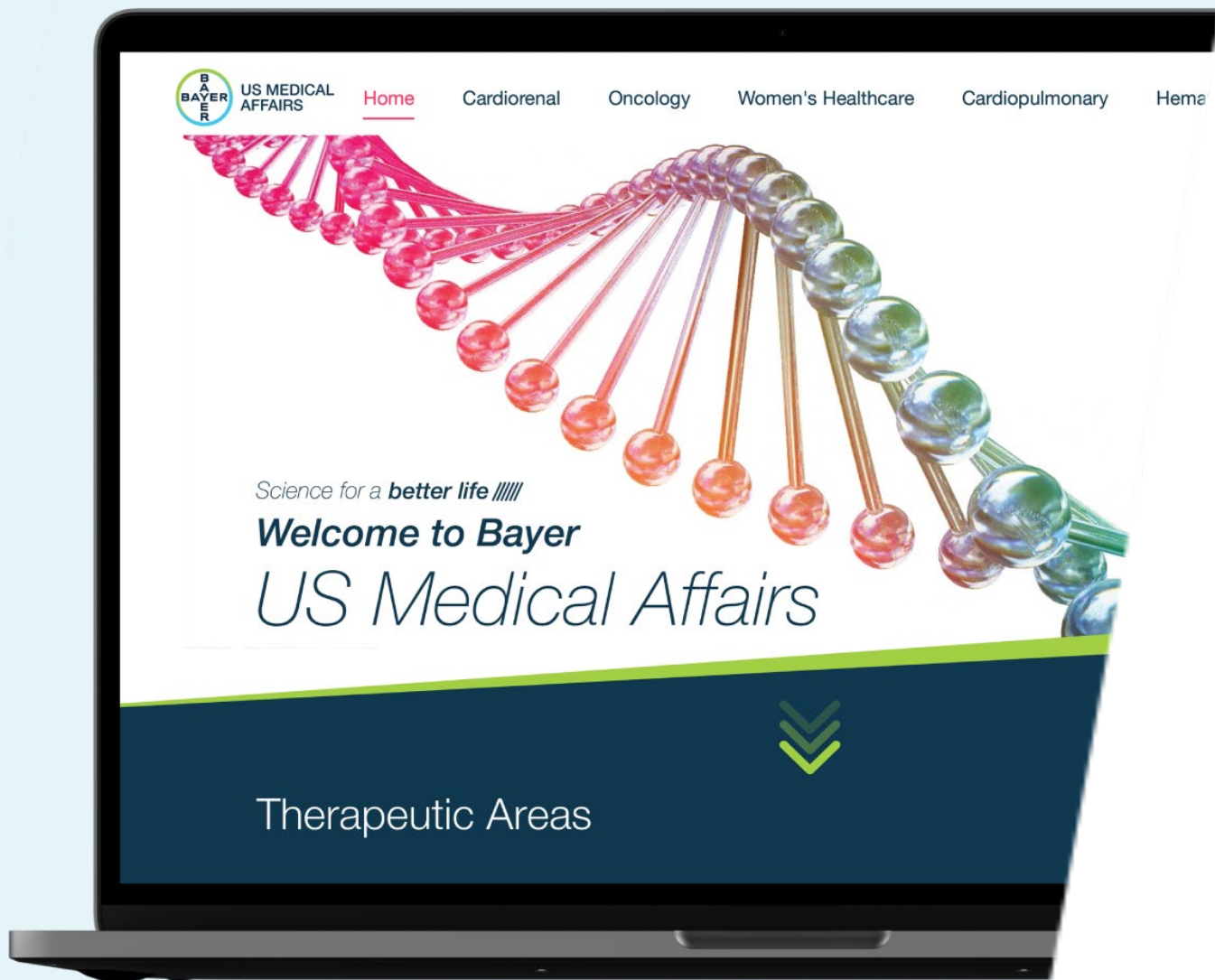
Skyla[®] (levonorgestrel-releasing
intrauterine system) 13.5mg

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

PP-PF-WHC-IUS-US-1726-3, Feb 2026

The program may refer to women, she, or her. We recognize that gender identity is diverse and not all people with a uterus identify as women.





medicalaffairs.bayer.com

Explore Clinical and Scientific Resources

- Disease Education
- Publications
- Clinical Trials & Pipeline
- Congress Library
- Continuing Education
- And more...

Scan to Start Exploring >



Person-Centered Contraceptive Care



Focus on providing contraception services in alignment with each individual's values, preferences, needs, and desires

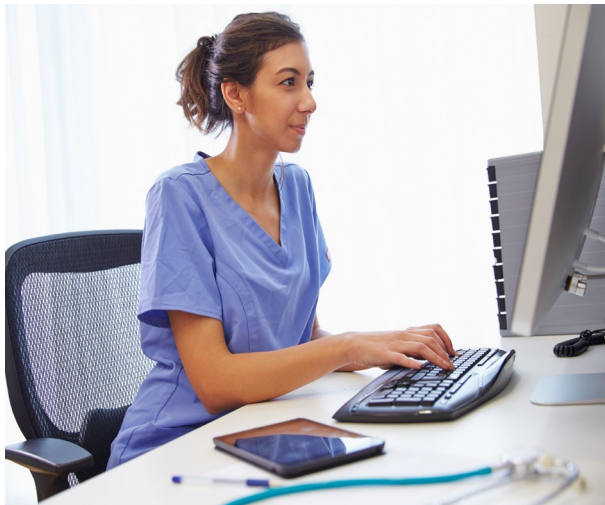
Health Care Providers can incorporate family planning services, when the primary reason for the visit might not be family planning, such as:

Telehealth

Annual Physical

Pre/Post Natal Visits

Sick Visits



Reproductive Planning: Start the Discussion



Assess each patient's short- and long-term reproductive plans

“Every woman, every time”¹

Every patient encounter, regardless of the chief reason for the visit, is an important “teachable moment” to assess short- and long-term reproductive plans, reducing unintended pregnancy, promoting maternal health, and improving pregnancy outcomes.¹



Person-Centered Contraceptive Care

US Office of Population Affairs (OPA)

KEY STEPS IN PROVIDING CONTRACEPTIVE SERVICES





IUD (Intrauterine Device) as a Contraceptive Option

Part of contraceptive counseling involves assessing a person's preferences, values, and goals.¹

For those patients who are seeking a highly effective method, without a daily routine, they may be interested in an IUD (Intrauterine Device).²



What are Mirena, Kyleena, & Skyla?



Indications



Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

- Prevention of pregnancy for up to 8 years; replace after the end of the eighth year
- Treatment of heavy menstrual bleeding for up to 5 years in women who choose to use intrauterine contraception as their method of contraception; replace after the end of the fifth year if continued treatment of heavy menstrual bleeding is needed

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

- Prevention of pregnancy up to 5 years
- Replace the system after 5 years if continued use is desired

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

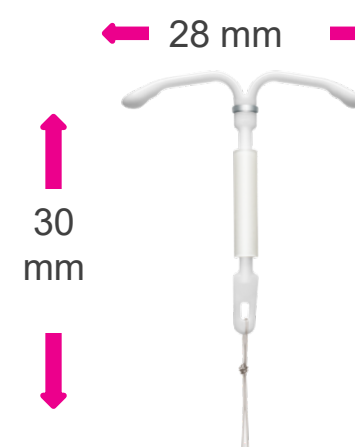
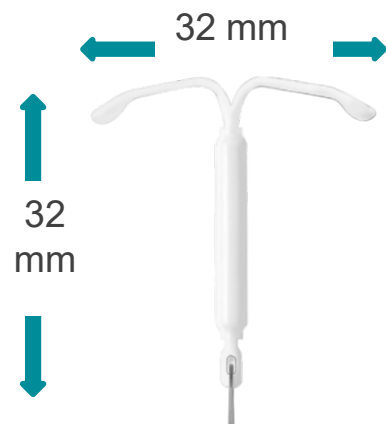
- Prevention of pregnancy up to 3 years
- Replace the system after 3 years if continued use is desired

Properties

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Hormone Reservoir (Total Amount)	52mg LNG	19.5mg LNG	13.5mg
Insertion Tube Diameter	4.4 mm	3.8 mm	3.8mm
Release Rate After 1 Year	19 mcg/d	9.8 mcg/d	~6 mcg/d
Thread color	Brown	Blue	Brown
Silver Ring / MR Compatibility	No Silver Ring	Yes / MR Conditional	Yes / MR Conditional

The combination of silver ring and thread color will help identify the brand of IUD

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Important Safety Information for Mirena, Kyleena, and Skyla

Contraindications



- Known or suspected pregnancy and cannot be used for post-coital contraception
- Congenital or acquired uterine anomaly including fibroids if they distort the uterine cavity
- Known or suspected breast cancer or other progestin-sensitive cancer, now or in the past
- Known or suspected uterine or cervical malignancy
- Liver disease, including tumor
- Untreated acute cervicitis or vaginitis, including lower genital tract infections (e.g. bacterial vaginosis) until infection is controlled
- Postpartum endometritis or infected abortion in the past 3 months
- Unexplained uterine bleeding
- Current IUD
- Acute pelvic inflammatory disease (PID) or a history of PID (except with later intrauterine pregnancy)
- Conditions increasing susceptibility to pelvic infections
- Hypersensitivity to any component of the Mirena, Kyleena, or Skyla

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important Safety Information

Clinical Considerations for Use and Removal



Use Mirena, Kyleena, or Skyla with caution after careful assessment in patients with:

- Coagulopathy or taking anticoagulants
- Migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia
- Exceptionally severe headache
- Marked increase of blood pressure
- Severe arterial disease such as stroke or myocardial infarction
- Consider removing the intrauterine system if these or the following arise during use: Uterine or cervical malignancy or jaundice
- If the threads are not visible or are significantly shortened they may have broken or retracted into the cervical canal or uterus
- If Mirena, Kyleena, or Skyla is displaced (e.g. expelled or perforated the uterus) remove it
- Kyleena and Skyla can be safely scanned with MRI only under specific conditions

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

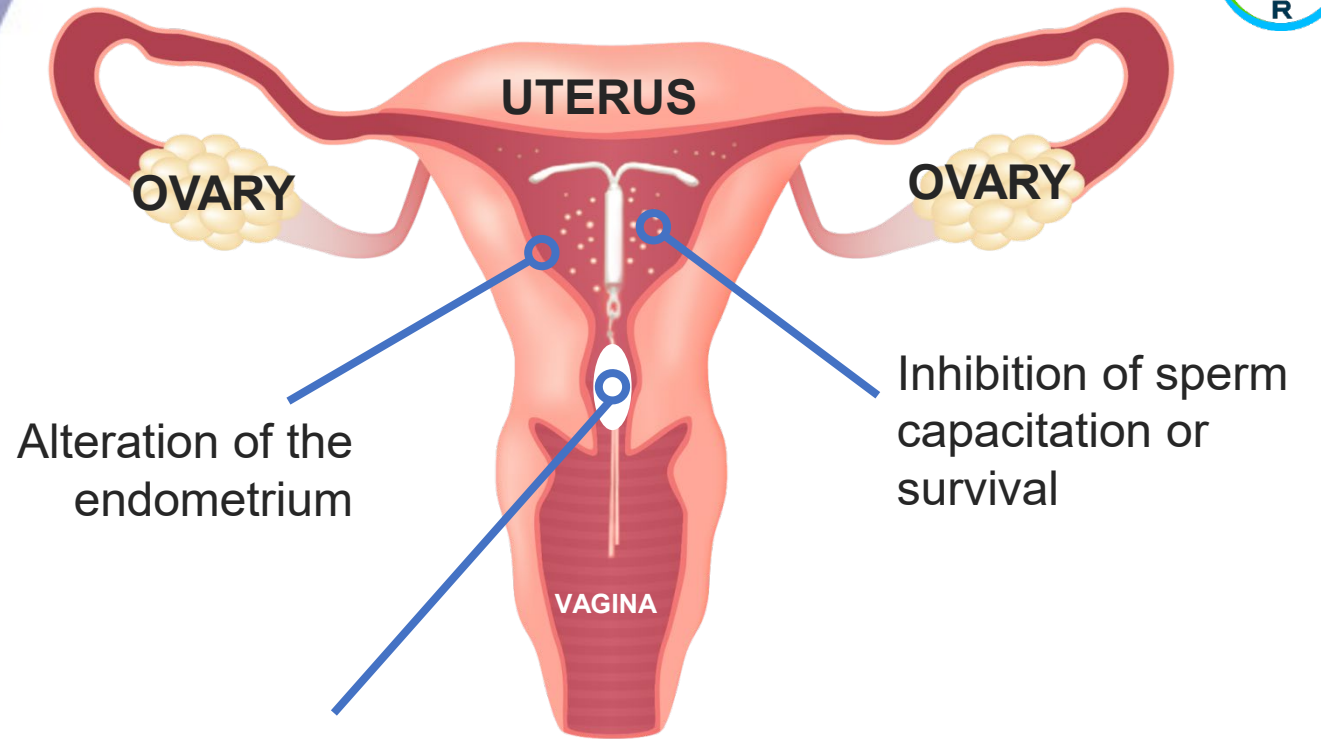
Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Suggested Mechanism of Action

The local mechanism of action has not been conclusively demonstrated.

Studies of Mirena, Kyleena, Skyla and similar LNG-IUS prototypes have suggested several mechanisms that may prevent pregnancy.



Thickening of cervical mucus (CM) preventing passage of sperm into the uterus

[\(click to view an example of thickened CM from LNG-IUS user\)](#)



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

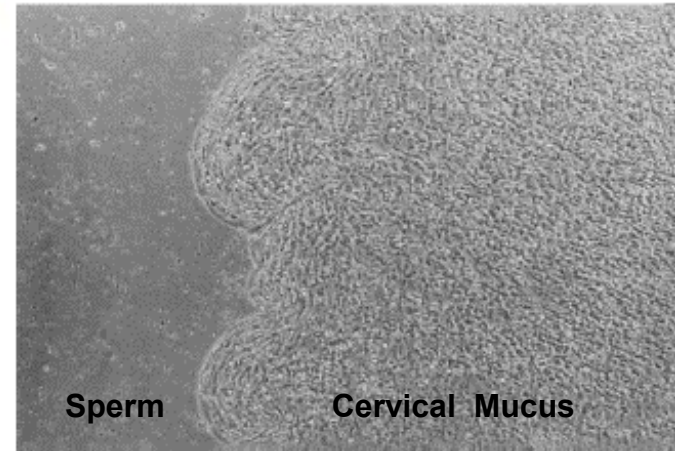
Examples of Cervical Mucus

Cervical Mucus Changes During LNG-IUS Use

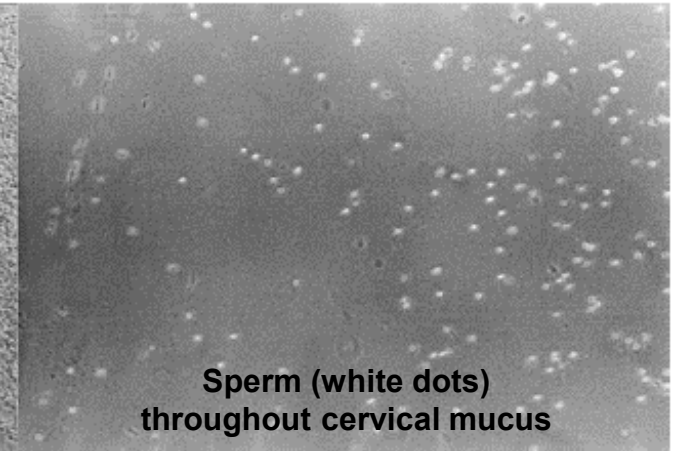
The local mechanism of action has not been conclusively demonstrated, and thickening of cervical mucus is one of the several suggested mechanisms that may prevent pregnancy.

