

Package leaflet: Information for the user

Kyleena 19.5 mg intrauterine delivery system

levonorgestrel

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 healthcare professional.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

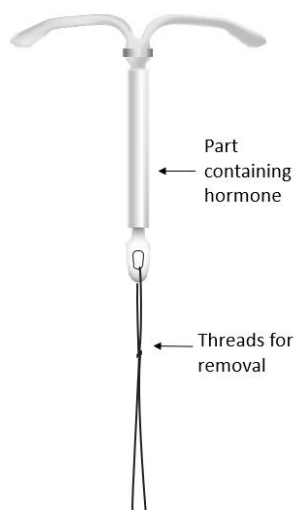
What is in this leaflet

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

1. What Kyleena is and what it is used for

Kyleena is a T-shaped intrauterine delivery system, also known as a hormone coil. It prevents pregnancy for up to five years – it is a contraceptive. Kyleena contains a hormone called levonorgestrel.

Figure 1: Kyleena hormone coil



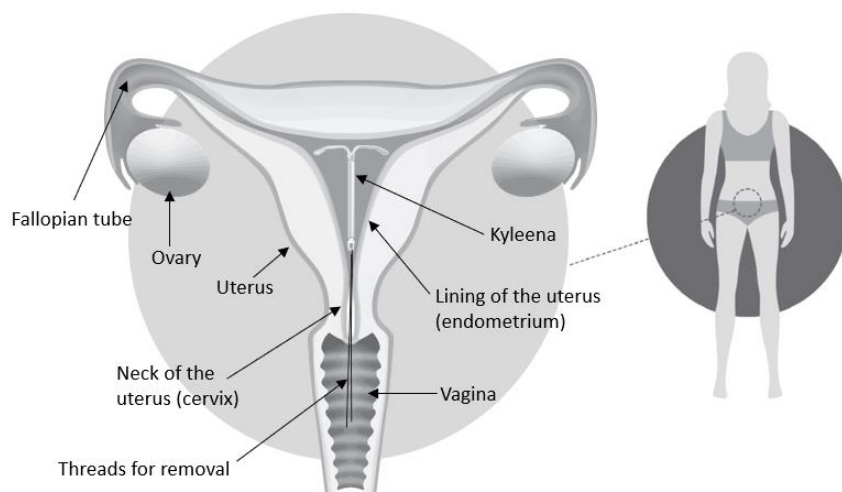
How Kyleena works

A healthcare professional will place Kyleena into your uterus. When it is in place, it releases a small amount of hormone continuously.

Kyleena prevents the sperm and egg from coming into contact and so prevents pregnancy. This is how:

- It makes the mucus in the neck of your uterus (cervix) thicken. This prevents sperm from passing through.
- It makes the lining of your uterus (endometrium) stay thin.

Figure 2: Kyleena in the uterus



2. What you need to know before you use Kyleena

Good to know about Kyleena

Your healthcare professional must be sure that this contraceptive is right for you. That is why they will first ask a few questions about your health. Only then will you get a prescription.

As a contraceptive, Kyleena prevents pregnancies. But no contraceptive prevents all pregnancies. Each year, about 2-3 out of 1000 women who use Kyleena become pregnant.

It does not protect you against HIV infection or other sexually transmitted diseases.

It is not an emergency contraception like a morning-after pill. Women who have had sexual intercourse without protection shortly before it is inserted can become pregnant.

Do NOT use Kyleena if:

- you are pregnant (see the section below 'Pregnancy, breast-feeding and fertility')
- you have an infection of your uterus, fallopian tubes or ovaries (pelvic inflammatory disease), or if you have had this several times in the past
- you have a disease that makes you more likely to get infections in your pelvis. For example: sexually transmitted diseases or diseases that lower your body's ability to fight off infections, like advanced stages of HIV
- you have an infection in your vagina or neck of your uterus (cervix)
- you have had a baby, abortion or miscarriage in the past three months and then had an infection of your uterus
- your latest smear test results (cervical screening) were abnormal
- you have cancer of your uterus or the neck of your uterus (cervix) - or your healthcare professional thinks you might have this
- you have a tumour which needs progestogen hormones to grow – such as breast cancer
- you are bleeding from your vagina, and the cause is unknown
- you have a cervix or uterus that does not have a normal shape – such as due to non-cancerous growths in the uterus (fibroids)
- you have liver disease or liver tumour
- you are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in section 6).

