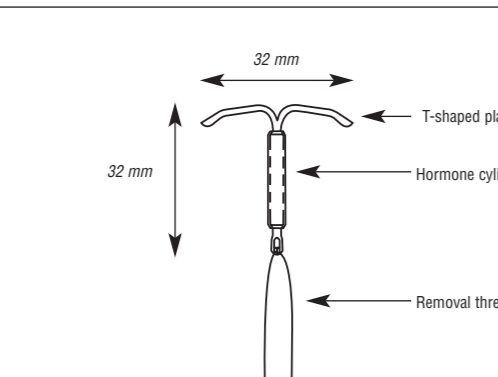


MIRENA®
Physician Prescribing Information

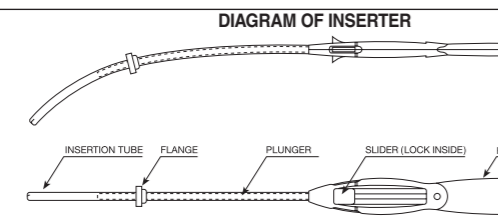
Physician Information

MIRENA®
(levonorgestrel-releasing intrauterine system)
PATIENTS SHOULD BE COUNSELED THAT THIS PRODUCT DOES NOT PROTECT AGAINST HIV INFECTION (AIDS) AND OTHER SEXUALLY TRANSMITTED DISEASES

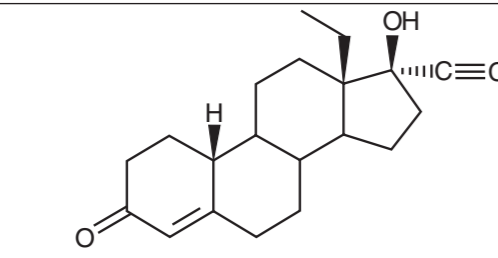
Rx only
DESCRIPTION
MIRENA® (levonorgestrel-releasing intrauterine system) consists of a T-shaped polyethylene frame (T-body) with a steroid reservoir (hormone elastomer core) around the vertical stem. The reservoir consists of a cylinder, made of a mixture of levonorgestrel and silicone (polydimethylsiloxane), containing a total of 52 mg levonorgestrel. The reservoir is covered by a silicone (polydimethylsiloxane) membrane. The T-body is 32 mm in both the horizontal and vertical directions. The polyethylene of the T-body is compounded with barium sulfate, which makes it radiopaque. A monofilament brown polyethylene removal thread is attached to a loop at the end of the vertical stem of the T-body.



INSERTER
MIRENA® is packaged sterile within an inserter. The inserter, which is used for insertion of MIRENA® into the uterine cavity, consists of a symmetric two-sided body and slider that are integrated with flange, lock, pre-bent insertion tube and plunger. Once MIRENA® is in place, the inserter is discarded.



MIRENA® is intended to provide an initial release rate of 20 µg/day of levonorgestrel. Levonorgestrel USP, (-)-13-Ethyl-17-hydroxy-18,19-dinor-17α-pregn-4-en-20-yn-3-one, the active ingredient in MIRENA®, has a molecular weight of 312.4, a molecular formula of C₂₁H₃₀O₂, and the following structural formula:



CLINICAL PHARMACOLOGY
Levonorgestrel is a progestogen used in a variety of contraceptive products. Low doses of levonorgestrel can be administered into the uterine cavity with the MIRENA® intrauterine delivery system. Initially, levonorgestrel is released at a rate of approximately 20 µg/day. This rate decreases progressively to half that value after 5 years. MIRENA® has mainly local progestogenic effects in the uterine cavity. Morphological changes of the endometrium are observed, including stromal pseudocysticization, glandular atrophy, a leukocytic infiltration and a decrease in glandular and stromal mitoses.

Ovulation is inhibited in some women using MIRENA®. In a 1-year study approximately 45% of menstrual cycles were ovulatory and in another study after 4 years 75% of cycles were ovulatory. The local mechanism by which continuously released levonorgestrel enhances contraceptive effectiveness of the IUS has not been conclusively demonstrated. Studies of MIRENA® prototypes have suggested several mechanisms that prevent pregnancy: thickening of cervical mucus preventing passage of sperm into the uterus, inhibition of sperm capacitation or survival, and alteration of the endometrium.

Clinical Pharmacokinetics
Following insertion of MIRENA®, the initial release of levonorgestrel into the uterine cavity is 20 µg/day. A stable plasma level of levonorgestrel of 150-200 pg/mL occurs after the first few weeks following insertion of MIRENA®. Levonorgestrel levels after long term use of 12, 24, and 60 months were 160±66 pg/mL, 192±140 pg/mL, and 159±59 pg/mL, respectively. The plasma concentrations achieved by MIRENA® are lower than those seen with levonorgestrel contraceptive implants and with oral contraceptives. Unlike oral contraceptives, plasma levels with MIRENA® do not display peaks and troughs.

