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KYLEENA™

INFORMATION FOR
USERS

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Jenapharm



Love. Life. Health.



 kyleena™



This brochure will provide information about:

- What is Kyleena™ and how does it work?
- After inserting Kyleena™
- Frequently asked questions regarding Kyleena™

Welcome to Kyleena™

Your gynecologist has discussed the Kyleena™ intrauterine device with you and recommended it for contraception. Here you will find answers to the most frequently asked questions about contraception using Kyleena™.



What is Kyleena™?

Kyleena™ is used for contraception for up to five years. Kyleena™ is a T-shaped intrauterine device (IUD) that continuously releases a small amount of the hormone levonorgestrel (LNG) into the uterus after insertion. The T-shaped body of Kyleena™ is only 3 cm in length and 2.8 cm in width. Two thin strings are attached to it, which your doctor can use to remove Kyleena™ anytime in the future.

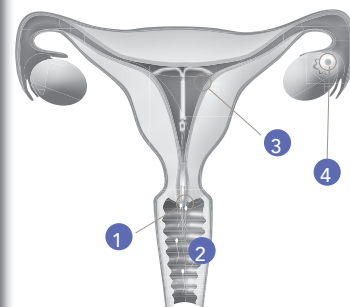


Have you ever held a Kyleena™ model in your hand? Ask your doctor to show you what Kyleena™ looks and feels like.

Kyleena™ at a glance

- superior contraceptive safety from day one
- no contraceptive uncertainties, such as:
 - forgetting to take your daily pill
 - gastrointestinal problems
 - drug interaction with medications
- release of levonorgestrel into the uterus
- doesn't contain any estrogen
- does not normally suppress ovulation and so the natural, female hormonal process remains undisturbed
- menstrual bleeding is usually shorter and weaker, less frequent and less painful, and may not occur at all

How Kyleena™ works



- 1 The mucus in the cervix thickens and thus prevents sperm from entering the uterus.
- 2 Sperm activity and ability to fertilize are inhibited.
- 3 The periodic thickening of the uterine lining is reduced.
- 4 With Kyleena™, ovulation usually continues to occur and the woman's natural hormonal cycle is usually maintained

Unlike the pill and most other hormonal contraceptive methods, ovulation is not usually inhibited with Kyleena™, so the woman's natural cycle and hormone balance are usually maintained with Kyleena™.

What happens if I want to get pregnant?

Kyleena™ is completely reversible. This means that natural, age-appropriate fertility is restored immediately after Kyleena™ is removed.

Kyleena™ can be removed at any time. If you want to get pregnant, Kyleena™ can be pulled out right away by your gynecologist.



After inserting Kyleena™

How does Kyleena™ impact my menstrual bleeding?

Most of the time, menstrual bleeding with Kyleena™ is regular and usually weaker, shorter and also less painful. Monthly periods can also become less frequent, to the point where there is no menstruation at all with Kyleena™.

However, especially in the first three to six months, intermenstrual bleeding and spotting may occur more frequently between menstrual periods

Overall, however, the amount of blood and the number of bleeding days can be expected to decrease month by month. For some women, menstrual bleeding eventually stops altogether.

- This is due to the way Kyleena™ works: To prevent pregnancy, the hormone levonorgestrel reduces the monthly thickening of the uterine lining. The less the mucous membrane thickens, the less it sheds as menstrual bleeding. The absence of your menstrual bleeding does not adversely affect your future fertility
- No menstrual bleeding does not necessarily mean that you are pregnant. However, if you notice any other pregnancy symptoms, please contact your gynecologist immediately.

On the next page you will find a menstrual diary that you can detach from the booklet along the perforation. This menstrual diary helps you to document changes in your bleeding pattern to show to your gynecologist. Alternatively, the MyIUS app** can be used for this purpose. In addition, after 90 days, users of the MyIUS app receive a customized forecast of their expected bleeding pattern in the next six months.

After the removal of Kyleena™, your menstrual bleeding will usually return very quickly to what it used to be previously.

