

Mirena® (levonorgestrel-releasing intrauterine system) 52mg

Clinical Presentation

Please see Important Safety Information throughout.

Please see full Prescribing Information for Mirena, that is available at this presentation.

PP-MIR-US-0439-1 APPROVED: August 2022



Assessing a Woman's Reproductive Life Plan



How many of you routinely ask about a patient's reproductive plans?



Assess each patient's shortand long-term reproductive plans

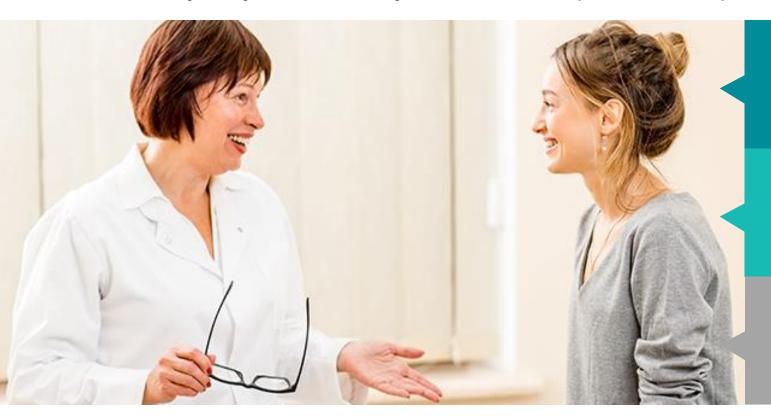
"Every woman, every time¹"

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

Assessing a Woman's Reproductive Life Plan



How many of you routinely ask about a patient's reproductive plans?



"Would you like to become pregnant in the next year?"

"Do you have any children now?"

"Do you want to have (more) children?"

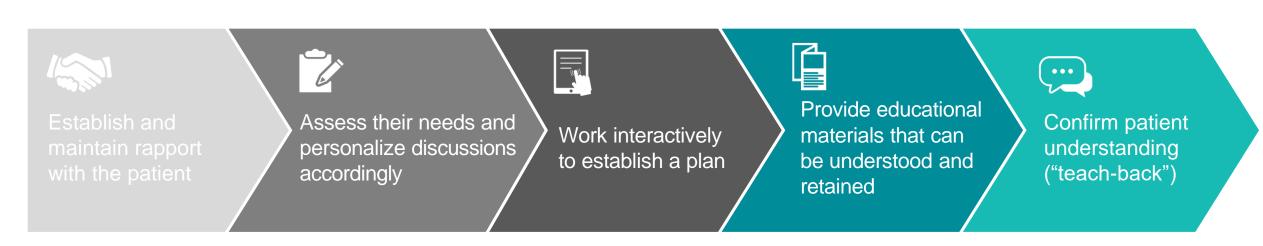
"How many more children would you like to have and when?"

Every patient encounter, regardless of the chief reason for the visit, is an important "teachable moment" to assess each patient's 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

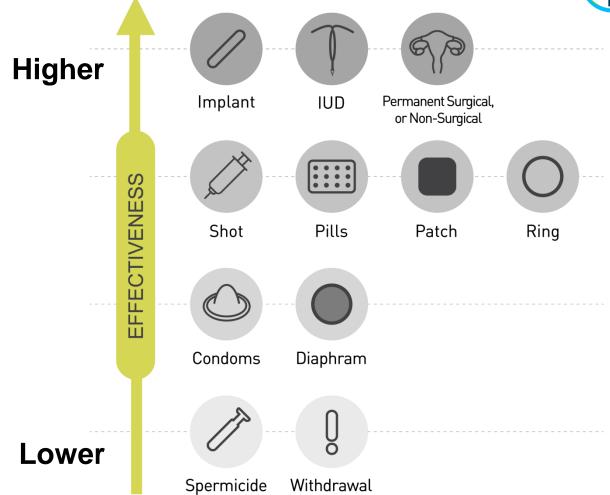


KEY STEPS IN PROVIDING CONTRACEPTIVE SERVICES



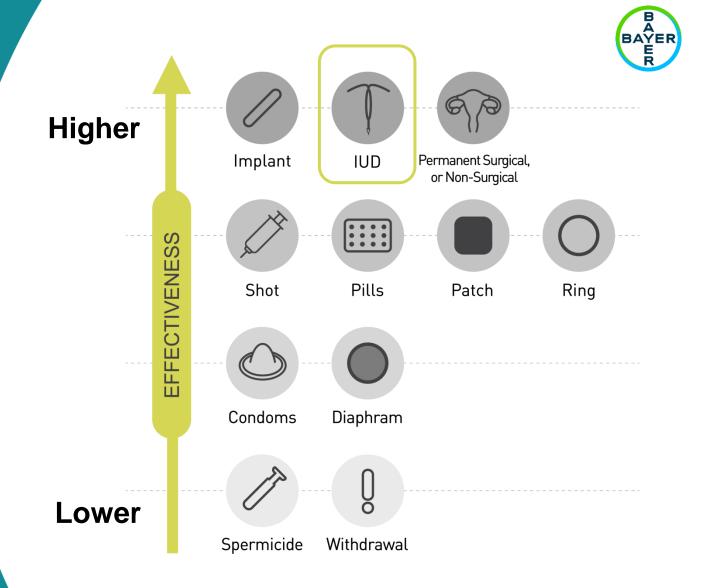


Contraceptive Efficacy



Contraceptive Efficacy

An IUD (Intrauterine Device) is a long-acting method of birth control, and is considered to be one of the most effective reversible methods¹





Indication





- 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

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 tumors
- 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 Mirena



Clinical Considerations for Use and Removal



Use Mirena 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

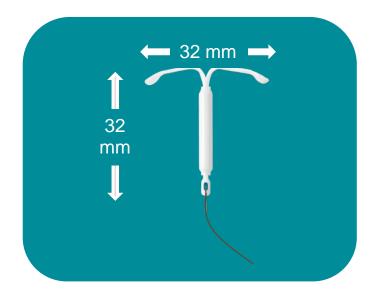
- Consider removing the intrauterine system if these or the following arise during use: Uterine or cervical malignancy or jaundice
- If the threads are not visible or are significantly shortened they may have broken or retracted into the cervical canal or uterus
- If Mirena is displaced (e.g. expelled or perforated the uterus) remove it



Properties





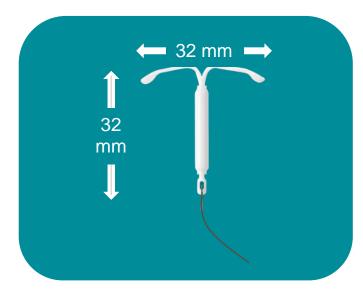


Hormone Reservoir (Total Amount) **52 mg**

Properties







Hormone Reservoir (Total Amount) **52 mg**





T-body arms in ready to load position

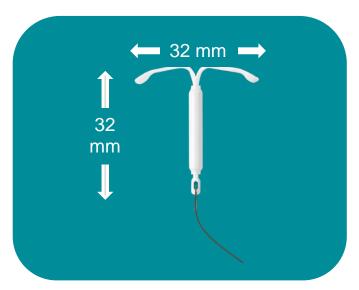
Threads contained within insertion tube handle

No natural rubber latex

Properties







Hormone Reservoir (Total Amount)
52 mg

Daily release rate: 19 mcg/d (after year 1)

Brown Removal Threads No metal 4.4 mm insertion tube diameter

T-body arms in ready to load position

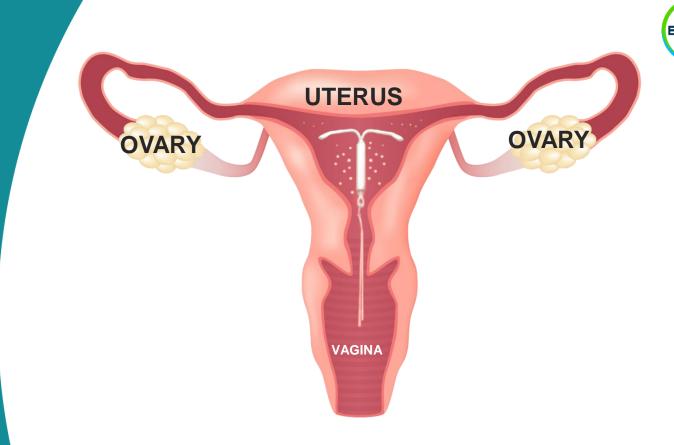
Threads contained within insertion tube handle

No natural rubber latex



The local mechanism of action has not been conclusively demonstrated.

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

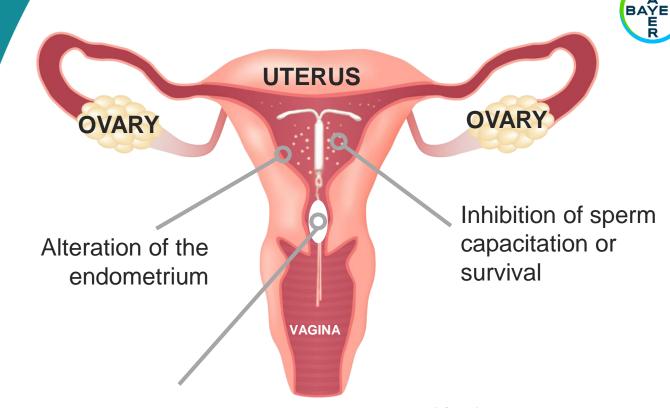




Suggested Mechanism of Action

The local mechanism of action has not been conclusively demonstrated.

Studies of Mirena 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

(<u>click to view an example of thickened</u> <u>CM from LNG-IUS user</u>)







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.

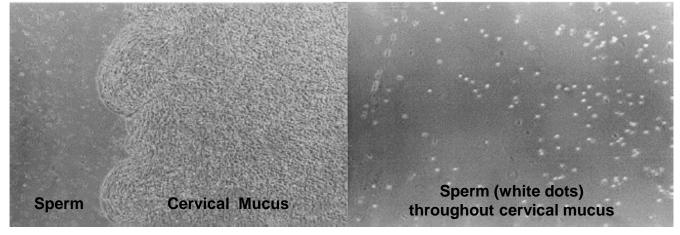
These examples show how cervical mucus from an LNG-IUS user is thick, compared to a control patient (not using contraception).

