PRESCRIBING INFORMATION

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases. The IUB™ Ballerine® MIDI Intrauterine Device should be placed and removed only by appropriately trained health care professionals.

Device Description

The IUB™ Ballerine® MIDI Intrauterine Device ("IUB™") is a sphere-shaped copper intrauterine device (IUD) measuring about 15mm in diameter. A monofilament blue polypropylene thread double tailed thread is attached to one end of the PET coated frame, each at 10.5 cm in length, to aid in detection and removal of the device. The frame is made of nitinol, an alloy of nickel and titanium.

The IUB™ also contains copper: the total exposed copper surface area is 300mm². One IUB™ weighs less than 1 (1) gram. No component of IUB™ or its packaging contains latex.

The IUB™ is supplied sterile, pre-loaded in a scaled PVC insertion tube. Also supplied are a solid purple polycarbonate push rod and a sliding flange, the latter is fitted on the insertion tube and aids in gauging the depth of insertion through the cervical canal and into the uterine cavity.

IUB™ – Clinical Pharmacology

The contraceptive effectiveness of the IUB™ is based on the accepted mechanism of actions of intrauterine devices: placement of a foreign body in the uterine cavity produces a local reaction. Mechanism(s) by which the IUB™ provides contraceptive efficacy include interference with sperm motility and fertilization of an egg, and possibly prevention of implantation.

Indications and Usage for IUB™

The IUB™ is indicated for intrauterine contraception for up to 5 years. Contraception begins immediately after insertion. The Pearl index of copper IUDs with at least 300mm² copper surface in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

Perforation: Partial or complete perforation of the uterine wall or cervix may rarely occur during placement. If the IUB™ is not seen inside the uterus after insertion by US, perforation should be excluded. If perforation occurs during insertion, the IUB™ should be removed immediately using the removal tool. If perforation is diagnosed, surgery may be required.

Breast feeding women or those with cervical stenosis may have an increased risk of intrauterine device perforation during insertion. Stenosis:

1. Mal-positioning: Due to the spherical shape of the IUB™, mal-positioning may occur immediately after insertion. In case the IUB™ is in the cervical canal (partial expulsion), removal of the IUB™ immediately insertion of a new IUB™ is possible if patient desires and is not pregnant.

2. Vaginal bleeding: Spotting, light bleeding, heavier and longer periods may occur in the first 3 to 6 months following insertion. These bleeding patterns are not harmful and usually decrease with time. If these events continue or are severe, they should be reported to the physician.

3. Vasovagal reactions, including fainting during or right after insertion. Some women have vasovagal reactions immediately after insertion. Hence, patients should remain supine until feeling well and should be cautious when standing up.

4. Expulsion or partial expulsion: Follow routine placement and especially after birth or abortion. Ectopic pregnancy should be excluded before inserting a new IUB™. A new IUB™ can be immediately inserted if expelled or partially expelled. In case of expulsion, the IUB™ should be removed and replaced with a new IUB™. If expulsion occurs during menstruation, a new IUB™ should be placed in the uterine cavity. The IUB™ should be removed on or before 5 years from the date of insertion.

5. Perforation:

6. Known or suspected uterine or cervical malignancy.

7. Genital bleeding of unknown etiology.

8. Mucopurulent cervicitis - untreated acute cervicitis or vaginitis, including bacterial vaginosis or other lower genital tract infections until infection is controlled.


10. Allergy to any component of the IUB™

11. The device IUB™ Ballerine® is not intended as an emergency contraception.

12. Conditions associated with increased susceptibility to pelvic infection.

13. As generally applied to copper IUDs discretion is advised when considering the use of the IUB™ in women with known anemia, dysmenorrhea, severe menorrhagia or who use anticoagulants.

Warnings and Precautions

The following adverse events are associated with the use of copper intrauterine devices:

1. Intrauterine pregnancy. If intrauterine pregnancy occurs, the IUB™ should not be removed immediately due to increased risk of spontaneous abortion, premature delivery, sepsis, septic shock, and rarely, death. Removal may be followed by pregnancy loss. If the woman decides not to remove the IUB™, she should be warned of an increased risk of spontaneous abortion and sepsis, septic shock, and rarely, death. In addition, the risk of premature labor and delivery is increased.

2. Ectopic pregnancy. In a case of positive pregnancy test with an IUB™ a CT or MRI scan should be evaluated. In the case of a confirmed ectopic pregnancy the woman should be treated by standard protocol for ectopic pregnancy – either a medical or surgical approach. The removal of the IUB™ is at the discretion of the health care provider.

3. Pelvic inflammatory disease (PID). In case of diagnosis of mild PID with an IUB™ in the uterus, proper antibiotic therapy should be initiated promptly. Removal of the IUB™ is indicated if the pelvic infection is severe or does not respond to treatment. PID can cause serious problems such as infertility, ectopic pregnancy, and chronic pelvic pain. More serious cases of PID require surgery or a hysterectomy and death.

4. Embodiment: Partial perforation or embodiment of IUB™ in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

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6. Breast feeding women or those with cervical stenosis may have an increased risk of intrauterine device perforation during insertion.

7. Applicator of a tenaculum to the cervix is optional for gentle traction of the cervical canal to align it with the uterine cavity.

8. Insert a sterile glove. Measure the depth of the uterine cavity in centimeters, check the patency of the cervix, confirm cavity direction and detect the presence of any uterine anomaly.

