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

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5mg

Mirena® (levonorgestrel-releasing intrauterine system) 52mg

Skyla® (levonorgestrel-releasing intrauterine system) 13.5mg

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

PP-PF-WHC-IUS-US-1567, August 2022
Program Overview & Resources

Overview of contraceptive counseling and Bayer IUDs

- Contraceptive Counseling
- Bayer IUDs - Safety & efficacy
- Appropriate patients for Bayer IUDs
- Insertion timing
- Insertion procedure

Insertion Steps Practice & Simulation

- Review equipment needed for IUD insertion
- Patient preparation & insertion steps
- Insertion timing & need for back-up contraception
- Perform complete insertion and removal procedure

Patient Counseling Resources

- Reproductive life planning questions
- Guidance from the CDC (Centers for Disease Control and Prevention) on Quality Contraceptive Counseling
- Counseling specific to Bayer IUDs
Reproductive Life Planning

A set of personal goals regarding whether, when and how to have children\textsuperscript{1}

Reproductive Life Planning: When?

A set of personal goals regarding whether, when and how to have children

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

<table>
<thead>
<tr>
<th>Telehealth</th>
<th>Annual Physical</th>
<th>Pre/Post Natal visits</th>
<th>Sick Visit</th>
</tr>
</thead>
</table>

Reproductive Life Planning: Start the Discussion

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

“Every woman, every time”

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

Principles of Quality Contraceptive Counseling
CDC and Office of Population Affairs

KEY STEPS IN PROVIDING CONTRACEPTIVE SERVICES

1. Establish and maintain rapport with the patient
2. Assess their needs and personalize discussions accordingly
3. Work interactively to establish a plan
4. Provide educational materials that can be understood and retained
5. Confirm patient understanding (“teach-back”)

Contraceptive Efficacy

An IUD (Intrauterine Device) is a long-acting method of birth control, and is considered to be one of the most effective methods of reversible birth control.¹

What are Kyleena & Mirena?

Indications

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

- 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

Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena, Mirena, and Skyla (levonorgestrel-releasing intrauterine system) 13.5mg that is available at this presentation.
Properties

<table>
<thead>
<tr>
<th></th>
<th>Kyleena®</th>
<th>Mirena®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormone Reservoir (Total Amount)</td>
<td>19.5mg LNG</td>
<td>52mg LNG</td>
</tr>
<tr>
<td>Insertion Tube Diameter</td>
<td>3.8 mm</td>
<td>4.4 mm</td>
</tr>
<tr>
<td>Release Rate After 1 Year</td>
<td>9.8 mcg/d</td>
<td>19 mcg/d</td>
</tr>
<tr>
<td>Thread color</td>
<td>Blue</td>
<td>Brown</td>
</tr>
<tr>
<td>Silver Ring / MR Compatibility</td>
<td>Yes / MR Conditional</td>
<td>No Silver Ring</td>
</tr>
</tbody>
</table>

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 Kyleena, Mirena, and Skyla (levonorgestrel-releasing intrauterine system) 13.5mg that is available at this presentation.
What is Skyla?
Indication & Properties

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hormone Reservoir (Total Amount)</strong></td>
<td>13.5mg</td>
</tr>
<tr>
<td><strong>Insertion Tube Diameter</strong></td>
<td>3.8mm</td>
</tr>
<tr>
<td><strong>Release Rate After 1 Year</strong></td>
<td>~6 mcg/d</td>
</tr>
<tr>
<td><strong>Thread color</strong></td>
<td>Brown</td>
</tr>
<tr>
<td><strong>Silver Ring / MR Compatibility</strong></td>
<td>Yes / MR Conditional</td>
</tr>
</tbody>
</table>

The combination of silver ring and thread color will help identify the brand of IUD.
Important Safety Information for Kyleena, Mirena, 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 Kyleena, Mirena, or Skyla

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

Additionally:

- 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 Kyleena, Mirena, 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 Kyleena, Mirena, and Skyla that is available at this presentation.
Suggested Mechanism of Action

The local mechanism of action has not been conclusively demonstrated.

