ON INTRA-UTERINE DRUG DELIVERY SYSTEM-A REVIEW

Margret chandira*, Debjit Bhowmik, chiranjib, B.jayakar

Vinayaka mission University
Salem,Tamilnadu
Email-debjit_cr@yahoo.com

ABSTRACT

An Intrauterine Device (IUD) is a small piece of plastic that is inserted by a clinician into the uterus to prevent pregnancy. It is approximately 1½ inches (3cm) in length. There are several different types of IUDs. The most common IUD is T-shaped and coated with copper. This can be left in the uterus for 2-5 years. Another type of IUD contains a hormone (progestin) but it needs to be replaced once a year. Attached to the IUD are two plastic threads or strings that hang down through the cervix into the vagina. The cervix is the opening to the uterus. The threads or strings do not hang outside the body. The IUD can also be used as an emergency method of birth control. An IUD is a good option for women who want a highly effective, long-term, easily reversible method of contraception. It can be an appropriate choice for women who can't use certain hormonal methods like birth control pills. An IUD won't protect you from sexually transmitted infections (STIs) and isn't recommended for women at high risk for STIs. The copper IUD may also be used for emergency contraception. If it's inserted within five days after unprotected sex, it's more effective than taking emergency contraceptive pills. Plus you can just leave it in for ongoing contraception. If an IUD is inserted within 7 days after unprotected vaginal sex it may prevent a pregnancy. An IUD is a small soft T-shaped device with a nylon
string attached. An IUD is inserted into the uterus (womb) by a health-care provider with specialized training. Exactly how the IUD works to prevent pregnancy is not fully understood. The IUD may: Cause slight inflammation of the lining of the uterus so that a fertilized egg cannot implant. Interfere with the movement of sperm or kill sperm Speed up the movement of the egg through the Fallopian tube. The IUD is 98% effective in preventing pregnancy. A clinician must insert an IUD. It is usually done when you are on your period. The clinician will perform a pelvic exam and check to see where your uterus is positioned. They will then insert a speculum into your vagina to see your cervix and then wash your cervix with an antiseptic solution. Next an IUD is put into your uterus and the strings are cut just below your cervix. IUD insertion can be uncomfortable. You may want to take pain pills before you have an IUD inserted. Removal of an IUD must also be done by a clinician.

INTRODUCTION

Intrauterine Device (IUD) is a small object that is inserted through the cervix and placed in the uterus to prevent pregnancy. A small string hangs down from the IUD into the upper part of the vagina. The IUD is not noticeable during intercourse. IUDs can last 1-10 years. They affect the movements of eggs and sperm to prevent fertilization. They also change the lining of the uterus and prevent implantation. IUDs are 99.2-99.9% effective as birth control. They do not protect against sexually transmitted infections, including HIV/AIDS. Insertion of an IUD takes only about 5 to 10 minutes. Your health care provider will first do a pelvic exam to measure the size, shape, and position of your uterus and other reproductive organs. Your health care provider will then put antiseptic solution onto your cervix. The IUD will be inserted up through the opening of your cervix into your uterus. It is put inside using a special applicator that keeps the IUD flat and closed until it is at the top of your uterus. You may feel cramping, but it usually is not much. After the IUD has been inserted, your health care provider will cut the string at the end of the IUD so that it is short enough where it won't bother you or partner. It will be long enough so you can check
to make sure that the IUD is in place. Your health care provider will then talk with you about what you need to do about checking the string. An IUD prevents pregnancy by stopping sperm from reaching an egg that your ovaries have released. It does this by not letting sperm go into the egg. An IUD also changes the lining of the uterus so an egg does not implant in the lining if it has been fertilized. Therefore, the egg has no place to grow. IUDs are the most effective form of nonpermanent birth control. They are more than 99% effective. This means that if 100 women use the copper IUD or the levonorgestrel IUS, less than 1 woman will become pregnant in a year. Every month a woman's ovary produces an egg. When a man ejaculates, his semen contains millions of sperm. It takes only one of these sperm to fertilise an egg and begin a pregnancy. If a couple has sex (penis in vagina) and do not take precautions, there is a high risk of pregnancy. Using contraception allows you to have sex and avoid an unintended pregnancy. Women at low risk of contracting sexually transmitted infections Women who cannot or do not wish to take The Pill. An intrauterine device (IUD) usually is a small, flexible plastic frame. It often has copper wire or copper sleeves on it. It is inserted into a woman’s vagina through her uterus. Almost all brands of IUDs have two strings, or threads, tied to them. The strings hang through the opening of the cervix into the vagina. A provider can remove the IUD by pulling gently on the strings with forceps.
HISTORY OF INTRAUTERINE DEVICES