** The MyIUS app is an app developed as a medical device under EU law for the digital support of Kyleena™ users. More at: <https://www.jenapharm.de/service/myius>

You can use this menstrual diary to document changes in your monthly bleeding. Note down your bleeding intensity and the day on which the bleeding occurred. Use the following

instructions to mark the corresponding square or day in the calendar:

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month 1																															
Month 2*																															
Month 3																															
Month 4																															
Month 5																															
Month 6																															

No bleeding Leave blank

●

Spotting Make a check mark

×

Normal bleeding Mark with an X

■

Heavy bleeding Fill out the box

■

* After the insertion of Kyleena™, a check-up should be done after four to six weeks.

Frequently asked questions regarding Kyleena™

How is Kyleena™ inserted, and how long does it take?

Inserting Kyleena™ is a routine procedure for your trained gynecologist and should not make you nervous. The insertion will not take more than a few minutes. Your gynecologist will normally carry out a standard gynecological examination at first. Then a thin, flexible tube containing Kyleena™ is inserted into your uterus. Once Kyleena™ is correctly inserted in place, your doctor will withdraw the tube and leave Kyleena™ in the proper place in the uterus. During the insertion, you may feel a menstrual-like pulling or squeezing sensation in your abdomen. Talk to your gynecologist beforehand if you do have any concerns about the insertion, so that your gynecologist is aware of them and can help you if necessary.

Even after the insertion, you may still feel a menstrual-like tugging or squeezing in your abdomen for a few hours or a few days. However, this usually disappears within a few days. If you experience severe pain or bleeding after the insertion of Kyleena™, or if the pain/bleeding lasts for more than a few days, please contact your gynecologist and tell them about your symptoms so that they can help you.

When should Kyleena™ be inserted?

Kyleena™ should be inserted within seven days of the start of your menstrual bleeding. The contraceptive protection of Kyleena™ begins immediately. If an intrauterine system is replaced with a new one, there is no need to wait for menstrual bleeding, but a new one can be placed immediately after removal. Contraceptive protection then continues without interruption.

Risks and side effects

Perforation

Perforation or penetration of the uterine wall can occur in rare cases, especially during the insertion of Kyleena™, although the perforation can be detected only after a certain period of time. Outside the uterus, Kyleena™ has no contraceptive effect and must be removed. The risk of perforation is increased in breastfeeding women and in women in whom the IUD is inserted within 36 weeks after birth. The risk of perforation may also be increased in women whose uterus is tilted backwards towards the bowel rather than forwards towards the bladder.

Does Kyleena™ need to be checked after insertion?

After the insertion of Kyleena™, a check-up should be done after four to six weeks and regularly thereafter, at least once a year. Your doctor can decide how often you should have a check-up and which check-ups are necessary in your case.

Kyleena™ in the uterus



What are those strings attached to Kyleena™?

With these two strings, the gynecologist can remove Kyleena™. Your doctor can show you how to check if the threads are still there. By feeling the strings, you can make sure that Kyleena™ still fits properly and provides effective contraception. If you have further questions about the strings, talk to your doctor.

Frequently asked questions regarding Kyleena™

How is Kyleena™ removed? What happens after five years?

Kyleena™ must be removed at the latest at the end of the fifth year of use. However, Kyleena™ can also be removed by your gynecologist any time before this period. After removal, your age-appropriate fertility returns immediately.



If you wish to continue using Kyleena™ after five years, your gynecologist can remove Kyleena™ and insert a new one immediately.

Is there a risk of infection with Kyleena™?

Kyleena™, like other hormonal contraceptive methods, does not provide protection against HIV infection (AIDS) or other sexually transmitted diseases. You should use condoms to protect yourself from sexually transmitted diseases.

Kyleena™ is sterile when inserted and the risk of infection is comparable to that of a woman who does not use an intrauterine system for contraception.

Nevertheless, there is a risk of pelvic inflammatory disease (e.g., infection of the endometrium or fallopian tubes) during insertion and in the first few weeks after insertion, which must be treated immediately if it occurs.

Before insertion, your gynecologist will carry out a gynecological examination to ensure that there are no infections. Please contact your gynecologist immediately if you experience symptoms such as abdominal pain and fever after the insertion, as these may be signs of a pelvic infection.