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Examples of Cervical Mucus

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



5-Year Trial



Contraceptive Efficacy

Contraception Clinical Trials

5 Year Trial: conducted in Finland & Sweden

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

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- 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 4.5-5years
- 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%)



Pregnancy Related Risks



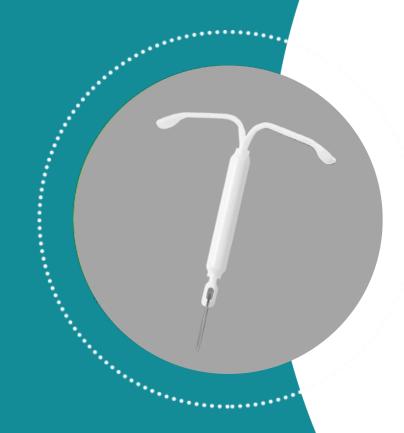
- If pregnancy should occur with Mirena in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and pre-term labor
- Advise her of isolated reports of virilization of the female fetus following local exposure to LNG during pregnancy with an LNG-IUS in place
- 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

- 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





Return to Fertility



In two studies, return to fertility was investigated in a total of 229 women who desired pregnancy after study discontinuation and provided follow-up information. The probability to conceive within 12 months after removal of Mirena was approximately 80%



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}

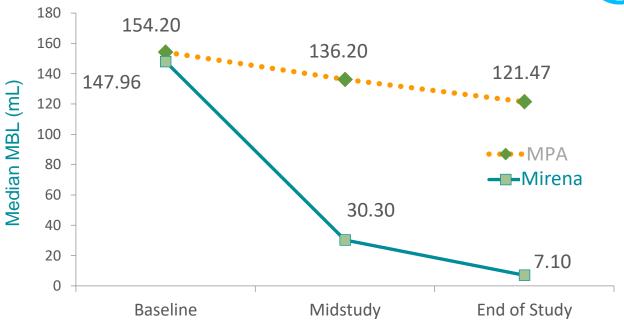
Women were randomized to 6 cycles of Mirena (n=79) or Medroxyprogesterone acetate (MPA) (n=81) 10 mg/day for 10 days beginning on day 16 of cycle^{1,2}

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

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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









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Insertion Timing

Timing of Insertion



Consider same day insertion if there is reasonable certainty the patient is not pregnant

	Insertion timing	Backup contraception?	
Patients not currently using hormonal or intrauterine contraception	 Any time there is reasonable certainty that they are not pregnant 	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	
	 Consider the possibility of ovulation and conception prior to initiation 	NO If inserted during the first 7 days of the menstrual cycle, or immediately after first trimester abortion	



Timing of Insertion



Consider same day insertion if there is reasonable certainty the patient is not pregnant

	Insertion timing	Backup contraception?		
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	 Consider the possibility of ovulation and conception prior to initiation 	NO If inserted during the first 7 days of the menstrual cycle, or immediately after first trimester abortion		
Switching from:				
Oral, transdermal, or vaginal hormonal contraceptive	Any time, including the hormone-free interval of the previous method	YES if inserted during active use of previous method, continue that method for 7 days after insertion, or until the end of the current treatment cycle		
		YES if inserted during use of continuous hormonal contraception, discontinue method 7 days after insertion		
Injectable progestin contraceptive	Any time	YES if inserted>3 months (13 weeks) after the last injection, Non-hormonal back-up birth control (such as condoms or spermicide) should also be used for 7 days		
		NO if inserted <3 months after last injection		
Implant or another IUS	 Anytime during the menstrual cycle Insert Mirena on the same day the implant or IUS is removed 	NO there is no need for backup contraception		





Timing of Insertion



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After First or Second Trimester Abortion or Miscarriage, and Childbirth

	Insertion timing		Backup contraception?
After 1st trimester abortion or miscarriage	 Can be inserted immediately, unless it's a septic abortion 	NO T	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	Insert after removal of placenta	NO There is no need for backup contraception	
Interval insertion following complete involution of the uterus	 Wait a minimum of 6 weeks, or until the uterus is fully involuted before insertion Insert Mirena 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
			If inserted during the first 7 days of the menstrual cycle



Educate her about Pelvic Inflammatory Disease (PID)



- Mirena is 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







- PID is often associated with sexually transmitted infections (STIs); Mirena, does not protect against STIs, including HIV.
- PID may be asymptomatic but still result in tubal damage and its sequelae
- In Mirena clinical trials, 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

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



Mirena Bleeding Patterns



(levonorgestrel-releasing

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5-Year Contraception Trial (n=1,169 women):

• ~20% of women developed amenorrhea by the end of the first year

Extension Trial (separate study of n=362 women who used Mirena for more than 5 years):

By the end of 8 years of use:

- 34% of women experienced amenorrhea
- 26% experienced infrequent bleeding
- 10% experienced irregular bleeding
- 3% experienced frequent bleeding
- 3% experienced prolonged bleeding

Heavy Menstrual Bleeding Patterns:

- Mirena should be replaced at the end of the fifth year if continued treatment of heavy menstrual bleeding
 is needed, because data on use in this indication beyond 5 years are limited
- In most women with HMB, the number of bleeding and spotting days may also increase during the
 initial months of therapy but usually decrease with continued use. The volume of blood loss per cycle
 progressively becomes reduced

 Mirena®





Mirena® (levonorgestrel-releasing intrauterine system) 52mg
Other serious complications and most common adverse reactions



Be aware of other serious complications and most common adverse reactions.

Some serious complications with IUDs like Mirena are sepsis, perforation and expulsion.

SEPSIS:

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





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

PERFORATION:

- Perforation (total or partial, including penetration/embedment of Mirena in the uterine wall or cervix)
 may occur, most often during insertion, although the perforation may not be detected until sometime
 later
- 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 Mirena is inserted when the uterus is fixed, retroverted or not completely involuted





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

PERFORATION:

- If perforation occurs, locate and remove Mirena
 - Surgery may be required
 - Delayed detection or removal of Mirena in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera
- In addition, perforation may reduce contraceptive efficacy and result in pregnancy.



APEX-IUD Study



Assessment of Perforation and Expulsion of Intrauterine Devices Study

Purpose: retrospective cohort study to assess the impact of breastfeeding (BF) and insertion timing on perforation and expulsion

	Perforation Rate in Patients Breastfeeding at the time of Insertion					
Timing of Postpartum insertion	(n=8/1,896) 0.4%	(n=120/10,735) 1.1%	(n=268/29,677) 0.9%	(n=43/6,139) 0.7%	No data available	
	0-3 days	4 days – 6 weeks	6-14 weeks	14-52 weeks	> 52 weeks or no delivery on record	
	0% (n=0/277)	1.2% (n=28/2,377)	0.7% (n=80/12,011)	0.2% (n=22/9,089)	0.1% (n=243/184,733)	
	Per Per	foration Rate i	n Patients Not Bre	astfeeding at the time o	f insertion	

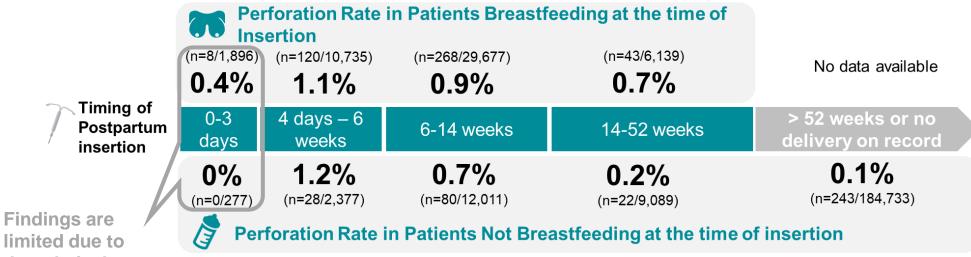


APEX-IUD Study

B A BAYER E R

Assessment of Perforation and Expulsion of Intrauterine Devices Study

Purpose: retrospective cohort study to assess the impact of breastfeeding (BF) and insertion timing on perforation and expulsion



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

Perforation Results:

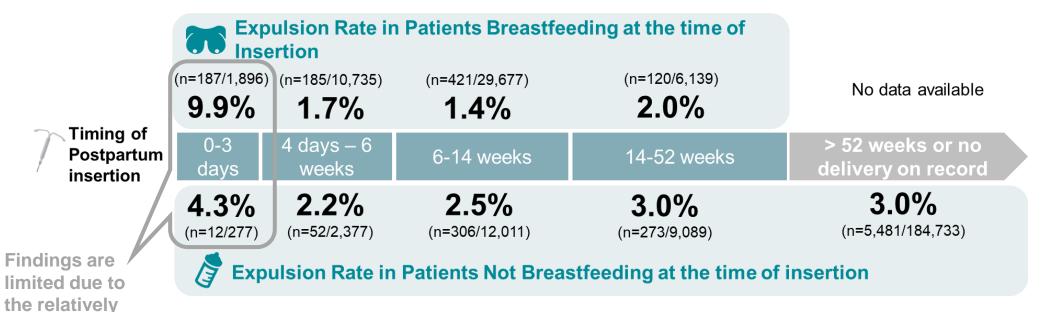
- Perforation rate was highest when IUDs were placed between 4 days-6 weeks after delivery
- Breastfeeding (vs. non) at the time of insertion was associated with a 33% higher risk of perforation (adjusted hazard ratio [HR]=1.33, 95% confidence interval [CI]: 1.07-1.64)



APEX-IUD Study (cont.)



Assessment of Perforation and Expulsion of Intrauterine Devices Study



Expulsion Results:

small number

of insertions

during this time

- 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)





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

EXPULSION:

- Partial or complete expulsion of Mirena 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 Mirena. If expulsion has occurred, a new Mirena 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



Important Safety Information



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

The most common adverse reactions reported in ≥5% of users were:			
Alterations in menstrual bleeding patterns Unscheduled uterine bleeding Decreased uterine bleeding Increased scheduled uterine bleeding Female genital tract bleeding	31.9% 23.4% 11.9% 3.5%	Breast pain	8.5%
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%



Important Safety Information



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

A separate study with 362 women who have used Mirena for more than 5 years showed a consistent adverse reaction profile in Years 6 through 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.

