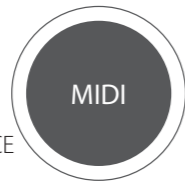






## The Intrauterine Ball

BALLERINE, IUB™ SCu300B MIDI INTRAUTERINE DEVICE



### INFORMATION FOR PATIENTS

The BALLERINE, IUB™ SCu300B 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 BALLERINE, IUB™ SCu300B MIDI Intrauterine Device (BALLERINE). You should also learn about other birth control methods that may be an option for you.

#### What is the BALLERINE?

The BALLERINE is a copper-releasing device that is placed in your uterus to prevent pregnancy for up to 5 years. The BALLERINE is intended for use by women at least 15 years of age.

The BALLERINE is made of a shape memory alloy (Nitinol) frame shaped as a 15 mm in diameter sphere. Copper is placed on the frame. Two threads are attached to the end of the frame. The threads are the only part of the BALLERINE that you may feel when the BALLERINE is in your uterus.

The BALLERINE and its components do not contain latex.

#### How long can I keep the BALLERINE in place?

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

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

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

#### How does the BALLERINE work?

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

#### Who might use the BALLERINE?

You might choose the BALLERINE 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 BALLERINE?

You should not use BALLERINE 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.
- Already have an intrauterine contraceptive in your uterus.

#### How is the BALLERINE placed in the uterus?

The BALLERINE 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 BALLERINE into your uterus. The tube is removed, leaving the BALLERINE inside your uterus. Two blue threads extend into your vagina. The threads are trimmed to minimize discomfort. As the BALLERINE 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.

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

#### How do I check that the BALLERINE is in my uterus?

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

#### What if I become pregnant while using the BALLERINE?

If you think you are pregnant, contact your healthcare professional right away. If you are pregnant and the BALLERINE 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 BALLERINE removed, even though removal may cause miscarriage.

If you continue a pregnancy with the BALLERINE 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 BALLERINE 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 BALLERINE does not seem to cause birth defects.

#### What side effects can I expect with the BALLERINE?

The most common side effects of the BALLERINE 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 BALLERINE 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 have 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 BALLERINE may be hard to remove because it is lodged in the uterus. Hysteroscopy may sometimes be needed to remove the BALLERINE.
- Perforation: Rarely, the BALLERINE goes through the wall of the uterus, especially during placement. This is called perforation. If the BALLERINE perforates the uterus, it should be removed. Surgery may be needed. Perforation can cause infection, scarring, or damage to other organs. If the BALLERINE perforates the uterus, you are not protected from pregnancy.
- Expulsion: the BALLERINE 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 BALLERINE than women who have been pregnant before. If you think that the BALLERINE 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 BALLERINE.

You may have other side effects with the BALLERINE. 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 BALLERINE 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 BALLERINE. 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 BALLERINE 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 BALLERINE. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about the BALLERINE that is written for healthcare professionals.

- Single use only.
- Ethylene oxide sterilized.
- Do not re sterilize.
- Do not use if package is damaged or open.
- Single unit per package.
- Consult instructions for use.
- Caution. There are specific precautions related to the device, refer to IFU.
- Recycle package after use.

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حالة طارئة قد تتطلب الجراحة. الحمل خارج الرحم يمكن أن يسبب نزيفاً داخلياً، أو العقم، أو الموت. نزيف مهبلي غير عادي أو ألم في البطن قد تكون من علامات الحمل خارج الرحم. لم يظهر أن النحاس في IUB™ يمكن أن يسبب تشوهات خلقية.

ما هي الآثار الجانبية التي يمكن أن أتوقعها عند استخدام IUB™؟

الآثار الجانبية الأكثر شيوعاً من IUB™ هي فترة حيض أثقل وأطول ونزف ما بين الدورات؛ معظم هذه الآثار الجانبية تزول بعد 2-3 أشهر. ومع ذلك، إذا استمر تدفق الطمث بكمية كبيرة أو لفترة أطول، أو استمر النزف بين الدورات، توجهي لمقدم الرعاية الصحية الخاص بك. نادراً، قد تحدث بعض الآثار الجانبية الخطيرة:

- مرض التهاب الحوض (PID): أحياناً يرتبط استخدام اللولب وكذلك IUB™ مع مرض التهاب الحوض (PID)، وهو عدوى تصيب الرحم والقنوات والأعضاء القريبة منها. هو أكثر احتمالاً للحدوث في 20 يوماً الأول بعد وضع IUB™. هناك فرصة أكبر للإصابة بـ PID إذا كنت أنت أو شريكك تمارسان الجنس مع أكثر من شخص واحد. يتم معالجة PID باستخدام المضادات الحيوية. ومع ذلك، يمكن أن يسبب هذا المرض مشاكل خطيرة مثل العقم والحمل خارج الرحم، وآلام الحوض المزمنة. وفي أحيان نادرة قد يسبب الوفاة. الحالات الأكثر خطورة من PID تتطلب جراحة أو استئصال الرحم (إزالة الرحم) (توجهي لمزود الرعاية الصحية على الفور إذا ظهرت لديك أي من أعراض PID: ألم في البطن أو الحوض أو الألم أثناء ممارسة الجنس، إفرازات مهبلية غير عادية أو كريهة الرائحة، قشعريرة، نزيف حاد، أو حمى.
- صعوبة الإزالة: أحياناً قد يكون من الصعب إزالة IUB™ بعد أن يعلق في الرحم. في بعض الأحيان قد تكون هناك حاجة لاستخدام المنظار الرحمي لإزالة IUB™.
- الثقب: في حالات نادرة، يخترق IUB™ جدار الرحم، وخصوصاً أثناء تثبيته. وهذا ما يسمى الثقب إذا ثقب IUB™ الرحم، ينبغي إزالتها. قد تكون هناك حاجة لعملية جراحية. الثقب يمكن أن يسبب العدوى، الندب، أو الإضرار بأعضاء حيوية أخرى. إذا ثقب IUB™ الرحم، فأنت غير محمية من حدوث الحمل. الطرد: قد يخرج IUB™ جزئياً أو كلياً خارج الرحم. وهذا ما يسمى الطرد. النساء اللواتي لم تحملن من قبل هن أكثر عرضة لطرده IUB™ من النساء اللواتي حملن من قبل. إذا كنت تعتقدين أن IUB™ قد خرج من مكانه جزئياً أو كلياً، استخدمي وسيلة إضافية لمنع الحمل، مثل الواقي الذكري، وتوجهي إلى مقدم الرعاية الصحية الخاص بك. لا تقم بإعادة إدخال IUB™ المستعمل.

قد تكون هناك آثار جانبية أخرى لاستخدام IUB™. على سبيل المثال، قد تصابن بفقر الدم (انخفاض عدد كريات الدم)، وآلام الظهر، وألم أثناء ممارسة الجنس، وتشنجات الحيض، والحساسية، والعدوى المهبلية، الإفرازات المهبلية، الارهاق، أو الألم. قد يشعر الزوج ببعض الضيق بسبب فتائل الإزالة خلال العلاقة الجنسية. يجب إعلام فنيو تصوير الرنين المغناطيسي (MRI) بوجود جهاز IUB™ قبل اجراء التصوير. هذه ليست القائمة الكاملة للآثار الجانبية المحتملة. إذا كان لديك أية أسئلة حول الآثار الجانبية للجهاز، توجهي إلى مقدم الرعاية الصحية الخاص بك.

متى علي التوجه لمقدم الرعاية الصحية؟

توجهي إلى مقدم الرعاية الصحية الخاص بك إذا كانت لديك أية مخاوف حول استخدام IUB™. وتأكد من التوجه إليه في حال:

- اعتقدت أنك حامل
- أحسست بألم في الحوض أو ألم أثناء ممارسة الجنس
- لديك إفرازات مهبلية غير عادية أو قروح تناسلية
- أصبت بحمى دون سبب واضح
- احتمال أنك تعرضت للعدوى بأحد الأمراض المنقولة جنسياً (STD)
- يمكنك الشعور بجزء آخر من IUB™ إلى جانب الفتائل
- أصبت بفيروس نقص المناعة البشرية أو أصيب شريكك بفيروس نقص المناعة البشرية - الإيدز
- لديك نزف مهبلي شديد أو لفترات طويلة
- فاتتكم فترة الحيض

تلخص هذه النشرة أهم المعلومات حول IUB™. إذا كنت ترغبين في مزيد من المعلومات، يرجى استشارة مزود الرعاية الصحية الخاص بك. يمكنك أن تسألني مزود الرعاية الصحية عن معلومات أخرى حول IUB™ مسجلة لدى المتخصصين في الرعاية الصحية.

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