These examples show how cervical mucus from an LNG-IUS user is thick, compared to a control patient (not using contraception).

LNG-IUS user



Control (No Contraception)



Lewis et al., 2010. Used with permission.

- Mid-cycle Cervical Mucus (CM) from LNG-IUS user (left) and control patient (right) were placed on slide and surrounded by sperm.
- Sperm are unable to penetrate CM from LNG-IUS user, but swim throughout control CM

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

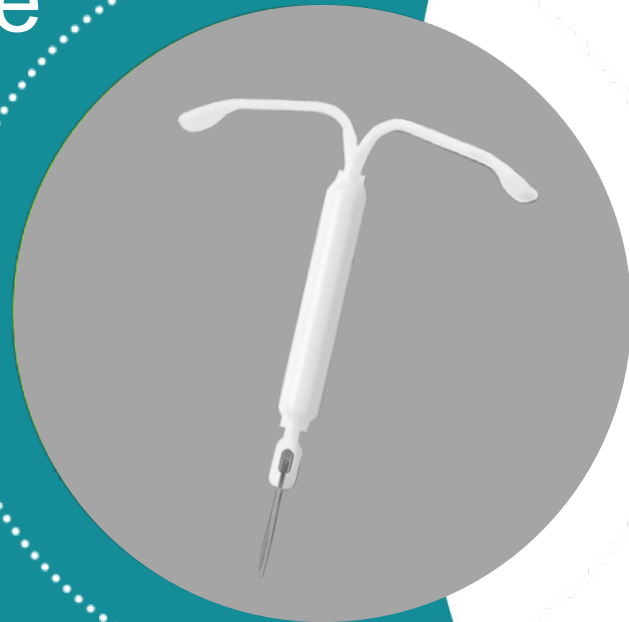
Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Mirena[®]

(levonorgestrel-releasing
intrauterine system) 52 mg

Contraceptive Efficacy

Contraception Clinical Trials



5 Year Trial: conducted in
Finland & Sweden

Extension Trial: multi-center, open
label, uncontrolled study in the US

Please see Important Safety Information throughout. Please see full
Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at
this presentation.



5-Year Trial

- N=1,169 women (18-35 years old)
- 5.6% nulliparous (n=66)
- 1-year pregnancy rate $\leq 0.2/100$ women (0.2%)
- 5-year cumulative pregnancy rate $\sim 0.7/100$ women (0.7%)

Extended Use Beyond 5 Years

- N=362 women (18-35 years old) using Mirena for 4.5-5 years
- 47.2% nulliparous
- BMI range: 15.4-57.7 kg/m² (avg=27.9 kg/m²)
- Pearl index: 0.34 (year 6), 0.40 (year 7), 0.00 (year 8)
- 3-year cumulative pregnancy rate (years 6-8) = 0.68% (95% Upper Confidence limit = 2.71%)

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Mirena®
(levonorgestrel-releasing
intrauterine system) 52 mg

Clinical Trial on Heavy Menstrual Bleeding

Trial Overview^{1,2}:

Randomized, open label, active control, parallel group trial of reproductive aged women with ≥80 mL menstrual blood loss (MBL)* confirmed with alkaline hematin method^{1,2}

Women were randomized to 6 cycles of Mirena (n=79) or Medroxyprogesterone acetate (MPA) (n=81) 10 mg/day for 10 days beginning on day 16 of cycle^{1,2}

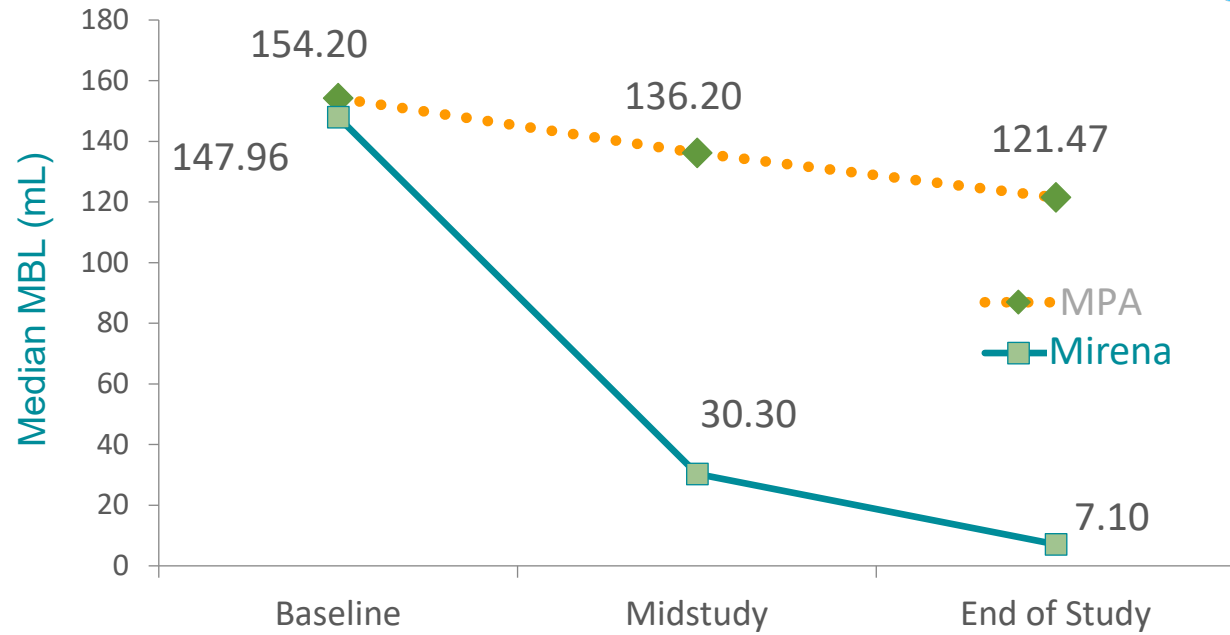
*Excluded were women with organic or systemic conditions that may cause heavy uterine bleeding

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

[1] Mirena Prescribing Information [2] Kaunitz AM, et al. Obstet Gynecol. 2010;116:625–32



Median MBL by Time and Treatment



Mirena, users demonstrated:
80% reduction in the median MBL at 3 cycles
95% reduction in the median MBL at 6 cycles

Mirena®
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena®
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla®
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Kyleena[®]

(levonorgestrel-releasing
intrauterine system) 19.5 mg

Contraceptive Efficacy

Contraception Clinical Trials



Multicenter, multi-national,
randomized, open-label study
conducted in 11 countries
including the USA

Please see Important Safety Information throughout. Please see full
Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at
this presentation.



Demographics

N=1,452 women (5 year trial)

- 18-35 years
- 40% nulliparous (n=574)
- BMI range: 15.2-57.6 kg/m²
(avg=25.3 kg/m²)

Efficacy

- Year 1 Pearl Index= 0.16
- Cumulative 5-year pregnancy
rate = 1.45% (95% Confidence
Interval: 0.82, 2.53)

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Contraceptive Efficacy

Contraception Clinical Trials



Multicenter, multi-national,
randomized, open-label study
conducted in 11 countries
including the USA

Please see Important Safety Information throughout. Please see full
Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at
this presentation.

Demographics

N=1,432 women (3 year trial)

- 18-35 years
- 38.8% nulliparous (n=556)
- BMI range: 16-55 kg/m²
(avg=25.3 kg/m²)

Efficacy

- Year 1 Pearl Index= 0.41
- Cumulative 3-year pregnancy
rate = 0.9% (upper 95%
Confidence Interval: 1.7%)

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important Safety Information

Pregnancy Related Risks



- If pregnancy should occur with Mirena, Kyleena, or Skyla in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor
- Advise her of isolated reports of virilization of the female fetus following local exposure to LNG during pregnancy
- Removal or manipulation may result in pregnancy loss
- Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with Mirena, Kyleena, or Skyla
- Also consider the possibility of ectopic pregnancy in the case of lower abdominal pain, especially in association with missed menses or if an amenorrheic woman starts bleeding
- Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility
- Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Insertion

Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Insertion Pain



- Patients may experience pain, bleeding or dizziness during and after placement
- If symptoms do not pass within 30 minutes, the Bayer IUD may not have been placed correctly
- If this happens, the patient should be examined to determine if the Bayer IUD needs to be removed or replaced



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Timing of Insertion

Same day insertion can be considered if it is reasonably certain the patient is not pregnant



	IUS insertion timing	Backup contraception?
Patients not currently using hormonal or intrauterine contraception	<ul style="list-style-type: none"> Any time there is reasonable certainty they are not pregnant Consider the possibility of ovulation and conception prior to initiation 	YES If not inserted during the first 7 days of the menstrual cycle, a barrier method should be used or patient should abstain from vaginal intercourse for 7 days
		NO If inserted during the first 7 days of the menstrual cycle, or immediately after first trimester abortion
Switching from:		
Pills, transdermal patch, or vaginal ring	<ul style="list-style-type: none"> Any time, including the hormone-free interval of the previous method 	YES If inserted during active use of previous method, continue previous method for 7 days after insertion, or until the end of the current treatment cycle
		YES If inserted during use of continuous hormonal contraception, continue method for 7 days after insertion
Injectable progestin contraceptive	<ul style="list-style-type: none"> Any time 	YES If inserted >3 months (13 weeks) after the last injection, backup contraception (such as condoms or spermicide) should also be used for 7 days
		NO If inserted <3 months after last injection
Implant or IUS	<ul style="list-style-type: none"> Anytime during the menstrual cycle Insert on the same day as removal of the implant or IUS 	NO There is no need for backup contraception

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Timing of Insertion

After First or Second Trimester Abortion or Miscarriage, and Childbirth



	Insertion timing	Backup contraception?
After 1st trimester abortion or miscarriage	<ul style="list-style-type: none"> Can be inserted immediately, unless it's a septic abortion 	NO There is no need for backup contraception
After childbirth or 2 nd trimester abortion or miscarriage		
Immediate insertion after childbirth, or 2 nd trimester abortion or miscarriage	<ul style="list-style-type: none"> Insert after removal of placenta 	NO There is no need for backup contraception
Interval insertion following complete involution of the uterus	<ul style="list-style-type: none"> Wait a minimum of 6 weeks, or until the uterus is fully involuted before insertion Insert any time there is reasonable certainty that the patient is not pregnant 	YES If not inserted during the first 7 days of the menstrual cycle, a back-up method of contraception should be used, or the patient should abstain from vaginal intercourse for 7 days
		NO If inserted during the first 7 days of the menstrual cycle

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important Safety Information

Educate her about Pelvic Inflammatory Disease (PID)



- Mirena, Kyleena, and Skyla are contraindicated in the presence of known or suspected PID or in women with a history of PID unless there has been a subsequent intrauterine pregnancy
- IUDs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion; promptly examine users with complaints of lower abdominal pain or pelvic pain, odorous discharge, unexplained bleeding, fever, genital lesions or sores
- Inform women about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important Safety Information

Educate her about Pelvic Inflammatory Disease (PID)



- PID is often associated with sexually transmitted infections (STIs); Mirena, Kyleena, and Skyla do not protect against STIs, including HIV; PID may be asymptomatic but still result in tubal damage and its sequelae
- In clinical trials with:
 - **Mirena** – upper genital infections, including PID, occurred more frequently within the first year; in a clinical trial with other IUDs and a clinical trial with an IUD similar to Mirena, the highest rate occurred within the first month after insertion
 - **Kyleena & Skyla**– PID occurred more frequently within the first year and most often within the first month after insertion

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Effect on Bleeding

Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Important Safety Information

Expect changes in bleeding patterns



- Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months



- Periods may become shorter and/or lighter thereafter; cycles may remain irregular, become infrequent, or even cease

- Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation
- If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Other serious complications and most common adverse reactions

Mirena[®] (levonorgestrel-releasing
intrauterine system) 52mg

Kyleena[®] (levonorgestrel-releasing
intrauterine system) 19.5mg

Skyla[®] (levonorgestrel-releasing
intrauterine system) 13.5mg

Please see Important Safety Information throughout. Please see full
Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at
this presentation.

Important Safety Information



Be aware of other serious complications and most common adverse reactions. Some serious complications with IUDs like Mirena, Kyleena, and Skyla are sepsis, perforation and expulsion.

SEPSIS:

- Severe infection, or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of a LNG-releasing IUS
- Aseptic technique during insertion of the IUD is essential in order to minimize serious infections such as GAS

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important Safety Information



Be aware of other serious complications and most common adverse reactions (cont.):

PERFORATION:

- Perforation (total or partial, including penetration/embedment of Mirena, Kyleena, or Skyla in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later
- Perforation may reduce contraceptive efficacy and result in pregnancy
- The risk of uterine perforation is increased in women who have recently given birth, and in women who are breastfeeding at the time of insertion
 - In a large US retrospective, postmarketing safety study of IUDs, the risk of uterine perforation was highest when insertion occurred within ≤ 6 weeks postpartum, and also higher with breastfeeding at the time of insertion
- The risk of perforation may be increased if inserted when the uterus is fixed, retroverted or not completely involuted

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important Safety Information



Be aware of other serious complications and most common adverse reactions (cont.):

PERFORATION:

- If perforation occurs, locate and remove the intrauterine system
 - Surgery may be required
 - Delayed detection or removal of the intrauterine system in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

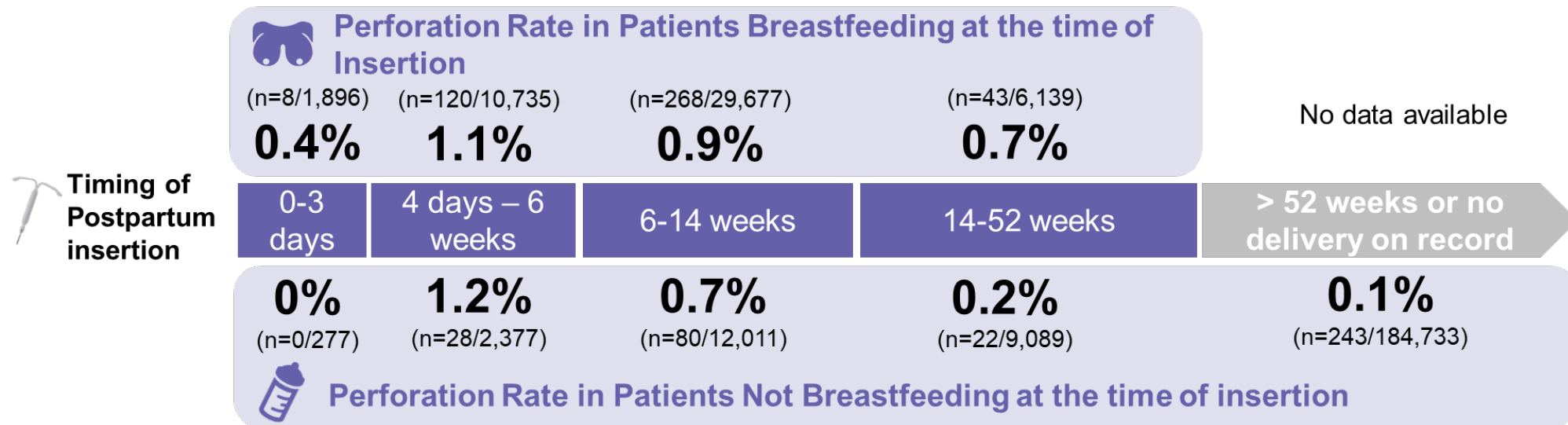
Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