9. The IUB™ should be inserted a depth of 6 to 9 cm except when inserting the IUB™ immediately post-abortion or post-partum. Insertion of the IUB™ into a uterine cavity measuring less than 6 cm may cause the incidence of expulsion, bleeding, pain, and perforation.

Side Effects

Adverse events associated with intrauterine contraception are discussed in WARNINGS and PRECAUTIONS.

INSTRUCTIONS FOR USE

The placement technique for the IUB™ is similar to that used for other IUDs. The health care professional should be familiar with the following instructions.

The IUB™ may be placed at any time during the cycle when the appropriately trained health care professional is reasonably certain the patient is not pregnant. However, it is preferable to place the IUB™ during menstruation. A single IUB™ should be placed in the uterine cavity. The IUB™ should be removed on or before 5 years from the date of insertion.

Before Placement:

1. Make sure that the patient is an appropriate candidate for IUB™ and that she is not pregnant.

2. Exclude pregnancy and confirm that there are no other contraindications to the use of the IUB™.

3. Following the insertion instructions as described in order to ensure proper placement of the IUB™.

4. Insertion may be associated with some pain and/or bleeding or vasovagal reactions. Use of an analgesic before insertion is at the discretion of the patient and the clinician.

5. The IUB™ should be inserted in the cervical canal using a tenaculum. Gently insert a sterile glove. Measure the depth of the uterine cavity in centimeters, check the patency of the cervix, confirm cavity direction and detect the presence of any uterine anomaly.

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7. If the woman decides not to remove the IUB™, she should be warned of an increased risk of spontaneous abortion and sepsis, septic shock, and rarely, death. In addition, the risk of premature labor and delivery is increased.

8. Perforation: Partial or complete perforation of the uterine wall or cervix may rarely occur during placement. If the IUB™ is not seen inside the uterus after insertion by US, perforation should be excluded. If perforation occurs during insertion, the IUB™ should be removed immediately using the removal tool. If perforation is diagnosed, surgery may be required.

9. The IUB™ should not be placed in the uterus, remove it and replace it with a new IUB™. Do not reinsert an expelled or partially expelled IUB™. IUB™ insertion is now complete.

How to Place the IUB™:

Open the sterile package. Use the flange to mark on the insertion tube the uterine depth that you measured with the US examination. Pass the loaded insertion tube through the cervical canal until the gauge is in touch with the cervical external os. CAUTION: applying excess force may cause injury, perforation or binding of the insertion tube. Pull the insertion tube back approximately 2.3 mm.

Insert the pull rod into the insertion tube and push forwards in moderation to deploy the IUB™ into the uterine cavity. Ensure the IUB™ is properly positioned avoid insertion tube withdrawal before or during deployment. The pull rod must be pushed fully into the insertion tube for the IUB™ to properly deploy.

Cut the threads perpendicular about 3 mm over the cervix by using a sharp, curved scissors; cutting threads at a flat angle may create sharp tips. Do not apply tension or pull on the threads when trimming to avoid IUB™ displacement.

Perform an US examination to make sure the IUB™ is in the center of the uterine cavity. Ultrasound imaging shall be performed in at least two different planes. If the IUB™ is not positioned completely within the uterus, remove it and replace it with a new IUB™.
The IUB™ is available in cartons of 1 (one) sterile unit. Each IUB™ is packaged in a sterile pouch together with an insertion tube, a slider and a push rod.

The IUB™ is supplied sterile. Method of sterilization is ethylene oxide.

How is the IUB™ Supplied

How to Remove the IUB™

The IUB™ should not remain in the uterus for more than 5 years.

• Prepare sterile gloves and sterile forceps. Remove the IUB™ with forceps, pulling gently on the exposed threads.
• If the threads are not visible, determine location of the IUB™ by ultrasound.
• Inspect to assure the integrity of the IUB™, specifically to the presence of the leading and trailing copper balls (see image below).

In case of absence of visible threads or breakage of the IUB™ removal can be difficult. Analgesia and cervical dilation may assist in removing the IUB™. An alligator forceps or other grasping instrument may be helpful. Hysteroscopy may also be helpful.

You may immediately insert a new IUB™ if the patient requests so and has no contraindications.

Patient Follow-up

• Following placement, examine the patient after her first menses to confirm that the IUB™ is still in place.
• If she feels any of the following symptoms she should contact her healthcare provider: abdominal or pelvic pain, cramping or tenderness; unusual or malodorous discharge; unexplained vaginal bleeding; unexplained fever, chills; painful sex; a missed period; feeling that the length of the threads changed or feeling any other part of the IUB™ besides the threads; an allergic reaction.
• Patients should contact her healthcare provider if: Patient thinks she is pregnant; becomes HIV positive or her partner becomes HIV positive; might be exposed to sexually transmitted diseases (STDs).
• If partial expulsion or expulsion occurred, the patient is not protected from pregnancy.

Instructions to be given to the patient by the doctor

• Invite the patient for a visit after her first menses to confirm that the IUB™ is still in place.
• If she feels any of the following symptoms she should contact her healthcare provider: abdominal or pelvic pain, cramping or tenderness; unusual or malodorous discharge; unexplained vaginal bleeding; unexplained fever, chills; painful sex; a missed period; feeling that the length of the threads changed or feeling any other part of the IUB™ besides the threads; an allergic reaction.
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