The mean ± SD levonorgestrel endometrial tissue concentration in four women using levonorgestrel intrauterine systems releasing 30 µg/day of levonorgestrel for 36-49 days was 808 ± 511 ng/g wet tissue weight. The endometrial tissue concentration in 2 women who had been taking a 250 µg levonorgestrel-containing oral contraceptive for 7 days was 3.5 ng/g wet tissue weight. In contrast, Fallopian tube and myometrial levonorgestrel tissue concentrations were of the same order of magnitude in the MIRENA® group and the oral contraceptive group (between 1 and 5 ng/g of wet weight of tissue). The pharmacokinetics of levonorgestrel itself have been extensively studied and reported in the literature. Levonorgestrel in serum is primarily bound to proteins (mainly sex hormone binding globulin) and is extensively metabolized to a large number of inactive metabolites. Metabolic clearance rates may differ among individuals by several-fold, and this may account in part for wide individual variations in levonorgestrel concentrations seen in individuals using levonorgestrel-containing contraceptive products. The elimination half-life of levonorgestrel after daily oral doses is approximately 17 hours; both the parent drug and its metabolites are primarily excreted in the urine. Pharmacokinetic studies of this product have not been conducted in special populations (pediatric, renal insufficiency, hepatic insufficiency, and different ethnic groups). Drug-Drug Interactions: The effect of other drugs on the efficacy of MIRENA® has not been studied.

INDICATIONS AND USAGE
MIRENA® is indicated for intrauterine contraception for up to 5 years. Thereafter, if continued contraception is desired, the system should be replaced.

RECOMMENDED PATIENT PROFILE
MIRENA® is recommended for women who have had at least one child, are in a stable, mutually monogamous relationship, have no history of pelvic inflammatory disease, and have no history of ectopic pregnancy or condition that would predispose to ectopic pregnancy.

Clinical Studies
MIRENA® has been studied for safety and efficacy in two large clinical trials in Finland and Sweden. In study sites having verifiable data and informed consent, 1169 women 18 to 35 years of age at enrollment used MIRENA® for up to 5 years, for a total of 45,000 women-months of exposure. The study population was predominantly Caucasian, and over 70% of the participants had previously used IUDs. The reported 12-month pregnancy rates were less than or equal to 0.2 per 100 women and the cumulative 5-year pregnancy rate was approximately 0.7 per 100 women. However, due to limitations of the available data a precise estimate of the pregnancy rate is not possible.

The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies. In this table, MIRENA® is identified as "LN20."

Table 1: Percentage of women experiencing an unintended pregnancy during the first year of typical use and first year of perfect use of contraception and the percentage continuing use at the end of the first year. United States

Method (1)	% of Women Experiencing an Unintended Pregnancy within the First Year of Use		Perfect Use* (3)	(4)
	Typical Use† (2)	Use† (3)		
Chances†	85	85		
Spermicides‡	26	6		40
Periodic abstinence	25			63
Calendar			9	
Ovulation method			3	
Sympto-thermal§			2	
Post-ovulatory¶			1	
Withdrawal	19	4		
Cap†				
Parous women	40	26		42
Nulliparous women	20	9		56
Sponge				
Parous women	40	20		42
Nulliparous women	20	9		56
Diaphragm†	20	6		56
Condom				
Female (Reality)	21	5		56
Male	14	3		61
Pill	5			71
progestin only combined		0.5		
IUD‡			0.1	
Progesterone T:	2.0	1.5		81
Copper T 380A	0.8	0.6		78
LN20	0.1	0.1		81
Nopla Provera	0.3	0.3		70
Depo and Norplant-2	0.05	0.05		88
Female sterilization	0.5	0.5		100
Male sterilization	0.15	0.10		100

Source: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Stewart F, Cates W, Stewart GK, Kowal D, Guest F, *Contraceptive Technology: Seventeenth Revised Edition*. New York NY: Irvington Publishers, 1998.

- Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any reason.
- Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any reason.
- Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year.
- The percents becoming pregnant in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within one year. This estimate was lowered slightly to 85% to represent the percentage who would become pregnant within one year among women now relying on reversible methods of contraception if they abandoned contraception altogether.
- Fams, creams, gels, vaginal suppositories, and vaginal film.
- Cervical mucus (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases.
- With spermicidal cream or jelly.
- Without spermicides.

