

# BIRTH CONTROL

*mirena*

## FDA HAS APPROVED THIS IUD (INTRAUTERINE DEVICE) FOR CONTRACEPTION + TREATMENT OF HEAVY MENSTRUAL BLEEDING

### Mirena IUD can cause:

- + Uterine/vaginal bleeding alterations
- + Amenorrhea (absence of a menstrual period)
- + Intermenstrual bleeding and spotting
- + Abdominal/pelvic pain
- + Ovarian cysts
- + Ectopic pregnancy
- + **Loss of fertility**
- + Pregnancy loss
- + Septic abortion (including septicemia, **shock and death**)
- + Breast tenderness/pain
- + Vaginal discharge
- + IUD expulsion
- + Angioedema
- + Device breakage
- + Group A streptococcal infection
- + Pelvic Inflammatory Disease (PID)
- + **Perforation may occur during insertion**
- + Embedment in the myometrium and partial or complete expulsion
- + Persistent enlarged ovarian follicles
- + Spontaneous reports of **breast cancer**
- + May affect glucose tolerance
- + **Decreased milk production**
- + Small amounts of progestins pass into the **breast milk** of nursing mothers, resulting in detectable steroid levels in infant serum
- + Premature labor and delivery
- + Headache/migraine
- + Acne
- + Depressed/altered mood
- + Menorrhagia

SOURCES FROM FDA + BAYER HEALTHCARE PHARMACEUTICALS INC.

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/021225s027lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021225s027lbl.pdf)

## THERE ARE MANY TYPES OF BIRTH CONTROL



**MIRENA IS A HORMONAL INTRAUTERINE DEVICE (IUD)**

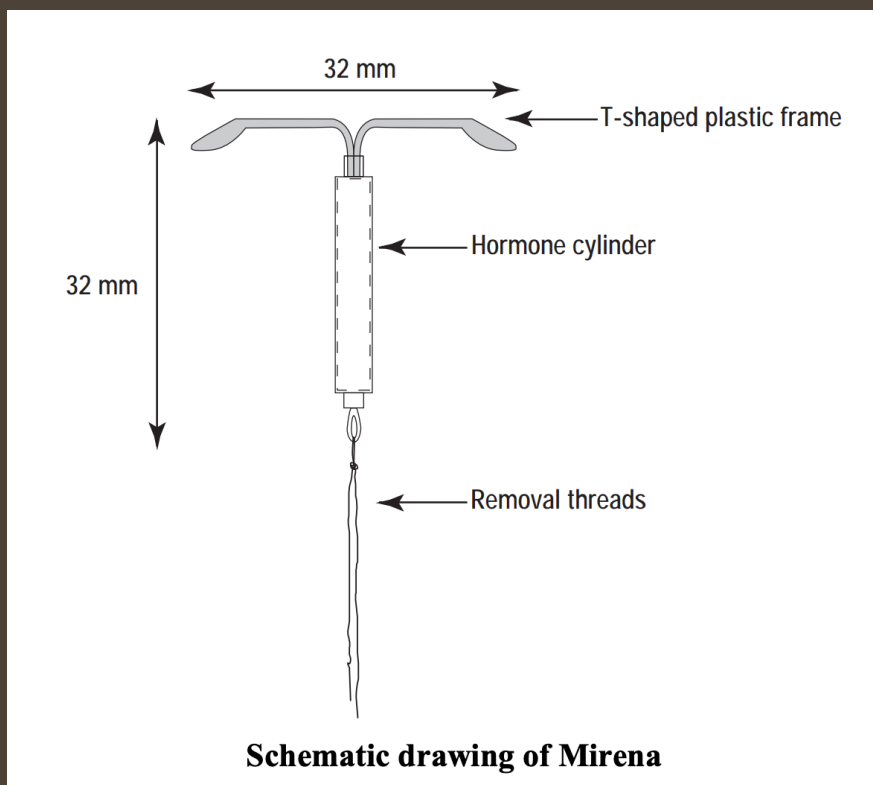
Mirena is a hormone-releasing system placed in your uterus to prevent pregnancy for up to 5 years.

