

FPAA has adopted the recommendation of the Faculty of Sexual & Reproductive Healthcare (UK) that the use of Mirena, and any 52mg levonorgestrel intrauterine device (LNG-IUD), can be extended to up to 6 years for contraception. (1) This recommendation is off-label, as currently Mirena is licenced for 5 years in Australia.(2)

There is no change in the pre-existing recommendations for those who have a Mirena inserted at age 45 years or older, where extended off-label use for contraception is acceptable until menopause or age 55 years (i.e. up to 10 years). (1, 3)

Extended use is not recommended for:

- those using Mirena for heavy menstrual bleeding or as part of menopausal hormone therapy.
- Kyleena, the 19.5mg LNG-IUD.

Rationale for change

There are several versions of the 52mg LNG-IUD available internationally with a licensed duration of use longer than 5 years for contraception. Levosert and Benilexa, available in the United Kingdom, are licenced for 6 years. (4, 5) Mirena continues to be licensed for 5 years in the UK and Australia and is licensed for 8 years in the USA and Europe. (2, 6-8)

The failure rate for the 52 mg LNG-IUD over 5 years is estimated to be less than 0.1 per 100 person years of use. (9) Several studies have shown a low contraceptive failure rate during the 6th and 7th year of use of the 52 mg LNG-IUD, Mirena. (10-13) A metaanalysis of these studies including around 2000 users, demonstrated a similar pregnancy rate to studies of Mirena over 5 years of use. (14)

Evidence for contraceptive efficacy up to 8 years

Although evidence supports efficacy of Mirena in preventing pregnancy for up to 8 years of use, the studies are small, and this extra extension of use is not currently recommended in Australia.

A recent small single arm study of 233 Mirena users who completed 8 years of use found an overall failure rate of 0.28 per 100 person years for years 6-8 of use with no pregnancies during the 8th year of use. (15) Although this rate is slightly higher than the pregnancy rate for Mirena over 5 years, this data supported a successful application for extended use of Mirena for up to 8 years for contraception in the USA. (7) A study of 343 women who completed 8 years of use of a 52mg LNG-IUD, Liletta (not available in Australia), showed no pregnancies during the 6th and 8th year of use, with 2 pregnancies occurring in the 7th year of use, giving an overall pregnancy rate similar to the 8 year extended use studies of Mirena. (16)

Extended use is further supported by a pharmacokinetic study that showed the release of levonorgestrel at the end of 8 years use of Mirena is similar to the release of levonorgestrel in the 19.5 mg LNG-IUD at 5 years. (17)

Updated advice about replacing hormonal IUDs		
Switching from	Switching to	Considerations
Mirena in situ < 6 years Kyleena in situ < 5 years	New hormonal or copper IUD	Can be changed without additional contraceptive precautions. Ideally abstain or use condoms for 7 days prior to change in case new device cannot be inserted.
Mirena in situ 6-7 years		Can change if pregnancy test negative on day of re-placement. Ideally abstain or use condoms for 7 days prior to change in case new device cannot be inserted. Use condoms for 7 days if new hormonal IUD inserted and repeat pregnancy test after 1 month.
Mirena in situ > 7 years Kyleena in situ > 5 years		Exclude pregnancy as you would if no IUD in situ (i.e., a negative pregnancy test after at least 3 weeks of either no sex or using an additional contraceptive method). Follow usual contraceptive precautions as you would if starting a new IUD (i.e., use condoms for 7 days if a hormonal IUD is inserted).