CONTRAINDICATIONS

- MIRENA® insertion is contraindicated when one or more of the following conditions exist:
- Pregnancy or suspicion of pregnancy.
 - Congenital or acquired uterine anomaly including fibroids if they distort the uterine cavity.
 - Acute pelvic inflammatory disease or a history of pelvic inflammatory disease unless there has been a subsequent intrauterine pregnancy.
 - Postpartum endometritis or infected abortion in the past 3 months.
 - Known or suspected uterine or cervical neoplasia or unresolved, abnormal Pap smear.
 - Genital bleeding of unknown etiology.
 - Untreated acute cervicitis or vaginitis, including bacterial vaginosis or other lower genital tract infections until infection is controlled.
 - Acute liver disease or liver tumor (benign or malignant).
 - Woman or her partner has multiple sexual partners.
 - Conditions associated with increased susceptibility to infections with microorganisms. Such conditions include, but are not limited to, leukemia, acquired immune deficiency syndrome (AIDS), and I.V. drug abuse.
 - Genital actinomycosis (See WARNINGS).
 - A previously inserted IUD that has not been removed.
 - Hypersensitivity to any component of this product.
 - Known or suspected carcinoma of the breast.
 - History of ectopic pregnancy or condition that would predispose to ectopic pregnancy.

WARNINGS:

- Ectopic Pregnancy**
In large clinical trials of MIRENA®, half of all pregnancies detected during the studies were ectopic. The per-year incidence of ectopic pregnancy in the clinical trials was approximately 1 ectopic pregnancy per 1000 users per year. The rate of ectopic pregnancies associated with MIRENA® use is not significantly different than the rate for sexually active women not using any contraception. Clinical trials of MIRENA® excluded women with a history of ectopic pregnancy. MIRENA® is not recommended for use in women with a history of ectopic pregnancy or conditions that increase the risk of ectopic pregnancy. Women who choose MIRENA® must be warned about the risks of ectopic pregnancy. They should be taught to recognize and report to their physician promptly any symptoms of ectopic pregnancy. Women should also be informed that ectopic pregnancy has been associated with complications leading to loss of fertility.
- Intrauterine Pregnancy**
In the event of an intrauterine pregnancy with MIRENA®, the following should be considered:
a. Septic abortion
In patients becoming pregnant with an IUD in place, septic abortion – with septicemia, septic shock, and death – may occur. If pregnancy should occur with a MIRENA® in place, MIRENA® should be removed. Removal or manipulation of MIRENA® may result in pregnancy loss.
b. Continuation of pregnancy
If a woman becomes pregnant with MIRENA® in place and if MIRENA® cannot be removed or the woman chooses not to have it removed, she should be warned that failure to remove MIRENA® increases the risk of miscarriage, septate premature labor and premature delivery. She should be followed closely and advised to report immediately any flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leakage of fluid.
c. Long-term effects and congenital anomalies
When pregnancy continues with MIRENA® in place, long-term effects on the offspring are unknown. Because of the intrauterine administration of levonorgestrel and local exposure to the hormone, the possibility of teratogenicity following exposure to MIRENA® cannot be completely excluded. Clinical experience with the outcomes of pregnancies is limited due to the small number of reported pregnancies following exposure to MIRENA®.

3. Septis

As of 1999, four cases of Group A streptococcal sepsis (GAS) out of an estimated 1.3 million MIRENA® users were reported. All four women experienced the symptom of severe pain within hours of insertion, and this was followed by sepsis within a few days (if insertion). All recovered with treatment. Since death from GAS is more likely if treatment is delayed, it is important to be aware of these rare but serious infections. Aseptic technique during MIRENA® insertion is essential. (GAS sepsis can also occur postpartum, after minor surgery, in wounds and in association with other IUDs.)

4. 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. Use of IUDs has been associated with an increased risk of PID. The highest risk of PID occurs shortly after insertion (usually within the first 20 days thereafter) (see Insertion Precautions). A decision to use MIRENA® must include consideration of the risks of PID.
a. Women at increased risk for PID
PID is often associated with a sexually transmitted disease, and MIRENA® does not protect against sexually transmitted disease. The risk of PID is greater for women who have multiple sexual partners, and also for women whose sexual partner(s) have multiple sexual partners. Women who have ever had PID are at increased risk for recurrence or re-infection.
b. PID warning to MIRENA® users
All women who choose MIRENA® must be informed prior to insertion about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or in infrequent cases can necessitate hysterectomy, or can cause death. Patients must be taught to recognize and report to their physician promptly any symptoms of pelvic inflammatory disease. These symptoms include development of menstrual disorders (prolonged or heavy bleeding), unusual vaginal discharge, abdominal or pelvic pain or tenderness, dyspareunia, chills, and fever.
c. Asymptomatic PID
PID may be asymptomatic but still result in tubal damage and its sequelae.