According to popular legend, Arab traders inserted small stones into the uteruses of their camels to prevent pregnancy during long desert treks. The story was originally a tall tale to entertain delegates at a scientific conference on family planning; although it was later repeated as truth, it has no known historical basis. Precursors to IUDs were first marketed in 1902. Developed from stem pessaries (where the stem held the pessary in place over the cervix), the 'stem' on these devices actually extended into the uterus itself. Also known as interuterine devices (because they occupied both the vagina and the uterus), they had high rates of infection and were condemned by the medical community. The first intrauterine device (contained entirely in the uterus) was described in a German publication in 1909, although the author appears to have never marketed his product. In 1929, Dr. Ernst Gräfenberg of Germany published a report on an IUD made of silk suture. He had found a 3% pregnancy rate among 1,100 women using his ring. In 1930, Dr. Gräfenberg reported a lower pregnancy rate of 1.6% among 600 women using an improved ring wrapped in silver wire. Unbeknownst to Dr. Gräfenberg, the silver wire was contaminated with 26% copper. Copper's role in increasing IUD efficacy would not be recognized until nearly 40 years later. In 1934, Japanese physician Tenrei Ota developed a variation of the Gräfenberg ring that contained a supportive structure in the center. The addition of this central disc lowered the IUD's expulsion rate. These devices still had high rates of infection, and their use and development was further stifled by World War II politics: contraception was forbidden in both Nazi Germany and Axis-allied Japan. The Western world did not learn of the work by Gräfenberg and Ota until well after the war ended.\[6\]

The first plastic IUD, the Margulies Coil or Margulies Spiral, was introduced in 1958. This device was somewhat large, causing discomfort to a large proportion of women users, and had a hard plastic tail, causing discomfort to their male partners. The Lippes Loop, a slightly smaller device with a monofilament tail, was introduced in 1962 and gained in popularity over the Margulies device.\[5\]
The stainless steel single-ring IUD was developed in the 1970s and widely used in China because of low manufacturing costs. The Chinese government banned production of steel IUDs in 1993 due to high failure rates (up to 10% per year). Dr. Howard Tatum, in the USA, conceived the plastic T-shaped IUD in 1968. Shortly thereafter Dr. Jaime Zipper, in Chile, introduced the idea of adding copper to the devices to improve their contraceptive effectiveness. It was found that copper-containing devices could be made in smaller sizes without compromising effectiveness, resulting in fewer side effects such as pain and bleeding. T-shaped devices had lower rates of expulsion due to their greater similarity to the shape of the uterus. The poorly designed Dalkon Shield plastic IUD (which had a multifilament tail) was manufactured by the A. H. Robins Company and sold by Robins in the United States for three and a half years from January 1971 through June 1974, before sales were suspended by Robins on June 28, 1974 at the request of the FDA because of safety concerns following reports of 110 septic spontaneous abortions in women with the Dalkon Shield in place, seven of whom had died. Robins stopped international sales of the Dalkon Shield in April 1975. Second-generation copper-T IUDs were also introduced in the 1970s. These devices had higher surface areas of copper, and for the first time consistently achieved effectiveness rates of greater than 99%. Worldwide today, with the exception of the new GyneFix, this is the only type of non-hormonal IUD available.

**ADVANTAGES**

- Highly effective in preventing pregnancy.
- Inexpensive.
- Does not interrupt sex.
- Does not require partner’s involvement.
- Can be used for a long period of time.
Can be used as an emergency method of birth control.

An IUD provides long-term contraception for 3 to 5 years and is cost-effective.

When you are ready to become pregnant, the IUD can be removed by a health-care provider.

It is convenient. You do not need to remember daily pills.

DISADVANTAGES

- Does not protect against sexually transmitted infections (STIs). If you get a sexually transmitted infection, the IUD could increase the likelihood of developing pelvic inflammatory disease (infection of the reproductive organs), which may lead to infertility.

- May increase the likelihood of ectopic pregnancy (pregnancy outside the uterus).

- Can cause heavier and more painful periods.

