

Differentiation of Mirena, Jaydess▼ and Kyleena



Overview

Kyleena is an intrauterine delivery system (IUS), containing 19.5 mg levonorgestrel (LNG), and is indicated for contraception for up to 5 years.

Until now the following Bayer IUS have been authorised to be marketed in the United Kingdom:

- **Jaydess**, 13.5 mg levonorgestrel (LNG)
- **Mirena**, 52 mg levonorgestrel (LNG).

There are differences between these 3 products:

Indication of use and treatment duration

- Mirena is licensed in the indications of:
 - Contraception for up to 5 years
 - Idiopathic menorrhagia for up to 5 years
 - Endometrial protection during oestrogen replacement therapy for up to 4 years
- Jaydess is licensed in the indication of contraception for up to 3 years
- Kyleena is licensed in the indication of contraception for up to 5 years

Pharmaceutical form and release rate

- All three IUS are T shaped devices that are placed within the uterine cavity and provide a continuous release of levonorgestrel. The insertion technique for placement of all three IUS is identical.
- Estimated average *in vivo* LNG release rates for all 3 products are summarised in Table 1 below:

Table 1: Average *in vivo* LNG release rates ($\mu\text{g}/\text{day}$) of the 3 LNG-IUS

	Mirena	Jaydess	Kyleena
Initial Release*	20	14	17.5
2 months	n/c	10	15
1 year	n/c	6	10
End of indicated period of use**	10	5	7

* For Jaydess and Kyleena determined on Day 25 post insertion, for Mirena determined shortly after insertion

** For Jaydess 3 years, for Kyleena and Mirena 5 years

n/c Not calculated

Physical Appearance

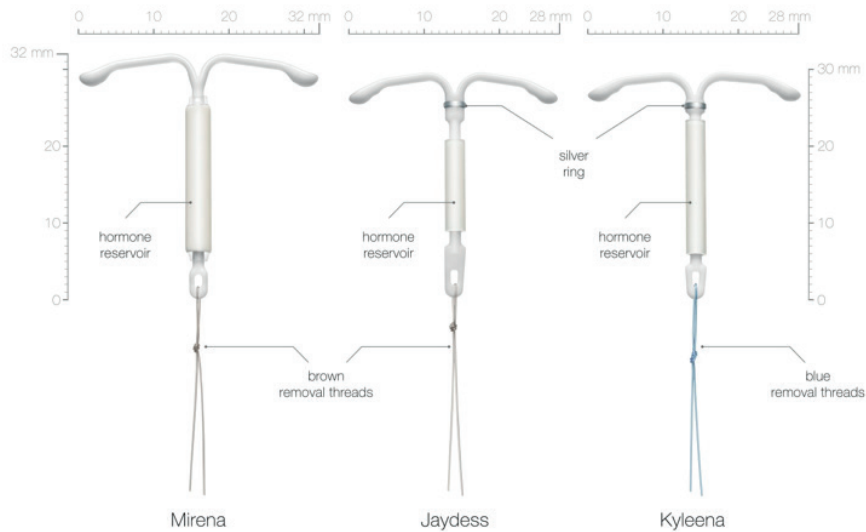


Figure 1: Physical appearance of Mirena, Jaydess and Kyleena.

- Jaydess and Kyleena are visually very similar. The upper end of the vertical stem of the T-body contains a silver ring for ultrasound identification and the T-body dimensions as well as the insertion tube diameter are smaller compared to Mirena (for dimensions see Figure 1 and Table 2).

The most prominent differences between these two products are:

- The hormone reservoir around the stem of the T-body is longer for Kyleena compared to Jaydess.
- Jaydess: *Brown* coloured removal threads are attached to the loop at the end of the T-body stem.
- Kyleena: *Blue* coloured removal threads are attached to the loop at the end of the T-body stem.
- Mirena has no silver ring and the T-body dimensions as well as the insertion tube diameter are bigger compared to Jaydess and Kyleena. *Brown* coloured removal threads are attached to the loop at the end of the T-body stem.

X-ray and Ultrasound Images

- The T-body of all three IUS contains barium sulphate which makes it visible in X-ray examination.
- Jaydess and Kyleena can be differentiated from Mirena by the silver ring that is visible in ultrasound.
- A distinction between Jaydess and Kyleena *in situ* on ultrasound is not possible. They can be distinguished by the different colour of the removal threads visible at the cervical os (see above).

