

Package leaflet: Information for the user
Jaydess 13.5 mg intrauterine delivery system
levonorgestrel

Patient's name: <...>

Doctor's name: <...>

Doctor's phone number: <...>

Date of insertion: <...>

Date of removal: <...>

First check-up visit: <...>

Next visits:

1. <...>
2. <...>
3. <...>

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects, you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Jaydess is and what it is used for
2. What you need to know before you use Jaydess
3. How to use Jaydess
4. Possible side effects
5. How to store Jaydess
6. Contents of the pack and other information

1. What Jaydess is and what it is used for

Jaydess is used for the prevention of pregnancy (contraception) for up to three years.

Jaydess is a T-shaped intrauterine delivery system (IUS) which after placement inside the womb slowly releases a small amount of the hormone levonorgestrel.

Jaydess works by reducing the monthly growth of the lining of the womb and thickening the cervical mucus. These actions prevent the sperm and egg from coming into contact and so prevent fertilization of an egg by sperm.

2. What you need to know before you use Jaydess

General notes

Before you can begin using Jaydess, your healthcare professional will ask you some questions about your personal health history.

In this leaflet, several situations are described where Jaydess should be removed, or where the reliability of Jaydess may be decreased. In such situations you should either not have sex or you should use a condom or another barrier method.

Jaydess, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Jaydess is not suitable for use as an emergency contraceptive (postcoital contraceptive).

Do NOT use Jaydess if you:

- are pregnant (see section “Pregnancy, breast-feeding and fertility”)
- currently have a pelvic inflammatory disease (PID; infection of the female reproduction organs) or have had this condition multiple times in the past.
- have conditions associated with increased susceptibility to pelvic infections
- have an infection in the lower genital tract (an infection in the vagina or the cervix [neck of the womb])
- have had an infection of the womb after delivery of a child, after an abortion or after miscarriage during the past 3 months
- currently have cell abnormalities in the cervix
- have cancer or suspected cancer of the cervix or womb
- have tumours which are sensitive to progestogen hormones to grow, e.g., breast cancer
- have unexplained vaginal bleeding
- have an abnormality of the cervix or womb including fibroids that distort the cavity of the womb
- have an active liver disease or liver tumour
- are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your healthcare professional before using Jaydess if you

- have diabetes. There is generally no need to alter your diabetic medication while using Jaydess, but this may need to be checked by your healthcare professional
- have epilepsy. A fit (seizure) can occur during placement or removal
- have had an ectopic or extrauterine pregnancy (pregnancy outside the womb) in the past.

In addition, also talk to your healthcare professional if any of the following conditions exist before you use Jaydess or appear for the first time while using Jaydess:

- migraine, with visual disturbances or other symptoms which may be signs of a transient cerebral ischemia (temporary blockage of the blood supply to the brain)
- exceptionally severe headache
- jaundice (a yellowing of the skin, whites of the eyes and/or nails)
- marked increase in blood pressure
- severe disease of the arteries such as stroke or heart attack.

The following signs and symptoms could mean that you may have an extrauterine pregnancy and you should see your healthcare professional immediately (see also section “Pregnancy, breast-feeding and fertility”):

- Your menstrual periods have stopped and then you start having persistent bleeding or pain
- You have pain in your lower abdomen that is severe or persistent
- You have normal signs of pregnancy, but you also have bleeding and feel dizzy.
- You have a positive pregnancy test

Contact your healthcare professional promptly if any of the following occur (see also section 4) and remind them that you have a Jaydess device, especially if they were not the person who inserted it:

- severe pain (like menstrual cramps) or heavy bleeding after placement or if you have pain/bleeding which continues for more than a few weeks. This may be for example a sign of infection, perforation or that Jaydess is not in the correct position.
- you no longer feel the threads in your vagina. This may be a sign of expulsion or perforation. You can check by gently putting a finger into your vagina and feeling for the threads at the end of your vagina near the opening of your womb (cervix). Do not pull the threads because you may accidentally pull out Jaydess. Avoid intercourse or use a barrier contraceptive (such as condoms) until your healthcare professional has checked that the IUS is still in position.
- you or your partner can feel the lower end of Jaydess. Avoid intercourse until your healthcare professional has checked that the IUS is still in position.
- your partner feels the removal threads during intercourse.
- you think you may be pregnant
- you have persistent abdominal pain, fever, or unusual discharge from the vagina, which may be a sign of infection. Infections must be treated immediately.
- you feel pain or discomfort during sexual intercourse, which may be for example a sign of infection, ovarian cyst or that Jaydess is not in the correct position.

