SCHOOL OF MEDICINE
DEPARTMENT OF OBSTETRICS & GYNECOLOGY

STANDARD OPERATING PROCEDURES- GUIDELINE

EXTENDED USE OF LONG-ACTING REVERSIBLE CONTRACEPTION

SCOPE/APPLICABILITY:

This standard operating procedure covers use of long acting reversible contraception (LARC) methods beyond current FDA-approved duration.

CONSIDERATIONS:

FDA guidelines and product package inserts state the following approved durations of use:

- The Copper T380A intrauterine device (IUD) (Paragard) – 10 years
- The 52 mg levonorgestrel intrauterine system (LNG IUS) (Liletta) – 8 years
- The 52 mg LNG IUS (Mirena) – 8 years
- The 19.5 mg LNG IUS (Kyleena) – 5 years
- The 13.5 mg LNG IUS (Skyla) – 3 years
- The etonogestrel implant (Nexplanon) – 3 years

Evidence demonstrates that some of these devices remain highly successful at prevention of pregnancy beyond these durations.

SUMMARY:

- A Copper T380A IUD (Paragard) may be continued for a total duration of **12 years**.
- People who elect placement of a Copper T380A IUD (Paragard) after age 35 can rely on this method through menopause.
- A 52 mg LNG IUS (Liletta, Mirena) may be continued for a total duration of **8 years**.
- There is no evidence to recommend continuing the 13.5 mg or 19.5 mg LNG IUSs (Skyla or Kyleena) beyond their FDA-approved durations of use.
- The etonogestrel implant (Nexplanon) may be continued for **5 years** for all users, regardless of BMI.

EVIDENCE:

Copper T380A IUD (ParaGard ®)

The copper IUD is highly effective, with a failure rate of 0.8 per 100 women (around 1%) in the first year of use. It is the only hormone-free LARC method and functions by dissolution of copper ions, acting as a spermicide through a sterile inflammatory process. The T380A Copper IUD remains extremely effective at prevention of pregnancy with a cumulative pregnancy rate at year 12 of 2.2 per 100 woman years of observation (around 2%). Additionally, the pregnancy rate in years 10-12 was observed to be zero, meaning that most failures likely occur earlier in use. (1)

For these reasons, a patient may be counseled:

- *A Copper T380A IUD may be continued for a total duration of 12 years and,*
- *People who elect placement of the device after age 35 can rely on this method through menopause.*

52 mg LNG IUS (Liletta, Mirena)

The 52 mg LNG IUS is highly effective, with a failure rate of 0.2 per 100 (around 0.2%) in the first year of use. The LNG diminishes menstrual bleeding and has similar primary mechanisms of action as the copper IUD, in addition to causing endometrial suppression and thickening of cervical mucus. The effectiveness of the 52mg LNG IUS through 8 years of use is 0.49 per 100 woman years, making it more effective than the copper IUD. (2,3)

For these reasons, a patient may be counseled:

- *A 52 mg LNG IUS may be continued for a total duration of 8 years.*

There are currently two brands of 52 mg LNG IUSs available: Mirena and Liletta; the dose and hormone release rates of Mirena and Liletta are the same. The FDA has approved both devices for continuing use to 8 years.

There is no evidence to recommend continuing the 13.5 mg or 19.5 mg LNG IUSs (Skyla or Kyleena) beyond their FDA-approved durations of use.

Etonogestrel Implant (Nexplanon)

The contraceptive implant is highly effective with a failure rate around 0.5% in the first year of use. It primarily functions by suppression of ovulation but also causes endometrial suppression and cervical mucus thickening. The observed cumulative 5 year pregnancy rate of the contraceptive implant is 0.6 per 100 woman years, but participants in this study had a mean BMI of 23.9 kg/m^2 (4). A different study found a cumulative 5 year pregnancy rate of zero, with no reduced efficacy in overweight and obese patients and no differences in etonogestrel levels regardless of BMI (5). Therefore, obese patients appear to maintain hormone levels high enough to suppress ovulation throughout 5 years of use and experience similar contraceptive efficacy.

For these reasons, a patient may be counseled:

- *The etonogestrel implant may be continued for 5 years for all users, regardless of BMI.*

REFERENCES:

1. Wu JP, Pickle S. Extended use of the intrauterine device: a literature review and recommendations for clinical practice. Contraception 2014 Jun;89(6):495–503.

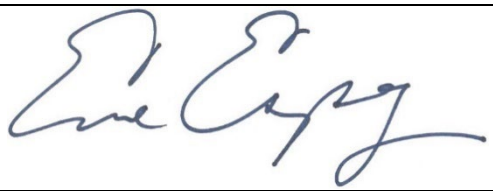
2. Creinin MD, Schreiber CA, Turok DK, Cwiak C, Chen BA, Olariu AI. Levonorgestrel 52 mg intrauterine system efficacy and safety through 8 years of use. Am J Obstet Gynecol 2022;XX:x.ex-x.ex.

3. 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 Jun;93(6):498–506.

4. Ali M, Akin A, Bahamondes L, Brache V, Habib N, Landoulsi S, et al. Extended use up to 5 years of the etonogestrel-releasing subdermal contraceptive implant: comparison to levonorgestrel-releasing subdermal implant. Hum Reprod Oxf Engl 2016 Nov;31(11):2491–8.

5. McNicholas C, Swor E, Wan L, Peipert JF. Prolonged use of the etonogestrel implant and levonogestrel intrauterine device: 2 years beyond Food and Drug Administration-approved duration. Am J Obstet Gynecol 2017;216:586.e1-6.

APPROVALS:

SOP Owner:	Lisa Hofler, MD	Date: 11/16/2022
Chair Approval:		Date: 11/16/2022
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