Mirena can also lessen menstrual blood loss in women who have heavy menstrual flow and who also want to use a birth control method that is placed in the uterus to prevent pregnancy.

Mirena is recommended for women who have had at least one child.

Mirena is T-shaped. It is made of flexible plastic and contains a progestin hormone called levonorgestrel that is often used in birth control pills. Mirena does not contain estrogen. Mirena releases the hormone into the uterus. Only small amounts of the hormone enter your blood.

Two threads are attached to the stem of Mirena. The threads are the only part of Mirena you can feel when Mirena is in your uterus.



## LET'S LOOK AT SOME OF THE ADVERSE REACTIONS

# ECTOPIC PREGNANCY

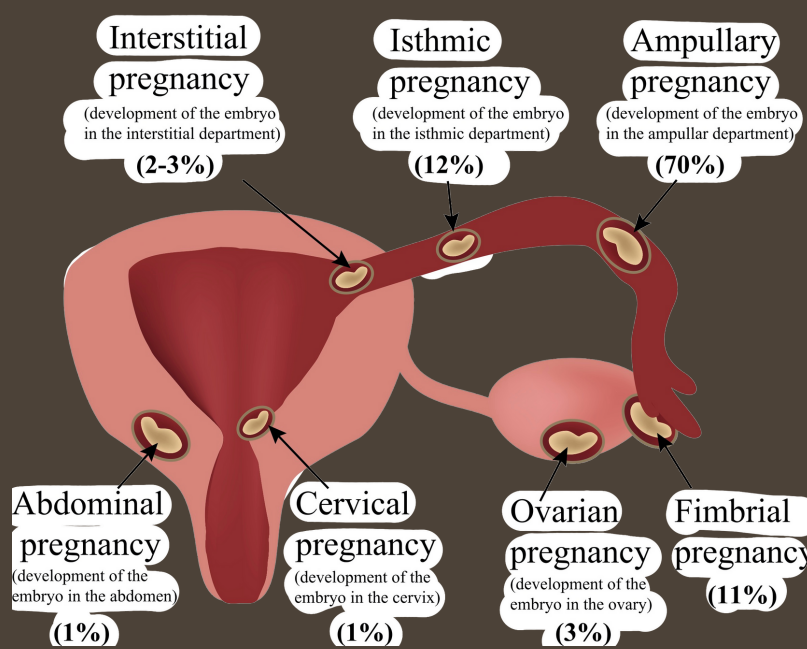
*according to the manufacturer,*

Evaluate women who become pregnant while using Mirena for ectopic pregnancy. Up to half of pregnancies that occur with Mirena in place are ectopic. The incidence of ectopic pregnancy in clinical trials that excluded women with risk factors for ectopic pregnancy was approximately 0.1% per year.

Tell women who choose Mirena about the risks of ectopic pregnancy, including the loss of fertility. Teach them to recognize and report to their physician promptly any symptoms of ectopic pregnancy. Women with a previous history of ectopic pregnancy, tubal surgery or pelvic infection carry a higher risk of ectopic pregnancy.

The risk of ectopic pregnancy in women who have a history of ectopic pregnancy and use Mirena is unknown. Clinical trials of Mirena excluded women with a history of ectopic pregnancy.

## Types of ectopic pregnancy



*according to acog,*

If the ectopic pregnancy has ruptured a tube, emergency surgery is needed. Sometimes surgery is needed even if the fallopian tube has not ruptured. In these cases, the ectopic pregnancy can be removed from the tube, or the entire tube with the pregnancy can be removed.

Once you have had an ectopic pregnancy, you are at higher risk of having another one. During future pregnancies, be alert for signs and symptoms of ectopic pregnancy until your ob-gyn or other health care professional confirms the next pregnancy is growing in the right place.