- there are sudden changes in your menstrual periods (for example, if you have little or no menstrual bleeding, and then you start having persistent bleeding or pain, or you start bleeding heavily), which may be a sign of Jaydess not being in the correct position or expelled.

Use of sanitary pads is recommended. If tampons are used, you should change them with care so as not to pull the threads of Jaydess.

Psychiatric disorders

Some women using hormonal contraceptives including Jaydess have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Children and adolescents

Jaydess is not indicated for use before the first menstrual bleeding (menarche).

Other medicines and Jaydess

Tell your healthcare professional if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

Pregnancy

Jaydess must not be used during pregnancy.

Some women may not have their periods while using Jaydess. Not having a period is not necessarily a sign of pregnancy. If you do not have your period and have other symptoms of pregnancy you should see your healthcare professional for an examination and have a pregnancy test.

If you have not had a period for six weeks and are concerned, then consider having a pregnancy test. If this is negative, there is no need to carry out another test unless you have other signs of pregnancy.

If you become pregnant with Jaydess in place, you should see your healthcare professional immediately to have Jaydess removed. There is a risk of spontaneous miscarriage if Jaydess is removed during pregnancy.

If you leave Jaydess in place during pregnancy, the risk of having a miscarriage, infection or preterm labour will be increased. Talk with your healthcare professional about the risks of continuing the pregnancy.

If you want to become pregnant you should contact your healthcare professional to have Jaydess removed.

Extrauterine pregnancy (pregnancy outside the womb)

It is uncommon to become pregnant while using Jaydess. However, if you become pregnant while using Jaydess, the risk that the pregnancy could develop outside the womb (have an extrauterine or ectopic pregnancy) is increased. Women who have already had an extrauterine pregnancy, surgery of the fallopian tubes or a pelvic infection carry a higher risk for this type of pregnancy. An extrauterine pregnancy is a serious condition which calls for immediate medical attention (see section 2, “Warnings and precautions for signs and symptoms”) and may impact future fertility.

Breast-feeding

You can use Jaydess during breast-feeding. Levonorgestrel (the active ingredient in Jaydess) has been identified in small quantities in the breast milk of breast-feeding women. However, no negative effects have been seen on infant growth and development or the amount or the quality of the breast milk.

Fertility

Your usual level of fertility will return after Jaydess is removed.

Driving and using machines

Jaydess has no influence on the ability to drive or use machines.

3. How to use Jaydess

Placement of Jaydess

Jaydess can either be placed:

- within seven days from the start of your menstrual bleed (your monthly period)
- immediately after a first trimester abortion provided that there are no genital infections
- after giving birth only after the womb has returned to its normal size, and not earlier than 6 weeks after delivery (see section 4 “Possible side effects – Perforation”).

Examination by your healthcare professional before placement may include:

- a cervical smear test (Pap smear)
- examination of the breasts
- other tests, e.g. for infections, including sexually transmitted diseases, as necessary. Your healthcare professional will also do a gynaecological examination to determine the position and size of the womb.

After a gynaecological examination:

- An instrument called a speculum is placed into the vagina, and the cervix may be cleansed with an antiseptic solution. Jaydess is then placed into the womb using a thin, flexible plastic tube (the placement tube). Local anaesthesia may be applied to the cervix prior to placement.
- Some women feel dizzy or faint during placement or after Jaydess is placed or removed.
- You may experience some pain and bleeding during or just after placement.

Follow-up examination and when to seek advice from your doctor:

You should have your Jaydess checked 4-6 weeks after placement, and thereafter regularly, at least once a year. Your doctor may determine how often and what kinds of check-ups are required in your particular case. In addition, you should contact your doctor if any of the symptoms described in section 2 “Warnings and precautions” occur.

Removal of Jaydess

Jaydess should be removed no later than the end of the third year of use.

Jaydess can be easily removed at any time by your healthcare professional, after which pregnancy is possible. Some women feel dizzy or faint during or after Jaydess is removed. You may experience some pain and bleeding during removal of Jaydess.

If pregnancy is not desired, Jaydess should not be removed after the seventh day of the menstrual cycle (monthly period) unless you use other methods of contraception (e.g. condoms) for at least seven days before the IUS removal.

In the case you do not have periods (menses), you should use a barrier method of contraception for seven days before removal.

