



KYLEENA®

INSERTION INSTRUCTIONS

EASY

- Ergonomically shaped slider and handle
- Centimeter scale visible on both sides of the insertion tube
- Narrow insertion tube: 3.8 mm diameter

SIMPLE

- Threads integrated into the handle
- Kyleena® pre-loaded in the correct horizontal position for insertion
- One-step loading process



 **Kyleena®**
19.5 MG LEVONORGESTREL
INTRAUTERINE DELIVERY SYSTEM

5 years. Low dose.

INSERTION INSTRUCTIONS

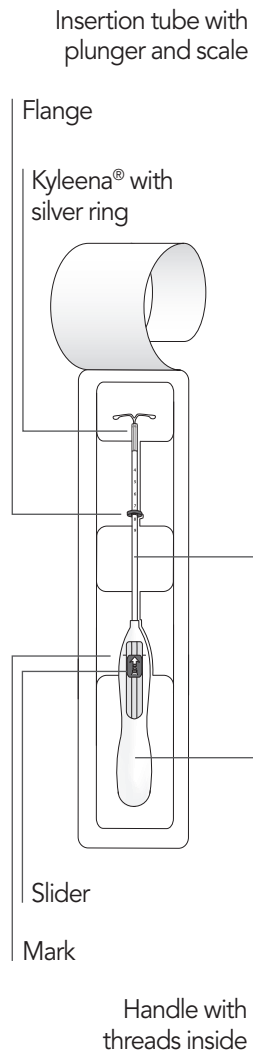
With the Bayer Inserter, **Kyleena®** offers a single-handed inserter design and insertion technique. The insertion tube diameter is 3.8 mm.

- Examine the patient to establish the size and position of the uterus, in order to detect any signs of acute genital infections or other contra-indications for the insertion of Kyleena® and to exclude pregnancy.
- Insert a speculum, visualise 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 stabilise 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, sub-mucous 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.

1

OPEN THE PACKAGE

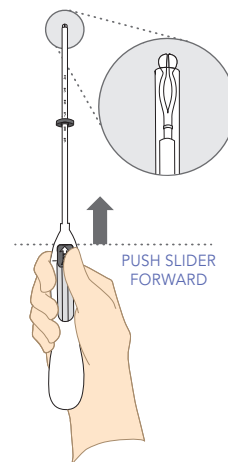
First, open the sterile package completely. Then use aseptic technique and sterile gloves.



2

LOAD KYLEENA® INTO THE INSERTION TUBE

Push the slider in the direction of the arrow to the furthest position to load Kyleena® into the insertion tube.



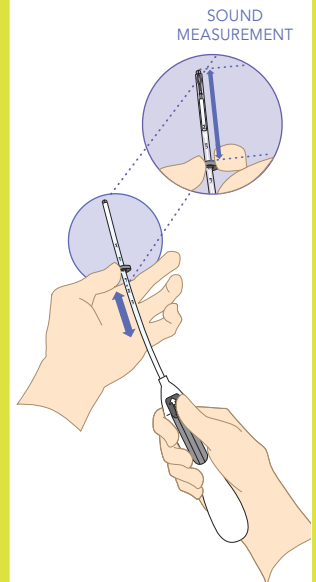
Important!

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

3

SET THE FLANGE

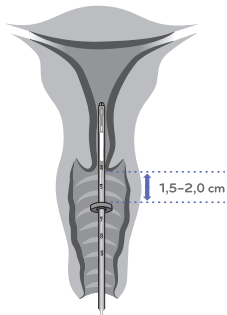
Holding the slider in the furthest position, set the **upper** edge of the flange to correspond to the sound measurement of the uterine depth.



4

ADVANCE THE INSERTER THROUGH THE CERVIX

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.



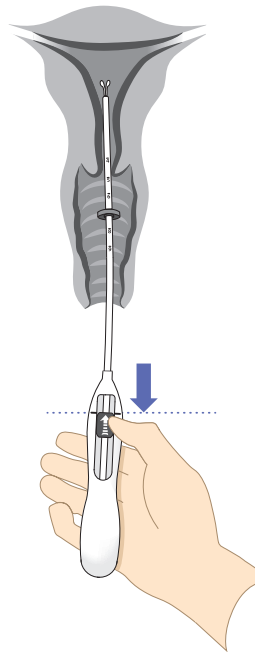
Important!

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

5

OPEN THE ARMS

While holding the inserter steady, **pull the slider to the mark** to open the horizontal arms of Kyleena®.



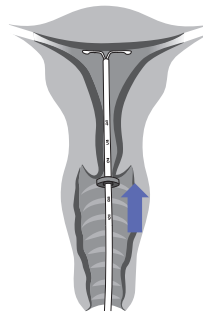
Important!

Wait 5–10 seconds for the horizontal arms to open completely.

6

ADVANCE TO THE FUNDAL POSITION

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

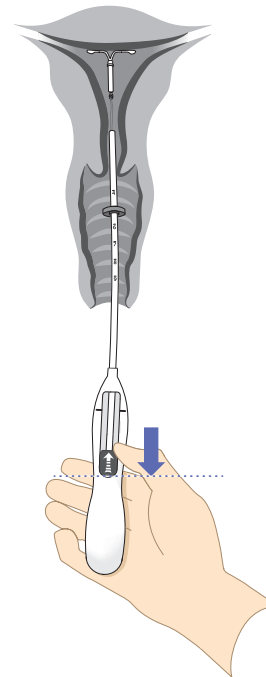


7

RELEASE AND WITHDRAW THE INSERTER

Holding the inserter in place, release Kyleena® 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.



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. If there is clinical concern, exceptional pain or bleeding during or after insertion, appropriate steps (such as physical examination and ultrasound) should be taken immediately to exclude perforation.

KYLEENA® – THE 5-YEAR, LOW DOSE OPTION

0.29 LOWEST DAILY
HORMONE DOSE

5-years Pearl Index^{2*} available in a 5-year IUS^{2,3}

SMALL T-BODY WITH
A NARROW, FLEXIBLE
INSERTION TUBE^{2,4,5}



Upon removal women usually return to their
normal fertility²

* Year 1 Pearl Index: 0.16 (95% CIs 0.02–0.58). 5-years Pearl Index: 0.29 (95% CIs 0.16–0.50). The failure rate was approximately 0.2% at 1 year. The cumulative failure rate was approximately 1.4% at 5 years.

1. Kyleena® Insertion Instructions. 2. Kyleena® Professional Information, Nov 2017. 3. Mirena® Professional Information, June 2019. 4. Nelson A *et al.* *Obstet & Gynecol* 2013;122:1205-1213. 5. Kyleena® Patient Information Leaflet. 23 November 2017.

S4 Kyleena® Levonorgestrel intrauterine system. ch sterile intrauterine system contains levonorgestrel 19.5mg. RSA Reg. No.: 47 /32.9/0037. Namibia: NS1 Reg. No.: 23/32.9/0012.

For full prescribing information, please refer to the Professional Information approved by the SAHPRA.

Bayer (Pty) Ltd, Reg. No. 1968/011192/07.
Scan the QR code for the MAH/HCR address
Tel: 011 921 5000.

www.bayer.co.za



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