



Jaydess[®]

Frequently Asked Questions

 jaydess[®]
INTRAUTERINE LEVONORGESTREL DELIVERY SYSTEM

Introducing
Jaydess[®]



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What is Jaydess?

Jaydess is a hormone-releasing IUS (intrauterine system) that is 99.1% effective in preventing pregnancy for up to 3 years.¹

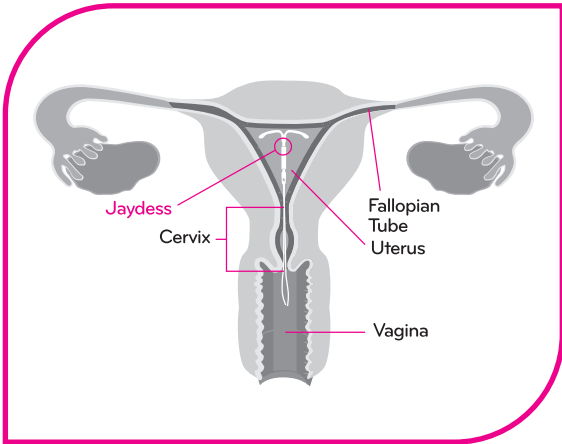
- Jaydess is a T shaped frame that contains a hormone called levonorgestrel¹
- The frame is made of soft, flexible plastic^{1,2}
- Jaydess is placed in your uterus by your doctor¹
- Jaydess is reversible and can be removed by your doctor at any time if you change your mind and want to try for a baby¹



Actual size



Jaydess sits in your uterus, where a baby would normally develop. It's carefully inserted there through your vagina by a doctor who has been specially trained.



Because Jaydess is in your uterus, not your vagina:

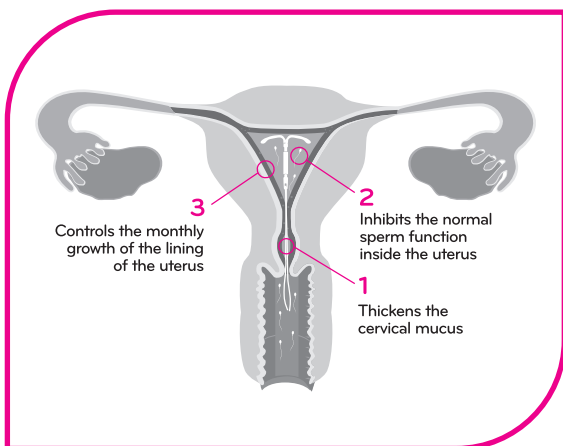
- You can still use tampons.
- You shouldn't be able to feel it.
- You and your partner should not feel it during sex. If you do, discuss with your doctor.
- You should make sure Jaydess is in place with a simple monthly check. Your doctor can show you how.

How does Jaydess work?

Jaydess works in three ways.

- 1.** It thickens the mucus in the cervix making it harder for sperm to reach the egg^{1,2}
- 2.** It stops sperm moving normally inside the uterus, preventing fertilisation^{1,2}
- 3.** It controls the monthly growth of the lining of the uterus so it doesn't become thick enough to support pregnancy^{1,2}

After 3 years Jaydess must be removed. Your doctor can place a new Jaydess during the same appointment if you choose to continue using Jaydess.

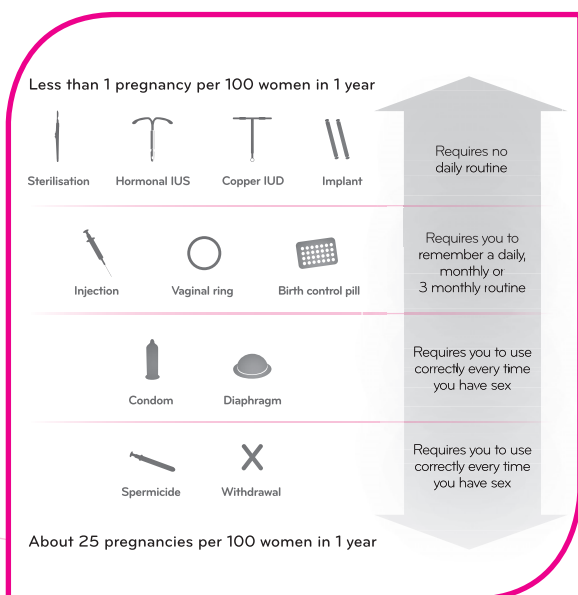


How effective is Jaydess?