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Prior to insertion, the physician, nurse, or other trained health professional must provide the patient with the Patient Package Insert. The patient should be given the opportunity to read the information and discuss fully any questions she may have concerning MIRENA® as well as other methods of contraception. Careful and objective counseling of the user prior to insertion regarding the expected bleeding pattern, the possible interindividual variation in changes in bleeding and the etiology of the changes may have an effect on the frequency of removal due to bleeding problems and amenorrhea.
The patient should be told that some bleeding such as irregular or prolonged bleeding and spotting and/or cramps may occur during the first few months of insertion. If her symptoms continue or are severe she should report them to her health care provider. She should also be given instructions on what other symptoms require her to call her health care provider. She should be instructed on how to check after her menstrual period to make certain that the thread still protrudes from the cervix and

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3. Fix the threads tightly in the cleft at the end of the handle (figure 4).

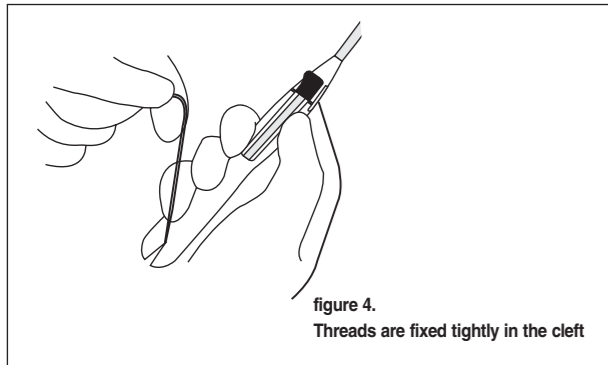


figure 4.
Threads are fixed tightly in the cleft

4. Set the flange to the depth measured by the sound, as indicated in figure 5.

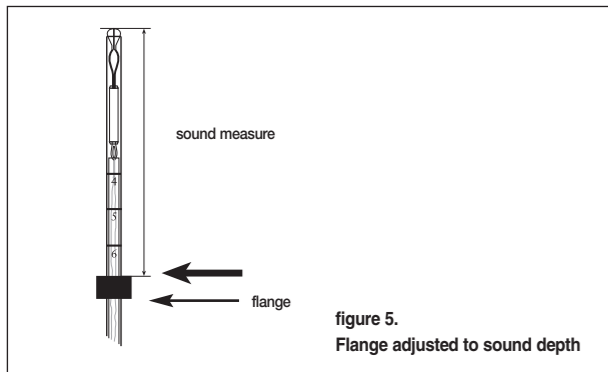


figure 5.
Flange adjusted to sound depth

5. MIRENA[®] is now ready to be inserted.

Hold the slider firmly in the furthestmost position (at the top of the handle). Grasp the cervix with the tenaculum and apply gentle traction to align the cervical canal with the uterine cavity. Gently insert the inserter into the cervical canal and advance the insertion tube into the uterus until the flange is situated at a distance of about 1.5-2 cm from the external cervical os to give sufficient space for the arms to open (figure 6).

NOTE! Do not force the inserter.

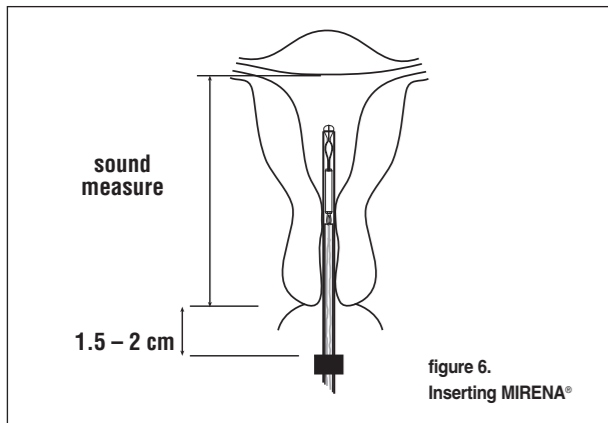


figure 6.
Inserting MIRENA[®]

6. While holding the inserter steady release the arms of MIRENA[®] (figure 7a) by pulling the slider back until the top of the slider reaches the mark (raised horizontal line on the handle) (figure 7b).

