IUB™ Ballerine®

MIDI

IUB™ Ballerine® MIDI Intrauterine Device

INFORMATION FOR PATIENTS

The IUB™ Ballerine MIDI Intrauterine Device is used to prevent pregnancy.
It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.
It is important for you to understand this brochure and discuss it with your healthcare provider before choosing the IUB™ Ballerine MIDI Intrauterine Device (IUB™). You should also learn about other birth control methods that may be an option for you.

What is the IUB™?

The IUB™ is a copper-releasing device that is placed in your uterus to prevent pregnancy for up to 5 years. The IUB™ is intended for use by women at least 15 years of age. Contraception begins immediately after insertion.

The IUB™ is made of a shape memory alloy (nickel and titanium) frame shaped as a 15 mm in diameter sphere. The frame is coated with polyethylene terephthalate (PET shrink tubing). Copper is placed on the frame.

Two threads made of Polypropylene are attached to the end of the frame. The threads are the only part of the IUB™ that you may feel when the IUB™ is in your uterus.

The IUB™ and its components do not contain latex.

How long can I keep the IUB™ in place?

You can keep the IUB™ in your uterus for up to 5 years. After 5 years, you should have the IUB™ removed by your healthcare provider. If you wish and if it is still right for you, you may get a new IUB™ during the same visit.

What if I change my mind and want to become pregnant?

Your healthcare provider can remove the IUB™ at any time. After discontinuation of the IUB™, its contraceptive effect is reversed.

How does the IUB™ work?

Widely accepted theories on how the IUB™ works include preventing sperm from reaching the egg, preventing sperm from fertilizing the egg, and preventing the egg from attaching (implanting) in the uterus. IUB™ does not stop your ovaries from making an egg (ovulating) each month.

Is it effective?

The Pearl index of copper IUDs with at least 300mm^2 copper surface area is 0.1 to 1.4 with current IUB™ data suggesting comparable performance. Overall expulsion and perforation risks for the IUB™ Ballerine product family as suggested by initial data is under 5% and under 1:2,000, respectively.

Who might use the IUB™?

You might choose the IUB™ if you would like
- Birth control that is very effective.
- Birth control that stops working when you stop using it.
- Birth control that is easy to use.
- To avoid using synthetic hormones for contraception.

Who should not use the IUB™?

You should not use the IUB™ if you
- Might be pregnant.
- Have an abnormally shaped uterus.
- Have a pelvic infection called pelvic inflammatory disease (PID) or have current behavior that puts you at high risk of PID (for example, because you or your partner are having sexual intercourse with multiple partners).
- Have had an infection in your uterus after a pregnancy or abortion in the past 3 months.
- Have cancer of the uterus or cervix.
- Have unexplained bleeding from your vagina.
- Have an infection in your cervix.
- Have Wilson's disease (a disorder in how the body handles copper).
- Are allergic to any of the IUB™'s materials. (copper, nickel, titanium, PET, polypropylene)
- Already have an intrauterine contraceptive in your uterus.

How is the IUB™ placed in the uterus?

The IUB™ is placed in your uterus during an office visit. Your appropriately trained health care professional first examines you to find the position of your uterus. Next, he or she will cleanse your vagina and cervix, measure your uterus, and then slide a plastic tube containing the IUB™ into your uterus. The tube is removed, leaving the IUB™ inside your uterus. Two blue threads extend into your vagina. The threads are trimmed to minimize discomfort. As the IUB™ is inserted, you may feel cramping or pinching. Some women feel faint, nauseated, or dizzy for a few minutes afterwards. Use of an analgesic before insertion is at the discretion of the patient and the clinician.

Your healthcare provider may ask you to lie down for a while before leaving.

How is the IUB™ removed?

The IUB™ should only be removed by a healthcare professional and is conducted by pulling the removal threads.

The device is for single use only. Reusing a device might cause infections and risk of misplacement (including perforation) and should be avoided.

How do I check that the IUB™ is in my uterus?

Visit your healthcare provider for a check-up about one month after placement to make sure the IUB™ is still in your uterus.

If the IUB™ is in the wrong place, your chances of getting pregnant are increased. If you can't see your healthcare provider right away, use an additional birth control method.
You may use tampons when you are using the IUB™.

What if I become pregnant while using the IUB™?

If you think you are pregnant, contact your healthcare professional right away. If you are pregnant and the IUB™ is in your uterus, you may get a severe infection or shock, have a miscarriage or premature labor and delivery, or even die. Because of these risks, your healthcare provider will recommend that you have the IUB™ removed, even though removal may cause miscarriage.