Jaydess is a very effective form of contraception and has been shown to be 99.1% effective at preventing pregnancy over 3 years.¹

Generally the less you have to remember, the more effective the contraceptive. Contraceptive methods that rely on you using them every time you have sex tend to be less effective than contraceptive methods that require no daily or monthly routine.³ Jaydess is one contraceptive option that doesn't require a daily or monthly routine. We do, however, advise that you check the Jaydess threads once a month. Your doctor will show you how.¹

Comparing typical effectiveness of different contraceptives³



How is Jaydess fitted?

Jaydess should be fitted within 7 days from the beginning of your period by a doctor who has been trained to insert intrauterine systems (IUS).²

First your doctor will examine you to find the exact position of your uterus. They will then clean your vagina and cervix with an antiseptic solution and slide a slim plastic tube containing Jaydess into your uterus. Your doctor will then remove the plastic tube and leave Jaydess in your uterus. Your doctor will cut the threads to the right length.

You should have Jaydess checked usually 4-12 weeks after it is placed and then once a year until it is removed. It can stay in place for 3 years.

Will it hurt to have Jaydess fitted?

Everyone is different, and some women may experience pain, bleeding, dizziness, feel faint or experience spotting during or after placement. These symptoms should go away. If they don't, Jaydess may not have been placed correctly and you should talk to your doctor, who may want to examine you to make sure that everything is OK.^{1,2}

Do I have to use Jaydess for 3 years?

No. Jaydess can be removed at any time by your doctor. You may become pregnant as soon as Jaydess is removed, so you should use another method of contraception in the week before removal of Jaydess if you do not want to become pregnant.^{1,2}



What if I change my mind and want to try to get pregnant?

Jaydess can be removed at any time by your doctor and you can try getting pregnant right away. Because Jaydess is completely reversible, there's no waiting period and you will return to your normal fertility. About 4 out of 5 women who want to become pregnant will become pregnant sometime in the first year after Jaydess is removed.¹

Does Jaydess start working right away?

The system should be inserted within 7 days from the beginning of your period. If you already have the system and it is time to replace it with a new one, you do not need to wait for your period.²

You should be protected from pregnancy as soon as Jaydess is placed. The current recommended action is to wait about 24 hours after having the Jaydess inserted before having sexual intercourse.² However, it is best to wait about 48 hours before having sexual intercourse.^{2,4}

If you are not using any contraception and you have had unprotected intercourse prior to the insertion, pregnancy must first be excluded before a Jaydess is fitted.

Can I use tampons or menstrual cups?

Yes. Because Jaydess is in your uterus, not your vagina, you can still use tampons or menstrual cups. However, nothing should be inserted into the vagina for 48 hours following insertion of Jaydess, including tampons or menstrual cups. After this time, tampons and menstrual cups can be used. Tampons will not change the position or effectiveness of Jaydess, however, while it is unlikely to happen, care must be taken when changing them so the threads of Jaydess are not pulled and Jaydess accidentally removed.

While there is no evidence that the use of menstrual cups is associated with a risk of Jaydess being expelled or falling out, caution may be warranted in the first few weeks after insertion.⁴

How will Jaydess change my periods?

For the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding. After you have used Jaydess for a while, the number of bleeding and spotting days is likely to lessen. There is a small chance that your periods will stop altogether.²



Can I use Jaydess while breastfeeding?

You may use Jaydess when you are breastfeeding if more than 6 weeks have passed since you had your baby. If you are breastfeeding, Jaydess is not likely to affect the quality or quantity of breast milk or the health of your baby. Only very small amounts (about 0.1% of the hormone dose, levonorgestrel) pass into the breast milk.¹

Will my partner feel Jaydess during sex?