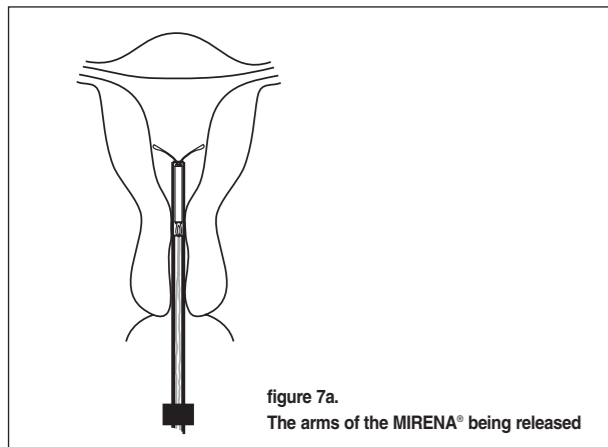


figure 7a.
The arms of the MIRENA[®] being released

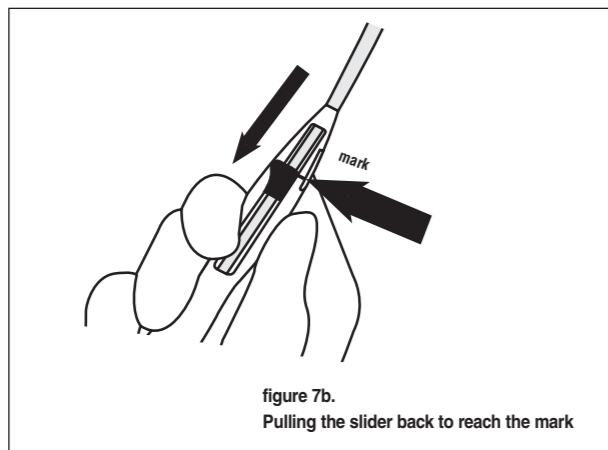


figure 7b.
Pulling the slider back to reach the mark

7. Push the inserter gently into the uterine cavity until the flange touches the cervix. MIRENA[®] should now be in the fundal position (figure 8).

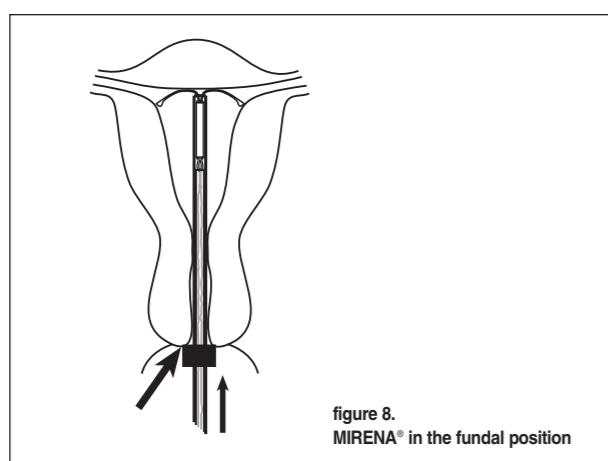


figure 8.
MIRENA[®] in the fundal position

8. Holding the inserter firmly in position release MIRENA[®] by pulling the slider down all the way. The threads will be released automatically (figure 9).

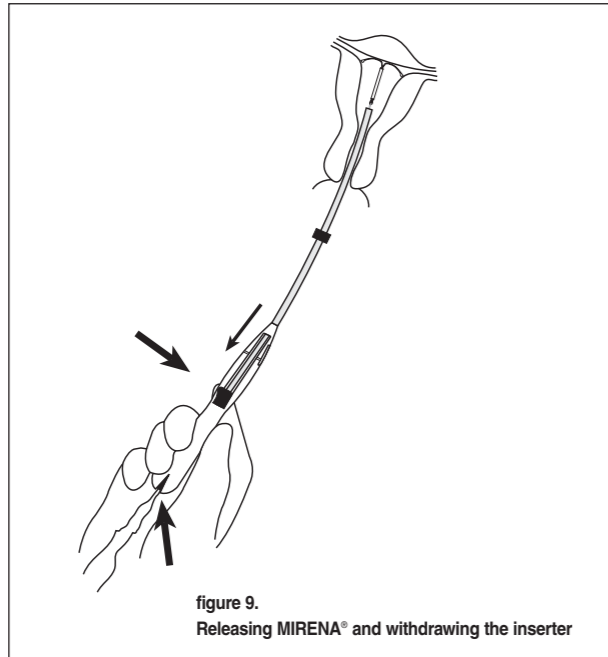


figure 9.
Releasing MIRENA[®] and withdrawing the inserter

9. Remove the inserter from the uterus. Cut the threads to leave about 2-3 cm visible outside the cervix (figure 10).

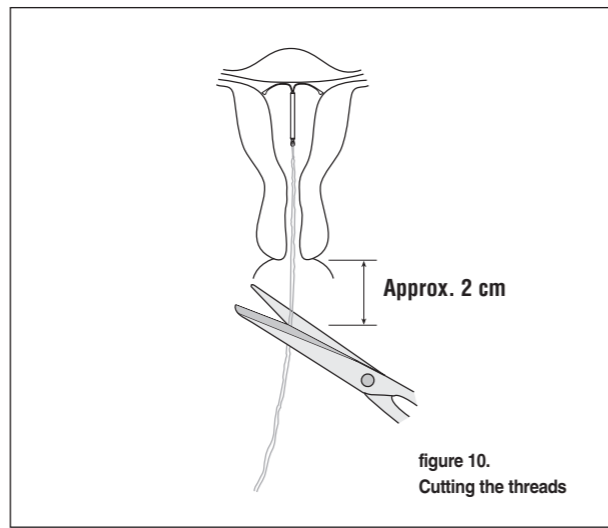


figure 10.
Cutting the threads

IMPORTANT!
If you suspect that the system is not in the correct position, check placement, (with ultrasound, for example). Remove the system if it is not positioned completely within the uterus. Do not reinsert a removed system.

