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A GUIDE TO YOUR INTRAUTERINE CONTRACEPTIVE

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WHAT IS KYLEENA®?

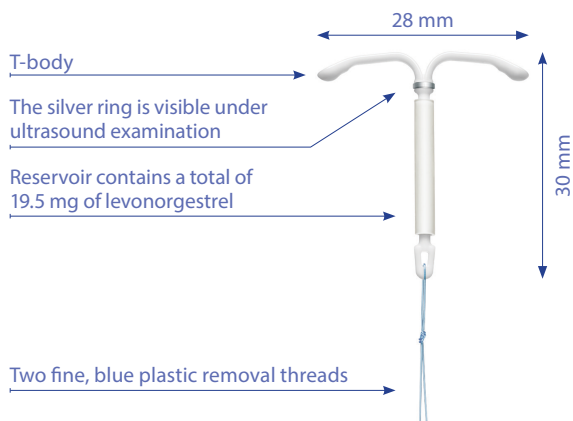
KYLEENA® is an intrauterine system (IUS) used for the prevention of pregnancy for up to 5 years.

What does KYLEENA® look like?

KYLEENA® consists of a small, white, T-shaped body made from soft, flexible plastic.

The vertical and horizontal arms of the T-body are about 3 cm long. The vertical arm is surrounded by a narrow, cylindrical-shaped drug reservoir that contains levonorgestrel. Two fine, blue plastic threads are attached to the tip of the vertical arm. These threads are used for removal of the system. The threads can also be used to check if KYLEENA® is in place. In addition, the vertical stem contains a silver ring located close to the horizontal arms, which is visible under ultrasound. KYLEENA® is packaged with the Evol inserter® (which is used to insert KYLEENA®).

KYLEENA® – Actual size

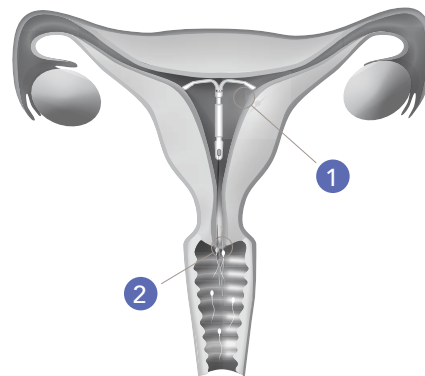


Important aspects of KYLEENA®:

- Releases a low amount of a hormone called levonorgestrel directly into the uterus every day (KYLEENA® contains 19.5 mg of levonorgestrel)
- Does not contain any estrogen

How does KYLEENA® work?

KYLEENA® may work to prevent pregnancy in several ways: reducing the monthly thickening of the lining of the uterus ¹, thickening the mucus in the cervix (this makes it harder for sperm to pass through the cervix) ², and impairing sperm movement and function. These actions together prevent the sperm and egg from coming into contact and work together to prevent pregnancy.



How effective is KYLEENA®?

Clinical trials found that there was less than 1 pregnancy per year for every 100 women using KYLEENA®.

TYPICAL PREGNANCY RATES for different methods of birth control, and pregnancy rate when no birth control is used

Product	Reported pregnancies per 100 women within the first year of use
Hormonal intrauterine system (IUS)	Less than 1
Copper intrauterine device (IUD)	Less than 1
Progesterone injection	6
Combined hormonal contraceptive (pill, patch or ring)	9
Diaphragm	12
Male condom	18
Female condom	21
Sponge, spermicide	12–28
Withdrawal method	22
Natural family planning	24
No birth control	85

PLACEMENT

Some important information you should know about starting with KYLEENA®



When should KYLEENA® be placed?

KYLEENA® should be placed within 7 days of starting your period. It is best to wait 24–48 hours before having intercourse in case of discomfort. In this case, no backup birth control is needed. If it is certain that you are not pregnant, KYLEENA® may also be placed at any other time during your cycle.

Tell your healthcare professional if you have had unprotected sex since your last period. If KYLEENA® is placed more than 7 days since your period started, use a condom or diaphragm, or do not have sex for the next 7 days. KYLEENA® cannot be used as emergency birth control.

- When replacing an existing system for a new one, it is not necessary to wait for your period
- Following childbirth, KYLEENA® should be placed only after the uterus has returned to its normal size, and not earlier than 6 weeks after delivery
- KYLEENA® can be placed immediately after a first trimester abortion; if an abortion takes place in the second trimester, placement of KYLEENA® should be delayed for 6 weeks or until the uterus has returned to normal size

How is KYLEENA® placed?

- After a pelvic examination, your healthcare professional will place a thin, flexible plastic tube containing KYLEENA® into your uterus – at this point you may feel some discomfort
- Once KYLEENA® is in the correct position, your healthcare professional will withdraw the tube, leaving the system in place in the uterus
- Finally, your healthcare professional will trim the removal threads to a suitable length

Some women may feel dizzy after KYLEENA® is placed. This feeling goes away after a short rest. The placement may cause a seizure in patients who have epilepsy. You may also experience some bleeding during or just after placement. After placement you may feel some cramp-like menstrual pain; however, this usually stops within a few days.