If you continue a pregnancy with the IUB™ in place, see your healthcare provider regularly. Contact your healthcare provider right away if you get fever, chills, cramping, pain, bleeding, flu-like symptoms, or an unusual, bad smelling vaginal discharge.

A pregnancy with the IUB™ in place has a greater than usual chance of being ectopic (outside your uterus). Ectopic pregnancy is an emergency that may require surgery. An ectopic pregnancy can cause internal bleeding, infertility, and death. Unusual vaginal bleeding or abdominal pain may be signs of an ectopic pregnancy.
Copper in the IUB™ does not seem to cause birth defects.

What side effects can I expect with the IUB™?

- The most common side effects of the IUB™ are heavier, longer periods and spotting between periods; most of these side effects diminish after 2-3 months. However, if your menstrual flow continues to be heavy or long, or spotting continues, contact your healthcare provider.

Infrequently, serious side effects may occur:
- Pelvic inflammatory disease (PID): Uncommonly, IUDs as well as the IUB™ are associated with PID. PID is an infection of the uterus, tubes, and nearby organs. PID is most likely to occur in the first 20 days after placement. You have a higher chance of getting PID if you or your partner has sexual intercourse with multiple partners. PID is treated with antibiotics. However, PID can cause serious problems such as infertility, ectopic pregnancy, and chronic pelvic pain. Rarely, PID may even cause death. More serious cases of PID require surgery.or a hysterectomy (removal of the uterus). Contact your healthcare provider right away if you have any of the signs of PID: abdominal or pelvic pain, painful sex, unusual or bad smelling vaginal discharge, chills, heavy bleeding, or fever.
- Difficult removals: Occasionally the IUB™ may be hard to remove because it is lodged in the uterus. Hysteroscopy may sometimes be needed to remove the IUB™.
- Perforation: Rarely, the IUB™ goes through the wall of the uterus, especially during placement. This is called perforation. There is an increased risk of IUD perforation if you are breastfeeding or have given birth within 36 weeks before insertion. If the IUB™ perforates the uterus, it should be removed. Surgery may be needed. Perforation can cause infection, scarring, or damage to other organs. If the IUB™ perforates the uterus, you are not protected from pregnancy.
- Expulsion: the IUB™ may partially or completely fall out of the uterus. This is called expulsion. Women who have never been pregnant may be more likely to expel the IUB™ than women who have been pregnant before. If you think that the IUB™ has partly or completely fallen out, use an additional birth control method, such as a condom and call your healthcare provider. Do not reinsert a used IUB™.

You may have other side effects with the IUB™. For example, you may have anemia (low blood count), backache, pain during sexual intercourse, menstrual cramps, allergic reaction, vaginal infection, vaginal discharge, faintness, or pain. Sexual partner discomfort stemming from removal threads.

Magnetic resonance imaging (MRI) personnel must be made aware of the presence of the IUB™ prior to imaging.

This is not a complete list of possible side effects. If you have questions about a side effect, check with your healthcare provider

When should I call my healthcare provider?

Call your healthcare provider if you have any concerns about the IUB™.
Be sure to call if you
- Think you are pregnant.
- Have pelvic pain or pain during sexual intercourse.
- Have unusual vaginal discharge or genital sores.
- Have unexplained fever.
- Might be exposed to sexually transmitted diseases (STDs).
- Can feel any other part of the IUB™ besides the threads.
- Become HIV positive or your partner becomes HIV positive.
- Have severe or prolonged vaginal bleeding.
- Miss a menstrual period.

This brochure summarizes the most important information about the IUB™. If you would like more information, talk with your healthcare provider.

You can ask your healthcare provider for information about the IUB™ that is written for healthcare professionals.

REF	Catalogue number
LOT	Batch code
	Date of manufacture
	Use-by date
	Manufacturer
EC REP	Authorized representative in the European Community
STERILE EO	Sterilized using ethylene oxide
CE 0459	European Conformity mark Notified Body: LNE-G-MED (0459)
	Do not re-sterilize
	Do not re-use
	Do not use if package is damaged
	Temperature limit
	Keep dry
	Consult instructions for use
	Caution
MR	MR Conditional
	Recycle package after use

MRI Safety Information

Magnetic resonance imaging (MRI) personnel must be made aware of the presence of the IUB™ prior to imaging.
Non-clinical testing demonstrated that the IUB™ is MR Conditional.
A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:
- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system
- Under the scan conditions defined, the IUB™ is expected to produce a maximum temperature rise of 1.4 ˚C after 15-minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the IUB™ extends approximately 2 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

CE 0459

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