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

- Alteration of the endometrium
- Inhibition of sperm capacitation or survival
- Thickening of cervical mucus (CM) preventing passage of sperm into the uterus

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

- 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.

Lewis et al., 2010. Used with permission.
**Contraceptive Efficacy**

**Contraception Clinical Trials**

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

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**Demographics**

- N=1,452 women (5 year trial)
  - 18-35 years
  - 40% nulliparous (n=574)
  - BMI range: 15.2-57.6 kg/m\(^2\) (avg=25.3 kg/m\(^2\))

**Efficacy**

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

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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 Kyleena, Mirena, 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 ≤0.2/100 women (0.2%)
- 5-year cumulative pregnancy rate ~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%)
Clinical Trial on Heavy Menstrual Bleeding

Trial Overview\textsuperscript{1,2}:

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

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

\[\text{Baseline} \quad 154.20\]
\[\text{Midstudy} \quad 147.96\]
\[\text{End of Study} \quad 121.47\]

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

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

Contraceptive Efficacy

Contraception Clinical Trials

Demographics
- N=1,432 women (3 year trial)
  - 18-35 years
  - 38.8% nulliparous (n=556)
  - BMI range: 16-55 kg/m$^2$ (avg=25.3 kg/m$^2$)

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

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 Kyleena, Mirena, and Skyla that is available at this presentation.
Important Safety Information
Pregnancy Related Risks

• If pregnancy should occur with Kyleena, Mirena 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 Kyleena, Mirena 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.

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Insertion

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5mg

Mirena® (levonorgestrel-releasing intrauterine system) 52mg

Skyla® (levonorgestrel-releasing intrauterine system) 13.5mg

Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena, Mirena, 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 Kyleena, Mirena, and Skyla that is available at this presentation.
## Timing of Insertion
Same day insertion can be considered if it is reasonably certain the patient is not pregnant

<table>
<thead>
<tr>
<th>Patients not currently using hormonal or intrauterine contraception</th>
<th>IUS insertion timing</th>
<th>Backup contraception?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Any time there is reasonable certainty they are not pregnant</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>• Consider the possibility of ovulation and conception prior to initiation</td>
<td>NO If inserted during the first 7 days of the menstrual cycle, or immediately after first trimester abortion</td>
<td></td>
</tr>
</tbody>
</table>

### Switching from:

<table>
<thead>
<tr>
<th>Pills, transdermal patch, or vaginal ring</th>
<th>IUS insertion timing</th>
<th>Backup contraception?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Any time, including the hormone-free Interval of the previous method</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES if inserted during use of continuous hormonal contraception, continue method for 7 days after insertion</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Injectable progestin contraceptive</th>
<th>IUS insertion timing</th>
<th>Backup contraception?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Any time</td>
<td>YES if inserted &gt;3 months (13 weeks) after the last injection, backup contraception (such as condoms or spermicide) should also be used for 7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO if inserted &lt;3 months after last injection</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Implant or IUS</th>
<th>IUS insertion timing</th>
<th>Backup contraception?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Anytime during the menstrual cycle</td>
<td>NO there is no need for backup contraception</td>
<td></td>
</tr>
<tr>
<td>• Insert on the same day as removal of the implant or IUS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Timing of Insertion

After First or Second Trimester Abortion or Miscarriage, and Childbirth

<table>
<thead>
<tr>
<th>Timing of Insertion</th>
<th>Insertion timing</th>
<th>Backup contraception?</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 1st trimester abortion or miscarriage</td>
<td>• Can be inserted immediately, unless it’s a septic abortion</td>
<td>NO</td>
</tr>
<tr>
<td>After childbirth or 2nd trimester abortion or miscarriage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate insertion after childbirth, or 2nd trimester abortion or miscarriage</td>
<td>• Insert after removal of placenta</td>
<td>NO</td>
</tr>
</tbody>
</table>
| Interval insertion following complete involution of the uterus | • 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 |
Kyleena, Mirena, 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 Kyleena, Mirena, and Skyla that is available at this presentation.
Important Safety Information
Educate her about Pelvic Inflammatory Disease (PID)

- PID is often associated with sexually transmitted infections (STIs); Kyleena, Mirena, 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:
  - **Kyleena & Skyla** – PID occurred more frequently within the first year and most often within the first month after insertion.
  - **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.