Is there a risk of pregnancy outside of the uterus with Kyleena™?

Pregnancy is very rare when Kyleena™ is used. However, if you become pregnant while using Kyleena™, there is an increased risk that the embryo is implanted outside the uterus (e.g., occurrence of an ectopic pregnancy). Women who have already had a pregnancy outside of the uterus or pelvic inflammatory disease, or who have had surgery of the fallopian tubes, have a higher risk of pregnancy outside of the uterus. Pregnancy outside the of the uterus needs immediate medical attention and can affect future fertility. You should tell your



gynecologist if you have abdominal pain, especially if your menstrual bleeding has stopped (and you previously had regular cycles), and/or if you have unexpected bleeding and/or pregnancy symptoms, as it could be a pregnancy outside of the uterus.

Can Kyleena™ get ejected?

Kyleena™ lies well protected in the uterus. Slippage or ejection is rare. But if this does happen, you have no contraceptive protection. An indication of this can be heavier bleeding again or more severe pain during menstruation. However, you should feel safe with regular check-ups with your gynecologist. By feeling for the strings in your vagina, you can also check for yourself if Kyleena™ still fits properly and provides effective contraception.

If you think Kyleena™ has slipped or even come out completely, please use an additional method of contraception (e.g., condoms) until your appointment with your gynecologist.

Does Kyleena™ interfere with sexual intercourse?

Neither you nor your partner should feel Kyleena™ during sexual intercourse. Kyleena™ is in the uterus, not the vagina, and the strings should be cut long enough that they do not interfere with sexual intercourse either.

Frequently asked questions regarding Kyleena™

Does Kyleena™ protect against sexually transmitted infections?

No, Kyleena™ does not protect against sexually transmitted infections, such as HIV/AIDS. To protect against sexually transmitted infections, it is advisable to use condoms as well.



Can I continue to use tampons and menstrual cups?

You can continue to use tampons and also menstrual cups during your menstrual bleeding, but be careful when changing tampons or menstrual cups. Be careful not to accidentally pull the Kyleena™ strings.

And what if I do want to have a baby?

Kyleena™ can be removed at any time and your natural, age-appropriate fertility immediately returns.

What are the possible side effects of Kyleena™?

Like all medications, Kyleena™ can cause side effects, but not everybody gets them. Below are possible side effects listed in order of frequency. Very common side effects (occurring in 1 or more per 10 women) are headache, abdominal or pelvic pain, acne or oily skin, altered bleeding, ovarian cysts, and vaginitis. Common side effects (occur in less than 1 in 10 women but more than 1 in 100 women) are depressed mood/depression, migraine, nausea, hair loss, upper genital tract infection, painful menstruation, breast pain, IUD expulsion (complete and partial) and vaginal discharge, dizziness and weight gain. Occasional and rare side effects include excessive body hair and perforation of the uterus (see page 9 for more information).

Where can I get more information?

This brochure does not replace the patient information or the instruction for use. If you have any further questions, please contact your gynecologist or visit www.pi.bayer.com/kyleena/de for more information.

Kyleena™ at a glance

- 1) very high contraceptive safety with a Pearl index of 0.29
- 2) reliable behavior-independent contraception for 5 years
- 3) no usage mishaps, such as forgetting or taking medication too late
- 4) interaction with other medications is unlikely
- 5) contraceptive safety is not compromised due to gastrointestinal problems such as vomiting or diarrhea
- 6) contraceptive effect, especially in the uterus
- 7) estrogen-free
- 8) ovulation, and thus the woman's natural hormonal cycle, are usually maintained
- 9) monthly bleeding usually becomes shorter and weaker, less painful and less frequent, to the point where there may be no bleeding at all

Patient name:

Batch number:

Date of insertion:

Date of removal/change:

Name of the gynecologist:

Telephone number of the gynecologist:

DIGITALE COMPANION

***EXCLUSIVELY FOR KYLEENA™
USERS, CODE: 5555***



MyIUS-APP

IUS = Intrauterine system, also called hormonal spiral or contraceptive shield

Jenapharm 
Love. Life. Health.

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