A new Jaydess can also be placed immediately after removal, in which case no additional protection is needed.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following is a list of possible side effects by how common they are:

Very common side effects: may affect more than 1 in 10 people

- headache
- abdominal/pelvic pain
- acne/greasy skin
- bleeding changes including increased and decreased menstrual bleeding, spotting, infrequent periods and absence of bleeding (see also following section on irregular and infrequent bleeding)
- ovarian cyst (see also following section on ovarian cyst)
- inflammation of the external genital organs and vagina (vulvovaginitis)

Common side effects: may affect up to 1 in 10 people

- depressed mood/depression
- migraine
- feeling sick (nausea)
- upper genital tract infection
- painful menstruation
- breast pain/discomfort
- device expulsion (complete and partial) - (see the following section on expulsion)
- hair loss
- genital discharge

Uncommon side effects: may affect up to 1 in 100 people

- excessive body hair

Rare side effects: may affect up to 1 in 1,000 people

- perforation of the womb (see also following section on perforation)

Description of selected possible side effects:

- Allergic reactions including rash, hives (urticaria) and angioedema (characterized by sudden swelling of e.g. the eyes, mouth, throat) have been reported with similar products.

Irregular or infrequent bleeding

Jaydess is likely to affect your menstrual cycle. It can change your menstrual periods so that you have spotting (a small amount of bleeding), shorter or longer periods, lighter or heavier bleeding, or no bleeding at all.

You may have bleeding and spotting between menstrual periods, especially during the first 3 to 6 months. Sometimes the bleeding is heavier than usual at first.

Overall, you are likely to have a gradual reduction in the amount and number of days of bleeding each month. Some women eventually find that periods stop altogether.

The monthly thickening of the lining of the womb may not happen due to the effect of the hormone and therefore there is nothing to come or shed away as a menstrual period. It does not necessarily mean that you have reached menopause or are pregnant. Your own hormone levels usually remain normal.

When the system is removed, your period should soon return to normal.

Pelvic Infection

The Jaydess inserter and Jaydess itself are sterile. Despite this, there is an increased risk of pelvic infection (infections in the lining of the womb or the fallopian tubes) at the time of placement and during the first 3 weeks after the placement.

Pelvic infections in IUS users are often related to the presence of sexually transmitted diseases. The risk of infection is increased if you or your partner have multiple sexual partners or if you have had pelvic inflammatory disease (PID) before.

Pelvic infections must be treated promptly.

Pelvic infections such as PID may have serious consequences and it may impair fertility and increase the risk of a future extrauterine pregnancy (pregnancy outside the womb). In extremely rare cases severe infection or sepsis (very severe infection, which may be fatal) can occur shortly after insertion.

Jaydess must be removed if you experience recurring PID or if an infection is severe or does not respond to treatment.

Expulsion

The muscular contractions of the womb during menstruation may sometimes push the IUS out of place or expel it. It is rare but possible for Jaydess to come out during your menstrual period without you noticing.

It is also possible for your Jaydess to partially expel from your womb, meaning that it is displaced but not completely expelled (you and your partner may notice this during sexual intercourse). If Jaydess is completely or partially expelled, you will not be protected from pregnancy.

Perforation

Perforation or penetration of the wall of the womb may rarely occur. The risk of perforation is increased to uncommon (may affect up to 1 in 100 people) in breast-feeding women and in women who have insertion up to 36 weeks after birth, and may be increased in women with the uterus leaning backwards (fixed retroverted uterus).

If perforation does occur, it most often happens during placement, even though it may not be detected until sometime later. If Jaydess becomes lodged outside the cavity of the womb, it is not effective at preventing pregnancy. You may need surgery to have Jaydess removed.

Ovarian cyst

Since the contraceptive effect of Jaydess is mainly due to its local effect in the womb, ovulation (release of the egg) usually continues while using Jaydess. Sometimes an ovarian cyst may develop. In most cases there are no symptoms.

An ovarian cyst may require medical attention, or more rarely surgery, but it usually disappears on its own.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Jaydess

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not open the blister. Only your doctor or nurse should do this.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Jaydess contains

The **active substance** is levonorgestrel. The intrauterine delivery system contains 13.5 mg levonorgestrel.

The **other ingredients** are:

- polydimethylsiloxane elastomer
- silica, colloidal anhydrous
- polyethylene
- barium sulfate
- iron oxide, black (E172)
- silver

What Jaydess looks like and contents of the pack

Jaydess is a T-shaped intrauterine delivery system (IUS). The vertical arm of the T-body carries a drug reservoir containing levonorgestrel. Two removal threads are tied to the loop at the lower end of the vertical arm. In addition, the vertical stem contains a silver ring located close to the horizontal arms, which is visible under ultrasound examination.