APEX-IUD Study

Assessment of Perforation and Expulsion of Intrauterine Devices Study



Purpose: retrospective cohort study (>320,000 IUD insertions) to assess the impact of breastfeeding (BF) and insertion timing on perforation and expulsion



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

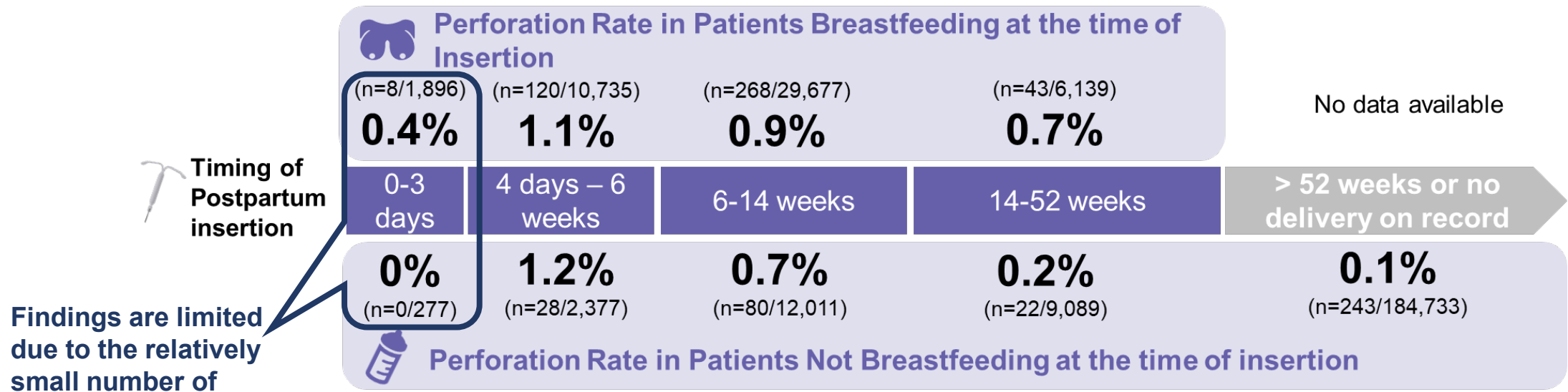
Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

APEX-IUD Study

Assessment of Perforation and Expulsion of Intrauterine Devices Study



Purpose: retrospective cohort study (>320,000 IUD insertions) to assess the impact of breastfeeding (BF) and insertion timing on perforation and expulsion



Findings are limited due to the relatively small number of insertions during this time

Perforation Results:

- Perforation rate was highest when IUDs were placed between 4 days-6 weeks after delivery
- Breastfeeding (vs. non) at the time of insertion was associated with a 33% higher risk of perforation (adjusted hazard ratio [HR]=1.33, 95% confidence interval [CI]: 1.07-1.64)

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing intrauterine system) 13.5 mg

APEX-IUD Study (cont.)

Assessment of Perforation and Expulsion of Intrauterine Devices Study



Expulsion Rate in Patients Breastfeeding at the time of Insertion

Timing of Postpartum insertion	(n=187/1,896)	(n=185/10,735)	(n=421/29,677)	(n=120/6,139)	No data available
0-3 days	9.9%	1.7%	1.4%	2.0%	
4 days – 6 weeks					
6-14 weeks					
14-52 weeks					
> 52 weeks or no delivery on record					
	4.3% (n=12/277)	2.2% (n=52/2,377)	2.5% (n=306/12,011)	3.0% (n=273/9,089)	3.0% (n=5,481/184,733)



Findings are limited due to the relatively small number of insertions during this time

Expulsion Results:

- Risk of expulsion was variable over the postpartum intervals through 52 weeks, and highest when the LNG-IUS was placed the first 3 days after delivery
- Breastfeeding (vs. non) at the time of insertion was associated with a 28% lower risk of expulsion (adjusted hazard ratio [HR]=0.72, 95% confidence interval [CI]: 0.64-0.80)

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing intrauterine system) 13.5 mg

Important Safety Information



Be aware of other serious complications and most common adverse reactions (cont.):

EXPULSION:

- Partial or complete expulsion of Mirena, Kyleena, or Skyla may occur resulting in the loss of contraceptive protection
- The risk of expulsion is increased with insertions immediately after delivery and appears to be increased with insertion after second-trimester abortion based on limited data
- In the same postmarketing study, the risk of expulsion was lower with breastfeeding status
- Remove a partially expelled IUD
- If expulsion has occurred, a new Mirena, Kyleena, or Skyla can be inserted any time the provider can be reasonably certain the woman is not pregnant

OVARIAN CYSTS:

- Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia
- Evaluate persistent enlarged ovarian cysts

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important Safety Information



Be aware of other serious complications and most common adverse reactions (cont.): In clinical trials with:

Mirena – adverse reactions reported in ≥5% of users were:

Alterations in menstrual bleeding patterns			
Unscheduled uterine bleeding	31.9%	Breast pain	8.5%
Decreased uterine bleeding	23.4%		
Increased scheduled uterine bleeding	11.9%		
Female genital tract bleeding	3.5%		
Abdominal/pelvic pain	22.6%	Back pain	7.9%
Amenorrhea	18.4%	Benign ovarian cyst and associated complications	7.5%
Headache/migraine	16.3%	Acne	6.8%
Genital discharge	14.9%	Depression/depressive mood	6.4%
Vulvovaginitis	10.5%	Dysmenorrhea	6.4%

A separate study with 362 women who have used Mirena for more than 5 years showed a consistent adverse reaction profile in years 6 - 8. By the end of Year 8 of use:

- amenorrhea and infrequent bleeding were experienced by 34% and 26% of users, respectively;
 - irregular bleeding occurs in 10%,
 - frequent bleeding occurs in 3%, and
 - prolonged bleeding in 3% of users.
- In this study, 9% of women reported the adverse event of weight gain, it is unknown if the weight gain was caused by Mirena.

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important Safety Information



Be aware of other serious complications and most common adverse reactions (cont.):

Kyleena – the most common adverse reactions ($\geq 5\%$ users) were:

Vulvovaginitis	24%
Ovarian Cyst	22%
Abdominal/pelvic pain	21%
Headache/migraine	15%
Acne/seborrhea	15%
Dysmenorrhea/uterine spasm	10%
Breast pain/discomfort	10%
Increased bleeding	8%

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important Safety Information



Be aware of other serious complications and most common adverse reactions (cont.): In clinical trials with:

Skyla – the most common adverse reactions (≥5% users) were:

Vulvovaginitis	20.2%
Abdominal/pelvic pain	18.9%
Acne/seborrhea	15.0%
Ovarian cyst	13.2%
Headache	12.4%
Dysmenorrhea	8.6%
Breast pain/discomfort	8.6%
Increased bleeding	7.8%
Nausea	5.5%

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions; evaluate patients 4 to 6 weeks after insertion of Mirena, Kyleena, and Skyla and then yearly or more often if clinically indicated

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Confirm your
attendance

Please visit – IUDTraining.com to receive



A certificate of attendance

Access to additional educational
resources, support, and follow-up from
Bayer Representatives

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Insertion & Removal Procedure

Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

IUD Insertion*



*NOTE: The inserter provided with Mirena, Kyleena, and Skyla and the insertion procedure described here, are not applicable for immediate insertion after childbirth or second-trimester abortion or miscarriage. For immediate insertion the Bayer IUD should be removed from the inserter and inserted according to accepted practice.

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Preparation for Insertion

Preparation for
Insertion



- Obtain a complete medical and social history to determine conditions that might influence selection of a Bayer IUD for contraception
 - If indicated, perform a physical examination, and appropriate tests for any forms of genital or other sexually transmitted infections
- Because irregular bleeding/spotting is common during the first months of Mirena, Kyleena, or Skyla use, exclude endometrial pathology (polyps or cancer) prior to the insertion in patients with persistent or uncharacteristic bleeding
- Follow the insertion instructions exactly as described to ensure proper placement and avoid premature release of the Bayer IUD from the inserter; **once released, the Bayer IUD cannot be re-loaded**
- Check expiration date prior to initiating insertion
- Bayer IUDs should be inserted by a trained physician or healthcare provider; they should become thoroughly familiar with the insertion instructions before attempting insertion
- Insertion may be associated with some pain and/or bleeding or vasovagal reactions (for example, syncope, bradycardia) or seizure in an epileptic patient, especially in patients with a predisposition to these conditions; consider administering analgesics prior to insertion

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

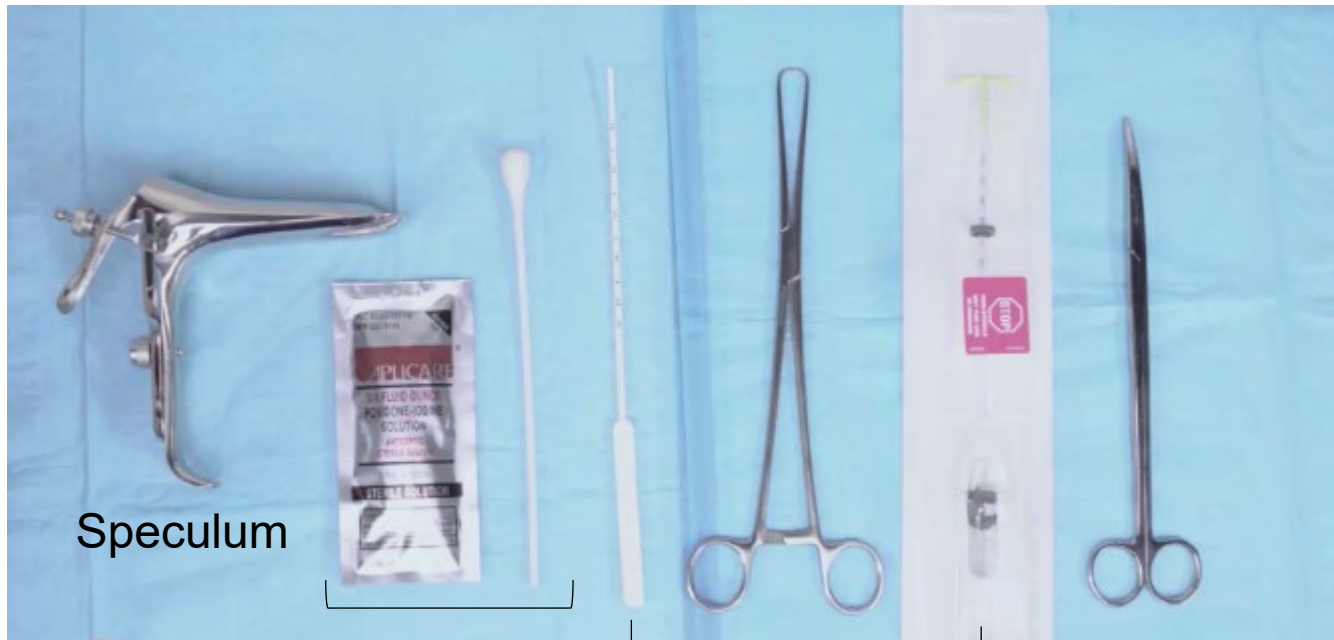
Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Preparation for Insertion: Tools

Preparation for Insertion



Speculum

Antiseptic solution, and applicator

Sterile uterine sound

Sterile tenaculum

IUD with inserter in sealed package (consider have an unopened backup of available)

Sterile, sharp curved scissors



Sterile gloves

If anticipated, also have instruments & anesthesia for paracervical block available

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing intrauterine system) 19.5 mg

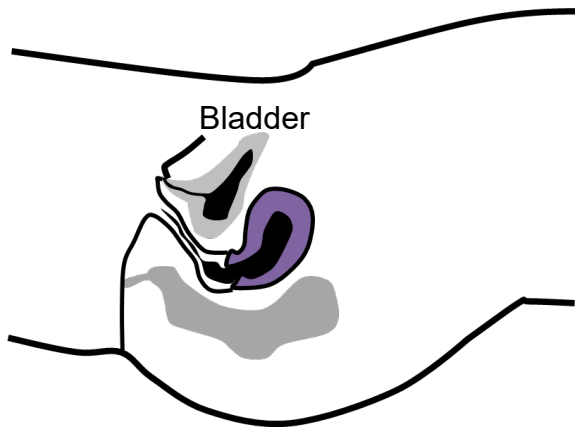
Skyla[®]
(levonorgestrel-releasing intrauterine system) 13.5 mg

Preparation for Insertion: Bimanual Exam

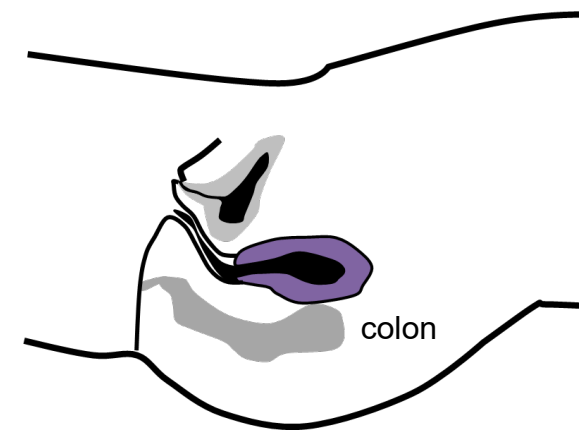
Preparation for
Insertion



- Exclude pregnancy and confirm that there are no other contraindications to use of Mirena, Kyleena, or Skyla
- With the patient comfortably in lithotomy position, do a bimanual exam to establish the size, shape and position of the uterus



Anteverted Uterus
(tilts toward bladder,
occurs in ~66% patients)



Retroverted Uterus
(tilts back toward colon
occurs in ~33% patients)

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

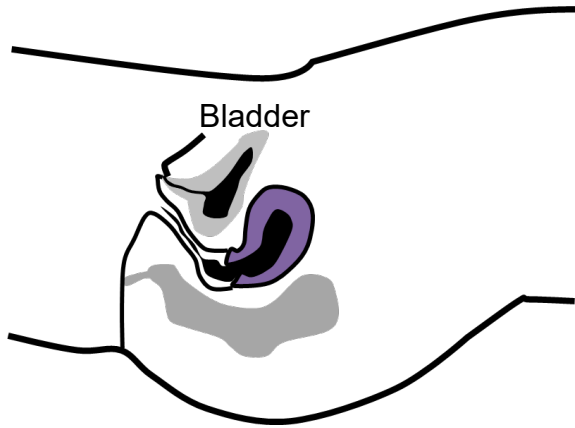
Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Preparation for Insertion: Bimanual Exam