Do not use Kyleena if any of the above apply to you – if you are unsure, talk to your healthcare professional.

Warnings and precautions

Before using Kyleena, talk to your healthcare professional if you:

- have diabetes. Generally, you would not need to alter your diabetes medicines while using Kyleena, but this may need to be checked by your healthcare professional
- have epilepsy - a fit (seizure) can happen during the insertion or removal of Kyleena
- have had a pregnancy outside the uterus (ectopic pregnancy) in the past
- have migraines that cause problems with your vision – such as sudden loss of vision in one eye – or that cause other problems (migraines with aura) or if you have other severe headaches of unknown origin
- have jaundice (your skin, nails and whites of the eyes turn yellow)
- have high blood pressure
- have ever had a stroke or heart attack.

If any of the above apply to you (or you are unsure), talk to your healthcare professional before having Kyleena inserted.

While using Kyleena, talk to your healthcare professional immediately if you:

- have signs of pregnancy. Or a positive pregnancy test – see the section below 'Pregnancy, breast-feeding and fertility'
- have signs of pregnancy but also pain, bleeding from your vagina or you feel dizzy. This may mean that you are having a pregnancy outside the uterus – see section 4 under 'Pregnancy outside the uterus'
- have stomach pain, fever, or unusual discharge from your vagina or pain during sexual intercourse – this may mean you have an infection and must get medication quickly. See section 4 under 'Pelvic infection'
- feel pain during sexual intercourse - you may have a small fluid-filled sac (cyst) in your ovary. See section 4 under 'Ovarian cyst'
- have severe pain, very heavy bleeding, or can no longer feel the threads of Kyleena – you may have a perforation. See section 4 under 'Perforation'.

Talk to your healthcare professional immediately if you have any of the above symptoms.

Also, talk to your healthcare professional about your Kyleena, if you:

- have a migraine or a very severe headache for the first time
- notice that your skin, nails and whites of your eyes turn yellow – these are signs of jaundice
- notice a rise in your blood pressure
- had a stroke or heart attack.

Your healthcare professional will decide whether it is still safe for you to keep using Kyleena.

Look out for signs that Kyleena might not be in place

Signs that Kyleena might not be in place are:

- you can no longer feel the threads of Kyleena in your vagina with your finger – see section 3 under 'How to check yourself that Kyleena is in place'
- you can feel the lower plastic end of Kyleena - or your partner feels it – see section 3 under 'How to check yourself that Kyleena is in place'
- you have sudden changes in your menstrual periods. For example: your periods have stopped with Kyleena, and then you suddenly have your period again.

These signs might mean that Kyleena has fallen out – see section 4 under 'If Kyleena falls out'. Or it might mean you have a perforation – see section 4 under 'Perforation'.

If you have any of these signs that Kyleena is not in place, talk to your healthcare professional straight away. You should not have sexual intercourse unless you use a condom or diaphragm until your healthcare professional checks that it is still in place.

Your partner may feel the threads of Kyleena during sexual intercourse. This does not mean that it is out of place. However, if your partner is uncomfortable feeling the threads, there are things your healthcare professional can do to help.

Menstrual hygiene products

If you have your period, it is best to use sanitary pads. If you use tampons or a menstrual cup, change it carefully. Otherwise, you might accidentally pull the threads of Kyleena. If you think you may have pulled it out of place (see list above for possible signs), you should not have sexual intercourse unless you use a condom or diaphragm until you see your healthcare professional.

Breast cancer

Women who take the pill (contraceptive) have a slightly increased risk of breast cancer. This returns to the age-appropriate basic risk within 10 years of stopping the pill.

Some scientific studies have suggested a slightly increased risk of breast cancer with use of levonorgestrel IUS like Kyleena while other studies have not suggested an increased risk. Talk to your doctor if you have any concerns.

Mental health problems

Some women using hormonal contraceptives, including Kyleena, get depression or depressed mood. See section 4 under 'Mental health problems' for more information.

Children and adolescents

Girls who have not yet started their period should not use Kyleena.

Other medicines and Kyleena

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

Pregnancy, breast-feeding and fertility

Pregnancy

Do not have Kyleena inserted if you are pregnant.

If you stop having your menstrual period while using Kyleena

Some women do not have their menstrual period while using Kyleena. If you no longer have your menstrual period, that is probably due to Kyleena. You can read more about this in section 4, under 'Irregular or infrequent bleeding'.