Pack size:

- 1x1 intrauterine delivery system.
- 5x1 intrauterine delivery system.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bayer Limited,
The Atrium,
Blackthorn Road,
Dublin 18.

Manufacturer

Bayer OY
Pansiontie 47
20210 Turku
Finland

This medicinal product is authorised in the Member States of the EEA under the following names:

- Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom: **Jaydess**
- Estonia, Latvia, Lithuania: **Fleree**

This leaflet was last revised in To be inserted upon approval

The following information is intended for healthcare professionals only:

INSERTION INSTRUCTIONS

Jaydess 13.5 mg intrauterine delivery system

To be inserted by a healthcare provider using aseptic technique.

Jaydess is supplied within an inserter in a sterile package, which should not be opened until needed for insertion. Do not resterilize. As supplied, Jaydess is for single use only. Do not use if the blister is damaged or open. Do not insert after the expiry date which is stated on the carton and the blister after EXP.

Any unused product or waste material should be disposed of in accordance with local requirements.

Preparation for insertion

- Examine the patient to establish the size and position of the uterus, in order to detect any signs of acute genital infections or other contraindications for the insertion of Jaydess. If there is any doubt regarding pregnancy, a pregnancy test should be performed.
- Insert a speculum, visualize the cervix, and then thoroughly cleanse the cervix and vagina with a suitable antiseptic solution.
- Employ an assistant as necessary.
- Grasp the anterior lip of the cervix with a tenaculum or other forceps to stabilize the uterus. If the uterus is retroverted, it may be more appropriate to grasp the posterior lip of the cervix. Gentle traction on the forceps can be applied to straighten the cervical canal. The forceps should remain in position and gentle counter traction on the cervix should be maintained throughout the insertion procedure.
- Advance a uterine sound through the cervical canal to the fundus to measure the depth and confirm the direction of the uterine cavity and to exclude any evidence of intrauterine abnormalities (e.g., septum, submucous fibroids) or a previously inserted intrauterine contraceptive which has not been removed. If difficulty is encountered, consider dilatation of the canal. If cervical dilatation is required, consider using analgesics and/or a paracervical block.

Insertion

1. First, open the sterile package completely. Then use aseptic technique and sterile gloves.

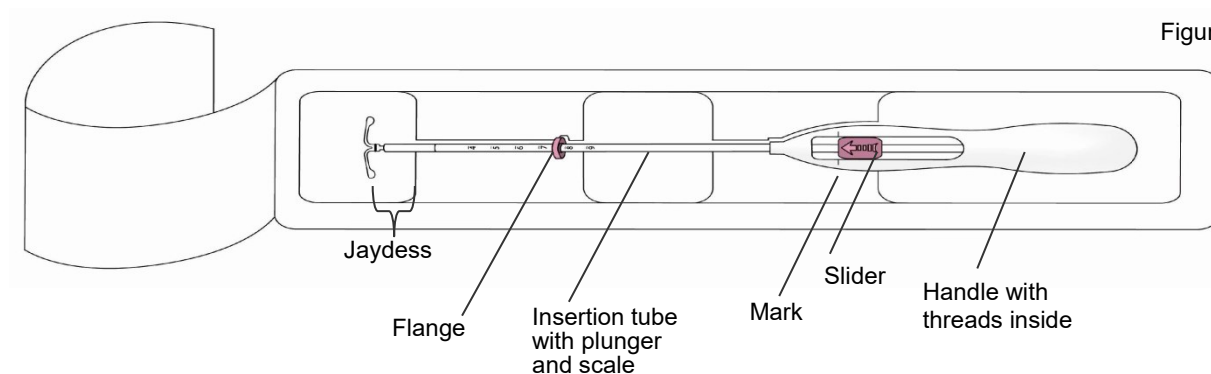


Figure 1

2. Push the slider **forward** in the direction of the arrow to the furthest position to load Jaydess into the insertion tube.