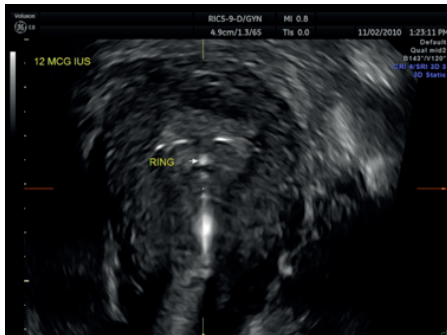


Figure 2: Jaydess – transverse plane (3D Imaging)

Source: Andrew Kaunitz, MD, Christine Bubier R.T.(R). RDMS, Grace Horton, RDMS and Gwyn Grabner, RDMS

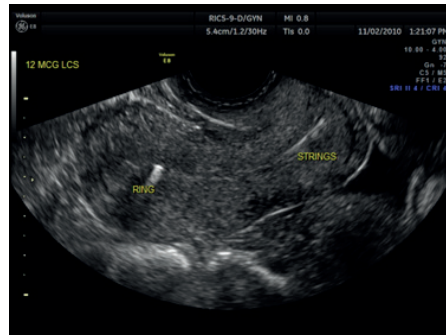


Figure 3: Jaydess – sagittal plane (2D Imaging)

Source: Andrew Kaunitz, MD, Christine Bubier R.T. (R). RDMS, Grace Horton, RDMS and Gwyn Grabner, RDMS

Please note, above pictures show Jaydess.
There is no difference in ultrasound imaging between Jaydess and Kyleena.

- Mirena has no silver ring

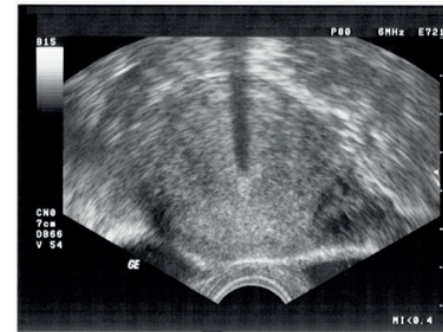


Figure 4: Mirena – transverse plane (2D Imaging)

Source: Dr. Armin Soder, Ettlingen, Germany

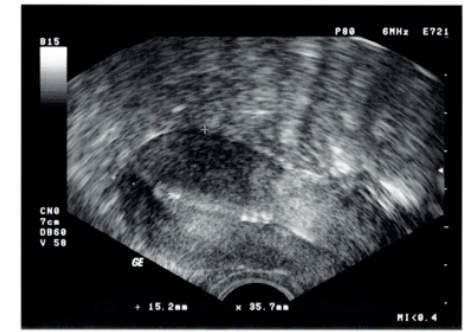


Figure 5: Mirena – sagittal plane (2D Imaging)

Source: Dr. Armin Soder, Ettlingen, Germany

Summary

Mirena can be distinguished from Jaydess and Kyleena by the combination of the absence of a silver ring and the brown colour of the removal threads. Mirena can be used for up to 5 years in the indication contraception and for the treatment of idiopathic menorrhagia. Mirena can also be used for endometrial protection during oestrogen replacement therapy, for up to 4 years.

Jaydess can be distinguished from Mirena and Kyleena by the combination of the visibility of the silver ring on ultrasound and the brown colour of the removal threads. Jaydess can be used for up to 3 years in the indication contraception.

Kyleena can be distinguished from Mirena and Jaydess by the combination of the visibility of the silver ring on ultrasound and the blue colour of the removal threads. Kyleena can be used for up to 5 years in the indication contraception.

The T-body of all three IUS contains barium sulphate which makes it visible in X-ray examination.

Table 2: Overview over the differences between the 3 Bayer LNG-IUS

	Mirena	Jaydess	Kyleena
Total LNG content [mg]	52	13.5	19.5
Maximum duration of use [years]	5	3	5
T-frame dimensions [mm]	32 x 32	28 x 30	28 x 30
Insertion tube diameter [mm]	4.40	3.80	3.80
Silver ring for improved visibility on ultrasound	no	yes	yes
Colour of removal threads	Brown	Brown	Blue

▼ Jaydess is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare Professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard



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