Have you not had your menstrual period for 6 weeks? Then you can do a pregnancy test. If the test says you are not pregnant, it is not necessary to do it again.

If you feel symptoms of pregnancy

If you have signs of pregnancy such as your menstrual periods stopped, feeling sick and tender breasts, you should:

1. take a pregnancy test
2. contact your healthcare professional for an examination.

If you get pregnant

If you get pregnant with Kyleena, see your healthcare professional immediately. They will remove Kyleena.

There is a risk you will have a miscarriage when Kyleena is removed. However, if you continue your pregnancy with Kyleena in place, you are at greater risk of:

- a miscarriage
- the baby being born prematurely

Talk with your healthcare professional about the benefits and risks of continuing the pregnancy with Kyleena in place. Your healthcare professional will closely monitor you. You should contact your healthcare professional right away if you experience:

- stomach cramps
- pain in your stomach
- fever

Kyleena contains a hormone called levonorgestrel. Ask your healthcare professional about the effect the hormone may have on your developing baby. There have been very few reports of levonorgestrel coils affecting the genitals of female babies in the uterus.

Pregnancy outside the uterus

The risk that you will become pregnant with Kyleena is very small. However, if you become pregnant while using Kyleena, you have a greater risk that the fertilised egg is not in your uterus but in your fallopian tube or abdominal cavity (ectopic pregnancy). Such a pregnancy is a serious condition and needs immediate medical attention. After an ectopic pregnancy it may be more difficult to get pregnant again. See section 4 under 'Pregnancy outside the uterus'.

Breast-feeding

You can use Kyleena during breast-feeding. A small amount of hormone ends up in breast milk. However, Kyleena is not likely to affect the quality or amount of your breast milk or the growth and development of your nursing baby.

Fertility

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

Kyleena does not affect fertility after it is removed.

Driving and using machines

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

3. How to use Kyleena

Starting to use Kyleena

- Before Kyleena is inserted, it needs to be ensured that you are not pregnant.
- You should have Kyleena inserted within 7 days from the start of your menstrual period. When it is inserted on these days, it works right away and will prevent you getting pregnant.
- If you cannot have Kyleena inserted 7 days from the start of your menstrual period or if your menstrual periods come at unpredictable times, then it can be inserted on any other day. In this case, you must not have had sexual intercourse without contraception since your last menstrual period, and you should have a negative pregnancy test before insertion. Also, Kyleena may not reliably prevent pregnancy right away. Therefore, you should use a barrier method of

contraception (such as condoms) or abstain from vaginal intercourse during the first 7 days after it is inserted.

- Kyleena is not an emergency contraception like a morning-after pill.

Starting to use Kyleena after giving birth

- Kyleena can be inserted after giving birth once the uterus has returned to normal size but not earlier than 6 weeks after delivery (see section 4 under 'Perforation').
- See also 'Starting to use Kyleena' above for what else you need to know about the timing of insertion.

Starting to use Kyleena at the time of delivery

In specific situations Kyleena can be placed while you are still in hospital immediately after you give birth (this is called immediate postpartum insertion, or IPPI). IPPI must be done by a healthcare professional trained in this procedure. Whilst you get contraception right after your delivery, this procedure comes with a high risk that your Kyleena is pushed out of place or expelled (see “If Kyleena falls out” below). It is recommended that you check for the threads of Kyleena yourself (self-examine) 6-8 weeks after placement, to make sure it is still in place (See section 3 “How to check yourself that Kyleena is in place”). If you are interested in contraception right after delivery, talk to your healthcare professional who will counsel on available options before your due date.

Starting to use Kyleena after an abortion

Kyleena can be inserted immediately after an abortion if the pregnancy was less than 3 months along provided that there are no genital infections. It will then work right away.

Starting to use a new Kyleena when your current one needs to be replaced

Kyleena can be replaced by a new Kyleena at any time of your menstrual cycle. It will then work right away.

Changing from another contraceptive method (such as combined hormonal contraceptives, implant)

- Kyleena can be inserted immediately if it is reasonably certain that you are not pregnant.
- If it has been more than 7 days since your menstrual bleeding began, you should abstain from vaginal intercourse or use additional contraceptive protection for the next 7 days.

What happens when Kyleena is inserted?