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







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Insertion & Removal



Video available at:
https://www.mirenahcp.com/
/insertion-and-removal

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IUD Insertion*





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





- Obtain a complete medical and social history to determine conditions that might influence selection of Mirena 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 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 Mirena from the inserter. **Once released, Mirena cannot be re-loaded**.
- Check expiration date of Mirena prior to initiating insertion
- Mirena 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



Preparation for Insertion: Tools



If anticipated, also have instruments &

paracervical block

anesthesia for

available







Sterile gloves

Antiseptic solution, and applicator

Sterile tenaculum Sterile, sharp curved scissors

Sterile uterine sound

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

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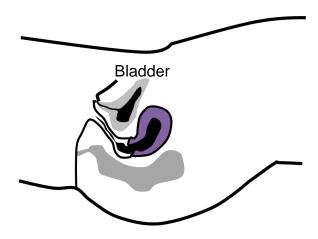
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Preparation for Insertion: Bimanual Exam



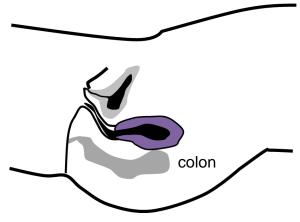


- Exclude pregnancy and confirm that there are no other contraindications to use of Mirena
- With the patient comfortably in lithotomy position, do a bimanual exam to establish the size, shape and position of the uterus



Anteverted Uterus

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



Retroverted Uterus

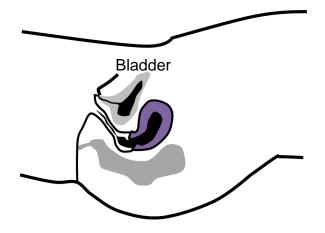
(tilts back toward colon occurs in ~33% patients)







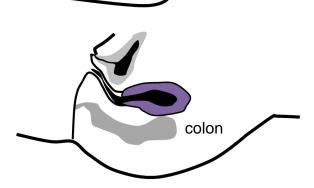
- Exclude pregnancy and confirm that there are no other contraindications to use of Mirena
- With the patient comfortably in lithotomy position, do a bimanual exam to establish the size, shape and position of the uterus



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)

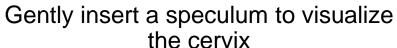


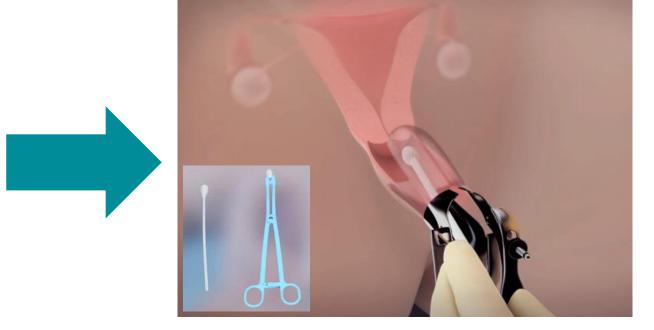
Preparation for Insertion: Cleansing











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



Preparation for Insertion: Tenaculum





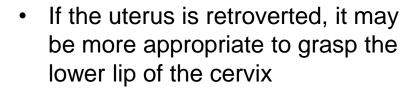
 Grasp the upper lip of the cervix with a tenaculum forceps and gently apply traction to stabilize and align the cervical canal with the uterine cavity. Perform a paracervical block if needed.

Before traction

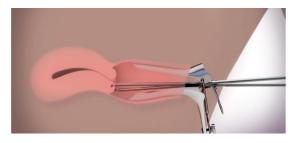


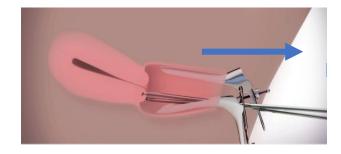




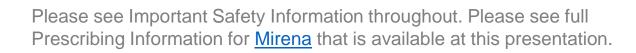








 The tenaculum should remain in position and gentle traction on the cervix should be maintained throughout the insertion procedure

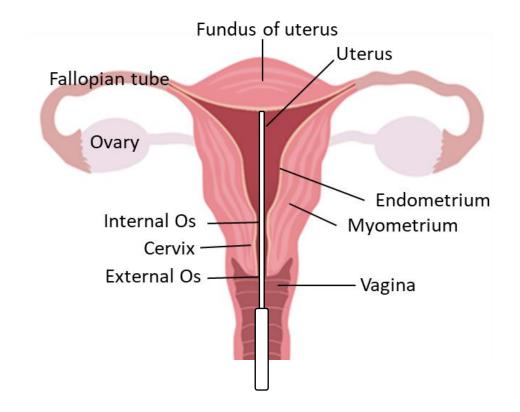




Preparation for Insertion: Sounding







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

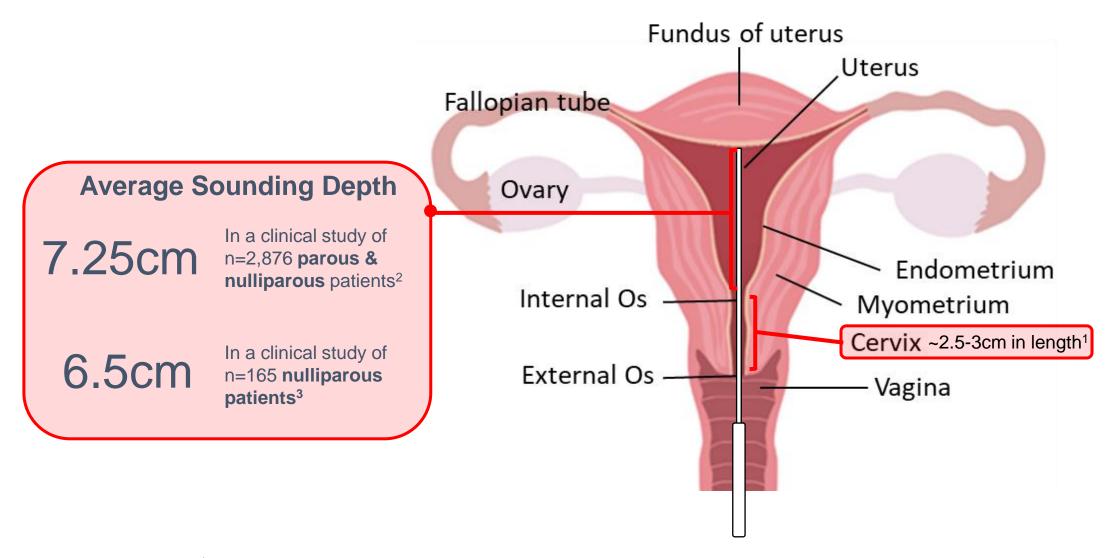
The uterus should sound to a depth of 6-10 cm. Insertion into a uterine cavity less than 6cm by sounding may increase the incidence of expulsion, bleeding, pain, perforation, and possibly pregnancy.

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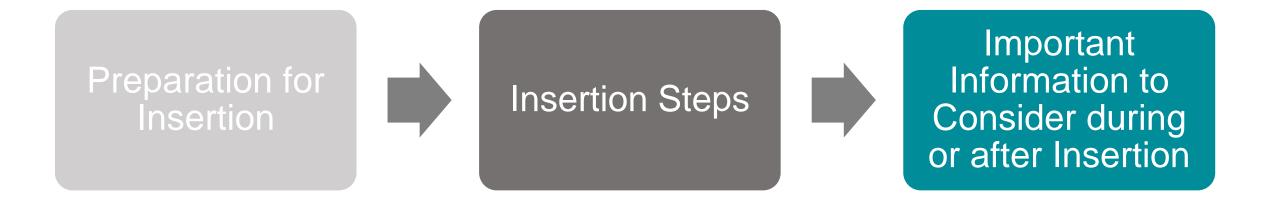
Sounding Depths



- 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*





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







Step1

Step 2

Step 3

Step 4

Step 5

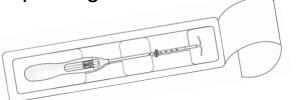
Step 6

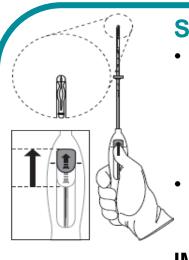
Step 7

Cut Threads

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





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 Tbody 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 <u>Mirena</u> that is available at this presentation.





Step1

Step 2

Step 3

Step 4

Step 5

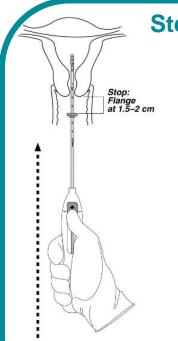
Step 6

Step 7

Cut Threads



- 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
- The uterus should sound to a depth of 6-10cm
- Insertion of Mirena into a uterine cavity less than 6 cm by sounding may increase the incidence of expulsion, bleeding, pain, perforation, and possibly pregnancy



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

(levonorgestrel-releasing intrauterine system) 52 mg

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Step1

Step 2

Step 3

Step 4

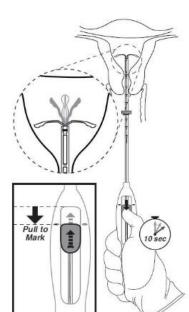
Step 5

Step 6

Step 7

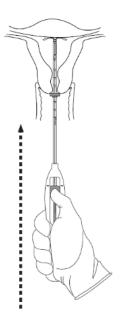
Cut Threads

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

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 is important to prevent expulsion

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







Step1

Step 2

Step 3

Step 4

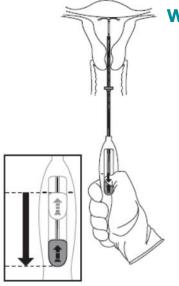
Step 5

Step 6

Step 7

Cut Threads

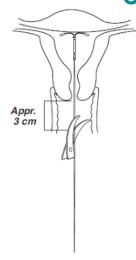
Step 7: Release the IUD and withdraw the Inserter



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

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

Insertion Using a Pelvic Model



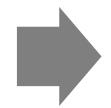




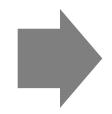
Important Information During & After Insertion



Preparation for Insertion



Insertion Procedure



Important Information to Consider during or after Insertion



If you suspect that Mirena 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





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 Mirena is in place once a month by feeling for the threads









For contraception, remove Mirena by the end of the eighth year and replace at time of removal with a new Mirena if continue use is desired. Replace Mirena by the end of the fifth year if continued treatment of HMB is needed.

If pregnancy is not desired, remove Mirena during the first 7 days of menstruation, provided the patient is still 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

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg

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

Removal: Tools





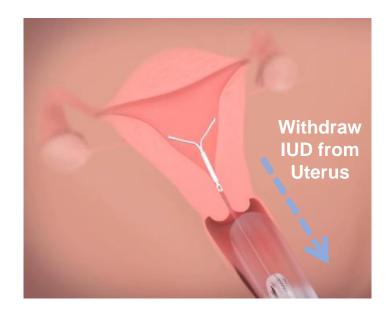
Tools for Removal:

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



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.