Preparation for
Insertion

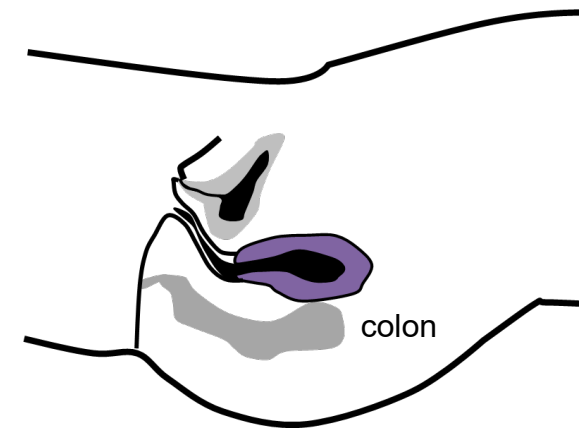


- Exclude pregnancy and confirm that there are no other contraindications to use of Mirena, Kyleena, or Skyla
- With the patient comfortably in lithotomy position, do a bimanual exam to establish the size, shape and position of the uterus



Anteverted Uterus
(tilts toward bladder,
occurs in ~66% patients)

Assessment of
uterine position may
dictate placement of
the tenaculum in
subsequent steps



Retroverted Uterus
(tilts back toward colon
occurs in ~33% patients)

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

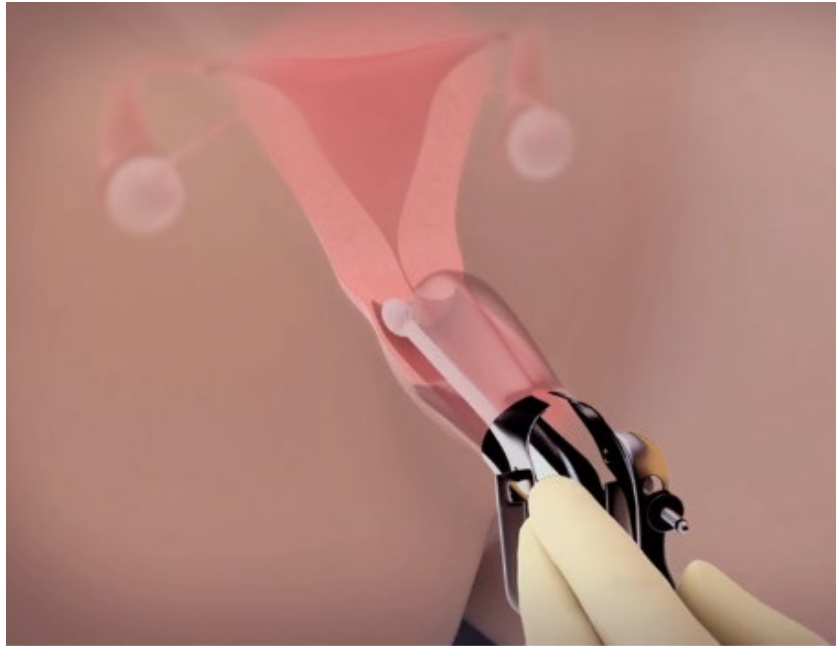
Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

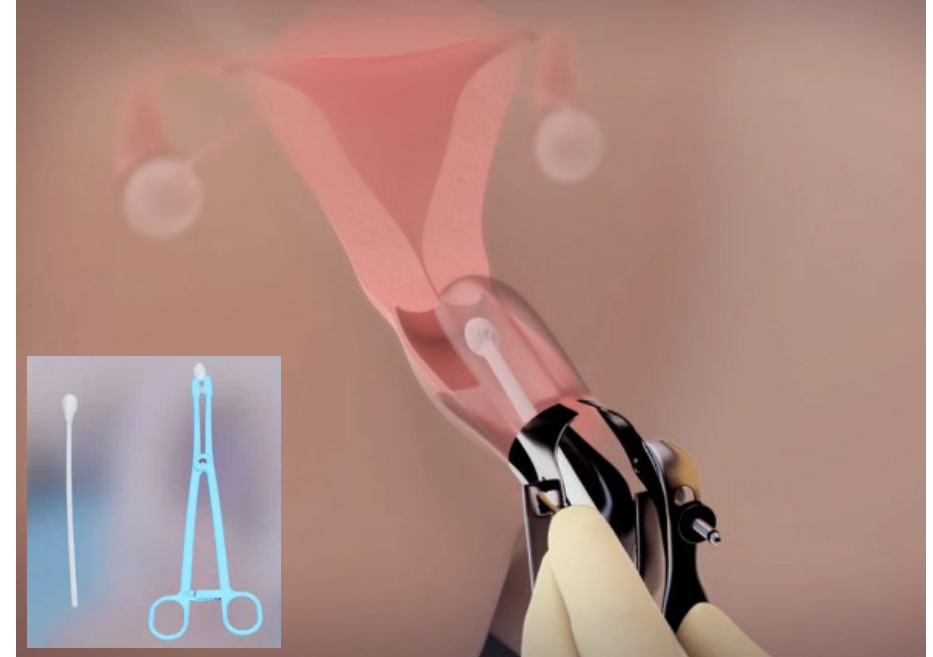
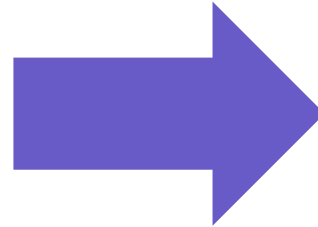
Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Preparation for Insertion: Cleansing

Preparation for
Insertion



Gently insert a speculum to visualize the cervix



Thoroughly cleanse the cervix and vagina with a suitable antiseptic solution and applicator

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

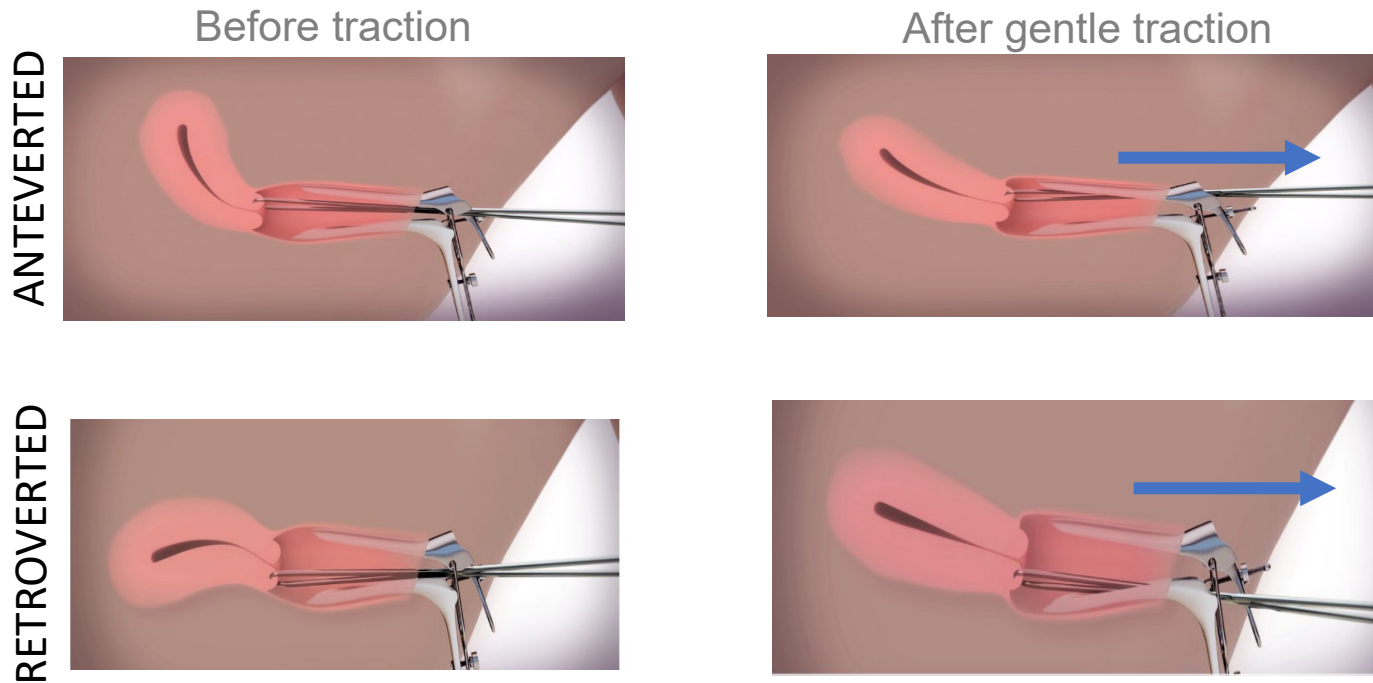
Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Preparation for Insertion: Tenaculum

Preparation for
Insertion



- Grasp the upper lip of the cervix with a tenaculum forceps and gently apply traction to stabilize and align the cervical canal with the uterine cavity; perform a paracervical block if needed



- If the uterus is retroverted, it may be more appropriate to grasp the lower lip of the cervix
- The tenaculum should remain in position and gentle traction on the cervix should be maintained throughout the insertion procedure

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

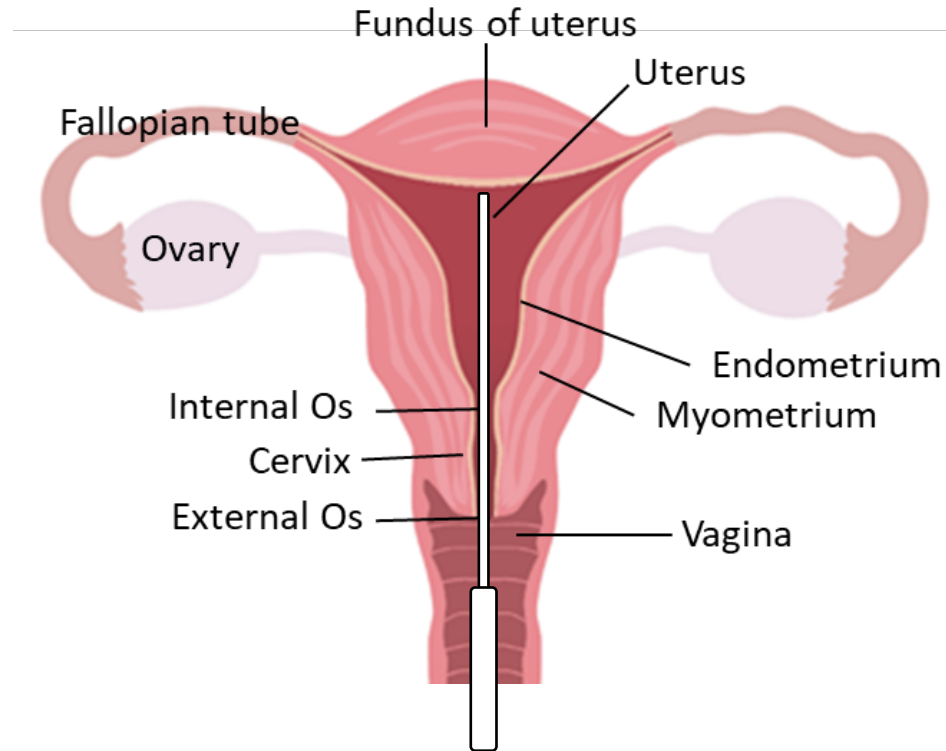
Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Preparation for Insertion: Sounding

Preparation for
Insertion



While maintaining traction on the tenaculum, gently insert a uterine sound to:

- check the patency of the cervix,
- measure the depth of the uterine cavity (in cm),
- confirm cavity direction, and
- detect the presence of any uterine anomaly

If you encounter difficulty or cervical stenosis, use dilatation, and not force, to overcome resistance

- If cervical dilation is required, consider using a paracervical block



Cervical Dilators

All patients should be sounded prior to insertion:

- Patients receiving Mirena should sound between 6-10cm;
- Kyleena and Skyla do not contain a sounding depth requirement

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

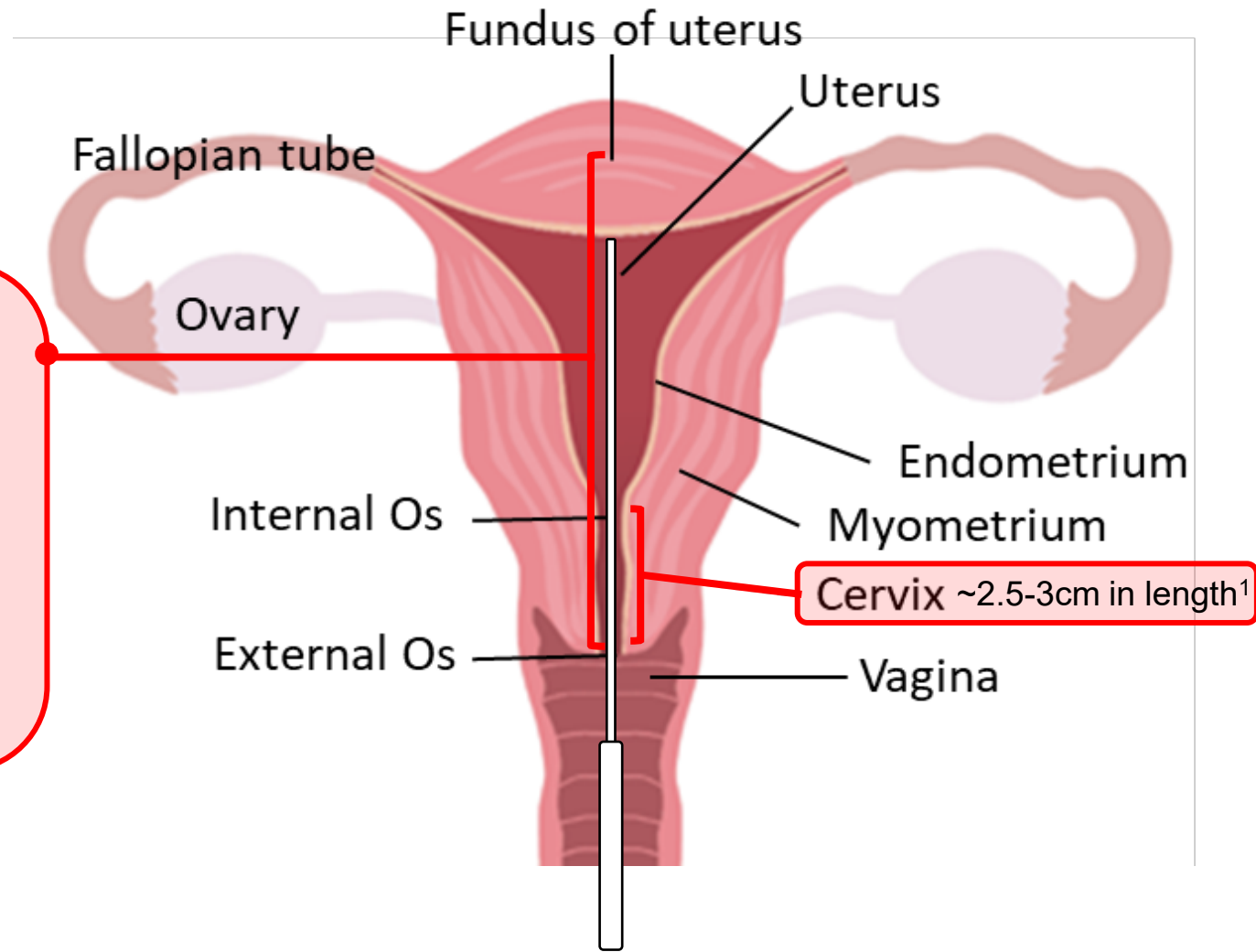
Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Sounding Depths

Average Sounding Depth

7.25cm In a clinical study of n=2,876 **parous & nulliparous** patients²

6.5cm In a clinical study of n=165 **nulliparous** patients³



1. Comprehensive GYN, 5th Ed., Katz, et al
2. Bayer Data on File; Clinical Study Report, Table 14.1.2 / 8
3. Kaislasuo, J et al. Human Reprod 2015 Jul;30(7):1580-8. Epub 2015 May 19.