Examination before insertion

Sometimes your healthcare professional will want to do some examinations before fitting Kyleena, for example:

- a swab smear of the neck of the uterus (smear test on your cervix)
- examination of the breasts
- if necessary, other tests, for example for sexually transmitted diseases.

Inserting Kyleena

First, the healthcare professional will examine how big your uterus is and how exactly it is positioned in your abdomen (pelvic exam).

The healthcare professional places an instrument (speculum) in your vagina and cleans the neck of your uterus (cervix) with an antiseptic liquid. Sometimes the healthcare professional applies local anaesthesia to the cervix. The healthcare professional then puts Kyleena in your uterus with a thin, flexible, plastic tube (insertion sleeve).

Sometimes, fitting Kyleena might be uncomfortable. Some women feel dizzy or faint. You may also have pain or some bleeding from your vagina. This is not unusual.

When the insertion is finished, your healthcare professional will give you a card: the patient reminder card. On this card, you can write down when you will have your next Kyleena check-up. Bring this card with you to every appointment.

Checking after insertion

You should have your Kyleena checked by a healthcare professional 4-6 weeks after insertion. Your healthcare professional will decide how often you should return for a check-up after that. You should come back for a check on your Kyleena at least once a year. Bring the patient reminder card to every appointment.

How to check yourself that Kyleena is in place

You can check this by gently inserting a finger into your vagina. You should then be able to feel the threads at the top of your vagina, near your cervix. Your cervix is the entrance to your uterus. Note: do not pull on the threads, as you may accidentally pull out Kyleena.

If you cannot feel the threads, you must have your healthcare professional check whether Kyleena is still in the right place. You should not have sexual intercourse unless you use a condom or diaphragm until you see your healthcare professional.

If you can feel the lower plastic end of Kyleena - or if your partner feels it - Kyleena is not in the right place. See your healthcare professional right away. You should not have sexual intercourse until you have been to your healthcare professional unless you use a condom or diaphragm.

Removal of Kyleena

Kyleena works up to 5 years. You should have it removed after 5 years, but you can also have it removed at any time before the 5 years are up. Your healthcare professional will remove it. After it has been removed, you can become pregnant again.

Removing Kyleena can be a bit uncomfortable. Some women feel dizzy or faint during removal or immediately afterwards. You may also feel a little pain and bleed from your vagina. This is not unusual.

Continuation of contraception after removal

If you do not want to become pregnant after Kyleena is removed, you should know:

- It is best to have Kyleena removed within 7 days after your period has started. If you have it removed outside of your period, you must use a condom or diaphragm during sexual intercourse for 7 days before removal.
- If you have irregular periods or no period at all, you must use a condom or diaphragm during sexual intercourse for 7 days before removal. Irregular periods mean the number of days between your menstrual cycles is not always the same.
- A new Kyleena can also be placed immediately after removal, in which case no additional protection is needed. If you do not wish to continue using the same method, ask your healthcare professional for advice about other reliable contraceptive methods.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

There are some serious side effects which means if you have them, you must talk to your healthcare professional immediately:

- stomach pain, fever, unusual discharge or abnormal bleeding from your vagina, or pain during sexual intercourse - this may be an infection of your uterus, fallopian tubes or ovaries – see below under 'Pelvic Infection'.
- severe pain like menstrual pain, more pain than you expected, or very heavy bleeding from your vagina after insertion. Or you have pain or bleeding that lasts longer than a few weeks, sudden changes in your menstrual pattern, pain during sexual intercourse, or can no longer feel the threads of Kyleena. These may be signs of a perforation – see below under 'Perforation'.
- your menstrual periods have stopped, but then you have bleeding from your vagina, which does not stop, or pain in the lower part of your stomach that is severe or does not go away – these may be signs of a pregnancy outside the uterus – see below under 'Pregnancy outside the uterus'.
- you have mood changes and depressive symptoms – see below under 'Mental health problems'.
- allergic reaction – such as skin rash, hives, or a swollen tongue, lips, face or throat. This type of reaction is very rare.

If you think any of the above applies to you, talk to your healthcare professional immediately.

Other side effects

Below are other side effects that you may get. The side effects that occur most often are at the top of this list, and those that occur least often are at the bottom.

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

- headache
- abdominal pain or pelvic pain
- spots (acne) or greasy skin
- changes in your period, for example:
 - bleeding more or less than usual
 - bleeding or bleeding a little (spotting) while not having a period
 - irregular or infrequent periods
 - no longer having periods at all

You can read more about this in the section 'Irregular or infrequent periods' below.