(levonorgestrel-releasing

intrauterine system) 52 mg

- 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
 Mirena®

Continuation of Contraception after Removal



- If pregnancy is not desired and if a patient wishes to continue using Mirena 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 Mirena 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





Click Here For Full Prescribing Information on Mirena® (levonorgestrel-releasing intrauterine system) 52mg

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

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Mirena® (levonorgestrel-releasing intrauterine system) 52mg

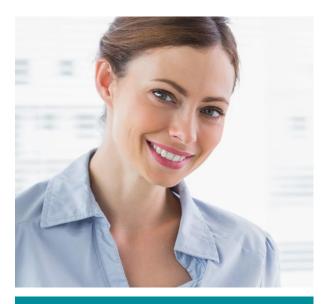
Appendix: Patient Conversations





- 19 y
- Gravida 0 (G0)
- Seeks birth control guidance





Cathy (she/her)

- 32 y
- Gravida 2, Para 1 (G2, P1)
- 8 weeks post-partum family planning

Please see Important Safety Information throughout. Please see full Prescribing Information for <u>Mirena</u> that is available at this presentation.





- 19 years old, nulliparous, G0
- Requests birth control before she returns to college
- Normal blood pressure, body mass index (BMI)





- 19 years old, nulliparous, G0
- Requests birth control before she returns to college
- Normal blood pressure, body mass index (BMI)





- 19 years old, nulliparous, G0
- Requests birth control before she returns to college
- Normal blood pressure, body mass index (BMI)

Assess her Reproductive Life Plan,
with a question such as:
How important is it for you to NOT get pregnant in
the next year?

Assess her preferences with questions such as: What methods have you used in the past? What methods are you currently using?





- 19 years old, nulliparous, G0
- Requests birth control before she returns to college
- Normal blood pressure, body mass index (BMI)

By asking open-ended questions and taking the time to listen closely to her answers and concerns, you learn that she:

- Has been sexually active with boyfriend for 3 months
- Currently uses condoms
- Does not desire pregnancy while in college
- Previously used oral contraceptives, but reports missed pills



What questions might you ask Sara during contraceptive counseling?

Why would Mirena® (levonorgestrel-releasing intrauterine system) 52mg be a good option for Sara?

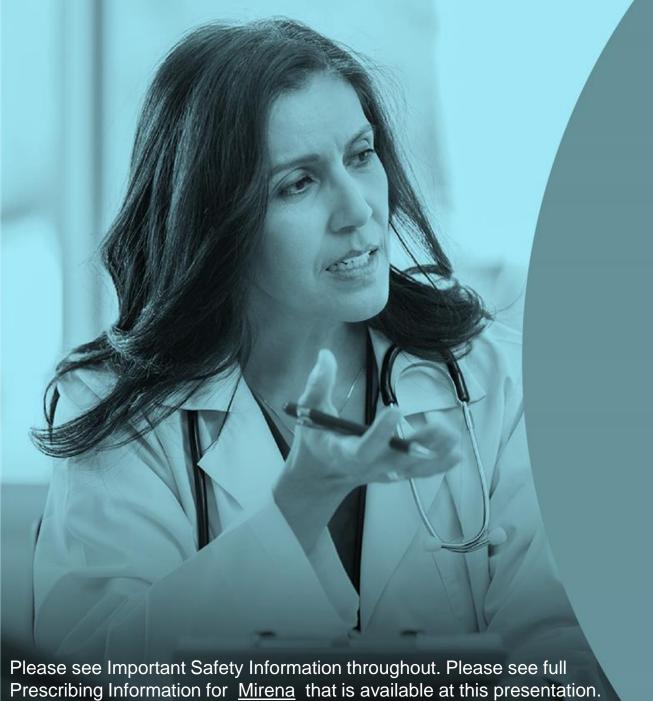
Sara (she/her)



- 19 years old, nulliparous, G0
- Requests birth control before she returns to college
- Normal blood pressure, body mass index (BMI)

By asking open-ended questions and taking the time to listen closely to her answers and concerns, you learn that she:

- Has been sexually active with boyfriend for 3 months
- Currently uses condoms
- Does not desire pregnancy while in college
- Previously used oral contraceptives, but reports missed pills

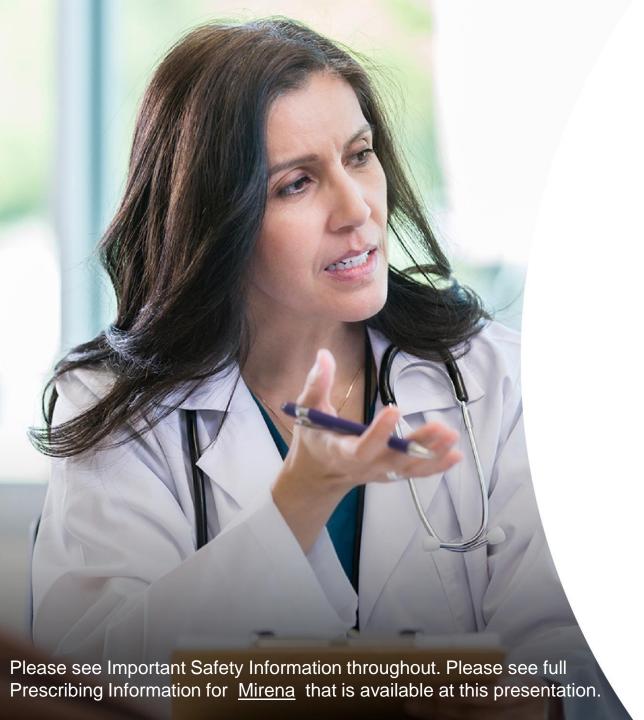




Explaining Mirena to Sara In patient-friendly language



Mirena®
(levonorgestrel-releasing intrauterine system) 52 mg



What is Mirena?

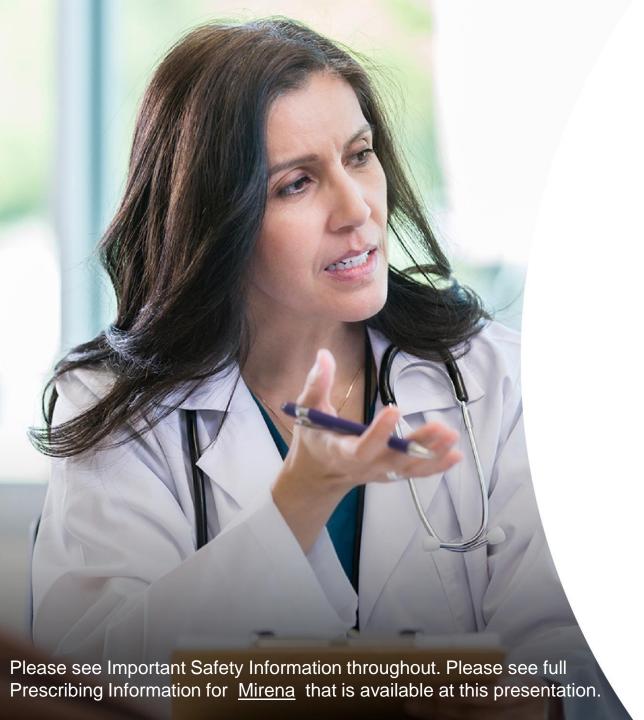


Mirena is a hormone releasing system placed in your uterus to prevent pregnancy for up to 8 years

Mirena can also be used to decrease menstrual blood loss for up to 5 years in women who have heavy menstrual flow and also want to use a birth control method that is placed in the uterus to prevent pregnancy

Mirena can be used whether or not you have given birth to a child





What is Mirena?



Mirena is a small, flexible, plastic, T-shaped system that slowly releases a progestin hormone called levonorgestrel (LNG) that is often used in birth control pills

Because Mirena releases LNG into your uterus, only small amounts of hormone enter your blood

Mirena does not contain estrogen

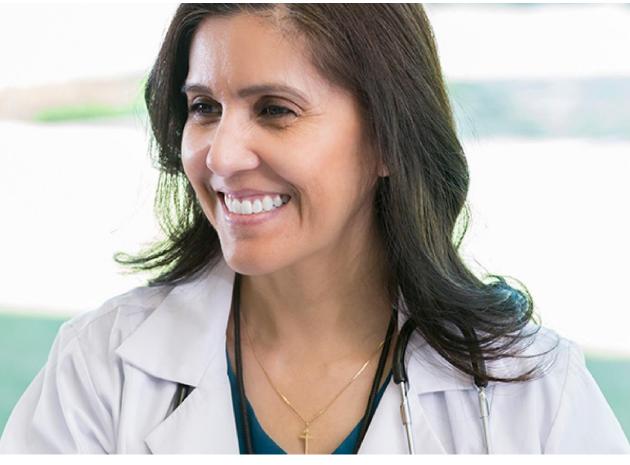


Inform Sara on what to expect with her periods





"How will Mirena change my periods?"





Please see Important Safety Information throughout. Please see full Prescribing Information for <u>Mirena</u> that is available at this presentation.

Inform Sara on what to expect with her periods







"How will Mirena change my periods?"

"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 and some women have heavy bleeding during this time. You may also have cramping during the first few weeks.



Please see Important Safety Information throughout. Please see full Prescribing Information for <u>Mirena</u> that is available at this presentation.





"How will Mirena change my periods?"

"After you have used Mirena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether."







"How will Mirena change my periods?"



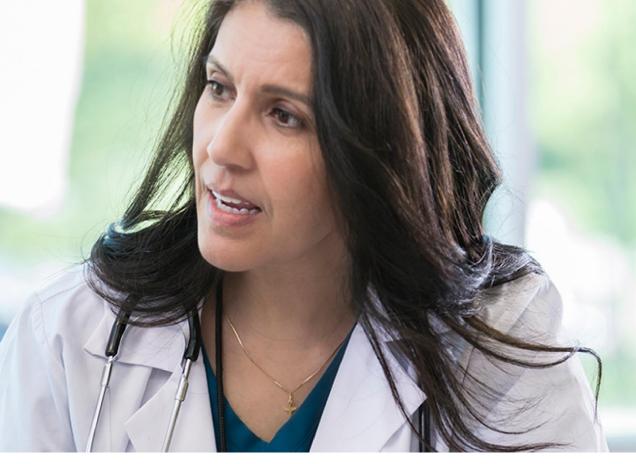
"In some women with heavy bleeding, the total blood loss per cycle progressively decreases with continued use. The number of spotting and bleeding days may initially increase but then typically decreases in the months that follow"







"Will my period come back when Mirena is removed?"









