



Differentiation of Kyleena, Jaydess and Mirena intrauterine delivery systems (Levonorgestrel)



Kyleena is a newly approved 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 authorized to be marketed in Ireland:

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

There are differences between these 3 products:

Indication of use and treatment duration

- Kyleena is licensed in the indication of contraception for up to 5 years
- Jaydess is licensed in the indication of contraception for up to 3 years
- Mirena is licensed in the indication of contraception for up to 5 years. Mirena is also licensed for the treatment of idiopathic menorrhagia and for protection from endometrial hyperplasia during estrogen replacement therapy 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.

Physical Appearance

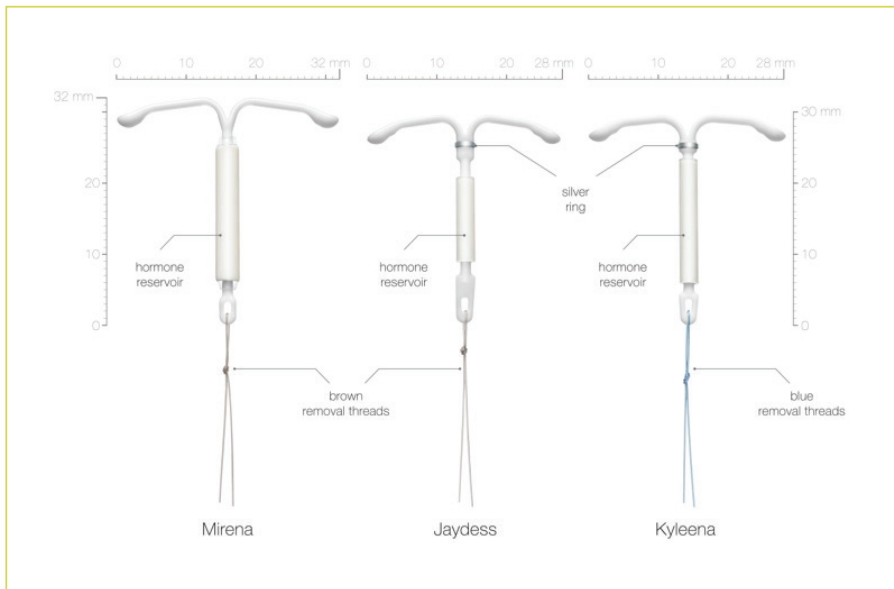


Figure 1: Physical appearance of Mirena, Jaydess, and Kyleena

Jaydess and Kyleena are visually very similar. The upper end of the vertical stem of the T-body contains a silver ring for ultrasound (US) 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 1).

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 per ultrasound is not possible. They can be distinguished by the different colour of the removal threads visible at the cervical os (see above).

Jaydess Ultrasound Images:



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

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

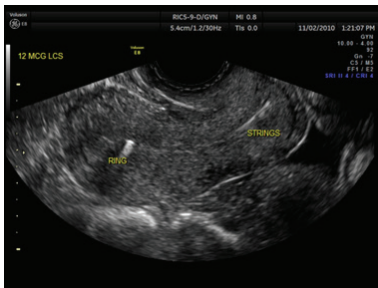


Figure 3: Jaydess – sagittal plane (2D Imaging)

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

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

Mirena Ultrasound Images:

Mirena has no silver ring

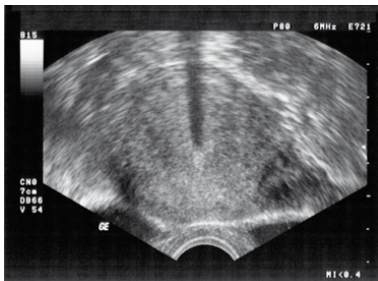


Figure 4: Mirena – transverse plane (2D Imaging)

Source: Dr. Armin Soder, Ettlingen, Germany

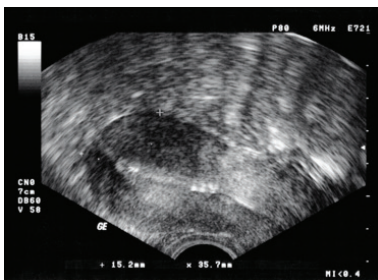


Figure 5: Mirena – sagittal plane (2D Imaging)

Source: Dr. Armin Soder, Ettlingen, Germany

Summary

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 of contraception.

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 of contraception.

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 of contraception. Mirena can also be used for the treatment of idiopathic menorrhagia and for protection from endometrial hyperplasia during estrogen replacement therapy, for up to 5 years.

Table 1: Overview of 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 in US	no	yes	yes
Colour of removal threads	brown	brown	blue

Local Safety Information

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: **+353 1 676 4971** Fax: **+353 1 676 2517** Website: www.hpra.ie e-mail: medsafety@hpra.ie

Adverse events or quality complaints should also be reported to Bayer Limited Drug Safety on **01-299 9313** or alternatively by email at adr-ireland@bayerhealthcare.com

Bayer Ltd., The Atrium, Blackthorn
Road, Sandyford, Dublin 18.

Tel: 01 299 9313

L.IE.MKT.10.2016.0714