REMOVAL OF MIRENA[®]
Remove MIRENA[®] by applying gentle traction on the threads with forceps. The arms of the system will fold upward as it is withdrawn from the uterus. The system should not remain in the uterus after 5 years.

SPECIAL NOTES IF A PATIENT WANTS TO CONTINUE CONTRACEPTION AFTER REMOVAL

You may insert a new MIRENA[®] immediately following removal. If a patient with regular cycles wants to start a different birth control method, remove the system during the first 7 days of the menstrual cycle and start the new method.

If a patient with irregular cycles or amenorrhea wants to start a different birth control method, or if you remove the system after the seventh day of the menstrual cycle, start the new method at least 7 days before removal.

PATIENT INFORMATION

MIRENA[®]
(levonorgestrel-releasing intrauterine system)

MIRENA[®] (Mur-à-nah) is used to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases (STDs).

Read this information carefully before you decide if MIRENA[®] is right for you. This information does not take the place of talking with your health care provider. If you have any questions about MIRENA[®], ask your health care provider. You should also learn about other birth control methods to choose the one that is best for you.

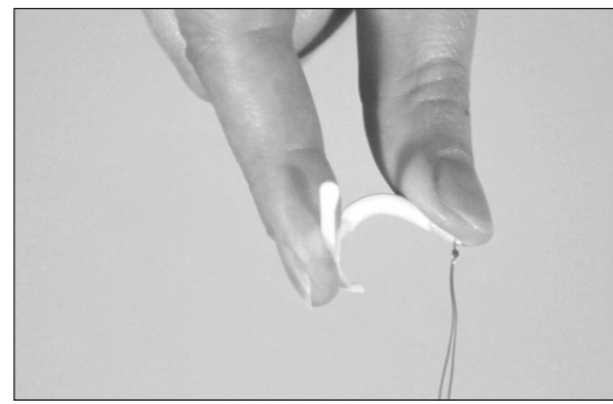
WHAT IS MIRENA[®]?
MIRENA[®] is a hormone-releasing system placed in your uterus to prevent pregnancy for up to 5 years.

MIRENA[®] is T-shaped. It contains a hormone called levonorgestrel. Levonorgestrel is a progestin hormone often used in birth control pills. MIRENA[®] releases the hormone into the uterus. Only small amounts of the hormone enter your blood.

Two brown threads are attached to the stem of the T. You can check that MIRENA[®] is in place by feeling for the threads at the top of your vagina with your fingers. Your health care provider can also remove MIRENA[®] at any time by pulling on the threads. The threads are the only part of MIRENA[®] you can feel when MIRENA[®] is in your uterus.



The MIRENA[®] is small...



and flexible

What if I need birth control for more than 5 years?

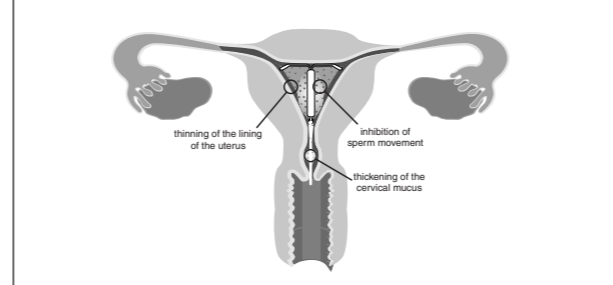
You must have MIRENA[®] removed after 5 years, but your health care provider can insert a new MIRENA[®] then if you choose to continue using MIRENA[®].

What if I change my mind about birth control and decide to have another baby?

Your health care provider can remove MIRENA[®] at any time by pulling on the threads. You may become pregnant as soon as MIRENA[®] is removed. About 8 out of 10 women who want to become pregnant will become pregnant some time in the first year after MIRENA[®] is removed.

How does MIRENA[®] work?

First, your health care provider will examine your pelvis to find the exact position of your uterus. Your health care provider will then clean your vagina and cervix with an antiseptic solution, and slide a thin plastic tube containing MIRENA[®] into your uterus. Your health care provider will then remove the plastic tube, leaving MIRENA[®] in your uterus. Finally, the strings will be cut to the proper length. Insertion takes only a few minutes.



How well does MIRENA[®] work?

Less than 1 out of 100 women using MIRENA[®] become pregnant during five years of MIRENA[®] use.

The following table shows how MIRENA[®] compares to other birth control methods. In this table MIRENA[®] is identified as "LNG 20".