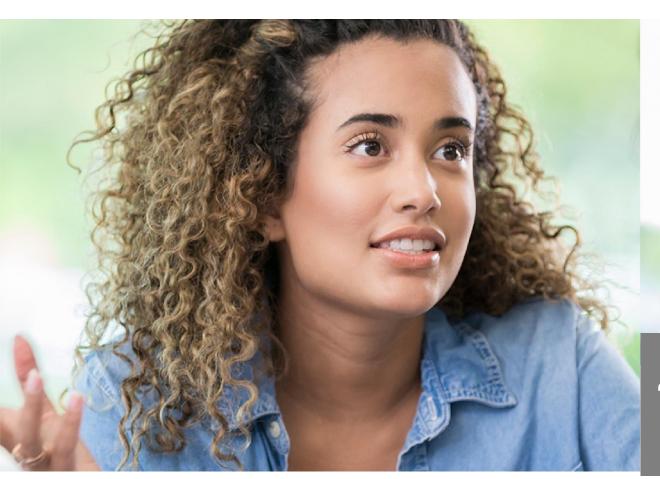
"Will my period come back when Mirena is removed?"

"Yes, when Mirena is removed, your menstrual periods should come back."



Inform Sara about side effects







"You may experience side effects with Mirena. I'd like to discuss those next"



Inform Sara about serious side effects







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



Inform Sara about some of the common side effects





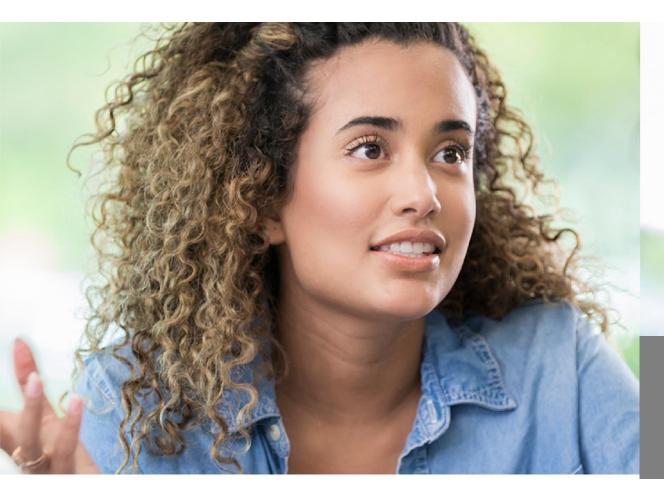


"Common side effects include pain, bleeding or dizziness during and after placement, changes in bleeding, missed menstrual periods, and cysts on the ovary. Other common side effects include: abdominal or pelvic pain; inflammation or infection of the outer part of your vagina; headache or migraine; vaginal discharge."



Inform Sara 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."

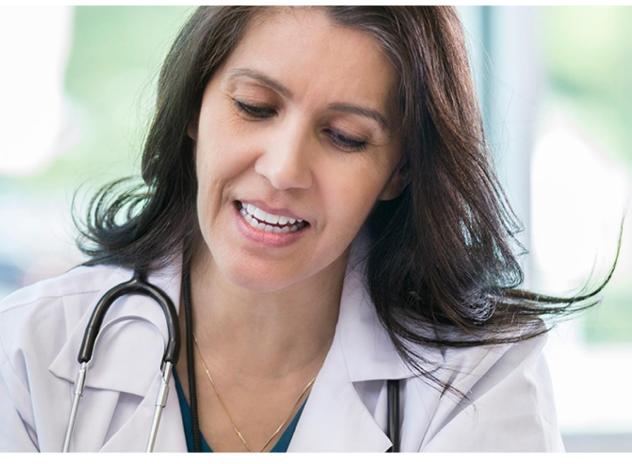


Sara asks about fertility





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





Sara asks about fertility



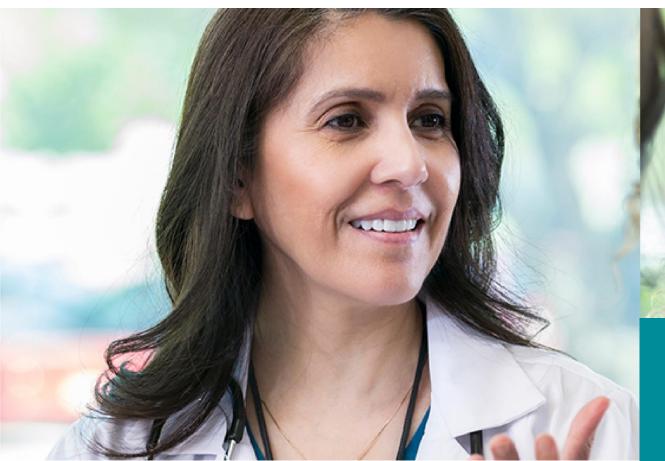


"If your plans change, I can remove Mirena at any time. You may become pregnant as soon as it's "What if I change my mind and want to get pregnant?" removed. About 8 in 10 women who want to become

pregnant will become pregnant sometime in the first vear after Mirena is removed."









"Can I have Mirena placed today?"









"Mirena can be placed anytime, we just need to make sure you're not pregnant."

"Have you been using a form of birth control regularly and correctly?"

"Can I have Mirena placed today?"







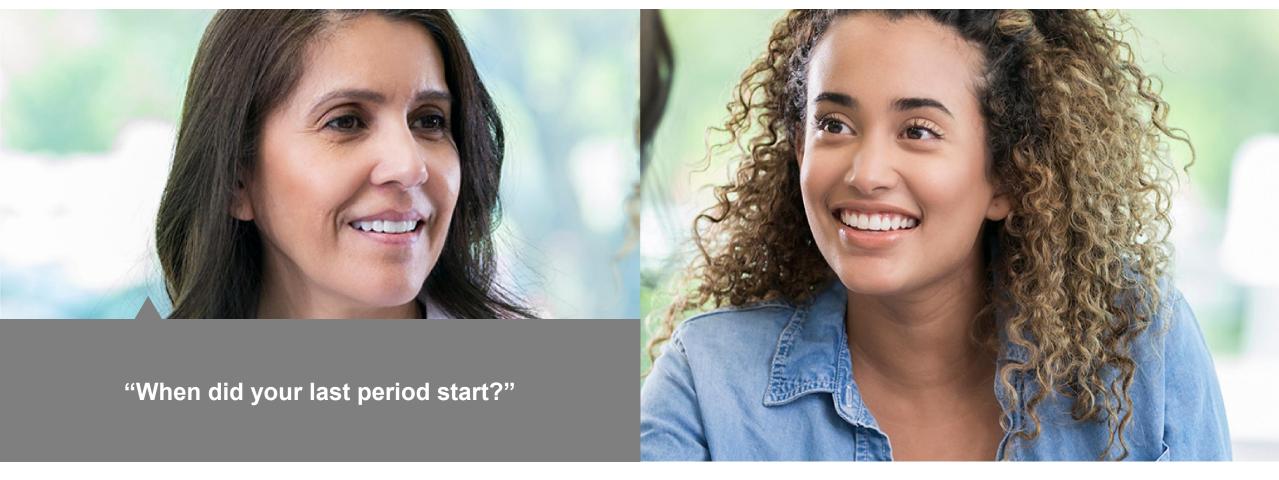
"Mirena can be placed anytime, we just need to make sure you're not pregnant."

"Have you been using a form of birth control regularly and correctly?"

"I always use condoms; I'm really careful about that."











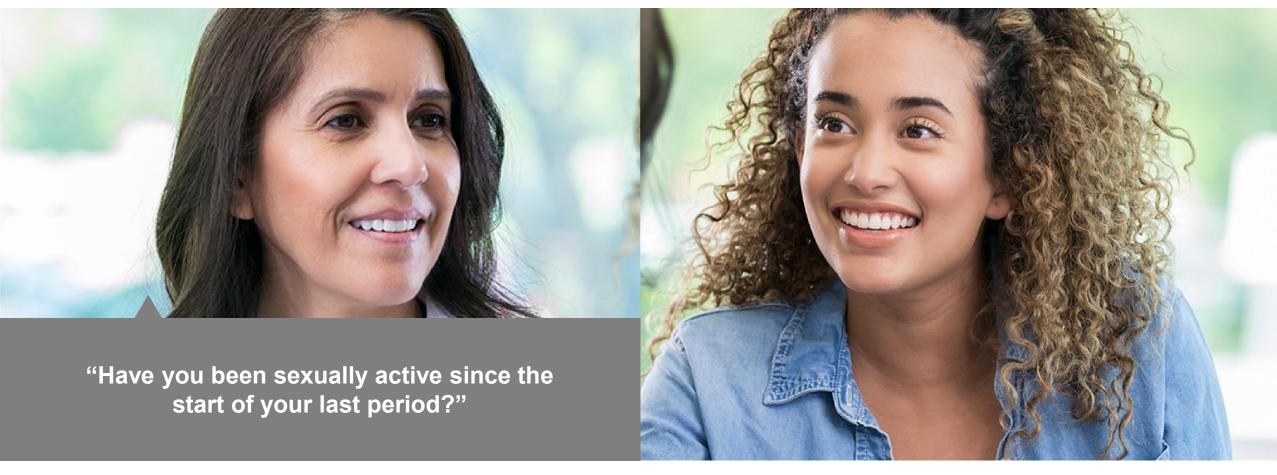


"When did your last period start?"

"My last period started just a few days ago."











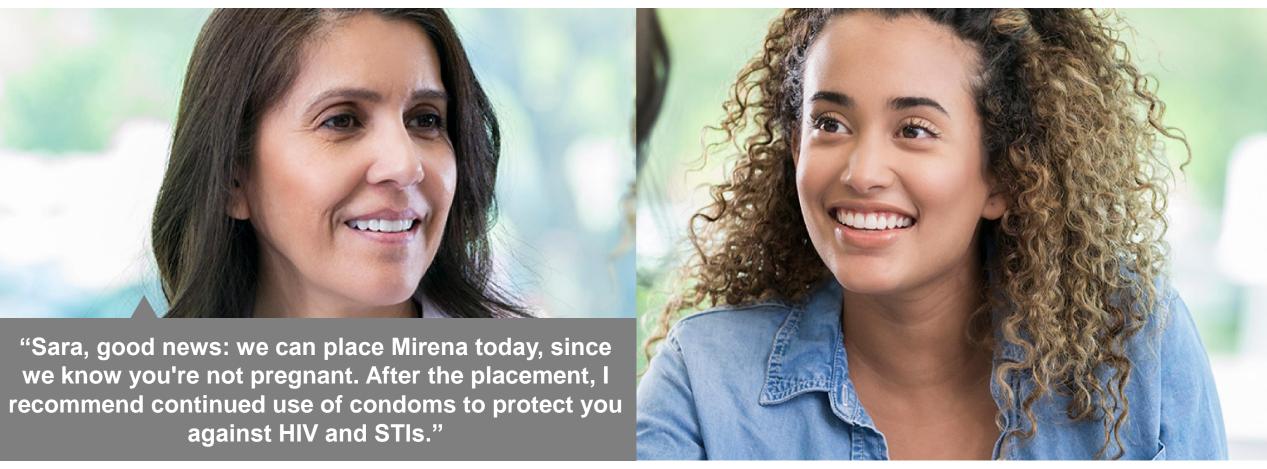


"Have you been sexually active since the start of your last period?"