- Cramping and discomfort during and 24-48 hours after insertion

- There are risks during insertion and removal that your clinician should discuss with you before inserting an IUD.
LIMITATION

Between 2 to 10 per cent of IUDs fall out, most commonly in the first year of use. There is an increased risk of falling out if:
- an IUD was inserted right after delivery.
- an IUD has fallen out previously.
- you have never been pregnant.

• There is an increased risk of miscarriage if an IUD is left in the uterus during a pregnancy.

• The risk of pelvic inflammatory disease (PID) may be increased slightly during the first month after an IUD inserted. After the first month the risk of STI is related to the exposure to STI, not the use of an IUD.

• An IUD, in rare cases, may attach to or perforate the wall of the uterus. The IUD may need to be removed through minor surgery.

• With Nova T or Flexi T 300 (copper) IUD you may experience more bleeding and cramping with periods. Sometimes, light bleeding and spotting can happen between periods.

• With Mirena IUD (hormonal) you may at first experience changes in bleeding pattern, headaches, breast tenderness, acne, weight changes or mood changes. These hormone changes usually decrease over time.

RISK OF INTRAUTERINE DEVICE
Every woman is different and IUDs are not recommended for all women. Due to the risk of serious health problems, women with the following conditions should not use IUDs:

- Recent or repeated pelvic infection
- Known or suspected pregnancy
- Severe cervicitis
- Salpingitis
- Malignant lesions in the genital tract
- Unexplained vaginal bleeding
- HIV/AIDS
- History of ectopic pregnancy
- History of Toxic Shock Syndrome
- Physical inability to check IUD

IUDs are not recommended for women who are at risk for PID, have lower immune response, abnormal pap smear, heart disease, anemia, a history of severe menstrual cramping and heavy flow, a history of ectopic pregnancy, or previous problems with an IUD. Copper IUDs are not recommended for women with Wilson’s disease or allergies to copper.

- Women with a history of breast cancer cannot use the Mirena IUD.
- Women with diabetes should be monitored carefully if they use the Mirena IUD.
- Breastfeeding women should be aware the synthetic hormone in the Mirena IUD is excreted in breast milk.

**WORKING OF INTRAUTERINE DEVICE**

An intrauterine device (IUD) is a small T-shaped plastic device that is placed in the uterus to prevent pregnancy. A plastic string is attached to the end to ensure correct placement and for removal. IUDs are an easily reversible form of birth control, and they can be easily
removed. However, an IUD should only be removed by a medical professional. Currently in the United States, 2 types of IUDs are available: copper and hormonal. Approximately 2% of women who use birth control in the United States currently use IUDs. The most recently introduced hormonal IUD is the levonorgestrel intrauterine system (LNG IUS or Mirena). Worldwide, IUDs are the most inexpensive long-term birth control method available. Hormonal and copper IUDs work in different ways. With a copper IUD, a small amount of copper is released into the uterus. This type of IUD does not affect ovulation or the menstrual cycle. Copper IUDs prevent sperm from being able to go into the egg by immobilizing the sperm on the way to the fallopian tubes. If an egg does become fertilized, implantation on the wall of the uterus is prevented because copper changes the lining of the uterus. With hormonal IUDs, a small amount of progestin or a similar hormone is released into the uterus. These hormones thicken cervical mucus and make it difficult for sperm to enter the cervix. Hormonal IUDs also slow down the growth of the uterine lining, making it inhospitable for fertilized eggs.

**PLACEMENT OF INTRAUTERINE DEVICE**

Before an IUD is placed, a physical examination is important to make sure that the reproductive organs are normal and that no infections are present. The clinician will ask about medical and lifestyle history. Being open and honest is important when answering these questions. IUDs are not appropriate for every woman. Before the IUD is placed, a woman should discuss any questions she has with her clinician. The clinician will also provide a consent form with detailed information about the IUD. The woman should make sure to read this form carefully and understand it before signing.