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Effect on Bleeding

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Mirena® (levonorgestrel-releasing intrauterine system) 52mg

Skyla® (levonorgestrel-releasing intrauterine system) 13.5mg

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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 Kyleena, Mirena, and Skyla that is available at this presentation.
Other serious complications and most common adverse reactions

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5mg

Mirena® (levonorgestrel-releasing intrauterine system) 52mg

Skyla® (levonorgestrel-releasing intrauterine system) 13.5mg

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Be aware of other serious complications and most common adverse reactions. Some serious complications with IUDs like Kyleena, Mirena, 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 Kyleena, Mirena, and Skyla that is available at this presentation.
Be aware of other serious complications and most common adverse reactions (cont.):

**PERFORATION:**

- Perforation (total or partial, including penetration/embedment of Kyleena, Mirena 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.
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 Kyleena, Mirena, and Skyla that is available at this presentation.
### 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

<table>
<thead>
<tr>
<th>Timing of Postpartum Insertion</th>
<th>Perforation Rate in Patients Breastfeeding at the Time of Insertion</th>
<th>Perforation Rate in Patients Not Breastfeeding at the Time of Insertion</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3 days</td>
<td>(n=8/1,896) 0.4%</td>
<td>(n=0/277) 0%</td>
</tr>
<tr>
<td>4 days – 6 weeks</td>
<td>(n=120/10,735) 1.1%</td>
<td>(n=28/2,377) 1.2%</td>
</tr>
<tr>
<td>6-14 weeks</td>
<td>(n=268/29,677) 0.9%</td>
<td>(n=80/12,011) 0.7%</td>
</tr>
<tr>
<td>14-52 weeks</td>
<td>(n=43/6,139) 0.7%</td>
<td>(n=22/9,089) 0.2%</td>
</tr>
<tr>
<td>&gt; 52 weeks or no delivery on record</td>
<td>No data available</td>
<td>(n=243/184,733) 0.1%</td>
</tr>
</tbody>
</table>

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

**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 **Kyleena**, **Mirena**, and **Skyla** that is available at this presentation.
APEX-IUD Study (cont.)
Assessment of Perforation and Expulsion of Intrauterine Devices Study

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 Kyleena, Mirena, and Skyla that is available at this presentation.
Important Safety Information

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

EXPULSION:

- Partial or complete expulsion of Kyleena, Mirena 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 Kyleena, Mirena or Skyla can be inserted any time the provider can be reasonably certain the woman is not pregnant.
Important Safety Information

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

OVARIAN CYSTS:

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

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

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vulvovaginitis</td>
<td>24%</td>
</tr>
<tr>
<td>Ovarian Cyst</td>
<td>22%</td>
</tr>
<tr>
<td>Abdominal/pelvic pain</td>
<td>21%</td>
</tr>
<tr>
<td>Headache/migraine</td>
<td>15%</td>
</tr>
<tr>
<td>Acne/seborrhea</td>
<td>15%</td>
</tr>
<tr>
<td>Dysmenorrhea/uterine spasm</td>
<td>10%</td>
</tr>
<tr>
<td>Breast pain/discomfort</td>
<td>10%</td>
</tr>
<tr>
<td>Increased bleeding</td>
<td>8%</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Mirena – adverse reactions reported in ≥5% of users were:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Alterations in menstrual bleeding patterns</td>
<td>31.9%</td>
</tr>
<tr>
<td>Unscheduled uterine bleeding</td>
<td>23.4%</td>
</tr>
<tr>
<td>Decreased uterine bleeding</td>
<td>11.9%</td>
</tr>
<tr>
<td>Increased scheduled uterine bleeding</td>
<td>3.5%</td>
</tr>
<tr>
<td>Female genital tract bleeding</td>
<td>Breast pain</td>
</tr>
<tr>
<td>Abdominal/pelvic pain</td>
<td>22.6%</td>
</tr>
<tr>
<td>Amenorrhea</td>
<td>18.4%</td>
</tr>
<tr>
<td>Headache/migraine</td>
<td>16.3%</td>
</tr>
<tr>
<td>Genital discharge</td>
<td>14.9%</td>
</tr>
<tr>
<td>Vulvovaginitis</td>
<td>10.5%</td>
</tr>
<tr>
<td>Breast pain</td>
<td>8.5%</td>
</tr>
<tr>
<td>Back pain</td>
<td>7.9%</td>
</tr>
<tr>
<td>Benign ovarian cyst and associated complications</td>
<td>7.5%</td>
</tr>
<tr>
<td>Acne</td>
<td>6.8%</td>
</tr>
<tr>
<td>Depression/depressive mood</td>
<td>6.4%</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>6.4%</td>
</tr>
</tbody>
</table>