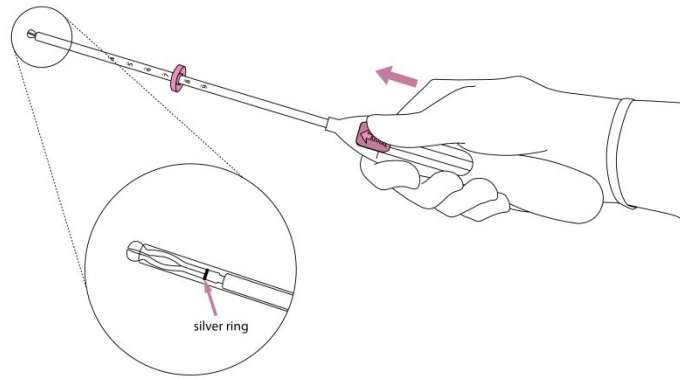


Figure 2

IMPORTANT! Do not pull the slider downwards as this may prematurely release Jaydess. Once released, Jaydess cannot be re-loaded.

3. Holding the slider in the furthest position, set the **upper** edge of the flange to correspond to the sound measurement of the uterine depth.

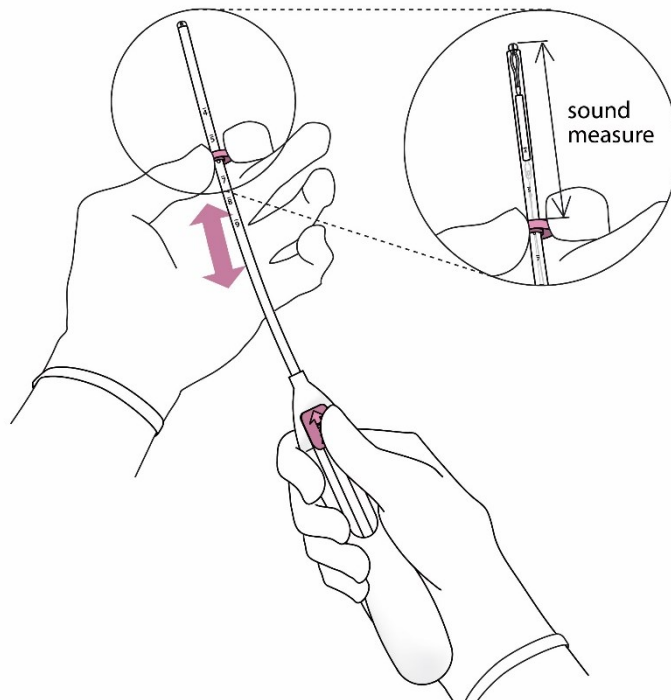


Figure 3

4. While holding the slider in the **furthest** position, advance the inserter through the cervix until the flange is approximately 1.5-2.0 cm from the uterine cervix.

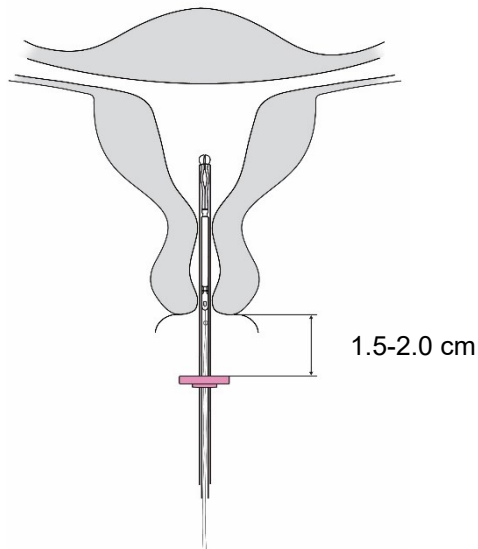


Figure 4

IMPORTANT! Do not force the inserter. Dilate the cervical canal, if necessary.

5. While holding the inserter steady, **pull the slider to the mark** to open the horizontal arms of Jaydess. Wait 5 -10 seconds for the horizontal arms to open completely.