<https://www.acog.org/en/Womens%20Health/FAQs/Ectopic%20Pregnancy>

# INTRAUTERINE PREGNANCY

If pregnancy should occur with Mirena in place, Mirena should be removed. Removal or manipulation of Mirena may result in pregnancy loss. In the event of an intrauterine pregnancy with Mirena, consider the following:

### Septic abortion

In patients becoming pregnant with an IUD in place, septic abortion—with septicemia, septic shock, and death—may occur.

The NEW ENGLAND JOURNAL of MEDICINE

Septic abortion, an abortion associated with infection and complicated by fever, endometritis, and parametritis,<sup>1</sup> remains one of the most serious threats to the health of women throughout the world.

<https://www.nejm.org/doi/full/10.1056/NEJM199408043310507>

### 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, sepsis, 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.



### Long-term effects and congenital anomalies

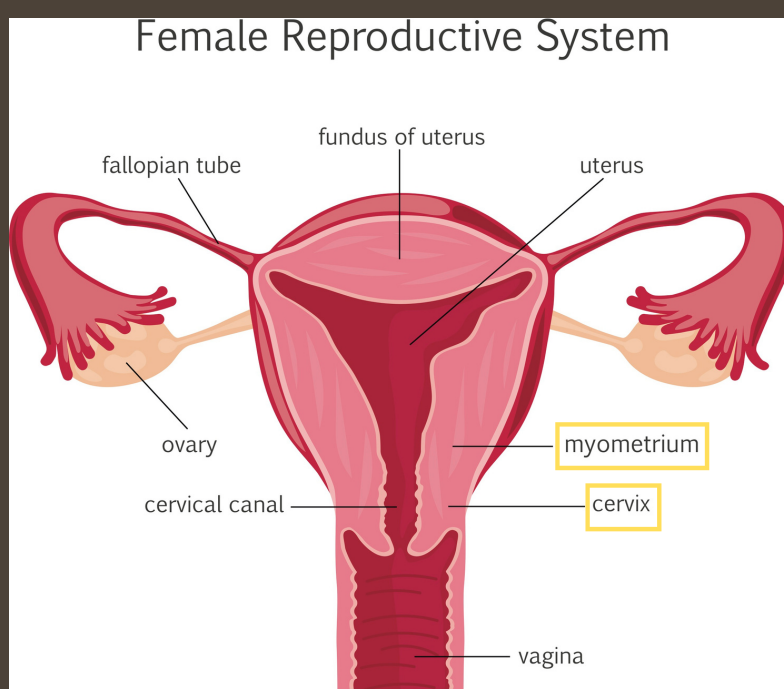
When pregnancy continues with Mirena in place, long-term effects on the offspring are unknown. As of September 2006, 390 live births out of an estimated 9.9 million Mirena users had been reported. Congenital anomalies in live births have occurred infrequently. No clear trend towards specific anomalies has been observed. Because of the intrauterine administration of levonorgestrel and local exposure of the fetus to the hormone, the possibility of teratogenicity following exposure to Mirena cannot be completely excluded. Some observational data support a small increased risk of masculinization of the external genitalia of the female fetus following exposure to progestins at doses greater than those currently used for oral contraception. Whether these data apply to Mirena is unknown.

Teratogenicity is the ability to cause defects in a developing fetus.

## PERFORATION + EMBEDMENT

Perforation or penetration of the uterine wall or cervix may occur during insertion although the perforation may not be detected until some time later. If perforation occurs, pregnancy may result [see Warnings and Precautions (5.1 and 5.2)]. Mirena must be located and removed; surgery may be required. Delayed detection of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of adjacent viscera.

The risk of perforation may be increased in lactating women, in women with fixed retroverted uteri, and during the postpartum period. To decrease the risk of perforation postpartum, Mirena insertion should be delayed a minimum of 6 weeks after delivery or until uterine involution is complete. If involution is substantially delayed, consider waiting until 12 weeks postpartum. Inserting Mirena immediately after first trimester abortion is not known to increase the risk of perforation, but insertion after second trimester abortion should be delayed until uterine involution is complete.