Insertion Steps*

Insertion
Procedure



*NOTE: The inserter provided with Mirena, Kyleena, and Skyla and the insertion procedure described here, are not applicable for immediate insertion after childbirth or second-trimester abortion or miscarriage. For immediate insertion the Bayer IUD should be removed from the inserter and inserted according to accepted practice.

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

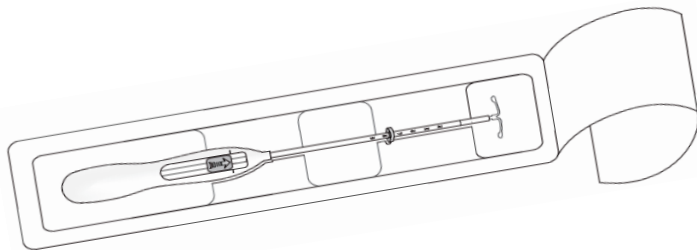
Insertion Steps

Insertion
Procedure



Step 1: Open the Package

- The contents of the package are sterile
- Using sterile gloves lift the handle of the sterile inserter and remove from the sterile package



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Insertion Steps

Insertion
Procedure



Step 1

Step 2

Step 3

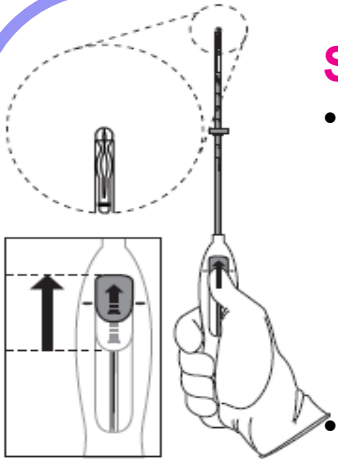
Step 4

Step 5

Step 6

Step 7

Cut
Threads



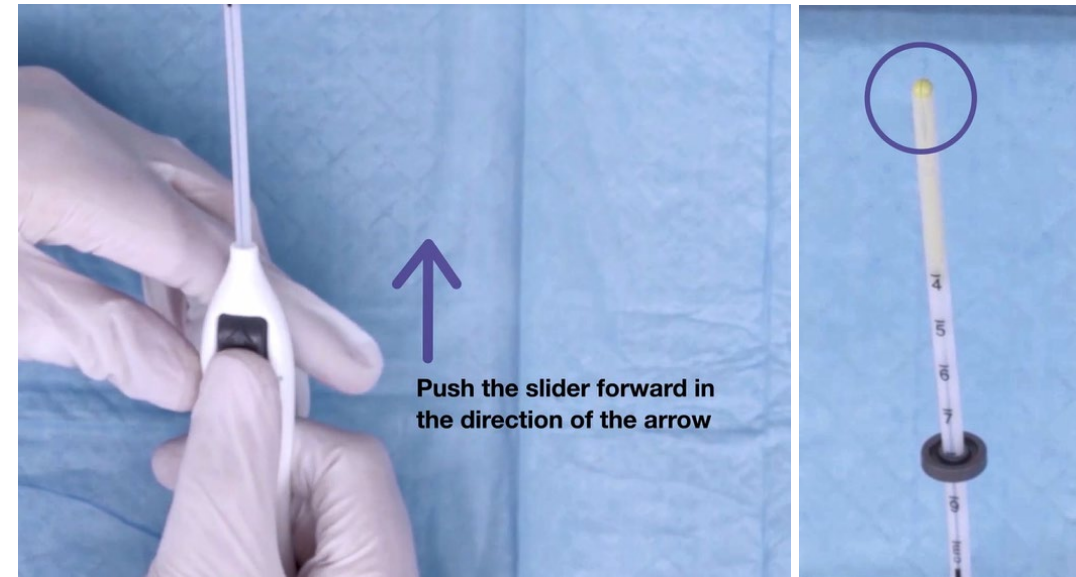
Step 2: Load the IUD into the insertion tube

- Push the slider **forward** as far as possible in the direction of the arrow thereby moving the insertion tube over the T-body to load the IUD into the insertion tube; the tips of the arms will meet to form a rounded end that extends slightly beyond the insertion tube
Maintain forward pressure with thumb or forefinger on the slider

IMPORTANT



DO NOT move the slider downward at this time as this may prematurely release the threads of the IUD; once the slider is moved below the mark, the IUD cannot be reloaded



Push the slider forward in the direction of the arrow

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

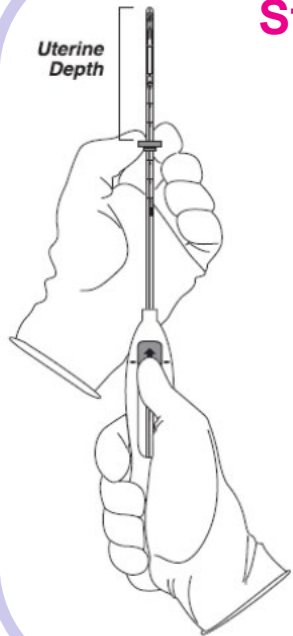
Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

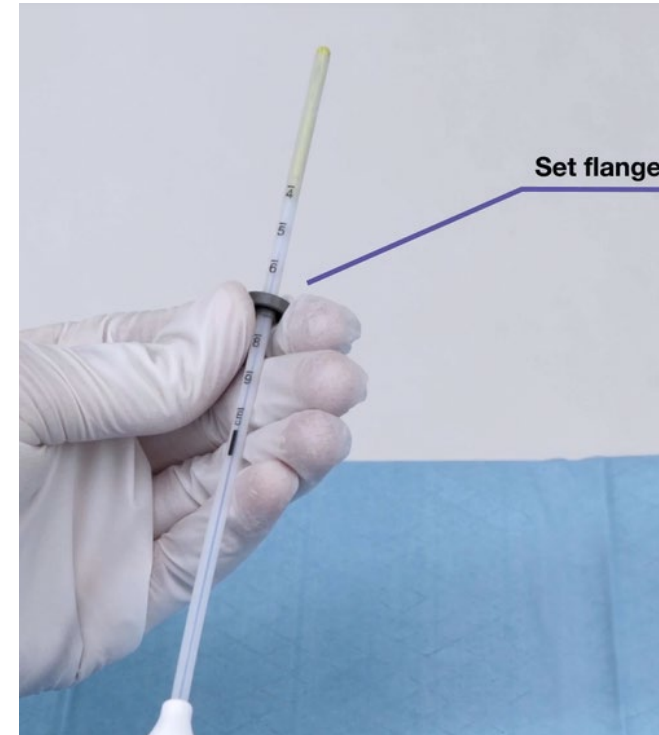
Insertion Steps

Insertion
Procedure



Step 3: Set the Flange

- Holding the slider in this forward position, set the upper edge of the flange to correspond to the uterine depth (in centimeters) measured during sounding
- **For Mirena, the uterus should sound to a depth of 6-10cm**
- **The Kyleena and Skyla labels do not specify a range for sounding depth**



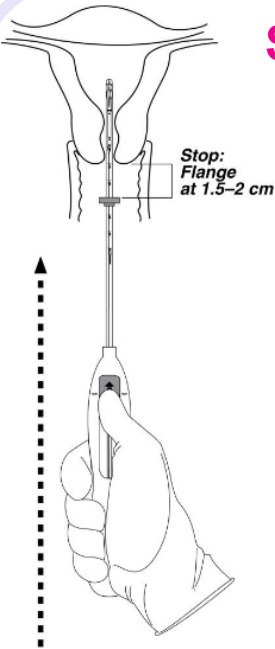
Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

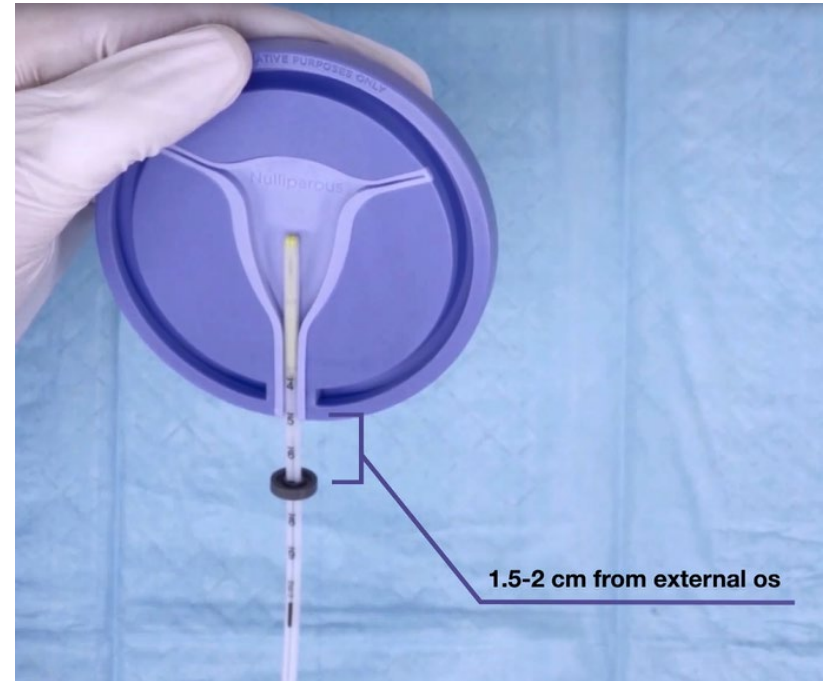
Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Insertion Steps



Step 4. The IUD is ready for insertion

- Continue holding the slider in this forward position; advance the inserter through the cervix until the flange is approximately 1.5 to 2 cm from the cervix and then pause
- **Do not force the inserter; if necessary, dilate the cervical canal**



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Insertion Steps

Insertion
Procedure



Step 1

Step 2

Step 3

Step 4

Step 5

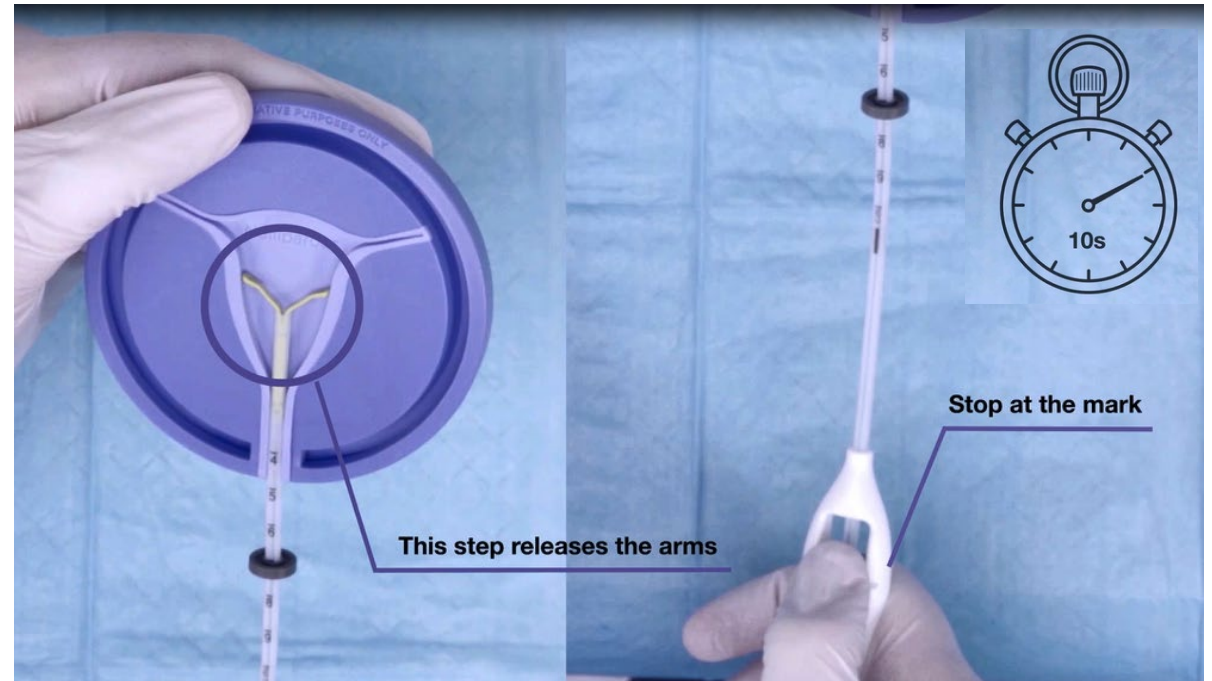
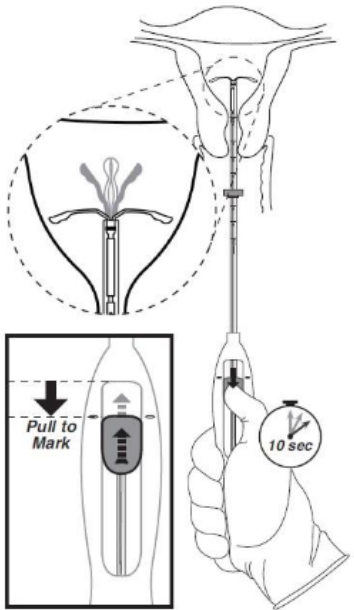
Step 6

Step 7

Cut
Threads

Step 5: Open the arms

- While holding the inserter steady, **move the slider down to the mark** to release the arms of the IUD
- Wait 10 seconds for the horizontal arms to open completely



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Insertion Steps

Insertion
Procedure



Step 1

Step 2

Step 3

Step 4

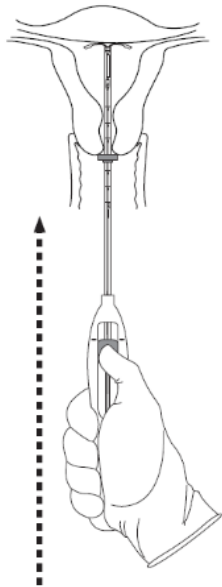
Step 5

Step 6

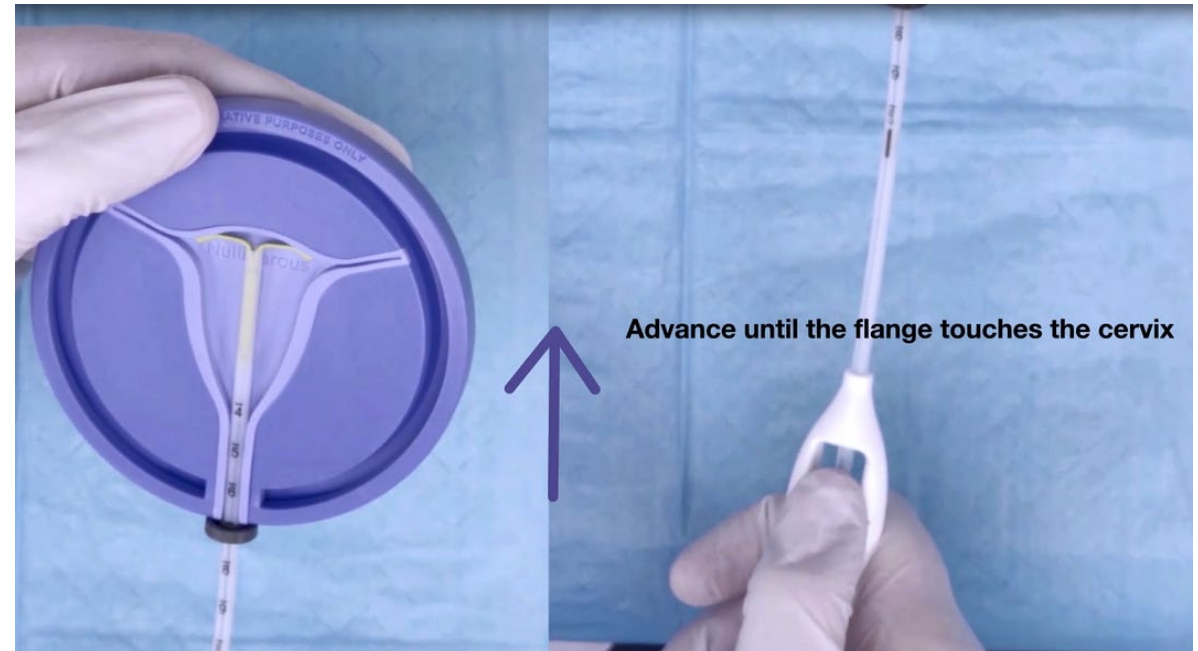
Step 7

Cut
Threads

Step 6. Advance to fundal position



- Advance the inserter gently towards the fundus of the uterus **until the flange touches the cervix**
- If you encounter fundal resistance do not continue to advance.
- The IUD is now in the fundal position
- **Fundal positioning of Mirena, Kyleena, or Skyla is important to prevent expulsion**