"No, I haven't had sex since then."













BAYER ER R

How is a Mirena placed during an in-office visit?



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







How is a Mirena placed during an in-office visit?



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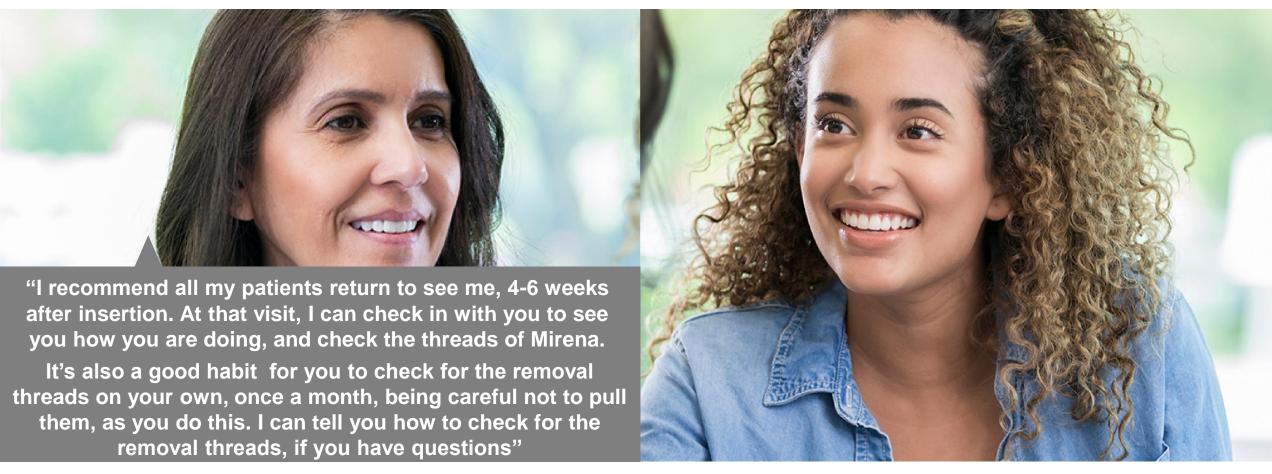


You may experience pain, bleeding, or dizziness during and after placement. If these symptoms do not resolve within 30 minutes, Mirena may not have been placed correctly. I will examine you to see if Mirena needs to be removed or replaced



Follow up with Sara after Insertion







Follow up with Sara after Insertion

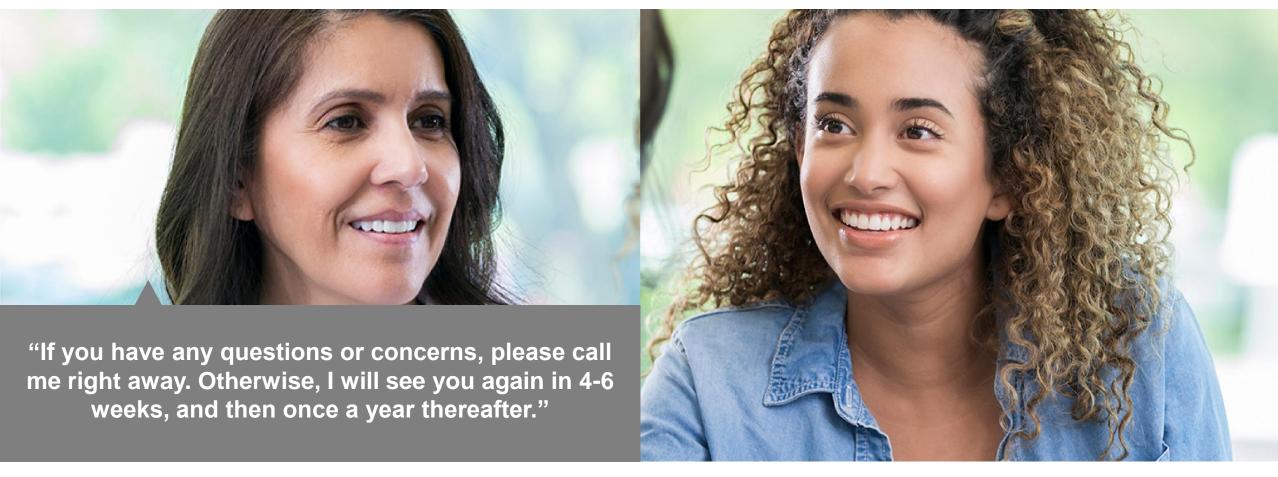






Follow up with Sara after Insertion









Cathy (she/her)



- 32 years old, G2P1
- Married with an 8 week old son
- Presents for post partum visit to discuss contraception
- Clinical exam shows her uterus is completely involuted





during contraceptive counseling?





- 32 years old, G2P1
- Married with an 8 week old son
- Presents for post partum visit to discuss contraception
- Clinical exam shows her uterus is completely involuted





What questions might you ask Cathy during contraceptive counseling?



B A BAYER E R

- 32 years old, G2P1
- Married with an 8 week old son.
- 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?









B A BAYER E R

- 32 years old, G2P1
- Married with an 8 week old son
- 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
- She has a history of heavy menstrual bleeding
- She previously used a vaginal ring and liked the nondaily administration
- She does not want a contraceptive that contains estrogen





What questions might you ask Cathy during contraceptive counseling?

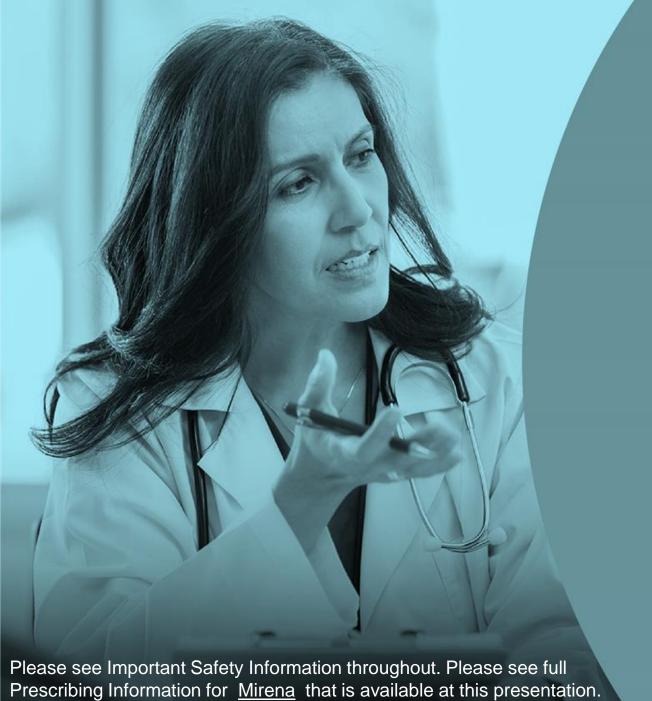
Why would Mirena be a good option for Cathy?



B A BAYER E R

- 32 years old, G2P1
- Married with an 8 week old son.
- Presents for post partum visit to discuss contraception
- Clinical exam shows her uterus is completely involuted
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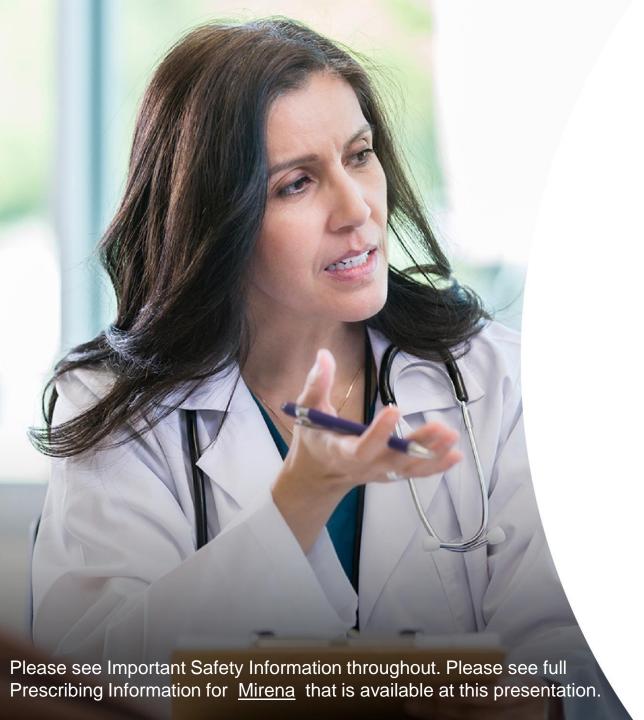




Explaining Mirena to Cathy In patient-friendly language



Mirena®
(levonorgestrel-releasing intrauterine system) 52 mg



What is Mirena?