It is uncommon, but KYLEENA® may go through the wall of the uterus during placement and come to rest outside the uterus. If this happens, KYLEENA® must be removed.

How long does placement take?

The placement procedure usually takes a few minutes after your healthcare professional has completed the pelvic examination.

How quickly does KYLEENA® start to work?

KYLEENA® starts to work right away if it is placed within 7 days of the start of your period. It is best to wait 24–48 hours before having intercourse in case of discomfort.

If KYLEENA® is placed more than 7 days after the start of your period, use a condom or diaphragm for the next 7 days. Alternatively, do not have sex for the next 7 days.

What is the risk of uterine perforation?

KYLEENA® may become attached to or go through the wall of the uterus, but this is uncommon and happens most often during placement. This is called perforation. If this happens, KYLEENA® must be removed. The risk of perforation is increased in breastfeeding women, and in women who have placement up to 36 weeks after delivery, and may be increased in women with a differently shaped uterus or a uterus that is fixed and leans backwards.

Is there a risk of infection with KYLEENA®?

Hormonal contraceptives including KYLEENA® DO NOT PROTECT against sexually transmitted infections (STIs) including HIV/AIDS. To protect yourself against STIs, you can use condoms with KYLEENA®.

In the first 3 weeks after placement of an IUS/IUD, there is an increased risk of a serious pelvic infection called pelvic inflammatory disease (PID). Other known risk factors for PID are having multiple sexual partners, frequent intercourse, sexually transmitted infections (STIs) and young age.

PID can cause serious problems such as difficulty getting pregnant, development of a pregnancy outside the uterus (ectopic pregnancy), or pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID may require surgery.

Tell your healthcare professional right away if you have signs of PID. These can include long-lasting or heavy bleeding, unusual vaginal discharge, pain in your lower stomach area, painful sex, chills or fever.

Is there a risk of ectopic pregnancy with KYLEENA®?

While using KYLEENA®, the risk of pregnancy is low. However, if you get pregnant while using KYLEENA®, it is more likely that the pregnancy will be ectopic. This means that the pregnancy is not in the uterus. Ectopic pregnancy is a serious condition. Tell your healthcare professional immediately if you have lower abdominal pain, especially if you have missed a period and/or have unexpected bleeding. These can be signs of an ectopic pregnancy.

YOUR FIRST FEW DAYS AND MONTHS WITH KYLEENA®

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Here are some additional things you should know as you continue with KYLEENA®

How will KYLEENA® affect my periods?

KYLEENA® may affect your menstrual cycle. 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 vaginal bleeding. Some women have heavy or prolonged bleeding during this time. Contact your healthcare professional if this persists.

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.

When KYLEENA® is removed, periods soon return to normal.

What if I stop having periods?

Over time, your menstrual period may gradually disappear when using KYLEENA®. This is because of the effect of the hormone on the lining of the uterus. The normal monthly thickening of the uterine lining with blood does not happen; therefore, there is little or no bleeding, as happens during a usual menstrual period. It does not necessarily mean you have reached menopause or are pregnant.

If, however, you are having regular menstrual periods and then do not have one for 6 weeks or longer, it is possible that you may be pregnant. You should speak to your healthcare professional.

Can KYLEENA® fall out?

Although unlikely, KYLEENA® may fall out on its own. KYLEENA® could be pushed out either fully or partially during your period. This is called expulsion. This is more likely to occur if you are overweight or have a history of heavy periods. If KYLEENA® is out of place, it may not work as expected. If this happens, you are not protected against pregnancy.

Some symptoms of an expulsion are pain and abnormal bleeding. KYLEENA® may also come out without you noticing. An unusual increase in the amount of bleeding during your period might be a sign that this has happened.

If you think KYLEENA® has fallen out (fully or partially), avoid intercourse or use a non-hormonal method of birth control (like condoms) and talk to your healthcare professional. They might do an ultrasound and x-ray to confirm if KYLEENA® has fallen out. KYLEENA® should be removed if it is pushed out partially. KYLEENA® can be replaced with a new one once pregnancy is ruled out. Your healthcare professional will decide what is best for you.

How can I check if KYLEENA® is in place?

After each menstrual period or about once a month, you should check by feeling if the threads are still in place. Your healthcare professional will show you how to do this. Do not pull on the threads, as you may accidentally pull KYLEENA® out.

If you cannot feel the threads, this may indicate that KYLEENA® has fallen out or uterine perforation has occurred. See your healthcare professional and, in the meantime, use another method of birth control (like condoms) that does not include hormones. You should also see your healthcare professional if you can feel the lower end of KYLEENA® itself.

How often should I have KYLEENA® checked?

You should have your KYLEENA® checked about 4 to 12 weeks after placement, again at 12 months and then once a year until it is removed. KYLEENA® can stay in place for up to 5 years before it must be removed. You should receive a Patient Reminder Card from your healthcare professional after the placement of KYLEENA®. Keep this card until KYLEENA® is removed and bring it with you to every medical appointment.