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 Kyleena, Mirena, and Skyla that is available at this presentation.
**Important Safety Information**

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vulvovaginitis</td>
<td>20.2%</td>
</tr>
<tr>
<td>Abdominal/pelvic pain</td>
<td>18.9%</td>
</tr>
<tr>
<td>Acne/seborrhea</td>
<td>15.0%</td>
</tr>
<tr>
<td>Ovarian cyst</td>
<td>13.2%</td>
</tr>
<tr>
<td>Headache</td>
<td>12.4%</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>8.6%</td>
</tr>
<tr>
<td>Breast pain/discomfort</td>
<td>8.6%</td>
</tr>
<tr>
<td>Increased bleeding</td>
<td>7.8%</td>
</tr>
<tr>
<td>Nausea</td>
<td>5.5%</td>
</tr>
</tbody>
</table>

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

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

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5mg

Mirena® (levonorgestrel-releasing intrauterine system) 52mg

Skyla® (levonorgestrel-releasing intrauterine system) 13.5mg

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

*NOTE: The inserter provided with Kyleena, Mirena, 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 Kyleena, Mirena, and Skyla that is available at this presentation.
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 Kyleena, Mirena 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 Kyleena, Mirena, and Skyla that is available at this presentation.
Preparation for Insertion: Tools

- Speculum
- Antiseptic solution, and applicator
- Sterile uterine sound
- Sterile tenaculum
- Sterile, sharp curved scissors
- IUD with inserter in sealed package (consider have an unopened backup of available)
- Sterile gloves

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

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

• Exclude pregnancy and confirm that there are no other contraindications to use of Kyleena, Mirena, or Skyla

• With the patient comfortably in lithotomy position, do a bimanual exam to establish the size, shape and position of the uterus

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

- Exclude pregnancy and confirm that there are no other contraindications to use of Kyleena, Mirena, 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)

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

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

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 Kyleena, Mirena, and Skyla that is available at this presentation.
Preparation for Insertion: Tenaculum

• 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.

Before traction

After gentle traction

• 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 Kyleena, Mirena, and Skyla that is available at this presentation.
Preparation for Insertion: Sounding

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

All patients should be sounded prior to insertion:

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

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

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

6.5 cm
In a clinical study of n=165 nulliparous patients

2. Bayer Data on File; Clinical Study Report, Table 14.1.2 / 8
**Insertion Steps**

*NOTE: The inserter provided with Kyleena, Mirena, 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.*

Preparation for Insertion → Insertion Steps → Important Information to Consider during or after Insertion

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

Please see Important Safety Information throughout. Please see full Prescribing Information for **Kyleena, Mirena,** and **Skyla** that is available at this presentation.
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.
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.
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 Kyleena, Mirena, and Skyla that is available at this presentation.
**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 Kyleena, Mirena, or Skyla is important to prevent expulsion.**
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 Kyleena, Mirena, and Skyla that is available at this presentation.
Insertion Steps

**Cut the Threads**

**Using a sharp, curved scissors, 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 **Kyleena**, **Mirena**, and **Skyla** that is available at this presentation.
Important Information During & 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 Kyleena, Mirena, and Skyla that is available at this presentation.
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 Kyleena, Mirena, and Skyla that is available at this presentation.
Insertion Video for Kyleena and Mirena