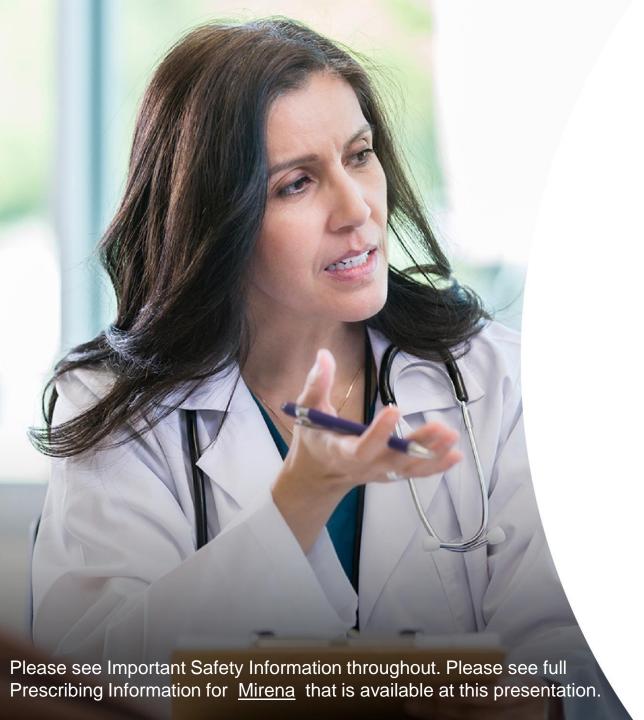


Mirena is a hormone releasing system placed in your uterus to prevent pregnancy for up to 8 years

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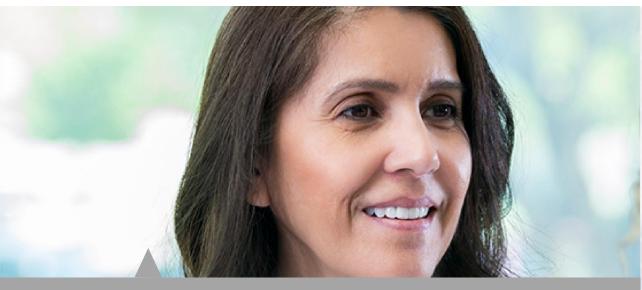
Because Mirena releases LNG into your uterus, only small amounts of hormone enter your blood

Mirena does not contain estrogen



Mirena and Breast Feeding





"You may use Mirena while breastfeeding. Mirena 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 among women using progestin-only birth control pills. The risk of Mirena becoming attached to (embedded) or going through the wall of the uterus is increased when I place Mirena while you are breastfeeding"



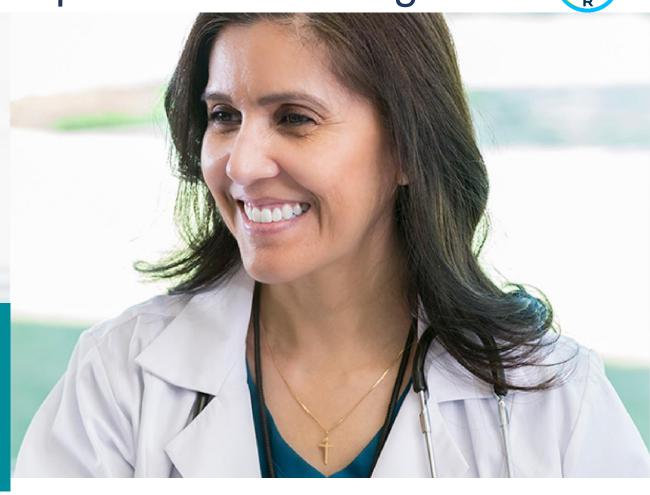


Inform Cathy about what to expect with bleeding





"How will Mirena change my periods?"





Inform Cathy about what to expect with bleeding





"How will Mirena change my periods?"



"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 and some women have heavy bleeding during this time. You may also have cramping during the first few weeks. After you have used Mirena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether"



Inform Cathy about what to expect with bleeding







"How will Mirena change my periods?"

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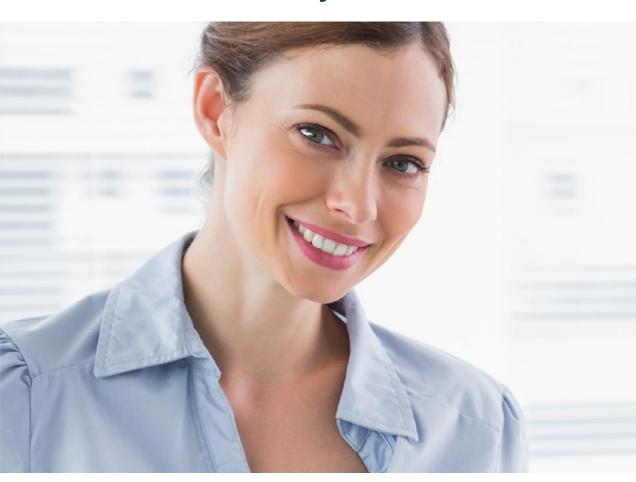


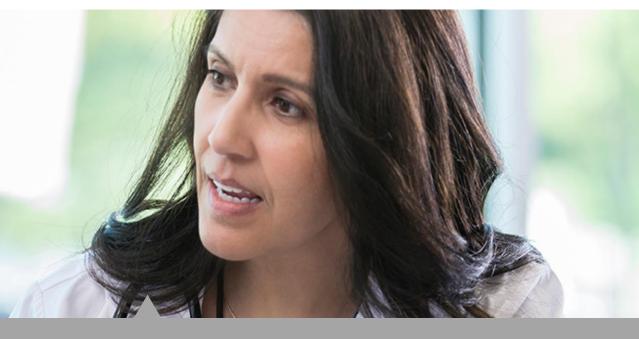




Inform Cathy about side effects





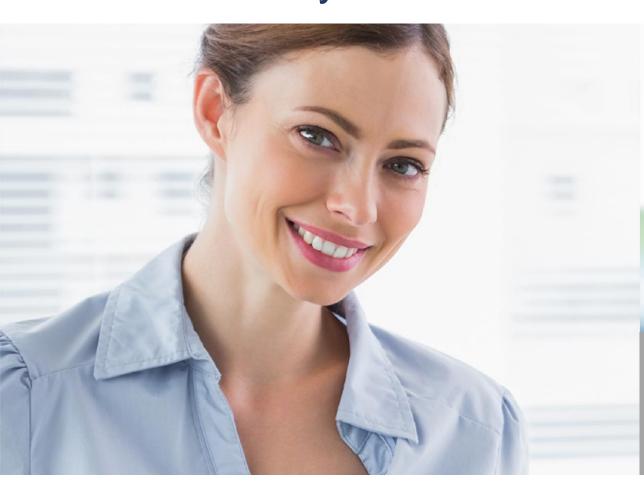


"You may experience side effects with Mirena. I'd like to discuss those next"



Inform Cathy about serious side effects





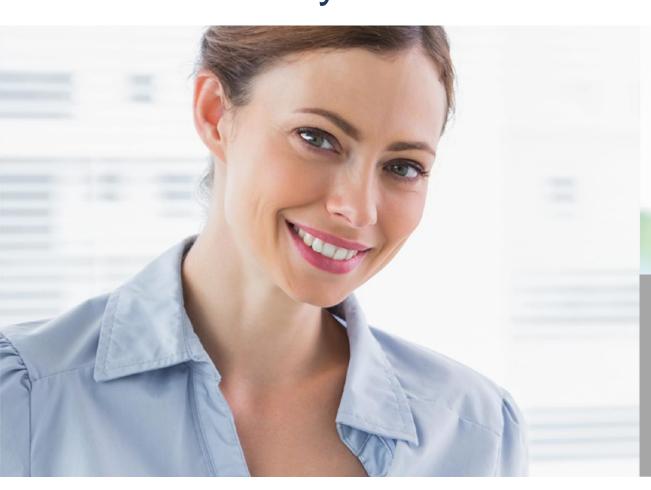


"Mirena can cause serious side effects, including ectopic and intrauterine pregnancy risks, life threatening infection, Pelvic Inflammatory Disease (PID), perforation, and expulsion."



Inform Cathy about some of the common side effects





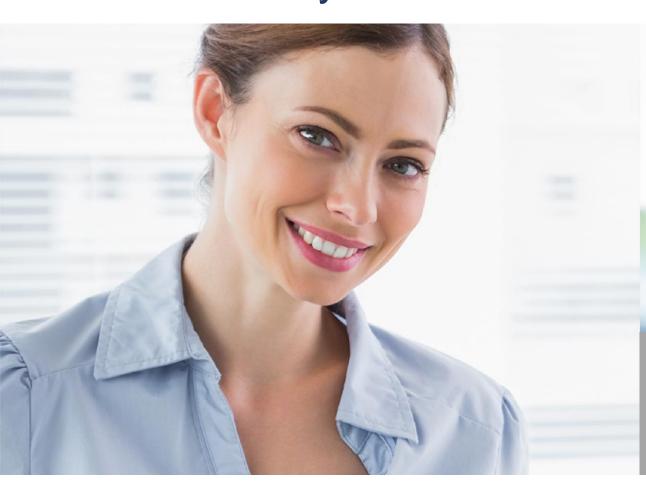


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Inform Cathy about side effects







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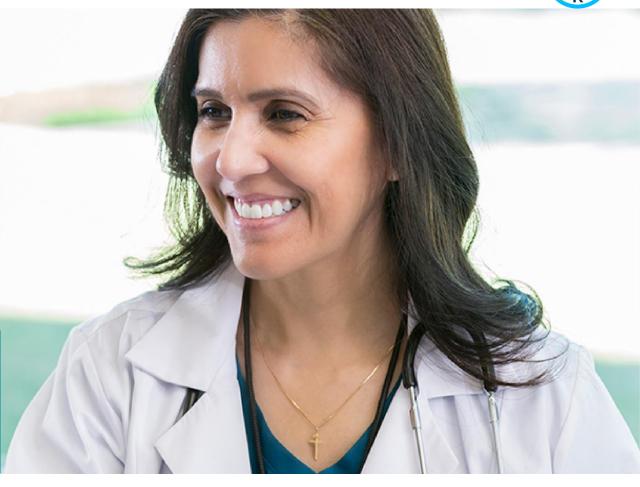


Cathy asks about fertility





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





Cathy asks about fertility





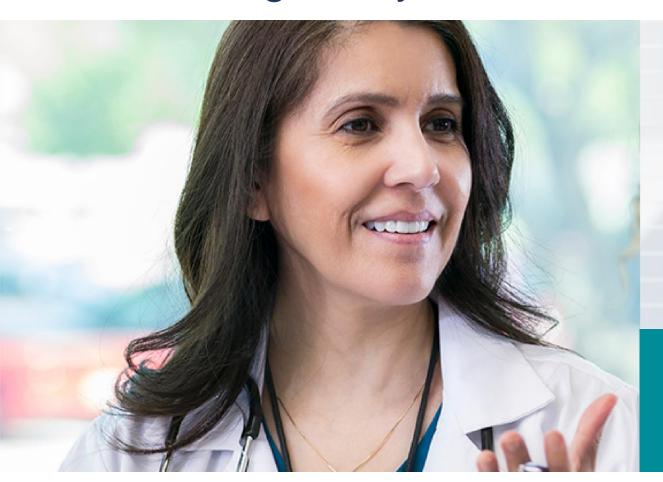
"What if I change my mind and want to get pregnant?"