Will KYLEENA® be felt during sexual intercourse?



During sexual intercourse, you or your partner should not be able to feel KYLEENA®.

After KYLEENA® is placed, it is recommended to wait 24 to 48 hours before having sexual intercourse. If you can feel KYLEENA®, or if you feel any pain, avoid having sex until your healthcare professional has checked if KYLEENA® is still in the correct position. The removal threads may be felt by your partner during intercourse.



SAFE SEX: Does KYLEENA® protect against sexually transmitted infections (STIs)?

Hormonal contraceptives including KYLEENA® **DO NOT PROTECT** against sexually transmitted infections (STIs) including HIV/AIDS.

To protect yourself against STIs, you can use condoms with KYLEENA®.

WHAT ARE THE SIDE EFFECTS OF KYLEENA®?

The following is a list of possible side effects. These are not all the possible side effects you may feel when taking KYLEENA®. If you experience any side effects not listed here, contact your healthcare professional.

- acne/oily skin
- nausea
- hair loss
- infection of the ovaries, fallopian tubes, or uterus
- painful periods
- breast pain/discomfort
- discharge from the vagina
- excess hair on the face, chest, stomach, or legs
- breakage of the IUS
- increased blood pressure

Side effects with KYLEENA® are more common during the first months of use; they gradually decrease over time. Differences in your menstrual bleeding are the most common side effects of KYLEENA® during the first months after the system is placed, but these effects should decrease over time.

Few women using KYLEENA® after delivery have reported less milk production.

YOUR NEXT FEW YEARS WITH KYLEENA®



What if I decide to have a baby?

Your usual level of fertility should return soon after KYLEENA® is removed.

If you wish to become pregnant, ask your healthcare professional to remove KYLEENA®.

How is KYLEENA® removed?

How do I continue with KYLEENA® after 5 years?

KYLEENA® should not be left in place for more than 5 years. KYLEENA® can be easily removed by your healthcare professional if you wish to become pregnant.

KYLEENA® may break, most often during a difficult removal. Broken pieces must be found and removed. Surgery may be needed to do this.

You may become pregnant upon removal of KYLEENA® if you have had sexual intercourse during the previous week. You could become pregnant as soon as KYLEENA® is removed, so you should use another method of birth control if you do not want to become pregnant. Talk to your healthcare professional about the best birth control methods for you, because your new method may need to be started 7 days before KYLEENA® is removed to prevent pregnancy. Tell your healthcare professional if you have had sexual intercourse during the week before.



If you wish to continue using KYLEENA® after 5 years, your healthcare professional can place a new system immediately after removing the old system.

If the same KYLEENA® system has been left in place for longer than 5 years, you may become pregnant. Pregnancy should be ruled out before placement of a new system.

KYLEENA® MENSTRUAL DIARY

Use the KYLEENA® menstrual diary to keep track of any spotting or bleeding that may occur in the next few months.*

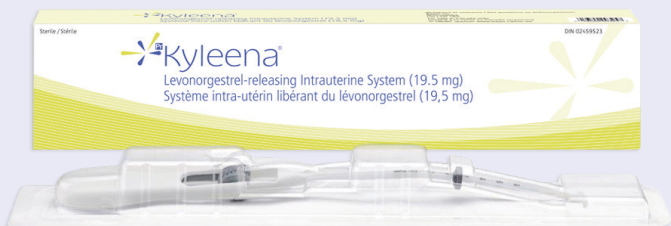
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month 1																															
Month 2																															
Month 3																															
Month 4																															
Month 5																															
Month 6																															

Patient instructions

Record your menstrual blood flow or any bleeding that occurs between periods by marking in the appropriate square (day) of the calendar, using the following guide.

■ Heavy Flow – Fill in the box	• Spotting – Mark a dot
X Normal Flow – Mark an X	No Bleeding – Leave blank

*You should have a check-up about 4 to 12 weeks after KYLEENA® is placed, again at 12 months and then once a year until it is removed.



The box holds more than just KYLEENA®

It also includes the insertion device. Ask your healthcare professional to show it to you.



For more information about KYLEENA®, visit kyleena.ca (for full access, enter the Drug Identification Number [DIN] 02459523 when requested).

KYLEENA® may be reimbursed – patients should contact their insurance provider for more information.

Serious Warnings and Precautions

- Hormonal contraceptives including KYLEENA® DO NOT PROTECT against sexually transmitted infections (STIs) including HIV/AIDS. To protect yourself against STIs, you can use condoms with KYLEENA®.
- Cigarette smoking increases the risk of serious side effects on the heart and blood vessels. You should talk to your healthcare professional about the risks of smoking.
- KYLEENA® may become attached to (embedded) or go through the wall of the uterus. This is called perforation. If you experience severe abdominal or pelvic pain with or without vaginal bleeding, contact your healthcare professional immediately.

Please refer to the KYLEENA® patient information leaflet for full indications, contraindications, warnings, precautions, side effects and patient selection criteria.

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* TM see www.bayer.ca/tm-mc

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