Neither you nor your partner should be able to feel Jaydess during sex. Sometimes your partner may feel the threads. If this happens, let your doctor know.¹

What if I become pregnant while using Jaydess?

Although the risk of becoming pregnant is low, if you think you may be pregnant call your doctor right away.

If you become pregnant while using Jaydess there is an increased risk that the pregnancy may be ectopic. This means that the pregnancy is not in the uterus.

These symptoms (listed below) could mean that you may have an ectopic pregnancy and you should see your doctor immediately:

- Your periods stop and then you start having bleeding or pain
- You have vague or very bad pain in your lower abdomen
- You have normal signs of pregnancy but you also have bleeding and feel dizzy

Ectopic pregnancy is a serious medical condition that requires immediate medical attention.^{1,2}

There are also risks if you get pregnant while using Jaydess and the pregnancy is in the uterus. Miscarriage and premature delivery can occur with pregnancies that continue with an intrauterine system. Because of this, your doctor may try to remove Jaydess, even though removing it may cause a miscarriage. If Jaydess cannot be removed, talk with your doctor about the benefits and risks of continuing the pregnancy.¹

What are the possible side effects of Jaydess?

All medicines have side effects. Sometimes they are serious, most of the time they are not. If you feel unwell or you suspect you may have a side effect it's important that you speak to your doctor.

Don't be alarmed by the following lists of side effects. You may not experience any of them. Side effects are most common during the first months after Jaydess is placed and decrease as time goes on.

Common side effects of Jaydess include:

Changes in bleeding

It is not uncommon to have bleeding and spotting between periods, especially during the first 3 to 6 months using Jaydess. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than normal. Call your doctor if the bleeding remains heavier than usual, is irregular or increases after it has been light for a while.^{1,2}

Pain, bleeding, or dizziness during and after placement

If these symptoms do not stop soon after placement, Jaydess may not have been placed correctly. Your doctor will examine you to see if Jaydess needs to be removed or replaced.^{1,2}



Expulsion

Jaydess may come out by itself. This is called an expulsion. If this occurs you may not be protected against pregnancy. If you think that Jaydess has come out, if you can feel the lower end of the system or you or your partner feel pain or discomfort during sex, use a back-up contraceptive method like condoms and call your doctor.²

Missed periods

About 1 out of 16 women stop having periods after 1 year of Jaydess use. Following removal your usual level of fertility will return. If you do not have a period for 6 weeks during Jaydess use, and you become concerned that you may be pregnant, call your doctor.¹

Cysts on the ovary

Some women using Jaydess develop cysts on the ovary. These cysts usually disappear on their own in a month or two. Cysts may cause pain or result in pain during sex. If these symptoms occur, talk to your doctor.^{1,2}

Other common side effects of Jaydess include:

Headaches, abdominal or pelvic pain, acne, oily skin, itching, redness or swelling of the vagina, depressed mood, migraine, nausea, hair loss or excessive hairiness, vaginal infections and discharge, menstrual pain, breast pain or discomfort.²

In addition it's important to be aware of the following:

Ectopic pregnancy

It is very rare to become pregnant while using Jaydess. However, if you become pregnant while using Jaydess, the risk of an ectopic pregnancy (where the pregnancy develops outside the womb) is increased. The following symptoms could mean that you have an ectopic pregnancy and you should see your doctor immediately: your periods stop and then you start having persistent bleeding or pain; you have vague or very bad pain in your lower abdomen; you have normal signs of pregnancy but you also have bleeding and feel dizzy.²

Infection

Jaydess is inserted in a way to minimise the chance of infection. Despite this, there is still an increased risk of pelvic infection in the first month of Jaydess use. You have an increased risk of infection if you have multiple sexual partners, STIs or a history of pelvic inflammatory disease. When having sex with anybody who is not a long-term partner, a condom should be used to minimise the risk of any infection. Infections must be treated immediately as they may impair fertility and increase the risk of an ectopic pregnancy. Tell your doctor if you have persistent lower abdominal pain, fever, pain during sex or abnormal bleeding.²

Perforation

Jaydess may become attached to (embedded) or go through the wall of the uterus. This is called perforation. If this occurs, Jaydess should be removed. The risk of perforation is increased in breastfeeding women, those who have recently had a baby or have a fixed retroverted uterus (tilted womb). If you experience excessive pain or bleeding after insertion, tell your doctor immediately.²

Does Jaydess protect against STIs/HIV?