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 Kyleena, Mirena, and Skyla that is available at this presentation.
Timing of Removal

Kyleena should not remain in the uterus after 5 years.
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;
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
Removal: Tools

Tools for Removal:

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

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

- Remove Mirena 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 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:
  - some 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 Kyleena, Mirena, and Skyla that is available at this presentation.
Continuation of Contraception after Removal

• If pregnancy is not desired and if a patient wishes to continue using Kyleena, Mirena 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 Kyleena, Mirena, and Skyla that is available at this presentation.
Questions?

Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena, Mirena, and Skyla that is available at this presentation.
Module 1: Equipment & Insertion Practice

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

- 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 using a tenaculum and sounding prior to IUD placement using a step by step guide, in a model with a pre-placed speculum
Insertion & Removal Procedure

Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena, Mirena, and Skyla that is available at this presentation.
Module 2: Complete Insertion & removal using patient case

Attendees will work in pairs for this final simulation, using a model which allows speculum placement.

- Practice for ~10 minutes using all tools
- One person will perform the insertion procedure (non-reloadable IUD so threads can be cut), while the other follows a step-by-step guide to ensure all steps were completed
- Following insertion, the IUD will be removed

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

Patient Scenarios

Susan (she/her)
35 years old, G1, P1.
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 yo, G3, P3.
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

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Complete Insertion & Removal Procedure

Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena, Mirena, and Skyla that is available at this presentation.
Module 3: Contraceptive Counseling

Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena, Mirena, and Skyla that is available at this presentation.
Principles of Quality Contraceptive Counseling
CDC and Office of Population Affairs

KEY STEPS IN PROVIDING CONTRACEPTIVE SERVICES

- Establish and maintain rapport with the patient
- Assess their needs and personalize discussions accordingly
- Work interactively to establish a plan
- Provide educational materials that can be understood and retained
- Confirm patient understanding (“teach-back”)

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Bayer IUDs: Comprehensive Counseling

Ensure patients understand the following, points, including any signs and symptoms which indicate they should promptly contact their physician or healthcare provider

- Bayer IUDs do not protect against HIV infection (AIDS) and other STIs
- Pregnancy or suspected pregnancy; Risk of Ectopic & Intrauterine Pregnancy
- Life Threatening Infection (Sepsis)
- Pelvic Infection (PID)
- Perforation & Expulsion
- Ovarian Cysts
- Bleeding Pattern Alterations (Irregular bleeding and amenorrhea)

- Kyleena & Skyla can be safely scanned with Magnetic Resonance Imaging (MRI) under certain conditions
- Clinical Considerations for Use and Removal. Contact their physician or provider if they experience:
  - stroke or heart attack,
  - very severe or migraine headaches,
  - unexplained fever
  - yellowing or the skin or whites of the eyes
  - pregnancy or suspected pregnancy,
  - pelvic or abdominal pain or pain during sex
  - HIV positive seroconversion (herself/ partner)
  - possible exposure to STIs,
  - unusual vaginal discharge or genital sores,
  - severe bleeding or bleeding that lasts a long time, if they miss a period,
  - if they can't feel the IUD threads

Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena, Mirena, and Skyla that is available at this presentation.
Nikki (she/her)

• 28 years old, G2P1
• Vaginal delivery, 8 weeks ago
• Presents for post partum visit to discuss contraception
• Clinical exam shows her uterus is completely involuted

Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena® (levonorgestrel-releasing intrauterine system) 19.5mg, Mirena® (levonorgestrel-releasing intrauterine system) 52mg and Skyla® (levonorgestrel-releasing intrauterine system) 13.5mg that is available at this presentation.
What questions might you ask Nikki during contraceptive counseling?

Nikki (she/her)

- 28 years old, G2P1
- Vaginal delivery, 8 weeks ago
- Presents for post partum visit to discuss contraception
- Clinical exam shows her uterus is completely involuted
Assess her preferences with questions such as:
What methods have you used in the past?
What methods are you currently using?