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Insertion Steps

Insertion
Procedure



Step 1

Step 2

Step 3

Step 4

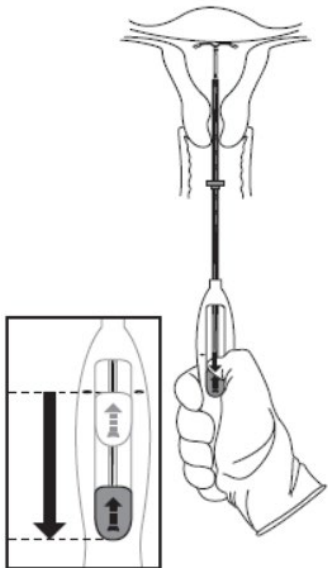
Step 5

Step 6

Step 7

Cut
Threads

Step 7: Release the IUD and withdraw the Inserter



Holding the entire inserter in place,
release the IUD by moving **the
slider all the way down**

Continue to hold the slider all the
way down while you slowly and
gently withdraw the inserter from
the uterus



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Insertion Steps

Insertion
Procedure



Step 1

Step 2

Step 3

Step 4

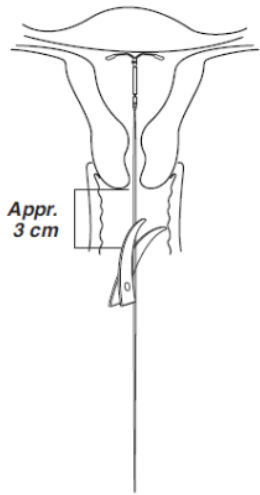
Step 5

Step 6

Step 7

Cut
Threads

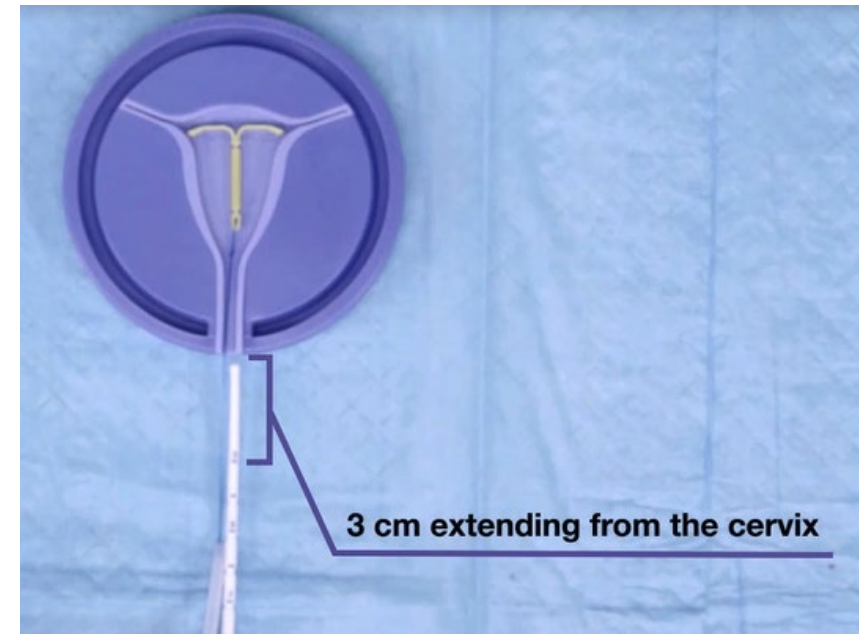
Cut the Threads



Using a sharp, curved scissor, cut the threads perpendicular, leaving about 3 cm visible outside the cervix (cutting threads at an angle may leave sharp ends)

Do not apply tension or pull on the threads when cutting to prevent displacing the IUD

Insertion is now complete; prescribe analgesics if indicated, and record the lot number in the patient's records



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

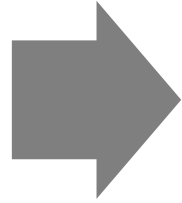
Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

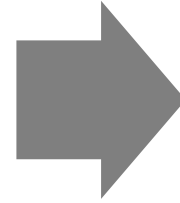
Important Information During & After Insertion



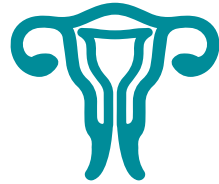
Preparation
for Insertion



Insertion
Procedure



**Important Information to
Consider During or After
Insertion**



If you suspect that the Bayer IUD, is not in the correct position, check for placement (for example with transvaginal ultrasound)

- Remove if it is not positioned completely within the uterus
- Do not reinsert a removed IUD



If there is clinical concern, exceptional pain, or bleeding during or after insertion, appropriate steps (such as physical examination and ultrasound) should be taken immediately to exclude perforation

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Important
Information to
Consider During
or After Insertion



Patient Follow-up



Reexamine and evaluate patients **4 to 6 weeks after insertion** and once a year thereafter, or more frequently if clinically indicated.

Advise patients to check that their IUD is in place **once a month** by feeling for the threads.

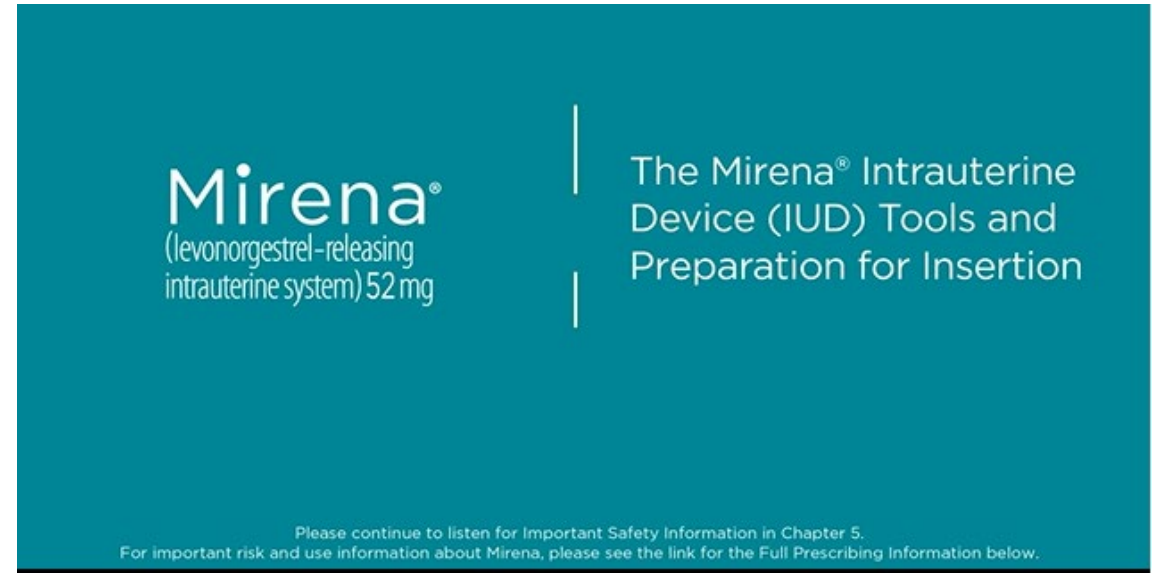
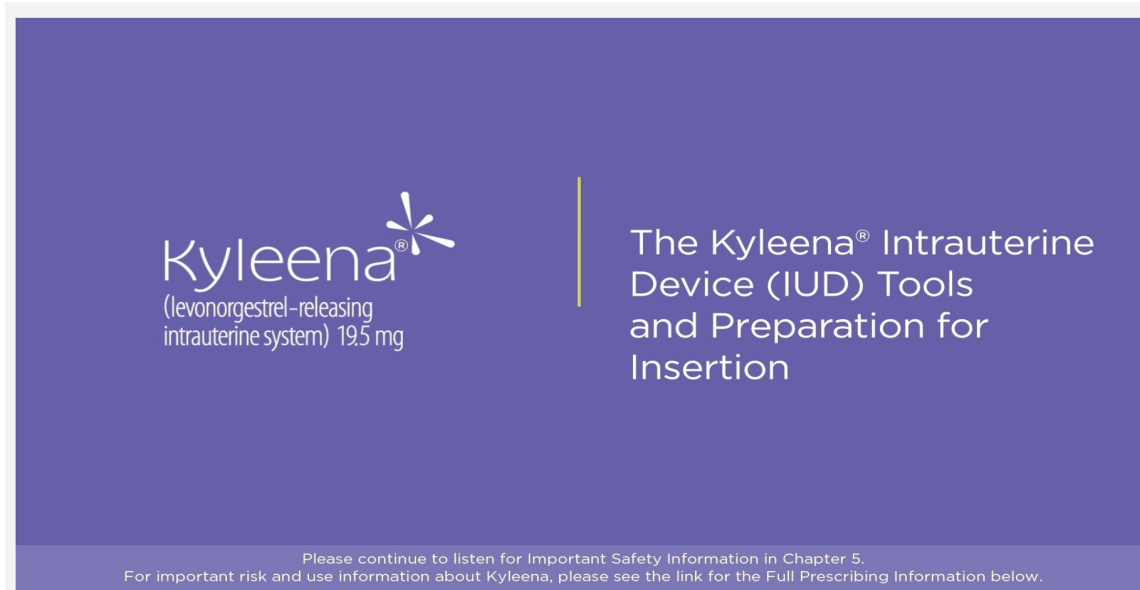
Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Insertion Video for Mirena and Kyleena



For insertion and removal steps for Skyla, please refer to the full [Prescribing Information](#) for Skyla

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena®
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena®
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla®
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Timing of Removal

Mirena should not remain in the uterus after 8 years for contraception, replace Mirena by the end of 5 years if continued treatment of HMB is needed;

Kyleena should not remain in the uterus after 5 years.

Skyla should not remain in the uterus after 3 years.

If pregnancy is not desired, removal should be carried out during the first seven days of menstruation, provided they are experiencing regular menses.

If removal will occur at other times during the cycle, or they do not experience regular menstrual cycles, they are at risk of pregnancy: start a new contraceptive method a week prior to removal for these patients.

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Removal: Tools



Tools for Removal:

- Preparation: gloves, speculum;
- Procedure: sterile forceps

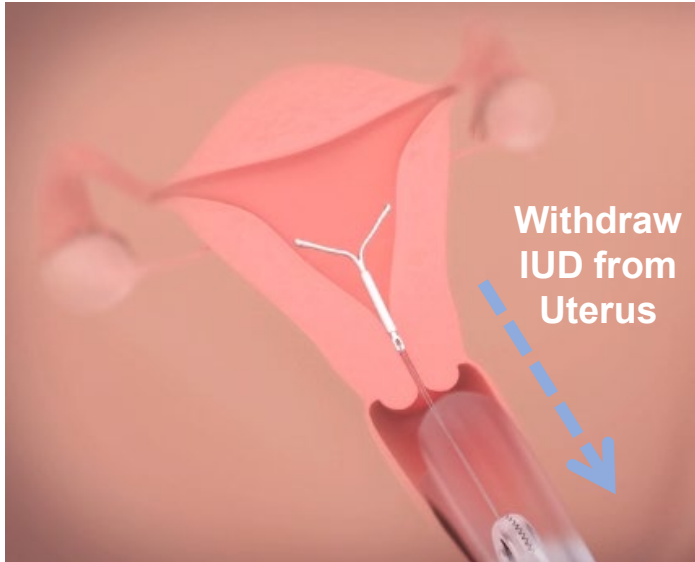
Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Removal: Procedure



- Remove the Bayer IUD by applying gentle traction on the threads with forceps
- If the threads are not visible:
 - Determine location by ultrasound
 - If found to be in the uterine cavity on ultrasound exam, it may be removed using a narrow forceps, such as an alligator forceps; this may require dilation of the cervical canal
 - After removal, the system should be examined to ensure that it is intact
 - The hormone cylinder of Mirena may slide over and cover the horizontal arms, giving the appearance of missing arms – this generally does not require further intervention once the system is verified to be intact



- If unable to remove with gentle traction, determine the location and exclude perforation by ultrasound or other imaging
- Removal may be associated with:
 - Pain and/or bleeding or vasovagal reactions (for example, syncope, bradycardia) or with seizure, especially in patients with a predisposition to these conditions
 - Breakage or embedment in the myometrium can make removal difficult; analgesia, paracervical analgesia, cervical dilatation, alligator forceps or other grasping instrument, or hysteroscopy may be used to assist in removal

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Continuation of Contraception after Removal



- If pregnancy is not desired and if a patient wishes to continue using Mirena, Kyleena, or Skyla a new system can be inserted immediately after removal any time during the cycle
- If a patient with regular cycles wants to start a different birth control method, time removal and initiation of new method to ensure continuous contraception:
 - Either remove the IUD during the first 7 days of the menstrual cycle and start the new method immediately thereafter, or
 - Start the new method at least 7 days prior to removal if occurring at other times during the cycle
- If a patient with irregular cycles or amenorrhea wants to start a different birth control method, start the new method at least 7 days before removal

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Thank you!

Questions?



Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Module 1: Equipment & Insertion Practice



- Review & Understand:
 - Insertion Timing
 - Instruments Needed for Bayer IUD Insertion
 - Patient Preparation Steps
 - Steps to Insert Bayer IUDs
 - Follow-up Information
 - What Patients Should Expect During Insertion
- Practice Insertion Using a Patient Scenario (next slide)

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

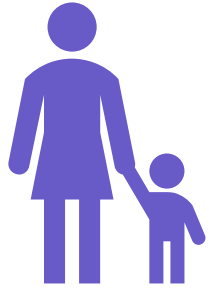
Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg

Complete Insertion & Removal Procedure

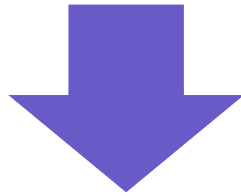


Patient Scenarios



Susan (she/her)

35-year-old G1P1
Good general health with no significant medical history
Currently on oral contraceptives
Has been counseled, and presents for Kyleena insertion



After 3 years, desires pregnancy and wants the IUD removed



Beth (she/her)

40-year-old G3P3
No significant past medical history and in good general health
Has been counseled on Mirena, and presents for Mirena insertion
Currently using condoms for birth control



After 2 years, requests IUD removal

Please see Important Safety Information throughout. Please see full Prescribing Information for [Mirena](#), [Kyleena](#), and [Skyla](#) that is available at this presentation.