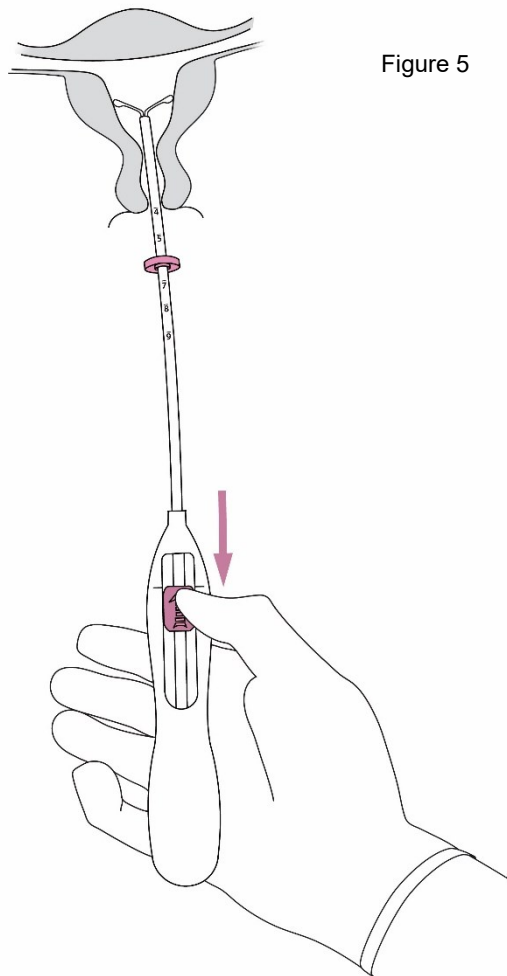


Figure 5

6. Advance the inserter gently towards the fundus of the uterus **until the flange touches the cervix**. Jaydess is now in the fundal position.

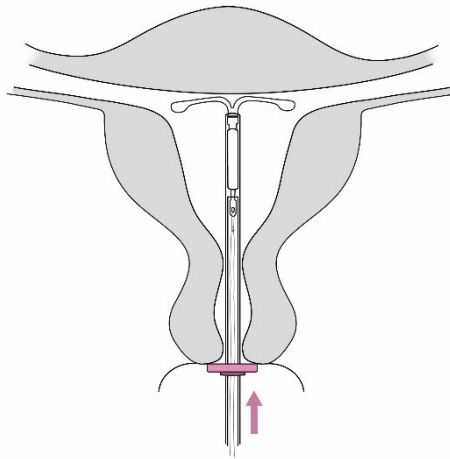


Figure 6

7. Holding the inserter in place, release Jaydess by pulling **the slider all the way down**. While holding the slider all the way down, gently remove the inserter by pulling it out. **Cut the threads** to leave about 2-3 cm visible outside of the cervix.

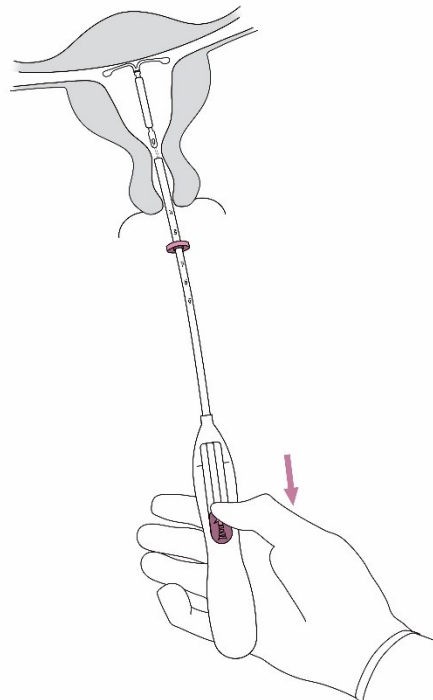


Figure 7

IMPORTANT! Should you suspect that the system is not in the correct position, check placement (e.g. with ultrasound). Remove the system if it is not positioned properly within the uterine cavity. A removed system must not be re-inserted.

Removal/ replacement

For removal/ replacement, please consult the Summary of Product Characteristics for Jaydess.

Jaydess is removed by pulling on the threads with a forceps.

You may insert a new Jaydess immediately following removal.

After removal of Jaydess, the system should be examined to ensure that it is intact.

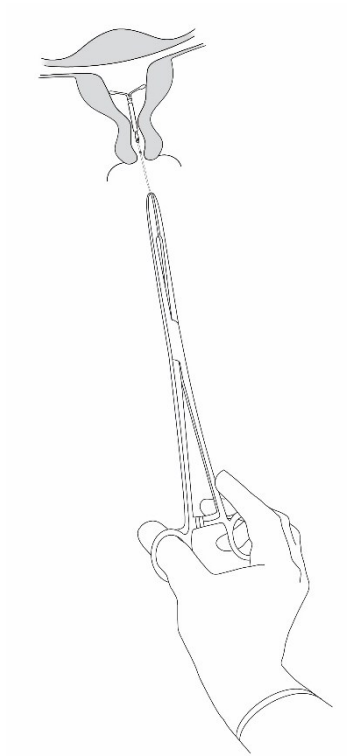


Figure 8