References

1. FSRH Guidance Intrauterine Contraception March 2023: Faculty of Sexual & Reproductive Healthcare Statement. Clinical Effectiveness Unit; 2023 [cited 2023 17 May]. Available from: <https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/1fsrh-clinical-guideline-intrauterine-contraception-mar23-6-.pdf>.
2. Mirena. Australian approved product information. Bayer Australia Ltd. Updated 20 September 2021.
3. Contraception [published 2020 December]. In: eTG complete [digital]. Melbourne: Therapeutic Guidelines Limited; [cited 2021 January]. Available from: <https://www.tg.org.au>. ETG; 2020.
4. Benilexa. UK approved product information. Gedeon Richter. Updated January 2023.
5. Levosert. UK approved product information. Gedeon Richter. Updated July 2022.
6. Mirena. UK approved product information. Bayer Australia PLC. Updated August 2022.
7. Mirena. USA approved product information. Bayer HealthCare Pharmaceuticals Inc. Updated August 2022.
8. Mirena® approved in Europe for extended duration of use in contraception: Bayer Global; [cited 2023 June]. Available from: <https://www.bayer.com/media/en-us/mirena-approved-in-europe-for-extended-duration-of-use-in-contraception/>.
9. Heinemann K, Reed S, Moehner S, Minh TD. Comparative contraceptive effectiveness of levonorgestrel-releasing and copper intrauterine devices: the European Active Surveillance Study for Intrauterine Devices. *Contraception*. 2015;91(4):280-3.
10. Ronnerdag M, Odland V. Health effects of long-term use of the intrauterine levonorgestrel-releasing system. A follow-up study over 12 years of continuous use. *Acta Obstet Gynecol Scand*. 1999;78(8):716-21.
11. Rowe P, Farley T, Peregoudov A, Piaggio G, Boccard S, Landoulsi S, et al. Safety and efficacy in parous women of a 52-mg levonorgestrel-medicated intrauterine device: a 7-year randomized comparative study with the TCu380A. *Contraception*. 2016;93(6):498-506.
12. McNicholas C, Maddipati R, Zhao Q, Swor E, Peipert JF. Use of the etonogestrel implant and levonorgestrel intrauterine device beyond the u.s. Food and drug administration-approved duration. *Obstet Gynecol*. 2015;125(3):599-604.
13. Bahamondes L, Fernandes A, Bahamondes MV, Juliato CT, Ali M, Monteiro I. Pregnancy outcomes associated with extended use of the 52-mg 20 mug/day levonorgestrel-releasing intrauterine system beyond 60 months: A chart review of 776 women in Brazil. *Contraception*. 2018;97(3):205-9.
14. Ti AJ, Roe AH, Whitehouse KC, Smith RA, Gaffield ME, Curtis KM. Effectiveness and Safety of Extending Intrauterine Device Duration: A Systematic Review. *American Journal of Obstetrics and Gynecology*. 2020.
15. Jensen JT, Lukkari-Lax E, Schulze A, Wahdan Y, Serrani M, Kroll R. Contraceptive efficacy and safety of the 52-mg levonorgestrel intrauterine system for up to 8 years: findings from the Mirena Extension Trial. *Am J Obstet Gynecol*. 2022.
16. Creinin MD, Schreiber CA, Turok DK, Cwiak C, Chen BA, Olariu AI. Levonorgestrel 52 mg intrauterine system efficacy and safety through 8 years of use. *Am J Obstet Gynecol*. 2022.
17. Jensen JT, Reinecke I, Post TM, Lukkari-Lax E, Hofmann BM. Extended use of levonorgestrel-releasing intrauterine system (LNG-IUS) 52 mg: A population pharmacokinetic approach to estimate in vivo levonorgestrel release rates and systemic exposure including comparison with two other LNG-IUSs. *Contraception*. 2023;109954.



familyplanningallianceaustralia.org.au

The Medical Advisory Committee of Family Planning Alliance Australia is comprised of senior medical educators, senior medical officers and medical directors of the member family planning organisations. The Clinical Reference Group of the Medical Advisory Committee exists as a means to review current clinical practice and provide evidence based recommendations for use by sexual and reproductive health practitioners where clinical guidance is lacking.

© Family Planning Alliance Australia. July 2023

Family Planning Alliance Australia has taken every care to ensure that the information contained in this publication is accurate and up-to-date at the time of being published. As information and knowledge is constantly changing, readers are strongly advised to confirm that the information complies with present research, legislation and policy guidelines. FPAA accepts no responsibility for difficulties that may arise as a result of an individual acting on this information and any recommendations it contains.

State / Territory sexual health and family planning organisations



Western Australia

SHQ (Sexual Health Quarters)
shq.org.au



Northern Territory

Family Planning Welfare
Association of NT
fpwnt.com.au



South Australia

SHINE SA
shinesa.org.au



Queensland

True
true.org.au



ACT

Sexual Health and Family
Planning ACT
shfpact.org.au



Victoria

Sexual Health Victoria
shvic.org.au



Tasmania

Family Planning Tasmania
fpt.asn.au