An IUD can be placed during an office visit and remains in place until a medical professional removes it. It can be inserted at any phase of the menstrual cycle, but the best time is right after the menstrual period because this is when the cervix is softest and when women are least likely to be pregnant. Women may be instructed to take an over-the-counter pain reliever an hour before insertion to prevent cramps. Women may also be given an antibiotic to prevent possible infection associated with insertion; however, some studies disagree about the benefit of antibiotics. To place the IUD, a speculum is used to hold the
vagina open. An instrument is used to steady the cervix and uterus, and a tube is used to place the IUD. The arms of the T shape bend back in the tube and then open once the IUD is in the uterus. Once the IUD is in place, the instruments are withdrawn. The string hangs about an inch out of the cervix but does not hang out of the vagina. Cramps may be uncomfortable during insertion, and some women feel dizzy. Breathing deeply and trying to relax should prevent these problems. Women may want to have someone with them to drive them home after IUD insertion. Once the IUD is placed, women can return to normal activities such as sex, exercise, and swimming as soon as they are comfortable. Strenuous physical activity does not affect the position of the IUD. Women can also use tampons as soon as they wish after an IUD is placed. An intra-uterine device is a special device that fits inside of the uterus. There is more than one type of IUD. One type contains the hormone levonorgestrel. The hormone is continuously released into the uterus. Another type of IUD is covered by copper. The copper IUD has copper wire coiled around the stem and arms of the device. Both are about 1 1/4 inches tall. Each IUD has a string attached to the end, so the woman can check that the IUD is in place and so it is easier for your health care provider to remove it. The IUD is inserted into your uterus through your vagina and protects against pregnancy.

REMOVAL OF INTRAUTERINE DEVICE

Women should never try to remove an IUD themselves. Serious damage can result. A clinician can usually remove an IUD very simply by carefully pulling the string ends at a certain angle. This causes the IUD arms to fold up and the IUD to slide out through the cervix. If the IUD is being replaced, a new one can usually be inserted immediately. Rarely, the cervix may need to be dilated and a grasping instrument is used to free the IUD. If this occurs, a local anesthetic is used. Very rarely, surgery may be necessary. Women may require hospitalization if an incision is required to remove an IUD.

OBTAINING AN INTRAUTERINE DEVICE
Women who are interested in using IUDs for birth control should contact their private doctor, health maintenance organization (HMO), or local Planned Parenthood health center. Not all clinicians insert IUDs, so ask in advance. Planned Parenthood states that the cost of the examination, insertion, and follow-up visit is $250-450. At some clinics, price may be based on income. Medicaid covers these services. For one-time insertion of a copper IUD that lasts 10 years, the cost is approximately $400. This breaks down to cost less per year than most other forms of reversible birth control.

Copper IUDs
The copper IUD is the most commonly used type of IUD. It can be left in the body for up to 10 years. It can be removed at any time if a woman wishes to become pregnant or if she does not want to use it anymore. The arms of this IUD contain some copper, which is slowly released into the uterus. The copper prevents sperm from making their way through the uterus into the tubes and prevents fertilization. If fertilization does occur, the copper prevents the fertilized egg from implanting on the wall of the uterus.

Hormonal IUDs
Hormonal IUDs that contain progesterone must be replaced every 5 years. They can be removed at any time if a woman decides she wishes to become pregnant or if she does not want to use it anymore. Hormones are in the arms of the IUD and are released slowly into the uterus. The Mirena levonorgestrel-releasing intrauterine system (IUS) contains the hormone levonorgestrel (LNg), which is similar to progesterone. The LNg IUS causes cervical mucus to thicken to prevent sperm from entering the cervix and reaching the egg. Only about 1 in 1,000 women who use the LNg IUS experience accidental pregnancy in the first year. The LNg IUS reduces the risk of tubal pregnancies and pelvic inflammatory disease. It also dramatically decreases menstrual blood loss. It is approved to protect women from pregnancy for up to 5 years when used in the United States and 7 years in Europe and A

**SIDE EFFECTS OF THE INTRAUTERINE DEVICE**
There are some side effects of the IUD, but not many. You may have uterine cramps (like menstrual cramps) or low backache when the IUD is inserted, and maybe for a few weeks after insertion. With the levonorgestrel IUS you will likely have much lighter periods or none at all. With the copper IUD, you may have increased menstrual flow and cramps, but this usually lessens after the first few months, as your uterus gets used to the IUD. You can relieve any discomfort by over-the-counter medications, such as acetaminophen (Tylenol), ibuprofen (Advil, Motrin, and Nuprin), or naproxen sodium (Aleve). Some women have spotting or bleeding between menstrual periods with the IUD. There is a slightly increased risk of infection, called pelvic inflammatory disease (PID) during the first 6 weeks after the IUD is inserted. After that, the risk for PID is very low. Very rarely, the uterus can be injured when the IUD is inserted.