- small fluid-filled sac on your ovary (ovarian cyst). You can read more about this in the section 'ovarian cyst' below
- inflammation of your labia and vagina (vulvovaginitis)

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

- decreased sex drive (decreased libido)
- migraine
- dizziness
- feeling sick (nausea)
- hair loss
- pain during your period
- painful or sensitive breasts
- Kyleena comes out by itself (completely or partially). You can read more about this in the section 'If Kyleena falls out' below
- discharge from the vagina
- increased weight

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

- increase in body hair

Description of selected possible side effects:

Pregnancy outside the uterus

The signs of pregnancy outside the uterus include:

- your menstrual periods have stopped, but then you start bleeding from your vagina again, and it does not stop
- you have pain in the lower part of your stomach that is severe or does not go away
- you have normal signs of pregnancy, for example, nausea or sensitive breasts, but you are also bleeding from your vagina and feel dizzy
- you have a positive pregnancy test

You should see your healthcare professional immediately if you have any of these symptoms.

The risk that you will become pregnant with Kyleena is very small. However, if you become pregnant while using Kyleena, you have a greater risk that the fertilised egg is not in your uterus but in your fallopian tube or abdominal cavity (ectopic pregnancy). About 2 in a 1000 women using Kyleena for a year will get a pregnancy outside the uterus. Such a pregnancy is a serious condition and needs immediate medical attention. You may need surgery.

Some women are more likely to have an ectopic pregnancy. These are women who:

- have had an ectopic pregnancy before
- have had surgery on the fallopian tubes
- have had a pelvic infection

Irregular or infrequent bleeding

It is likely that your period changes due to Kyleena. For example:

- You might bleed a little when not having your period. This bleeding is called spotting.
- You might have your period less regularly. In that case, the number of days between your menstrual cycle is not always the same.
- You might have a shorter or longer period.
- You might lose less or more blood than usual during your period.
- You might no longer have your period.

Sometimes these changes only occur in the first months after insertion. For example:

- Bleeding when not having your period or spotting are most common in the first 3 to 6 months.
- Some women have a heavier period at first than usual.

You may gradually lose less blood every month and have a shorter period. In the end, some women may stop having their periods.

Are you no longer having your period? This is usually normal. Most of the time, it does not mean that you are pregnant or in menopause. Here is why: normally, the lining of your uterus thickens every month to prepare for a pregnancy and then gets thin again when you have your period. Kyleena reduces the thickening of your uterine lining. This could stop your period. Your hormone levels usually remain normal.

If you have Kyleena removed, you usually get your normal period again. If that does not happen, contact your healthcare professional.

Pelvic Infection

Kyleena is free from bacteria, viruses and fungi (sterile). This also applies to the inserter. But you can still get an infection in your pelvis during insertion of Kyleena or within the first 3 weeks after

insertion. For example, in the lining of the uterus, the fallopian tubes or ovaries. This may affect up to 1 in 10 people.

You may get:

- stomach pain
- fever
- unusual discharge from your vagina
- pain during sexual intercourse

You have a greater risk of infection in your pelvis if:

- you have a sexually transmitted disease
- you or your partner have multiple sexual partners
- you already have had an infection in your pelvis before

With a pelvic infection, it is important to go to a doctor immediately. Pelvic infection can cause:

- fertility problems afterwards. This might mean that it will be more difficult to get pregnant
- a pregnancy outside the uterus (ectopic pregnancy) if you become pregnant
- a severe infection or blood poisoning. This is very rare and happens shortly after inserting Kyleena. Blood poisoning means you are very sick due to an infection. Blood poisoning may be fatal if not treated

You must have Kyleena removed if the pelvic infection:

- comes back several times
- is very serious
- does not go away with treatment

If Kyleena falls out

Kyleena may be pushed out of place or fall out. This is caused by the contractions of the muscles in your uterus when you are having your period. There is also a high risk of expulsion when your IUS is inserted immediately after you have given birth (see above under “Starting to use Kyleena at the time of delivery”). This may happen in up to 1 in 10 people, especially if you:

- are overweight when Kyleena is inserted
- have had heavy periods before

If Kyleena is out of place, it may no longer work properly. You will have a higher risk of getting pregnant. If it falls out, it will not prevent you from getting pregnant anymore.

