IUB™ Ballerine®

MIDI

IUB™ Ballerine® MIDI Intrauterine Device
FOR INSERTION BY APPROPRIATELY TRAINED HEALTHCARE PROFESSIONALS ONLY

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 double tailed thread is attached to one end of the PET coated frame, each at least 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 one (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 copper promotes 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 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 are under 5% and under 1:2,000, respectively.

Contraindications

The IUB™ should not be used in patients younger than 15 years or in patients with the following known or suspected diseases:

1. Pregnancy or suspicion of pregnancy.
2. Abnormalities of the uterus resulting in distortion of the uterine cavity.
3. Acute pelvic inflammatory disease or current behavior suggesting a high risk for pelvic inflammatory disease.
4. Postpartum endometritis or post-abortal endometritis in the past 3 months.
5. Known or suspected uterine or cervical malignancy.
6. Genital bleeding of unknown etiology.
7. Mucopurulent cervicitis - untreated acute cervicitis or vaginitis, including bacterial vaginosis or other lower genital tract infections until infection is controlled.
8. Wilson's disease.
9. Allergy to any component of the IUB™.
10. A previously placed IUD that has not been removed.
11. Conditions associated with increased susceptibility to pelvic infection.
12. 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 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 case of a positive pregnancy test with an IUB™ in the uterus, ectopic pregnancy should be excluded. In a case of verified 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.
4. **Embedment-** Partial penetration or embedment of IUB™ in the myometrium can make removal difficult. In some cases, surgical removal may be necessary
5. **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. When perforation occurs during insertion the IUB™ should be removed immediately using the removal thread. If perforation is diagnosed after insertion, surgery may be required. Breast feeding women or those within 36 weeks post-partum have an increased risk of intrauterine device perforation during insertion.
6. **Mal-positioning.** Due to the spherical shape of the IUB™, mal-positioning of the device in the uterus should not occur. In case the IUB™ is in the cervical canal (partial expulsion), remove the IUB™. Immediate insertion of a new IUB™ is possible if patient desires and is not pregnant.
7. **Wilson's disease.**
8. **Vaginal bleeding.** Spotting, light bleeding, heavier and longer periods may occur in the first 3 to 6 months following insertion. These bleeding pattern are not harmful and usually decrease with time. If these events continue or are severe, they should be reported to the physician.
9. **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.
10. **Expulsion or partial expulsio**n following routine placement and especially after birth or abortion. In case of partial expulsion, remove the IUB™. A new IUB™ can be immediately inserted if patient desires and if not pregnant.
11. **Medical diathermy.**
12. **Septic abortion.**
13. **Pain and cramps**
14. **Sexual partner discomfort** stemming from untrimmed removal threads. Examine the patient to confirm that the IUB™ is still in place. If the IUB™ has been partially or completely expelled, remove it. If the IUB™ is in place, trim the threads by using a sharp scissor.
15. Magnetic resonance imaging (MRI) personnel must be made aware of the presence of the IUB™ prior to imaging.

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 insert 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 has read the Patient information leaflet.
2. Exclude pregnancy and confirm that there are no other contraindications to the use of the IUB™.
3. Follow the insertion instructions exactly 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. Establish the size and position of the uterus by pelvic examination.
6. Insert a speculum and cleanse the vagina and cervix with an antiseptic solution.
7. Application of a tenaculum to the cervix is optional for gentle traction of the cervical canal to align it with the uterine cavity
8. Gently insert a sterile sound. 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 uterus should sound to 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 increase the incidence of expulsion, bleeding, pain, and perforation.
10. If you encounter cervical stenosis, avoid undue force. Dilators may be helpful in this situation.

Proceed with insertion only after completing the above steps and ascertaining that the patient is appropriate for the IUB™. Ensure use of aseptic technique throughout the entire procedure.

How to Place the IUB™:

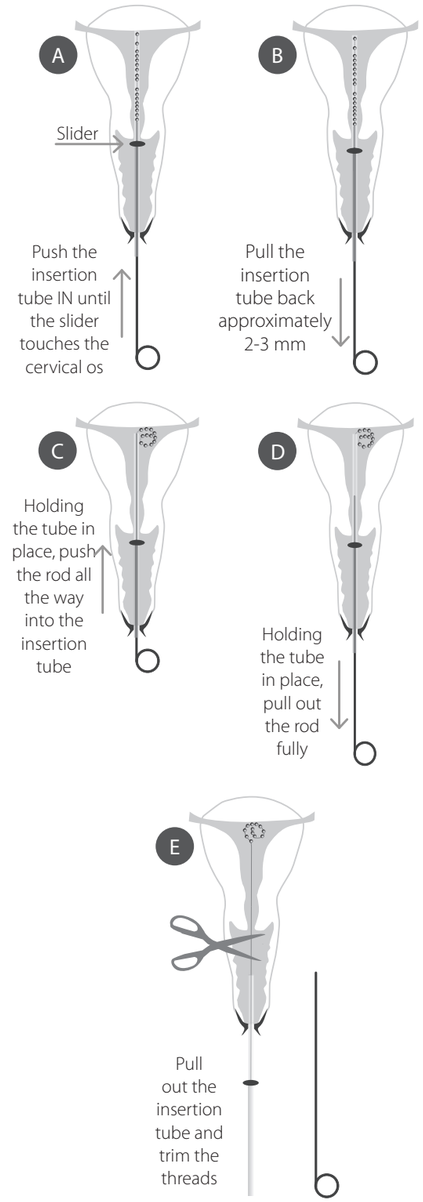
STEPS A,B — Open the sterile package; Use the flange to mark on the insertion tube the uterine depth that you measured with the sound; Insert the push rod into the insertion tube gently – stop before the first bead to make sure not to deploy the IUB™ yet; Pass the loaded insertion tube through the cervical canal until the gauge is in touch with the cervical external os. CAUTION: applying excess force may cause injury, perforation or bending of the insertion tube. Pull the insertion tube back approximately 2-3 mm.

STEP C — Push the rod in the insertion tube forwards in moderation to deploy the IUB™ into the uterine cavity. To ensure the IUB™ is properly positioned avoid insertion tube withdrawal before or during deployment. The push rod must be pushed fully into the insertion tube for the IUB™ to properly deploy.

STEP D — Pull out the rod fully and then pull out the insertion tube.

STEP E — Cut the threads perpendicular about 2cm out of the cervix by using a sharp, curved scissor, 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.

STEP F — If you suspect that IUB™ is not in the correct position, in the center of the uterine cavity, check placement with ultrasound, if necessary. Ultrasound imaging is recommended to be performed in at least two different plains. If the IUB™ is not positioned completely within 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.



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CAUTION

- Instrumentation of the cervical os may result in vasovagal reactions, including fainting. Have the patient remain supine until she feels well, and have her get up with caution.
- If there is clinical concern, exceptional pain or bleeding during or after insertion, appropriate steps (such as physical examination and ultrasound) should be taken immediately to exclude perforation.
- The device is for single use only. Reusing a device might cause infections and risk of misplacement (including perforation) and should be avoided.

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.
- Patient 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.

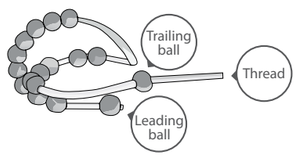
Patient Follow-up

- Following placement, examine the patient after her first menses to confirm that the IUB™ is still in place. You should be able to see or feel only the threads. If the IUB™ has been partially or completely expelled, remove it. You can place a new IUB™ if the patient desires and if she is not pregnant. Do not reinsert a used IUB™.
- Evaluate the patient promptly if she complains of any of the following: abdominal or pelvic pain, cramping, or tenderness; malodorous discharge, bleeding, fever or a missed period.
- The length of the visible threads may change with time. However, no action is needed unless you suspect partial expulsion, perforation, or pregnancy.
- If you cannot find the threads in the vagina, check that the IUB™ is still in the uterus. The threads can retract into the uterus or break, or the IUB™ may have perforated the uterus or expelled. Radiography or sonography may be required to locate the IUB™. If there is evidence of partial expulsion, perforation or breakage, remove the IUB™.

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.

How is the IUB™ Supplied

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.

Shipping and Storage Conditions

Store the IUB™ packaging in a dry environment at 15°C to 30°C. In these conditions the IUB™'s shelf life is 3 years.
Short term transportation of the IUB™ packaging should be limited to a temperature between -18°C and 55°C.

- SINGLE USE, DO NOT RESTERILIZE.
- NEVER RE-INSERT A USED IUB™.
- NEVER USE AN IUB™ IF THE PACKAGE IS DAMAGED OR OPEN.
- DO NOT USE PAST THE EXPIRY DATE.
- DISPOSE OF USED IUB™ AND ITS COMPONENTS USING BIO-HAZARD DISPOSAL PRACTICES.

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
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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