

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).

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