If Kyleena is out of place or has fallen out, you may have pain or bleeding from your vagina that is different from normal. It is also possible that Kyleena can fall out without you noticing it.

Kyleena usually decreases the amount of blood you lose during your period.

The longer you use it, the less blood you lose during your period. This means that if you suddenly start losing more blood again during your periods, Kyleena may have fallen out. See section 3 ‘How to check yourself that Kyleena is in place’ for how to check if it is in place and what to do if you suspect that it is no longer in place.

Perforation

It may happen that Kyleena is pushed into the wall of your uterus or through the wall of your uterus. This is called perforation. A perforation usually occurs at the time when Kyleena is inserted. A perforation doesn't always hurt, and therefore you may only notice it later. If it is no longer in the right place because of perforation it does not work against pregnancy anymore. A doctor must then remove it as quickly as possible. Sometimes surgery is necessary.

A perforation occurs in up to 1 in 1000 people. You have a greater risk (up to 1 in 100 people) of a perforation if:

- you are breast-feeding when you get Kyleena inserted
- you had a baby in the last 9 months before you get Kyleena inserted

You may have a perforation if you:

- have severe pain that feels like menstrual pain or more pain than you expected
- have very heavy bleeding from your vagina after insertion
- have pain or bleeding that lasts longer than a few weeks
- have sudden changes in your menstrual pattern
- have pain during sexual intercourse
- can no longer feel the threads of Kyleena

If you think you may have a perforation, contact a healthcare professional immediately. Remind them that you have Kyleena, especially if they are not the person who inserted it.

Ovarian cyst

Sometimes with Kyleena, a small fluid-filled sac appears on an ovary. Such a sac is called an ovarian cyst.

Signs of an ovarian cyst could be:

- pain in your pelvis
- pain or an uncomfortable feeling during sexual intercourse.

An ovarian cyst usually disappears on its own. However, it might need medical attention. In rare cases, you might need surgery. If you think you might have an ovarian cyst, contact your healthcare professional.

Mental health problems

Some women using hormonal contraceptives, including Kyleena, get depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you have mood changes and depressive symptoms, contact your healthcare professional as soon as possible. Depression and depressive mood may affect up to 1 in 100 people using Kyleena.

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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kyleena

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 (the plastic container holding Kyleena). Only your healthcare professional 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 Kyleena contains

The **active substance** is levonorgestrel. The intrauterine delivery system contains 19.5 mg levonorgestrel.

The **other ingredients** are:

- polydimethylsiloxane elastomer
- silica, colloidal anhydrous
- polyethylene
- barium sulfate
- polypropylene
- copper phthalocyanine
- silver

What Kyleena looks like and contents of the pack

Kyleena is a hormone coil (delivery system for use in the uterus). It has the shape of a letter T and is white. On the vertical part is a small container with the hormone levonorgestrel. There are two blue threads tied to the bottom loop. This allows a healthcare professional to remove Kyleena. There is also a silver ring on it, close to the horizontal arms of Kyleena. Your healthcare professional can see this ring during an ultrasound examination.

Pack size:

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bayer Limited
1st Floor
The Grange Offices
The Grange
Brewery Road
Stillorgan
Co. Dublin
A94 H2K7
Ireland

Manufacturer

Bayer OY
Pansiontie 47
20210 Turku
Finland

This medicine is authorised in the Member States of the European Economic Area under the following names:

- Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Italy, Latvia, Lithuania, The Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden: **Kyleena**

This leaflet was last revised in June 2026

Other sources of information

Detailed and updated information on this medicine is available by scanning the QR Code included in the package leaflet, outer carton and patient reminder card with a smartphone. The same information is also available on the following URL: www.pi.bayer.com/kyleena/ie and on the HPRA website at www.hpra.ie

[QR code to package leaflet to be included nationally]

The following information is intended for healthcare professionals only:

INSERTION INSTRUCTIONS

Kyleena 19.5 mg intrauterine delivery system
levonorgestrel

To be inserted by a healthcare professional using aseptic technique.

Kyleena is supplied in a sterile package within an integrated inserter that enables single handed loading. The package should not be opened until needed for insertion. Do not resterilize. As supplied, Kyleena 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.

Kyleena is supplied with a patient reminder card in the outer package. Complete the patient reminder card and give it to the patient, after insertion.