PROBLEMS WITH THE INTRAUTERINE DEVICE

If you have any problems with the IUD, call your health care provider. You definitely need to get in touch with your health care provider if you:

- can't feel the string attached to the IUD
- can feel the IUD at your cervix
- have pelvic pain or tenderness
- have severe cramping and/or abdominal (belly) pain
- have pain or menstrual bleeding when you have sexual intercourse
- have fever or chills for no reason
- start having sexual intercourse with more than one partner
- have a strange fluid or odor coming from your vagina.

You should not use an IUD if you:

- are pregnant
- are allergic to copper (for copper IUD only)
• have an abnormal uterus
• have an artificial heart valve
• have more than one sex partner
• are at risk for getting a sexually transmitted disease
• have a recent history of pelvic inflammatory disease or STDs have cervical, endometrial, or ovarian cancer that needs treatment

TYPES OF INTRAUTERINE SYSTEMS
The type now most widely used is:

Copper bearing IUDs (made of plastic wit copper sleeves and/or copper wire on the plastic). Tcu380A and MLCu-375 are this type.

Hormone-releasing IUDs (made of plastic; steadily release small amounts of hormone progesterone or another progestin such as levenorgesterel). LNG-20 and Progestasert are this type.

IUDs work chiefly by preventing sperm and egg from meeting. Perhaps the IUD makes it hard for sperm to move through the woman’s reproductive tract, and it reduces the ability of sperm to fertilize the egg. It could also prevent the egg from implanting itself in the wall of the uterus.

MECHANISMS OF CONTRACEPTION
The Mirena is intended to initially release a daily dose of 20 micrograms levonorgestrel (a progestin). No single mechanism accounts for the effectiveness of the IUS in preventing pregnancy; it has several effects on the reproductive system:
• Frequency of ovulation is reduced.
• Cervical mucus is changed to obstruct passage of sperm through the cervix.
The presence of a foreign body in the uterus prompts the release of leukocytes and prostaglandins by the endometrium, substances that are hostile to both sperm and eggs. Some physicians believe these substances are also hostile to very early embryos.

The endometrium is thinned. It has been suggested that this inhibits implantation of embryos, though no experiment has yet confirmed or disproved this theory. Because many pro-life individuals and organizations define fertilization as the beginning of pregnancy, this possible secondary mechanism of action has led some pro-life individuals and organizations to label the IUS an abortifacient.

**Effectiveness and mechanism of contraception**

All second-generation copper-T IUDs have failure rates of less than 1% per year, and cumulative 10-year failure rates of 2-6%. A copper IUD may also be used as emergency contraception. If an IUD is inserted within five days of unprotected intercourse, a woman's chance of pregnancy is reduced to that of ongoing IUD users. A large World Health Organization trial reported a cumulative 12-year failure rate of 2.2% for the T 380A (ParaGard) (an average failure rate of 0.18% per year over 12 years), equivalent to a cumulative 10-year failure rate of 1.8% following tubal ligation. The frameless GyneFix also has a failure rate of less than
1% per year. Worldwide, older IUD models with lower effectiveness rates are no longer produced. The presence of a device in the uterus prompts the release of leukocytes and prostaglandins by the endometrium. These substances are hostile to both sperm and eggs; the presence of copper increases this spermicidal effect. The current medical consensus is that spermicidal and ovicidal mechanisms are the only way in which IUDs work. Still, a few physicians have suggested they may have a secondary effect of interfering with the development of pre-implanted embryos; this secondary effect is considered more plausible when the IUD is used as emergency contraception. Controversially, the possibility of this secondary effect has led some to consider the IUD an abortifacient. Some barrier contraceptives protect against STDs. Hormonal contraceptives reduce the risk of developing pelvic inflammatory disease (PID), a serious complication of certain STDs. IUDs, by contrast, do not protect against STDs or PID.

**SIDE EFFECTS AND COMPLICATIONS USING INTRAUTERINE DEVICES**

**Location of device:**
Following insertion, the IUS may be expelled through the cervix. An expulsion rate of 4% was observed in the manufacturer's clinical trials, with most (3%) occurring in the first year of use. Expulsion is more common in younger women, women who have not had children, and when an IUS is inserted immediately after childbirth or abortion.

A rare but potentially serious complication is that of uterine perforation. This may occur either during the device's insertion, or from its later embedment into the myometrium (uterine wall) and subsequent migration through to the intra-abdominal cavity. Perforation can cause internal scarring, infection, or damage to other organs, and may require surgery. Uterine perforation has been reported at rates ranging from 1 to 2.6 per 1000 insertions. It is believed that perforations are significantly underreported, however, and actual perforation rates are likely higher.