Mirena[®]
(levonorgestrel-releasing
intrauterine system) 52 mg

Kyleena[®]
(levonorgestrel-releasing
intrauterine system) 19.5 mg

Skyla[®]
(levonorgestrel-releasing
intrauterine system) 13.5 mg



Module 2:
**Contraceptive
Counseling**

Steps to Providing Quality Person-Centered Counseling

Guidance from the US Office of Population Affairs (OPA)



Establish and maintain rapport



Assess their preferences, values and goals; personalize discussions accordingly



Work interactively to establish a plan



Provide accurate and understandable information that supports their desires



Confirm understanding

Steps to Providing Quality Person-Centered Counseling

Guidance from the US Office of Population Affairs (OPA)



Establish and maintain rapport

- Use simple acts such as a warm welcome, a handshake, and “taking the time to connect as human beings”
- Ensure privacy and confidentiality
- Ask permission to discuss sexual reproductive health (SRH) topics as well as inquiring, acknowledging, and centering their goals and desires for the visit
- Match the person’s tone, paraphrasing what they said, and asking if you got it right
 - *“What I am hearing is that you prefer....., do I have that right?”*
- Focus more attention on respectful listening versus talking at them

Steps to Providing Quality Person-Centered Counseling

Guidance from the US Office of Population Affairs (OPA)



Establish and maintain rapport



Assess their preferences, values and goals; personalize discussions accordingly

- **Open-ended questions** and structured questionnaires can contribute to understanding preferences, values and goals
- Assess the type of care and information a person might want or need and how the person prefers to receive information and make decisions
- Meet people where they are
- Avoid attempts to redirect their goals
- Set aside personal biases that may conflict with one's preferences and work to support their desired outcomes

Steps to Providing Quality Person-Centered Counseling

Guidance from the US Office of Population Affairs (OPA)



Establish and maintain rapport



Assess their preferences, values and goals; personalize decisions accordingly

- **Open-ended questions** and structured questionnaires can contribute to understanding preferences, values and goals
- Assess the type of care and information a person might want or need and how the person prefers to receive information and make decisions
- Meet people where they are
- Avoid attempts to redirect their goals
- Set aside personal biases that may conflict with one's preferences and work to support their desired outcomes



Example open-ended, person-centered questions to assess preferences:

- Can you tell me something (or some things) that are important to you in your contraception?
- What else are you looking for?
- Is there anything else you're hoping to get out of your contraception?
- Is there anything you don't want (or want to avoid) in a method?

Samantha (she/her)



- 25-year-old G0, in good general health
- Presents for flu shot

What questions could you ask to assess her contraceptive preferences?

Samantha (she/her)



- 25-year-old G0, in good general health
- Presents for flu shot
- She is currently taking oral contraceptives and is interested to hear about other methods
- She is not seeking pregnancy for several years

How can you use the framework below to help Samantha select an appropriate contraceptive method?
Could she initiate that method today?



Karen (she/her)



- 42-year-old G2P2
- Presents for birth control refill

What questions could you ask to assess her contraceptive preferences?
Is she interested in other birth control options?



Karen (she/her)



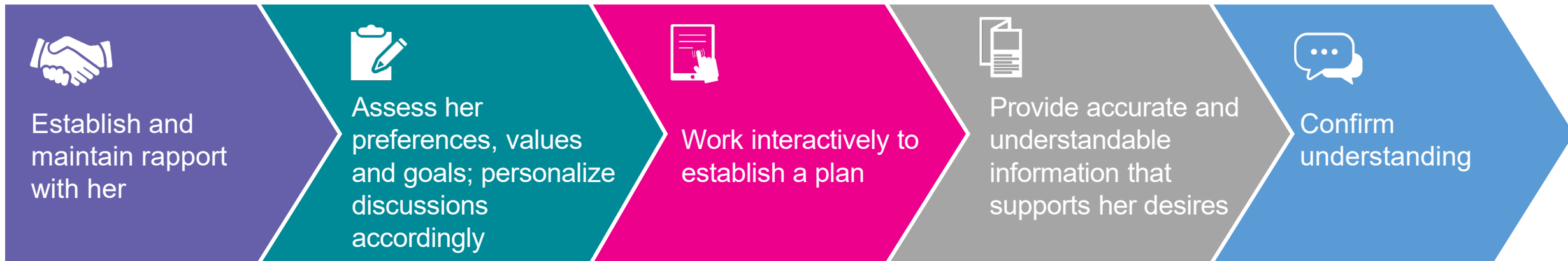
- 42-year-old G2P2
- Presents for birth control refill
- While discussing future childbearing plans, she mentions having heavy periods

Karen (she/her)



- 42-year-old G2P2
- Presents for birth control refill
- While discussing future childbearing plans, she mentions having heavy periods

What questions could you ask to learn more about her experience with heavy periods? How many pads or tampons does she use per cycle? How can you use the framework below to help Karen select an appropriate contraceptive method? Could she initiate that method today?





Thank you!

Any Questions?

Mirena[®] (levonorgestrel-releasing intrauterine system) 52mg

Kyleena[®] (levonorgestrel-releasing intrauterine system) 19.5mg

Skyla[®] (levonorgestrel-releasing intrauterine system) 13.5mg

Please see Important Safety Information throughout. Please see full Prescribing Information for Mirena, Kyleena, and Skyla that is available at this presentation.

Shoulder/ Trigger Point

Table 180.1

Relative Potency of Steroids.

Corticosteroid	Relative Antinflammatory Potency	Approximate Equivalent Dose (mg)
Short-Acting Preparations		
Cortisone	0.8	25
Hydrocortisone	1	20
Intermediate-Acting Preparations		
Prednisone	3.5	5
Prednisolone tebutate (Hydeltra-TBA)	4	5
Triamcinolone (Aristocort, Aristospan, Kenalog)	5	4
Methylprednisolone acetate (Depo-Medrol)	5	4
Long-Acting Preparations		
Dexamethasone (Decadron-LA)	25	0.6
Betamethasone (Celestone Soluspan)	25	0.6

Modified from Lerversee JH. Aspiration of joints and soft tissue injections. *Prim Care* 1986;13:572.

Pfenninger and Fowler's Procedure for Primary Care, 4th Ed.

Table 180.2

Common Corticosteroids and Recommended Dosages for Various Joint Injections

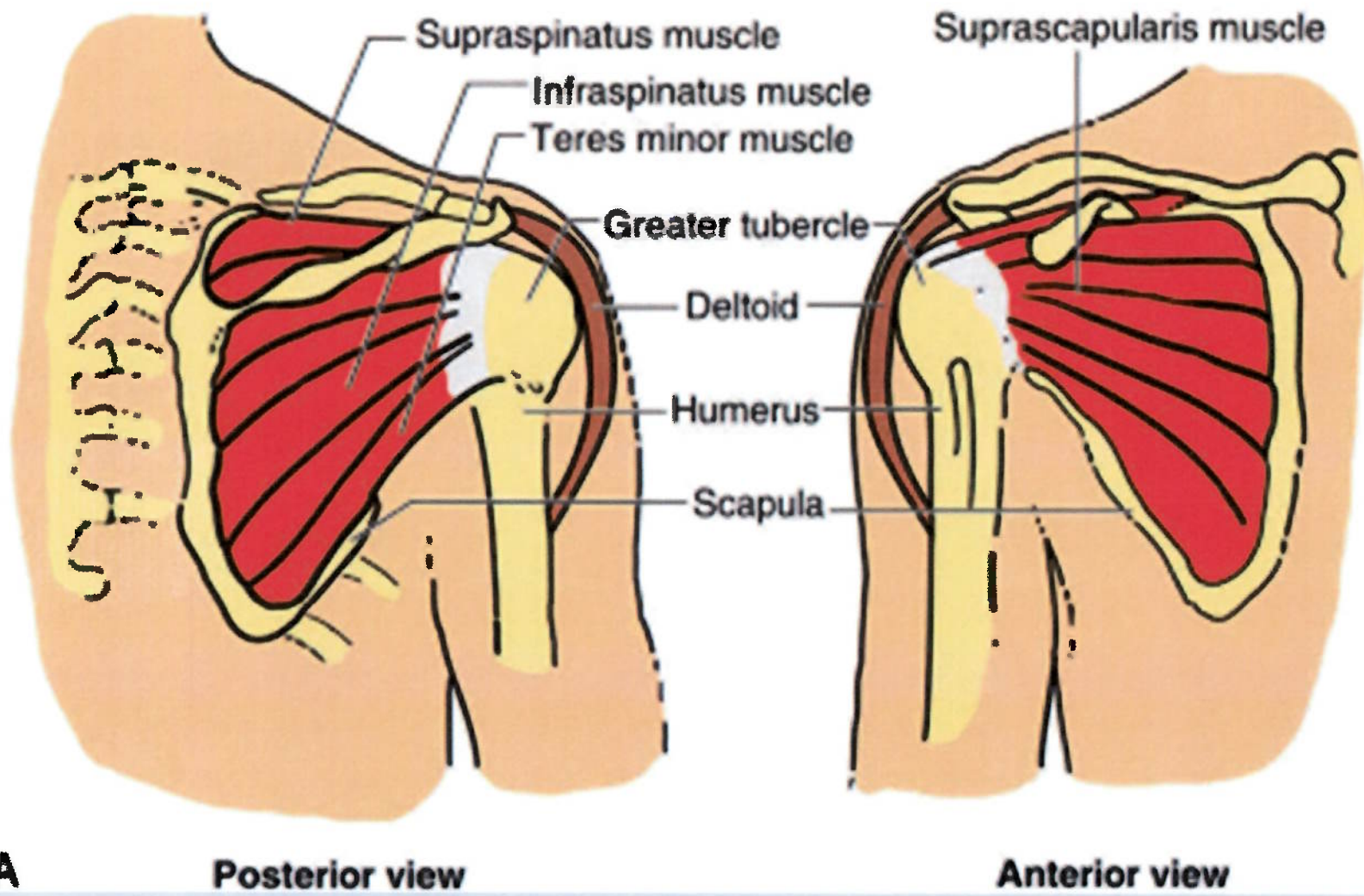
Corticosteroid	Concentration (mg/mL)	Large Joint* Dosage (mg)	Medium Joint† Dosage (mg)	Small Joint ^{†,‡} Dosage (mg)	Ganglia (mg)	Tendon Sheath (mg)	Bursa (mg)
Hydrocortisone acetate	25, 50	40-100	20-40	8-20	20-40	20-50	40-90
Prednisolone tebutate (Hydeltra-TBA)	20	20-30	10-20	8-10	10-20	4-10	20
Prednisolone sodium phosphate	20	10-20	5-10	4-5	5-10	3-8	20
Triamcinolone hexacetonide (Aristospan)	5, 20	20-30	10-20	8-10	10-20	4-10	20
Triamcinolone diacetate (Aristocrat)	25, 40	20-40	10-20	8-10	10-20	4-10	20
Triamcinolone acetonide (Kenalog)	10, 40	20-40	10-20	8-10	10-20	4-10	20
Methylprednisolone acetate (Depo-Medrol)	20, 40, 80	20-40	10-40	8-10	4-20	4-10	20
Dexamethasone sodium phosphate (Decadron)	4	2-4	1-3	0.8-1	1-2	0.4-1	2-3
Dexamethasone acetate (Decadron-LA)	8	2-4	1-3	0.8-1	1-2	0.4-1	2-3
Betamethasone acetate/phosphate (Celestine Soluspan)	6	6-12	3-6	1.5-3	1-3	1.5-2	3-6

Pfenninger and Fowler's Procedure for Primary Care, 4th Ed.

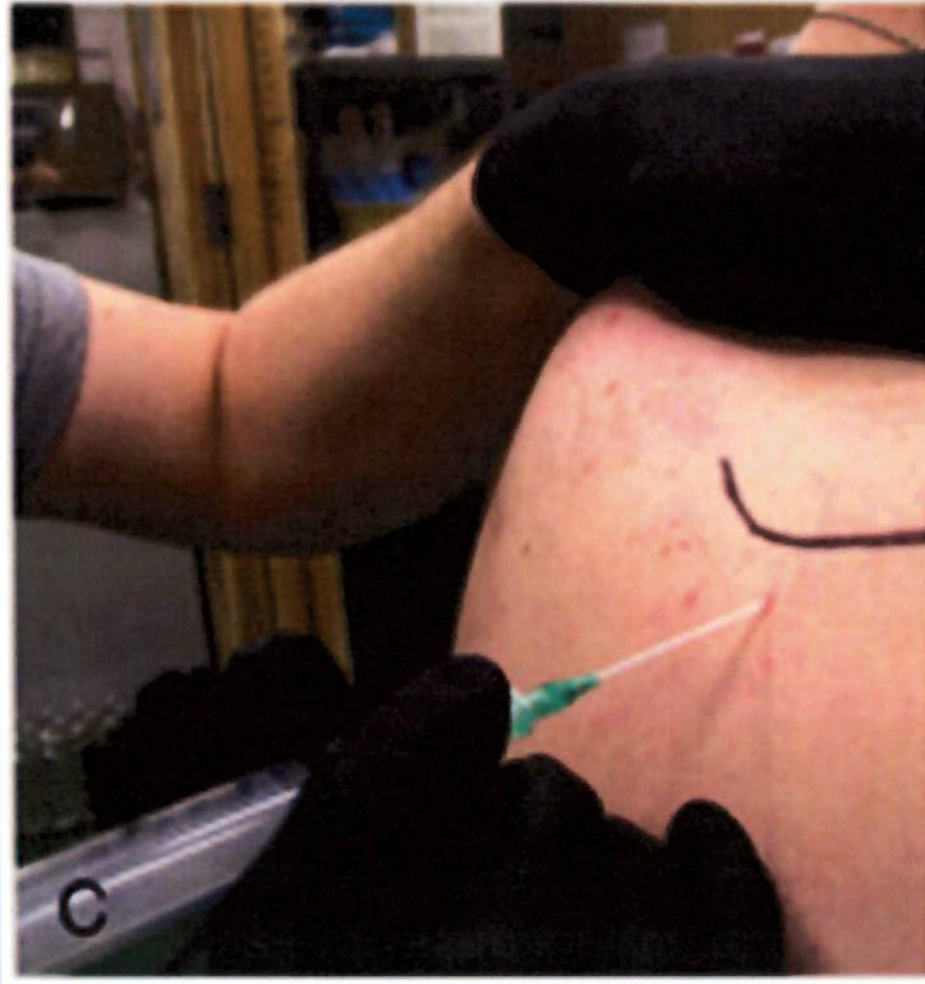
Shoulder Injection

- Equipment:
 - Sterile or Nonsterile Gloves
 - Betadine, Alcohol Swabs
 - Ethyl Chloride Spray (Optional)
 - 1 ½ inch 22-gauge needle
 - Cocktail: 4 cc 1% lidocaine without epi and 40 mg (1 cc of Kenalog)
 - Band-Aid.