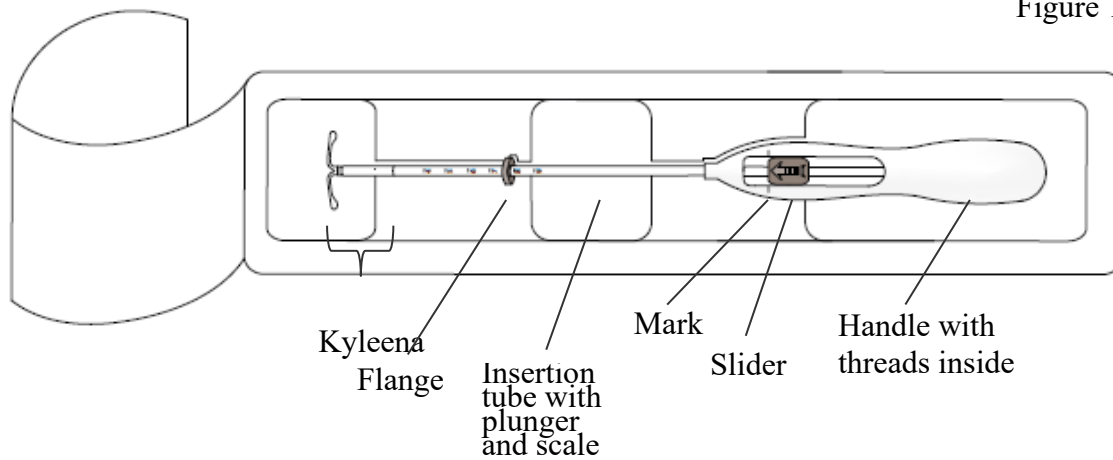
Preparation for insertion

- Examine the patient to rule out contraindications for the insertion of Kyleena (see Summary of Product Characteristics section 4.3 and section 4.4 under Medical examination/consultation).
- 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

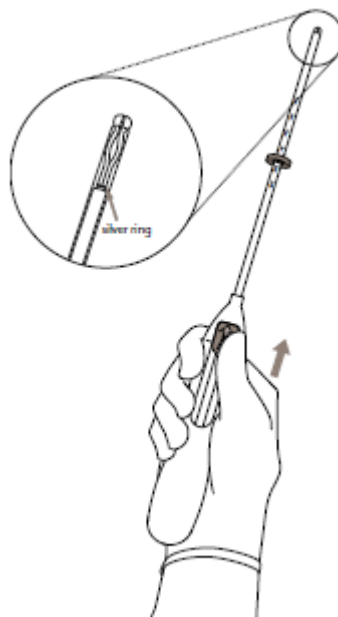
1. First, open the sterile package completely (Figure 1). Then use aseptic technique and sterile gloves.

Figure 1



2. Push the slider **forward** in the direction of the arrow to the furthest position to load Kyleena into the insertion tube (Figure 2).

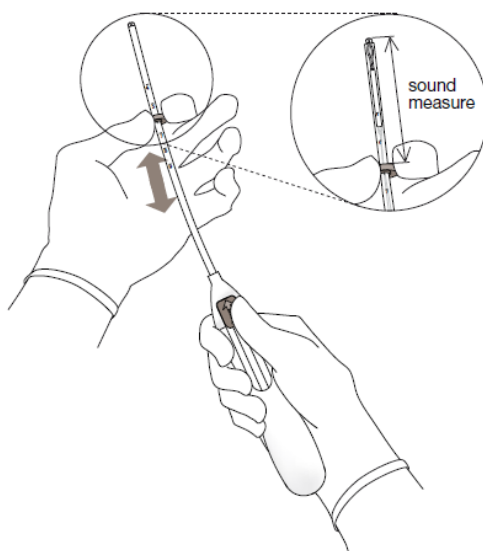
Figure 2



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

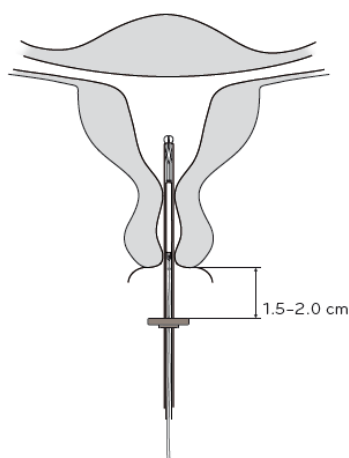
3. Holding the slider in the furthest position, set the **upper** edge of the flange to correspond to the sound measurement of the uterine depth (Figure 3).