Pregnancy Rates for Birth Control Methods
(For One Year of Use)

The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies. "Typical Use" rates mean that the method either was not always used correctly or was not used with every act of sexual intercourse (e.g., sometimes forgot to take a birth control pill as directed and became pregnant), or was used correctly but failed anyway. "Lowest Expected" rates mean that the method was always used correctly with every act of sexual intercourse but failed anyway (e.g., always took a birth control pill as directed but still became pregnant).

Method	Typical Use Rate of Pregnancy	Lowest Expected Rate of Pregnancy
Sterilization		
Male Sterilization	0.15%	0.1%
Female Sterilization	0.5%	0.5%
Hormonal Methods:		
Implant (Norplant [®] and Norplant-2 [®])	0.05%	0.05%
Hormone Shot (Depo-Provera)	0.3%	0.3%
Combined Pill (Estrogen/Progestin)	5%	0.1%
Minipill (Progestin only)	5%	0.5%
Intrauterine Devices (IUDs):		
Copper T	0.8%	0.6%
Progestasone T	2%	1.5%
LNG 20	0.1%	0.1%
Barrier Methods:		
Male Latex Condom ¹	14%	3%
Diaphragm ²	20%	6%
Vaginal Sponge (no previous births) ³	20%	9%
Vaginal Sponge (previous births) ³	40%	20%
Cervical Cap (no previous births) ¹	20%	9%
Cervical Cap (previous births) ¹	40%	26%
Female Condom	21%	5%
Spermicide (gel, foam, suppository, film)	26%	8%
Natural Methods:		
Withdrawal	19%	4%
Natural Family Planning (calendar, temperature, cervical mucus)	25%	1-9%
No Method:	85%	85%
1 Used Without Spermicide		
2 Used With Spermicide		
3 Contains Spermicide		

Data adapted from: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Stewart F, et al. Contraceptive Technology. Seventeenth Revised Edition. New York, NY: Ardent Media, 1998.

Who might use MIRENA[®]?

- You might choose MIRENA[®] if you
 - need birth control with a low failure rate
 - need birth control that is reversible
 - need birth control that is easy to use
 - have had at least one baby

Who should not use MIRENA[®]?

Do not use MIRENA[®] if you

- might be pregnant
- have had a serious pelvic infection called pelvic inflammatory disease (PID)
- have had a serious pelvic infection in the past 3 months after a pregnancy
- have more than one sexual partner or your partner has more than one partner
- have an untreated pelvic infection now
- can get infections easily. For example, you have problems with your immune system, leukemia, AIDS, or intravenous drug abuse.
- might have cancer of the uterus or cervix
- have bleeding from the vagina that has not been explained
- have liver disease or liver tumor
- have breast cancer now or in the past
- have had an ectopic pregnancy or know you are at high risk for ectopic pregnancy
- have an intrauterine device in your uterus already
- have a condition of the uterus that distorts the uterine cavity, such as large fibroid tumors
- are allergic to levonorgestrel, silicone, or polyethylene

Tell your health care provider if you

- recently had a baby or if you are breast feeding
- are diabetic
- were born with heart disease or have problems with your heart valves
- have problems with blood clotting or take medicine to reduce clotting

How is MIRENA[®] inserted?

First, your health care provider will examine your pelvis to find the exact position of your uterus. Your health care provider will then clean your vagina and cervix with an antiseptic solution, and slide a thin plastic tube containing MIRENA[®] into your uterus. Your health care provider will then remove the plastic tube, leaving MIRENA[®] in your uterus. Finally, the strings will be cut to the proper length. Insertion takes only a few minutes.

How can I check that MIRENA[®] is in place?

You can check yourself by reaching up to the top of your vagina with clean fingers to feel the threads. Do not pull on the threads. It is a good habit to check MIRENA[®] after each menstrual period. If you feel more of MIRENA[®] than just the threads, MIRENA[®] is not in the right place. Call your health care provider to check that MIRENA[®] is still in the right place.

Return to your health care provider in the first 3 months after MIRENA[®] is inserted to make sure that MIRENA[®] is in the right place. Using tampons will not change the position of MIRENA[®].

What if I become pregnant while using MIRENA[®]?

Call your health care provider right away if you think you are pregnant. If you get pregnant while using MIRENA[®], you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain may be a sign of ectopic pregnancy.

Ectopic pregnancy is an emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death. Do not use MIRENA[®] if you have had an ectopic pregnancy in the past or you are at high risk for ectopic pregnancy.

There are also risks if you get pregnant while using MIRENA[®] and the pregnancy is in the uterus. Severe infection, miscarriage, premature delivery, and even death can occur with pregnancies that continue with an intrauterine device. Because of this, your health care provider may try to remove MIRENA[®], even though removing it may cause a miscarriage. If MIRENA[®] cannot be removed, talk with your health care provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your health care provider regularly. Call your health care provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

We do not know if MIRENA[®] can cause long-term effects on the fetus if it stays in place during a pregnancy.