"If your plans change, I can remove Mirena at any time. You may become pregnant as soon as it's removed. About 8 in 10 women who want to become pregnant will become pregnant sometime in the first year after Mirena is removed."









"Can I have Mirena placed today?"









"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 Mirena today, if you're not pregnant. Have you had a period since your delivery?"

"Can I have Mirena placed today?"





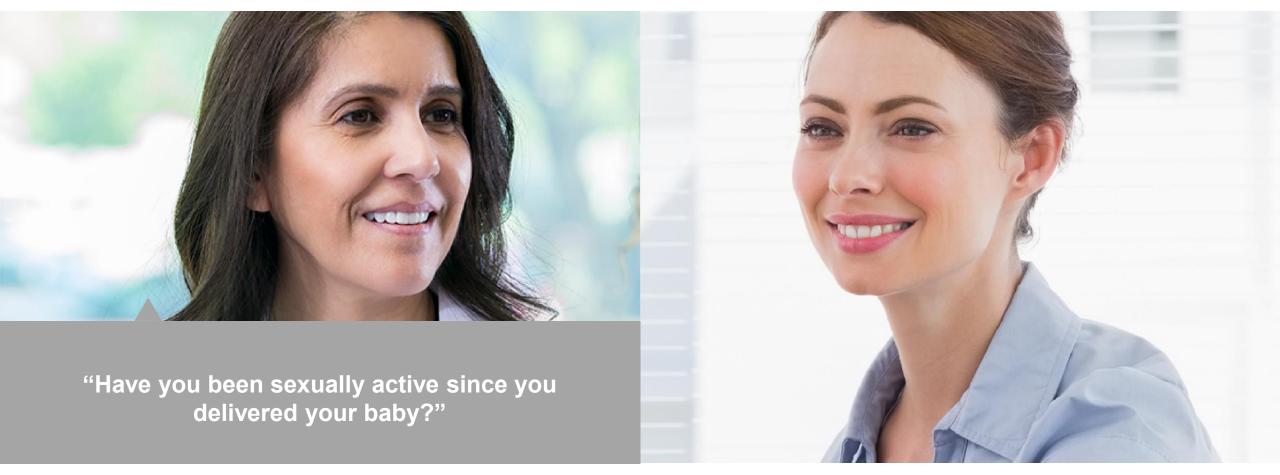


"Since you're 8 weeks post-partum, and I've determined that your uterus is back to its non-pregnant state, I may be able to place Mirena today, if you're not pregnant. Have you had a period since your delivery?"

"No, I haven't had a period yet."











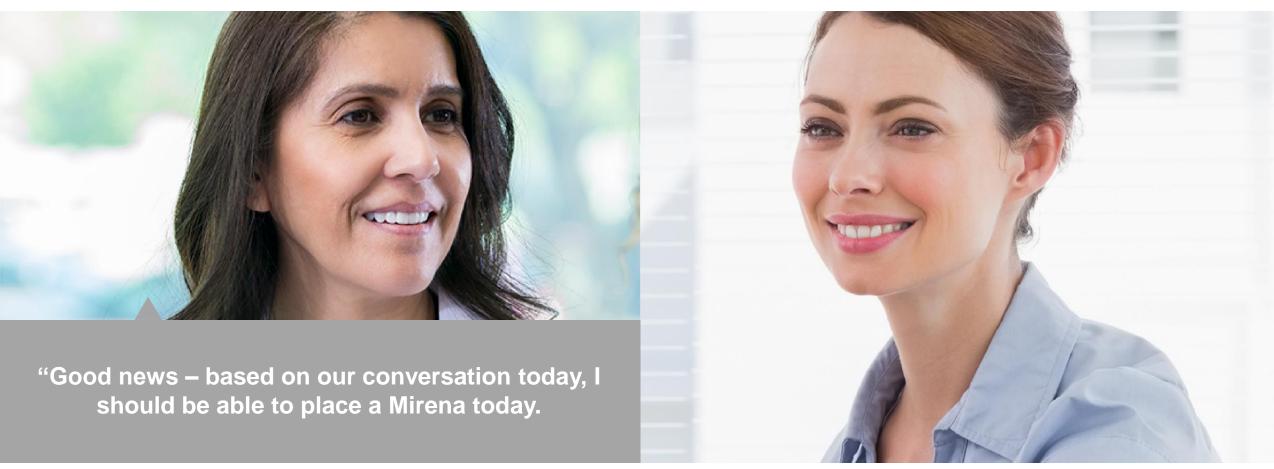


"Have you been sexually active since you delivered your baby?"

"No, I haven't had sex since then."



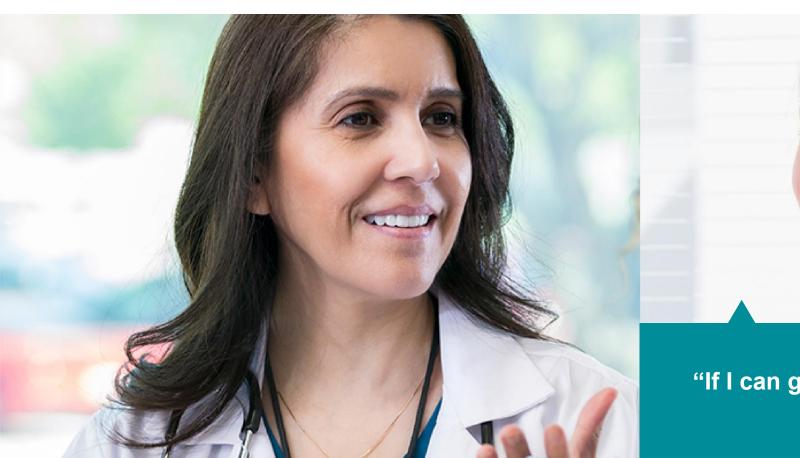






Cathy asks when Mirena will start working







"If I can get Mirena today, how soon will it start working?"



Cathy asks when Mirena will start working





"You will need a back-up method of nonhormonal contraception (condoms or spermicide) or abstain from vaginal intercourse for 7 days to prevent pregnancy."

"If I can get Mirena today, how soon will it start working?"





Explain Insertion to Cathy

How is a Mirena placed during an inoffice visit?



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





Explain Insertion to Cathy

How is a Mirena placed during an inoffice visit?



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



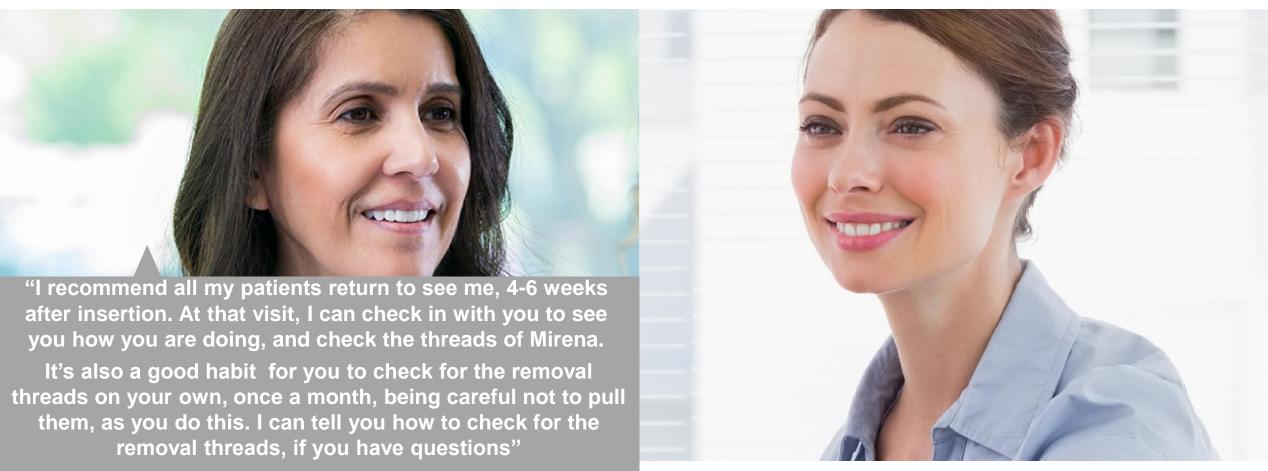
You may experience pain, bleeding, or dizziness during and after placement. If these symptoms do not resolve within 30 minutes, Mirena may not have been placed correctly. I will examine you to see if Mirena needs to be removed or replaced



Prescribing Information for Mirena that is available at this presentation.

Follow-up with Cathy after insertion







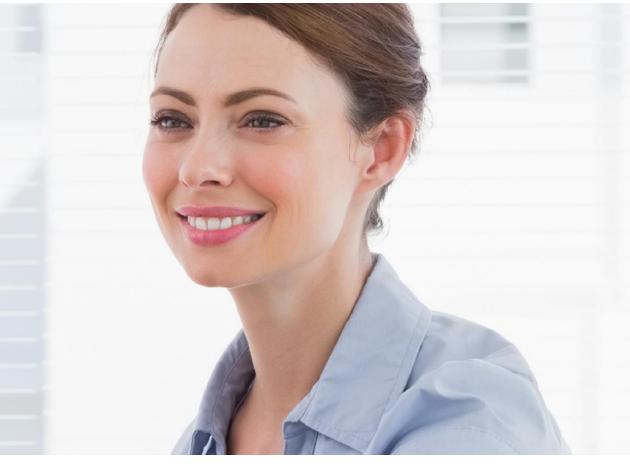
Follow-up with Cathy after insertion





"If you feel more than just the threads, or don't feel them at all, Mirena may not be in the right position, and may not prevent pregnancy.

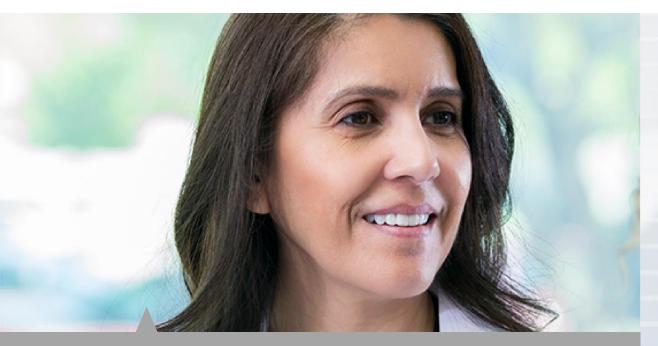
If this happens, avoid intercourse or use non-hormonal back-up contraception (such as condoms and spermicide), and follow-up with me as soon as possible"





Follow-up with Cathy after insertion





"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."