Both expulsion and perforation result in loss of contraceptive cover and the position of the thread of the IUS should be self-checked at least once per
menstrual cycle to verify that it is still in place, or, in the absence of menstrual cycles, once per month.

The string(s) may be felt by some men during intercourse. If this is problematic, the provider may tuck the strings behind the cervix, cut the strings shorter, or in more extreme cases cut the strings to level with the cervix. Cutting the strings even with the cervix prevents the woman from checking the device's correct placement, and may complicate removal.

**Pelvic inflammatory disease and sexually transmitted diseases**

Pelvic inflammatory disease (PID) is caused by certain sexually transmitted diseases (STDs). PID is a serious condition that may result in infertility. In women who have STDs, an IUD will increase the risk of PID. Therefore, IUDs are not recommended for women at high risk of STDs.

Women who have more than one sexual partner, or whose partners have more than one sexual partner, are at increased risk for STDs. Younger women are statistically at higher risk for STDs. [citation needed]

An animal study suggested that progestin-only hormonal contraceptives such as Mirena might increase the risk of HIV transmission, because of the thinning of the vaginal walls caused by these methods. However, a number of studies of human populations showed that progestin contraceptive use does not increase the risk of acquiring HIV.

However, like the oral contraceptive pill and other non-barrier forms of contraception, the IUS offers no protection against sexually transmitted disease.

**Postpartum and post-abortion insertion**

An IUS may be inserted immediately postpartum (within 48 hours). With insertions after 48 hours, perforation of the uterus is more likely to occur when uterine involution is incomplete; involution usually completes by 4-6 weeks postpartum. Special considerations apply to women who plan to breastfeed.

Also to allow for uterine involution, insertion of an IUS is not recommended for women who have had a D&E abortion (second-trimester abortion) within the past four weeks.
To reduce the risk of infection, insertion of an IUS is not recommended for women who have had a medical abortion but have not yet had an ultrasound to confirm that the abortion was complete, or who have not yet had their first menstruation following the medical abortion.

Expulsion is more common when an IUS is inserted immediately after childbirth or abortion.

**Hormonal side effects**

**Localised**

Menstrual periods become lighter, or, in about 20% of women, stop completely within one year of insertion. Irregular bleeding is common in the first few months after insertion, with the average user reporting 16 days of bleeding or spotting in the first month of use, but this diminishes to about four days at 12 months.

**Systemic**

The progestin in an IUS is intended to be released at a lower dose than that used in other progestogen-only contraceptives such as the mini-pill or Norplant (blood levels of levonorgestrel in Mirena users are half those found in Norplant users and one-tenth those found in users of levonorgestrel-only pills). Enlarged follicles (ovarian cysts) have been diagnosed in about 12% of the subjects using a levonorgestrel IUS. Most of these follicles are asymptomatic, although some may be accompanied by pelvic pain or dyspareunia. In most cases the enlarged follicles disappear spontaneously during two to three months observation. Surgical intervention is not usually required.

**Nursing mothers**

There is an increased risk of perforation in women who are lactating. Progestogen-only contraceptives such as an IUS are not believed to affect milk supply or infant growth. However, a study in the Mirena application for FDA approval found a lower continuation of breastfeeding at 75 days in IUS users (44%) versus copper IUD users (79%).

Levonorgestrel is found in nursing infants at 7% of the concentration found in their mothers using the Mirena IUS. A six-year study of breastfed infants whose mothers used a levonorgestrel-only method of birth control found the infants had
increased risk of respiratory infections and eye infections, though a lower risk of neurological conditions, compared to infants whose mothers used a copper IUD. No longer-term studies have been performed to assess the long-term effects on infants of levonogestrel in breast milk.

There are conflicting recommendations about use of Mirena while breastfeeding. The U.S. FDA does not recommend any hormonal method, including Mirena, as a first choice contraceptives for nursing mothers. The World Health Organization recommends against immediate postpartum insertion, citing increased expulsion rates. It also reports concerns about potential effects on the infant's liver and brain development in the first six weeks postpartum. However, it recommends offering Mirena as a contraceptive option beginning at six weeks postpartum even to nursing women. Planned Parenthood offers Mirena as a contraceptive option for breastfeeding women beginning at four weeks postpartum.