No, Jaydess does not protect against HIV or any other STIs. If you think that you or your partner may be at risk of getting an STI, you should use condoms and speak to your doctor.^{1,2}

Who should not use Jaydess?

You should not use Jaydess and should discuss with your doctor if you:

- Are or might be pregnant; Jaydess cannot be used as emergency contraception^{1,2}
- Have a serious pelvic infection called pelvic inflammatory disease (PID) or have had recurrent PID in the past¹
- Have had an infection of the womb following childbirth or after an abortion in the past 3 months¹
- Have an infection or cell abnormalities in the cervix¹
- Have or suspect you might have cancer of the uterus or cervix¹
- Have breast cancer or any other cancer that is sensitive to progesterone (a female hormone), now or in the past¹
- Have bleeding from the vagina that has not been explained¹
- Have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumours¹
- Have liver disease or liver tumours¹
- Are allergic to any components of Jaydess, which include levonorgestrel, silicone, polyethylene, silver, silica, barium sulphate or iron oxide¹
- Have conditions associated with an increased risk of developing a pelvic infection¹
- Have an untreated pelvic infection now¹

References: 1. Jaydess Data Sheet, 10 September 2020. 2. Jaydess Consumer Medicine Information, September 2020. 3. Trussell, J Contraception failure in the United States. *Contraception*. 2011;83: 397-404. 4. Family Planning New South Wales, Family Planning Victoria and True Relationships and Reproductive Health. *Contraception: An Australian Clinical Practice Handbook*, 4th Edition. Ashfield, NSW, 2016.

JAYDESS is an intrauterine system containing 13.5 mg levonorgestrel, which is slowly released over 3 years. JAYDESS is a **Prescription Medicine** for contraception. JAYDESS must not be used during pregnancy, if there is any sign of pelvic or genital tract infection, inflammation or cancer, if there is womb or cervical abnormality, confirmed or suspected hormone-sensitive cancer including breast cancer, undiagnosed abnormal bleeding, active liver disease or if you are allergic to any ingredients in JAYDESS. JAYDESS should be inserted by a doctor who has been trained in the insertion technique. Removal of JAYDESS is recommended if the following medical conditions occur: an increased susceptibility to pelvic infections, acute infection not responding to treatment. Migraine or severe headaches, jaundice, increased blood pressure, hormone-sensitive cancer, stroke, severe heart or blood vessel disease, and/or blood clots may occur during JAYDESS use; should this happen, your doctor may consider removal of JAYDESS. JAYDESS should be used with caution if you have diabetes or a heart condition from birth and are at risk of infection. JAYDESS must be removed if pregnancy (which might be outside the womb) or puncture of the womb is suspected, or if JAYDESS is partially expelled. JAYDESS does not protect against HIV infections (AIDS) and other sexually transmitted infections. Commonly reported side effects include headache/migraine, abdominal or back pain, acne/oily skin, changes to menstrual pattern, cysts in the ovaries, depressed mood, painful menstruation, nausea, hair loss, breast pain/discomfort, expelled device, and genital discharge, redness or itching. The possibility of side effects such as puncture of the womb, allergic reactions, bacterial infection of the blood, or pregnancy outside the womb should be discussed with your doctor, pharmacist or health professional. If symptoms persist or you have side effects, see your doctor for advice. JAYDESS is a fully funded medicine – a pharmacy charge and normal Doctor's visit fees and insertion fees may apply. JAYDESS has both risks and benefits. Use only as directed. Consult your doctor to see if JAYDESS is right for you. For more information, read the Consumer Medicine Information available at <https://www.medsafe.govt.nz/consumers/cmi/j/jaydess.pdf> Bayer New Zealand Limited, PO Box 2825, Shortland Street, Auckland 1140, telephone 0800 233 988.

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