Embedment of Mirena in the myometrium may occur. Embedment may decrease contraceptive effectiveness and result in pregnancy [see Warnings and Precautions (5.1 and 5.2)]. An embedded Mirena should be removed. Embedment can result in difficult removal and, in some cases surgical removal may be necessary.

## IRREGULAR BLEEDING + AMENORRHEA

Mirena can alter the bleeding pattern and result in spotting, irregular bleeding, heavy bleeding, oligomenorrhea and amenorrhea. During the first three to six months of Mirena use, the number of bleeding and spotting days may be increased and bleeding patterns may be irregular. Thereafter the number of bleeding and spotting days usually decreases but bleeding may remain irregular. If bleeding irregularities develop during prolonged treatment, appropriate diagnostic measures should be taken to rule out endometrial pathology.

The FDA has approved Mirena for treatment of heavy menstrual bleeding. Why does the manufacturer state that very thing can be caused by this product?

Endometrial pathology refers to an abnormality of the endometrium (lining in the uterus).

Amenorrhea develops in approximately 20% of Mirena users by one year.

Amenorrhea (uh-men-o-REE-uh) is the absence of menstruation — one or more missed menstrual periods. Women who have missed at least three menstrual periods in a row have amenorrhea, as do girls who haven't begun menstruation by age 15.

## LEVONORGESTREL

*according to the manufacturer,*

Low doses of levonorgestrel are administered into the uterine cavity with the Mirena intrauterine delivery system.

Levonorgestrel is a synthetic progesterone used in Mirena and other contraceptives.



GHS (Globally Harmonized System of Classification and Labelling of Chemicals) is a United Nations system to identify hazardous chemicals and to inform users about these hazards. GHS has been adopted by many countries around the world and is now also used as the basis for international and national transport regulations for dangerous goods. The GHS hazard statements, class categories, pictograms, signal words, and the precautionary statements can be found on the PubChem GHS page.

Pictogram(s)



levonorgestrel

Signal **Danger**

H351 (96.15%): Suspected of causing cancer [[Warning](#) Carcinogenicity]

H360 (92.31%): May damage fertility or the unborn child [[Danger](#) Reproductive toxicity]

H362 (92.31%): May cause harm to breast-fed children [Reproductive toxicity, effects on or via lactation]

H400 (92.31%): Very toxic to aquatic life [[Warning](#) Hazardous to the aquatic environment, acute hazard]

H410 (92.31%): Very toxic to aquatic life with long lasting effects [[Warning](#) Hazardous to the aquatic environment, long-term hazard]

<https://pubchem.ncbi.nlm.nih.gov/compound/Levonorgestrel#section=GHS-Classification&fullscreen=true>

# ONGOING LEGAL CONCERNS

## Mirena Lawsuit Overview

Associated Products

**Mirena IUD**

Companies Involved

**Bayer**

Common Uses

**For the prevention of pregnancy in women for up to 5 years**

How Many Lawsuits

**2,700**

Major Side Effects

**Pseudotumor Cerebri, Idiopathic Intracranial Hypertension, Migration, Perforation, Embedment**

Settlement Details

**\$12.2 Million**

Lawsuit Locations

**Federal: Southern District of New York**

Prior to accepting this product, please read the manufacturer insert. Currently, there is conflicting information between the company website and the manufacturer insert filed with the FDA.

Mirena lawsuits stem from the device's [severe side effects](#). In early 2018, [Bayer](#) announced a settlement that resolved thousands of Mirena-related lawsuits. The settlement only included claims related to IUD migration and perforation.

However, many women have sued Bayer due to a serious condition known as pseudotumor cerebri ("false tumor"). This condition can cause tumor-like symptoms in the brain. Bayer's 2018 settlement did not settle any cases related to pseudotumor cerebri. [These cases are still pending](#).

<https://www.consumersafety.org/medical-device-lawsuits/mirena/>