**Effect on cancer rates**

The U.S. Food and Drug Administration has concluded that the carcinogenic potential of Mirena is low. According to a 1999 evaluation of the studies performed on progestin-only birth control by the International Agency for Research on Cancer, there is some evidence that progestin-only birth control reduces the risk of endometrial cancer. The IARC concluded that there is no evidence progestin-only birth control increases the risk of any cancer, though the available studies were too small to be definitively conclusive. The use of progestin alone in treatment of menopause has been associated with a doubling of risk for breast cancer versus nonuse.

Because breast cancer cells are often hormone-sensitive, Mirena and other hormonal birth control methods are not recommended for women who have, have had, or suspect they have breast cancer.

**Pregnancy**

Although the pregnancy rate during IUS use may be low, it is not a 100% effective method of birth control. If pregnancy does occur, presence of the IUD increases the risk of miscarriage, particularly during the second trimester. It also increases the risk of premature delivery. These increased risks end if the IUD is
removed after pregnancy is discovered. No pattern of birth defects has been suggested by the 35 babies for whom birth outcomes were available at the time of FDA approval.

As many as half of pregnancies that occur in Mirena users may be ectopic. The incidence rate of ectopics is approximately 1 per 1000 users per year.

**Bone Density**

No evidence has been identified to suggest Mirena affects bone mineral density (BMD). The only published study on the effect of Mirena on BMD showed that long-term users, at 7 years of use, had similar BMD at the midshaft of the ulna and at the distal radius as nonusers matched by age and BMI. In addition, BMD measurements were similar to the expected values for women in the same age group as the participants. The authors of the study said their results were predictable since it is well established that the main factor responsible for bone loss in women is hypoestrogenism and, in agreement with previous reports, they found estradiol levels in Mirena users to be normal.

**Future Fertility**

Women who want to become pregnant may have their IUD removed at any time. While most women who stop using IUDs are able to become pregnant, IUDs can have negative effects on a woman’s fertility. If perforation, embedding, or pelvic infection occurs, the uterus or tubes may become damaged and lower the chance of pregnancy. In cases of severe damage or infection of the uterus, a hysterectomy (removal of the uterus) may be required, resulting in permanent sterility. The synthetic hormone in the Mirena IUD can cause a delay in return of menstruation and fertility after it is removed.
CONCLUSION

The IUD is a good form of contraception if you are not at risk of getting a sexually transmitted disease. It is best for women who have already had children and are in a steady relationship with one partner. Many providers recommend the progestin IUD for women who suffer from extremely heavy, prolonged, or painful menstruation because it tends to lighten their periods or even suppress them altogether. And because they lose less blood, women using this IUD are less likely to develop iron-deficiency anemia, a condition that can cause fatigue and other symptoms. Some studies have found that women with copper IUDs tend to have a lower risk of endometrial cancer. And some experts suspect they'll find that the progestin IUD has the same effect, since that's the case for progestin-only contraceptives like the minipill and the shot. An IUD helps prevent egg and sperm from meeting. A woman does not get pregnant if sperm does not meet the egg. An IUD may stop a fertilized egg from growing inside the uterus. Nova T or Flexi T 300 IUD is about 98.7 per cent effective in preventing pregnancy. Irena IUD is 99 per cent effective in preventing pregnancy. Your risk for getting pregnant after the IUD has been inserted is very low. However, there is always a slight chance that you can get pregnant, since the IUD is not 100% effective. If you do get pregnant when the IUD is in place, you need to get the IUD removed. You should also see your health care provider to make sure that your pregnancy is not outside of the uterus (ectopic pregnancy). If your pregnancy is not ectopic, you can choose whether to continue the pregnancy. If you choose to continue it, your caregiver will remove the IUD if the strings are visible. She can remove the device easily without an invasive procedure. There's a slight risk that removing the IUD will cause you to lose the pregnancy, but you're much more likely to lose the baby to infection (and put your own health at risk) if you keep it in. In the unlikely event that the IUD can't be easily removed and you choose to continue
the pregnancy, you'll be carefully monitored. You're also at risk for preterm delivery if you get pregnant with an IUD, particularly if it's left in place.

References:

4) Planned Parenthood - Intrauterine Devices: national health care provider describes Paragard and Mirena as IUDs.

11) FDA Medical Review p.36

12) FDA Medical Review p.12