How will MIRENA[®] change my periods?

For the first 3 to 6 months, your monthly period may become irregular. You may also have frequent spotting or light bleeding. A few women have heavy bleeding during this time. After your body adjusts, the number of bleeding days is likely to decrease, and you may even find that your periods stop altogether.

What are the possible side effects of using MIRENA[®]?

The following are serious but uncommon side effects of MIRENA[®]:

- Pelvic inflammatory disease (PID). Some IUD users get a serious pelvic infection called pelvic inflammatory disease. PID is usually sexually transmitted. You have a higher chance of getting PID if you or your partner have sex with other partners. PID can cause serious problems such as infertility, ectopic pregnancy or constant pelvic pain.
- PID is usually treated with antibiotics. However, more serious cases of PID may require surgery. A hysterectomy (removal of the uterus) is sometimes needed. In rare cases, infections that start as PID can even cause death.

Tell your health care provider right away if you have any of these signs of PID: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal (stomach area) pain, painful sex, chills, or fever.

- Life-threatening infection. Life-threatening infection occurs rarely within the first few days after MIRENA[®] is inserted. Call your health care provider if you develop severe pain within a few hours after insertion.

- Perforation. MIRENA[®] may go through the uterus. This is called perforation. If your uterus is perforated, you may need surgery to remove MIRENA[®]. Perforation can cause internal scarring, infection, or damage to other organs.

- Expulsion. MIRENA[®] may come out by itself. This is called expulsion. You may become pregnant if MIRENA[®] comes out. Use a backup birth control method like condoms and call your health care provider if you notice that MIRENA[®] has come out.

There are several more common side effects of MIRENA[®]:

- Cramps, dizziness, or faintness while MIRENA[®] is being inserted. This is common. Sometimes, the cramping is severe.
- Missed menstrual periods. About 2 out of 10 of women stop having periods after 1 year of MIRENA[®] use. The periods come back when MIRENA[®] is removed. If you do not have a period for 6 weeks during MIRENA[®] use, contact your health care provider.
- Changes in bleeding. You may have bleeding and spotting between menstrual periods, especially during the first 3 to 6 months. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than usual and may be irregular. Call your health care provider if the bleeding remains heavier than usual or if the bleeding becomes heavier after it has been light for a while.
- Cyst on the ovary. About 10% (1 out of 10) of women using MIRENA[®] will have a cyst on the ovary. These cysts usually disappear on their own in a month or two. However, cysts can cause pain and sometimes cysts will need surgery. This is not a complete list of possible side effects. For more information, ask your health care provider.

When should I call my health care provider?

Call your health care provider if you have any concerns about MIRENA[®]. Be sure to call if you

- think you are pregnant
- have pelvic pain or pain during sex
- have unusual vaginal discharge or genital sores
- have unexplained fever
- might be exposed to sexually transmitted diseases (STDs)
- cannot feel MIRENA[®]'s threads
- develop very severe or migraine headaches
- have yellowing of the skin or whites of the eyes. These may be signs of liver problems.
- have a stroke or heart attack
- or your partner becomes HIV positive
- have severe or prolonged vaginal bleeding
- miss a menstrual period

General advice about prescription medicines

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. This leaflet summarizes the most important information about MIRENA[®]. If you would like more information, talk with your health care provider. You can ask your health care provider for information about MIRENA[®] that is written for health professionals.

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2313005 (B) 6004703

Manufactured for:

Berlex

Montville, NJ 07045

Manufactured in Finland

This patient information booklet was written December 2000.

Fill out the following checklist. Your answers will help you and your health care provider decide if MIRENA[®] is a good choice for you.

Do you have any of these conditions?	Yes	No	Don't know—will discuss with my health care provider
Abnormalities of the uterus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acquired immune deficiency syndrome (AIDS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anemia or blood clotting problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bleeding between periods	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cancer of the uterus or cervix	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
History of other types of cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Steroid therapy (for example, prednisone)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Possible pregnancy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ectopic pregnancy in the past	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fainting attacks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genital sores	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart murmur	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heavy menstrual flow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hepatitis or other liver disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Infection of the uterus or cervix	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IUD in place now or in the past	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IV drug abuse now or in the past	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Leukemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
More than one sexual partner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A sexual partner who has more than one sexual partner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pelvic infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abortion or miscarriage in the past 2 months	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pregnancy in the past 2 months	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Severe menstrual cramps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sexually transmitted disease (STD), such as gonorrhea or chlamydia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abnormal Pap smear	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unexplained genital bleeding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Uterine or pelvic surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vaginal discharge or infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HIV infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Breastfeeding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Manufactured for:

BERLEX[®]

1-866-647-3646

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