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).

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 Kyleena (Figure 5). Wait 5-10 seconds for the horizontal arms to open completely.

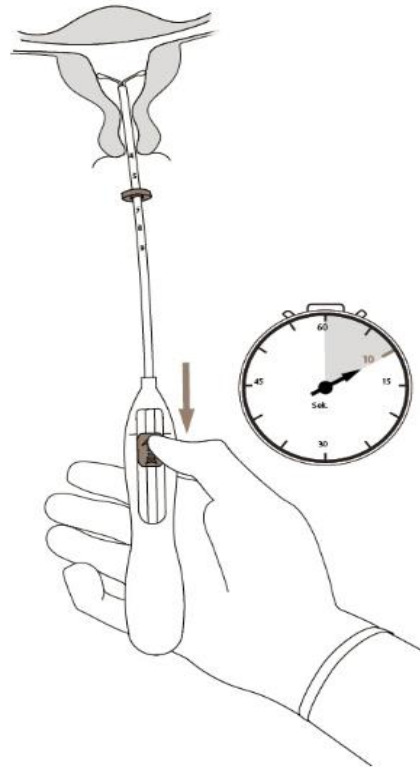


Figure 5

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

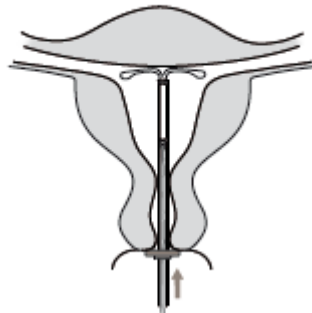


Figure 6

7. Holding the inserter in place, release Kyleena by pulling **the slider all the way down** (Figure 7). 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.

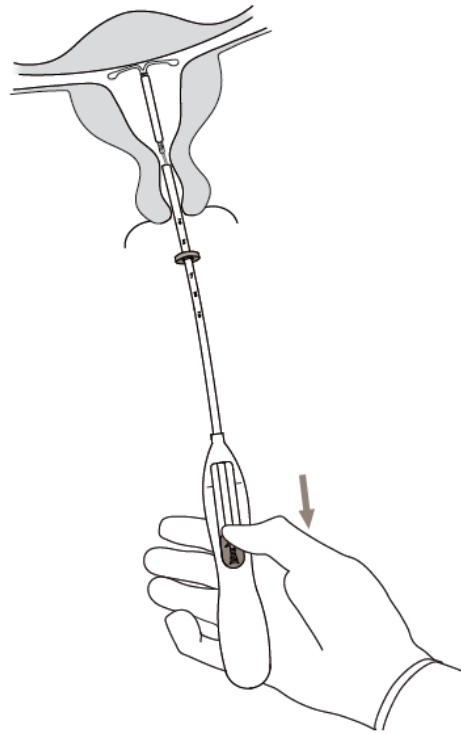


Figure 7

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 Kyleena.

Kyleena is removed by gently pulling on the threads with forceps (Figure 8).

You may insert a new Kyleena immediately following removal.

After removal of Kyleena, the system should be examined to ensure that it is intact and has been completely removed.

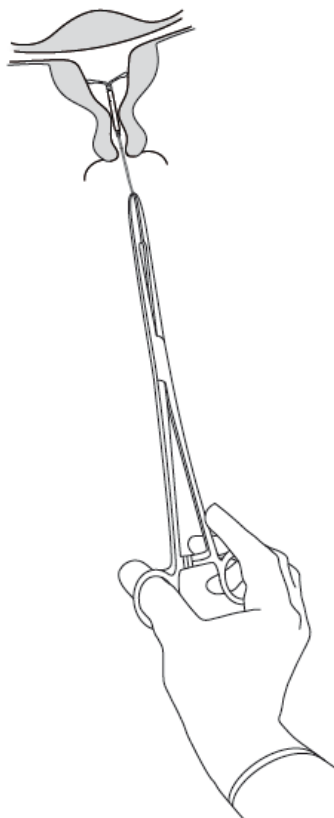


Figure 8

[QR code to Summary of Product Characteristics to be included nationally]

Summary of Product Characteristics for Kyleena online at www.pi.bayer.com/kyleena/ie