Assess her Reproductive Life Plan, with a question such as:
Would you like to have more children?

Nikki (she/her)
• 28 years old, G2P1
• Vaginal delivery, 8 weeks ago
• Presents for post partum visit to discuss contraception
• Clinical exam shows her uterus is completely involuted

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Nikki (she/her)

- 28 years old, G2P1
- Vaginal delivery, 8 weeks ago
- Presents for post partum visit to discuss contraception
- Clinical exam shows her uterus is completely involuted
- Does not desire pregnancy for the next few years
- She is exclusively breast feeding her son, has concerns about hormonal contraception and breast feeding
- She previously used a vaginal ring and liked the non-daily administration
- She does not want a contraceptive that contains estrogen

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Nikki (she/her)

• 28 years old, G2P1
• Vaginal delivery, 8 weeks ago
• Presents for post partum visit to discuss contraception
• Clinical exam shows her uterus is completely involuted
• Does not desire pregnancy for the next few years
• She is exclusively breast feeding her son, has concerns about hormonal contraception and breast feeding
• She previously used a vaginal ring and liked the non-daily administration
• She does not want a contraceptive that contains estrogen

Why would a low dose IUD like Kyleena be a good option for Nikki?

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Explaining Kyleena to Nikki
In Patient-friendly language

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What is Kyleena?

Kyleena is a small, flexible, plastic, T-shaped system that slowly releases a progestin hormone that is often used in birth control pills.
What is Kyleena?

Kyleena is a small, flexible, plastic, T-shaped system that slowly releases a progestin hormone that is often used in birth control pills.

Kyleena is placed in your uterus, and it prevents pregnancy for up to five years.

Because it releases this hormone into your uterus, only small amounts of hormone enter your blood.

Kyleena does not contain estrogen.

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Kyleena and Breast Feeding

“Kyleena is not likely to affect the quality or quantity of your breast milk, or the health of your nursing baby. However, isolated cases of decreased milk production have been reported.”

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Kyleena and Breast Feeding

“The risk of Kyleena going into the wall of the uterus (becoming embedded) or going through the wall of the uterus is increased when I place Kyleena while you are breastfeeding.

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Inform Nikki about what to expect with bleeding

“How will Kyleena change my periods?”

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For the first 3-6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding. You may also have cramping during the first few weeks.

“How will Kyleena change my periods?”

“Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena®, Mirena® (levonorgestrel-releasing intrauterine system) 52mg and Skyla® (levonorgestrel-releasing intrauterine system) 13.5mg that is available at this presentation.”
“After you have used Kyleena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether. When Kyleena is removed, your periods should return.”
Inform Nikki about side effects

“You may also experience other side effects with Kyleena. I’d like to discuss those next”

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Inform Nikki about serious side effects

“Kyleena can cause serious side effects, including ectopic pregnancy and intrauterine pregnancy risks, life threatening infection, Pelvic Inflammatory Disease (PID), perforation, and expulsion.”

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Inform Nikki about some of the common side effects

“Common side effects include pain, bleeding or dizziness during and after placement, changes in bleeding, missed menstrual periods, and cysts on the ovary. Other common side effects include: inflammation or infection of the outer part of your vagina; abdominal or pelvic pain; headache or migraine; acne or greasy skin; painful periods; or or painful breasts.”

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Inform Nikki about side effects

“If you ever have any questions or concerns after placement, please call the office right away. It might be something we can manage over the phone, or I may need to see you back in the office.”

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Nikki asks about fertility

“What if I change my mind and want to get pregnant?”

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Nikki asks about fertility

“What if I change my mind and want to get pregnant?”

“If your plans change, I can remove Kyleena at any time. About 7 out of 10 women who want to become pregnant do so within the first year after Kyleena removal.”

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Assessing Nikki for same day insertion

“Can I have Kyleena placed today?”

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“Since you’re 8 weeks post-partum, and I’ve determined that your uterus is back to its non-pregnant state, I may be able to place Kyleena today, if you’re not pregnant. Have you had a period since your delivery?”