Shoulder Injection



Pfenninger and Fowler's Procedure for Primary Care, 4th Ed.

Geisinger

Supraspinatus tendon

Acromion

Subacromial bursa

Glenohumeral joint capsule

Supraspinatus muscle

Coracoid process

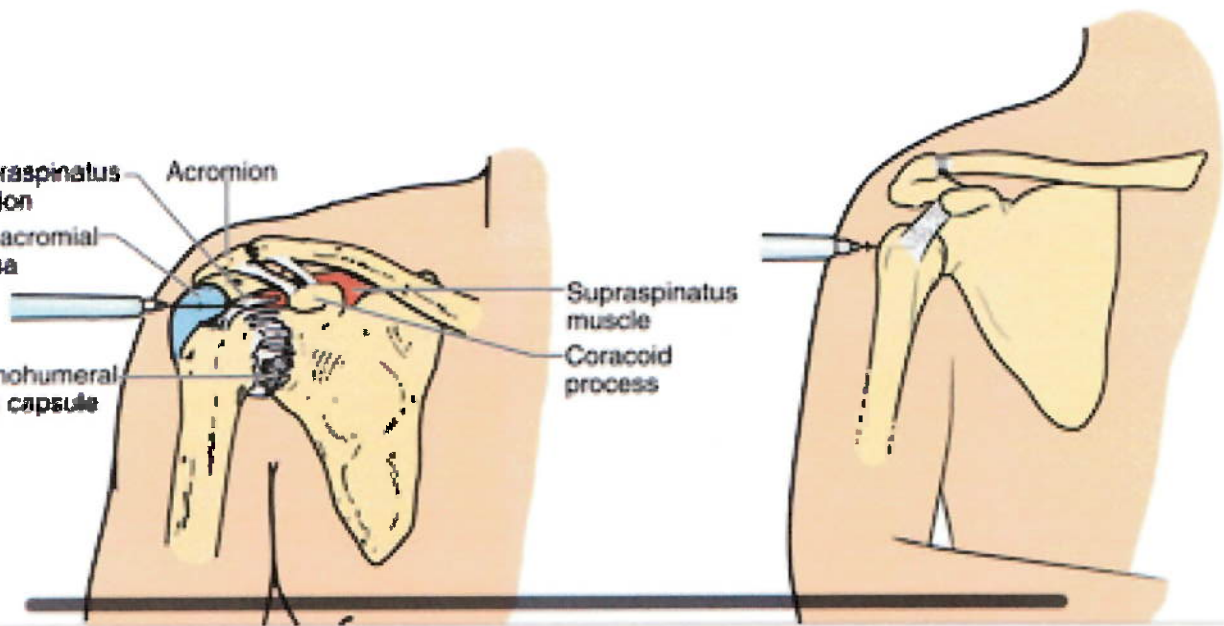


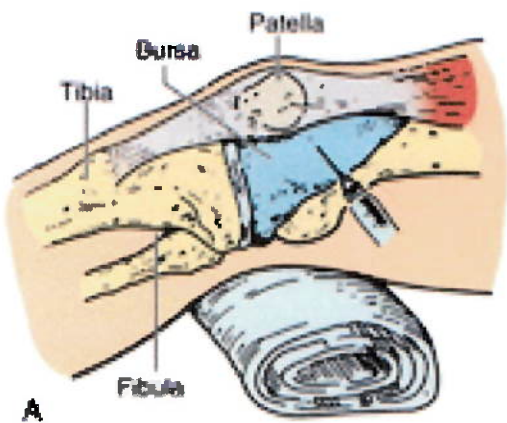
FIG. 180.12 Shoulder: Subacromial bursa. Most injection procedures involving the shoulder will include an injection into the subacromial bursa. Palpate the superior surface of the shoulder, progressing laterally until there is a slight drop-off. This is the lateral edge of the acromion. The now palpable soft spot above the humeral head is the location of the subacromial bursa. Direct the needle perpendicular to the surface and insert the needle through the deltoid muscle into the bursa. The needle should be free floating, since it is within a space, not in a muscle or tendon. The tendon of the supraspinatus, the muscle most commonly involved in a rotator cuff syndrome, is directly medial to this bursa and can be entered by directing the needle deeper. If the tendon is calcified as it is entered, a gritty sensation may be felt. Inject within the bursa, not within the tendon. (A) The muscles of the rotator cuff

inject within the bursa, not within the tendon. (A) The muscles of the rotator cuff are demonstrated. They include the supraspinatus, the infraspinatus, teres minor, and the subscapularis. (B) The technique of a subacromial bursa injection, anterior view. (C) Injecting the subacromial bursa, posterior approach. Use a 22-gauge, 1- to 1.5-inch needle with 5 to 7 mL 1% lidocaine and 30 to 40 mg of methylprednisolone acetate or equivalent (see Tables 180.2 and 180.5). It can be reached from anterior, lateral, or posterior approach, but outcome studies suggest using lateral approach, especially in women who may have slightly smaller bursa.

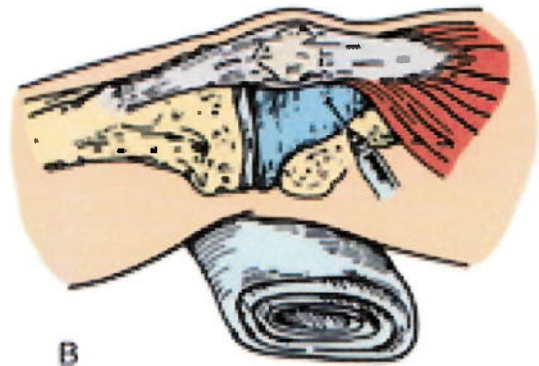
Knee Injection



Geisinger



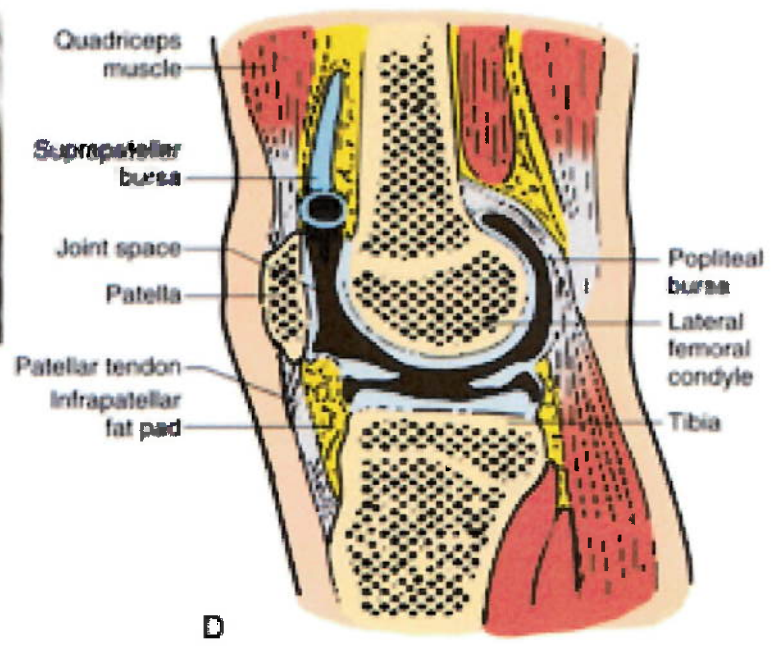
A



B



C

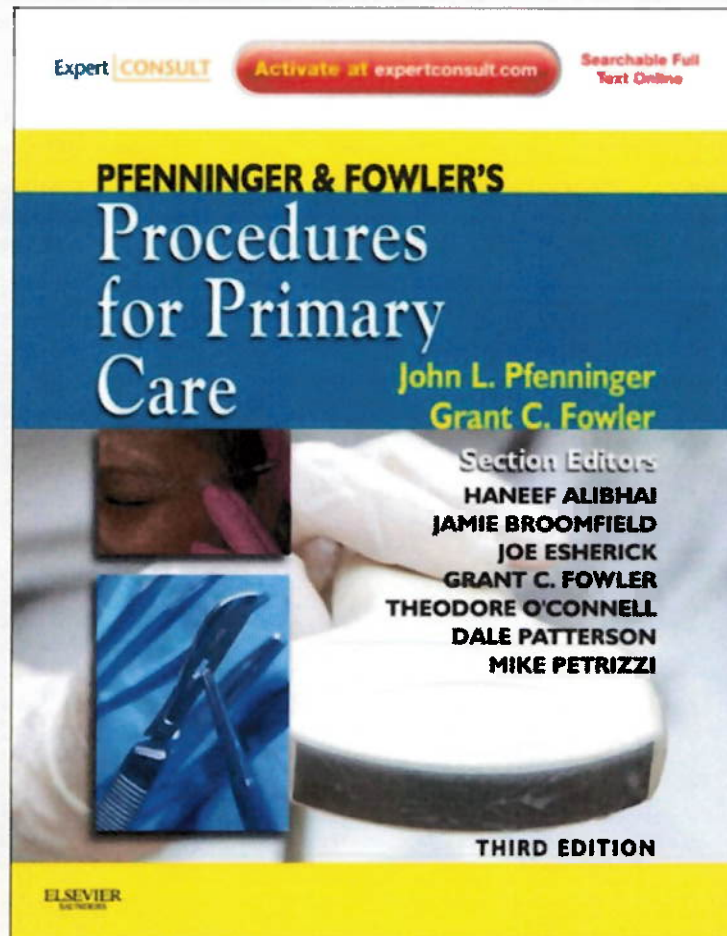


D

FIG. 180.20 Knee joint. The knee is one of the easiest joints to enter and one of the most common joints to aspirate and inject. Slightly flex the knee using a towel in the popliteal space with the patient lying on an examination table. Either a lateral (A) or medial (B) approach may be used. For the lateral approach, palpate the superior lateral aspect of the patella and insert the needle 1 cm superior and 1 cm lateral to this point. Apply gentle pressure on the contralateral side of the knee to encourage the fluid to pool in the area of aspiration. Direct the needle under the patella at a 45-degree angle to the midjoint area. Aspirate all fluid before injection. There should be no resistance. (C) Other approaches include entering medially or laterally directly above the joint line with the patient seated, or going directly through the patellar tendon just below the patella. Another option is to enter the joint capsule from either side of the patellar tendon just below the patella. This is an excellent location when there is little cartilage left; the knee is basically bone on bone so there is little room to maneuver the patella. (D) The knee joint space is large and is readily entered from multiple approaches. Use a 20-gauge, 1- to 1.5-inch needle with 5 mL 1% lidocaine

maneuver the patella. (D) The knee joint space is large and is readily entered from multiple approaches. Use a 20-gauge, 1- to 1.5-inch needle with 5 mL 1% lidocaine and 20 to 80 mg of methylprednisolone acetate or equivalent (see Tables 180.2 and 180.5). A Baker cyst is a sac of synovial fluid that has leaked out of a hole in the posterior capsule of the knee. It generally indicates significant internal knee problems, and steroid injections are only a temporary relief frowned on by many clinicians. Insert the needle 3 cm medial to the midline and 3 cm below the popliteal crease. Take care to avoid the popliteal artery, vein, and nerve. Use a 20-gauge, 1- to 1.5-inch needle with 5 mL 1% lidocaine and 20 to 80 mg of methylprednisolone acetate or equivalent (see Table 180.2).

Diagrams and Pictures Adapted from : Pfenninger JL, Fowler GC. *Pfenninger and Fowler's Procedures for Primary Care*. 3rd ed. Saunders; 2011



**Knee
Injections/
Trigger Finger**

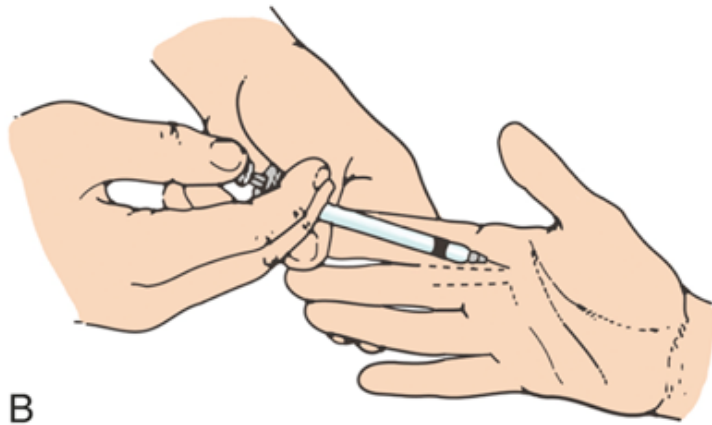
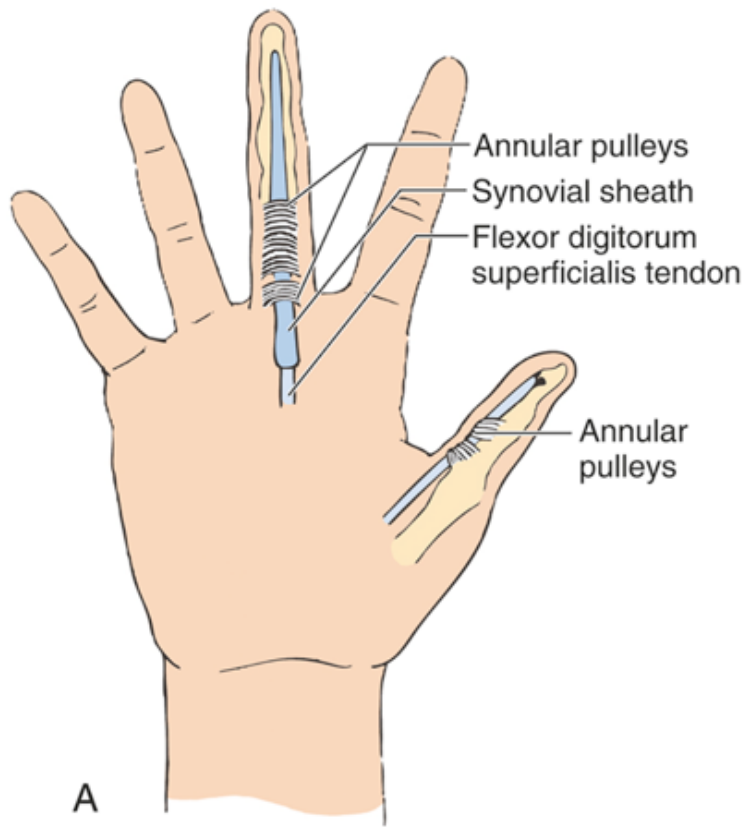


FIG. 180.3 Trigger finger. (A) The anatomy of a finger showing the annular pulleys, which maintain the flexor close to the bony structures. When the tendon

FIG. 180.3 Trigger finger. (A) The anatomy of a finger showing the annular pulleys, which maintain the flexor close to the bony structures. When the tendon becomes inflamed and enlarges, it catches on the pulleys, causing a snapping with extension or a “trigger finger.” (B) Identify the flexor tendon involved. Insert the needle at the distal palmar crease. Attempt to position it peritendinously. When the needle is in position, the syringe will move with flexion of the finger. Use a 25-gauge, 1-inch needle with 0.25 to 0.5 mL 1% lidocaine and 4 to 10 mg of methylprednisolone acetate or equivalent (see Tables [180.2](#) and [180.5](#)).

Diagrams and Pictures Adapted from : Pfenninger JL, Fowler GC. *Pfenninger and Fowler's Procedures for Primary Care*. 3rd ed. Saunders; 2011