“Can I have Kyleena placed today?”

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Assessing Nikki for same day insertion

“No, I haven't had a period yet.”

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Assessing Nikki for same day insertion

“Have you been sexually active since you delivered your baby?”

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Assessing Nikki for same day insertion

“Have you been sexually active since you delivered your baby?”

“No, I haven’t had sex since then.”

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Assessing Nikki for same day insertion

“Good news – based on our conversation today, I should be able to place a Kyleena today. Kyleena does not protect against STIs, so you should use condoms to protect against STIs and HIV.

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Nikki asks when Kyleena will start working

“If I can get Kyleena today, how soon will it start working?”

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“You will need a non-hormonal back-up method of contraception (condoms or spermicide) or abstain for vaginal intercourse for 7 days to prevent pregnancy.”

“Nikki asks when Kyleena will start working

“If I can get Kyleena today, how soon will it start working?”

Please see Important Safety Information throughout. Please see full Prescribing Information for Kyleena®, Mirena® (levonorgestrel-releasing intrauterine system) 52mg and Skyla® (levonorgestrel-releasing intrauterine system) 13.5mg that is available at this presentation.
I will place the IUD during today’s office visit

First, I will do an exam to find the exact position of your uterus. Then I will then clean the vagina and cervix with an antiseptic solution. Next, I will slide a slim plastic tube containing Kyleena through the cervix into the uterus. Then, I will remove the tube, leaving Kyleena in the uterus, and cut the threads.
I will place the IUD during today’s office visit.

First, I will do an exam to find the exact position of your uterus. Then I will then clean the vagina and cervix with an antiseptic solution. Next, I will slide a slim plastic tube containing Kyleena through the cervix into the uterus. Then, I will remove the tube, leaving Kyleena in the uterus, and cut the threads.

You may experience pain, bleeding, or dizziness during and after placement. If these symptoms do not resolve within 30 minutes, the IUD may not have been placed correctly. I will determine if the IUD needs to be removed or replaced.
Follow-up with Nikki after insertion

“I recommend all my patients return to see me, 4-6 weeks after insertion. At that visit, I can check in with you to see how you are doing, and check the threads of Kyleena.

It’s also a good habit for you to check for the removal threads on your own, once a month, being careful not to pull them, as you do this. I can tell you how to check for the removal threads, if you have questions.”

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Follow-up with Nikki after insertion

“If you feel more than just the threads, or don’t feel them at all, Kyleena may not be in the right position, and may not prevent pregnancy. If this happens, avoid intercourse or use non-hormonal back-up contraception (such as condoms or spermicide), and follow-up with me as soon as possible.”

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Follow-up with Nikki after insertion

“Also remember, that before you have an MRI, tell them you have a Kyleena, as it can be scanned under specific conditions.

If you have any questions or concerns, please call me right away. Otherwise, I will see you again in 4-6 weeks, and then once a year thereafter.”

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What questions could you ask to address her reproductive life plan? Is she currently using contraception, and is she looking to learn more about her other options?
Samantha (she/her)

- 25 years old, G0, in good general health
- Presents for flu shot
- She currently taking oral contraceptives, interested to hear about other methods
- She is not seeking pregnancy for several years
Samantha (she/her)

- 25 years old, G0, in good general health
- Presents for flu shot
- She currently taking oral contraceptives, 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?

- Establish and maintain rapport with the patient
- Assess their needs and personalize discussions accordingly
- Work interactively to establish a plan
- Provide educational materials that can be understood and retained
- Confirm patient understanding (“teach-back”)
Karen (she/her)

- 42 years old, G2P2
- Presents for birth control refill

What questions could you ask to address her reproductive life plan? Is she interested in other birth control options?
Karen (she/her)

- 42 years old, G2P2
- Presents for birth control refill
- While discussing future childbearing plans, she mentions having heavy periods
Karen (she/her)

- 42 years 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 for participating in this Educational Program on Bayer’s IUDs. Please provide us with your feedback about this program using the anonymous survey. It should take 1-2 minutes.