



Addressing Extended Long Acting Reversible Contraceptive (LARC) Use With Your Patients

Clinical research demonstrates that LARC use, including implants and intrauterine devices (IUDs), beyond the Food and Drug Administration (FDA) approved duration is safe and effective. Providing your patient this option can offer greater convenience as they are allotted more time before needing to have the device removed and replaced.

I. LARC Options

	Mirena® (LNg 52/5)	Liletta® (LNg 52/3)	Kyleena® (LNg 19.5/5)	Skyla® (LNg 13.5/3)	ParaGard® (TCu380A)	NEXPLANON® (ENG Implant)
Size	32mm x 32mm	32mm x 32mm	28mm x 30mm	28mm x 30mm	32mm x 36mm	4cm x 2mm
Manufacturer	Bayer	Medicines 360	Bayer	Bayer	TEVA	Merck
Insertion Device Diam.	4.4mm	-	3.8mm	3.8mm	4.0mm	-
Hormone Reservoir	52mg Levonorgestrel	52mg Levonorgestrel	19.5mg Levonorgestrel	13.5mg Levonorgestrel	380mm ² of Copper Surface area	68mg Etonogestrel
Release Rate	Initial → 5 years 20mcg/day → 10-14mcg/day	Initial → 6 years 20mcg/day → 8.6mcg/day	Initial → 5 years 17.5mcg/day → 7mcg/day	Initial → 3 years 14mcg/day → 5mcg/day		Initial → 3 years 60-70mcg/day → 25-30mcg/day
Plasma Concentration	~180 pg/mL at 1 year	~170 pg/mL at 1 year	~200 pg/mL at 1 year	~77 pg/mL at 1 year		~200pg/mL at 1 year
Duration of Action	FDA approved for 5 years	FDA approved for 6 years	FDA approved for 5 years	FDA approved for 3 years	FDA approved for 10 years	FDA approved for 3 years
Amenorrhea	44% of users at 6 months 50% of users at 1 year 50% of users at 3 years	-% of users at 6 months 19% of users at 1 year 38% of users at 3 years	5% of users at 6 months 12% of users at 1 year 20% of users at 3 years	3% of users at 6 months 6% of users at 1 year 12% of users at 3 years	At 3 months: 63% have more cramping, 71% have increased bleeding volume, 4% have increased bleeding frequency At 6 months: 14%, 19%, and 13%, respectively	Infrequent: 33.6%* Amenorrhea: 22.2%* Prolonged: 17.7%* Frequent: 6.7%* %* = percent of 90-day intervals with this bleeding pattern
Irregular Bleeding	25% of users at 6 months 11% of users at 1 year -% of users at 3 years	Unknown	25% of users at 6 months 17% of users at 1 year 10% of users at 3 years	28% of users at 6 months 23% of users at 1 year -% of users at 3 years		
Unique Features	Can be used as Emergency Contraception within 120 hours of unprotected sex ¹ FDA approved for treatment of heavy menstrual bleeding Contains Barium-Sulfate for radio-opacity	Can be used as Emergency Contraception within 120 hours of unprotected sex ¹ Contains Barium-Sulfate for radio-opacity Essentially the same device as Mirena®, except for the price		Silver ring for ID via U/S Contains Barium-Sulfate for radio-opacity	Can be used as Emergency Contraception within 120 hours of unprotected sex Barium-containing for radio-opacity	Subdermal Implant Contains Barium-Sulfate for radio-opacity
Government Pricing	\$524.15	\$316.42	\$518.83	\$341.45	\$405.43	\$581.94

¹ New England Journal of Medicine, Levonorgestrel vs. Copper Intrauterine Devices for Emergency Contraception, 2021 (<https://www.nejm.org/doi/full/10.1056/NEJMoa2022141>)



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2. Extended LARC Use

If the patient has chosen NEXPLANON®, Paragard®, or Mirena®, **share the clinical research indicating that use beyond the FDA-approved duration for these devices is safe and effective.** Tell the patient they have the choice to use their LARC for an extended duration in line with research summarized in the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin¹ and clinical practices by large centers that provide contraception such as Planned Parenthood.

Name of LARC	FDA-Approved Duration	Extended Duration
NEXPLANON® (Etonogestrel single rod implant)	3 years	4-5 years
Paragard® (Copper T380A IUD)	10 years	12 years
Mirena® (Levonorgestrel 52 mg IUD)	5 years	7 years
Liletta® (Levonorgestrel 52 mg IUD)	6 years	N/A
Kyleena® (Levonorgestrel 19.5 mg IUD)	5 years	N/A
Skyla® (Levonorgestrel 13.5 mg IUD)	3 years	N/A

3. Counseling Your Patient on Extended LARC Use

Counsel the patient on the benefits and risks of extended use of the LARC device:

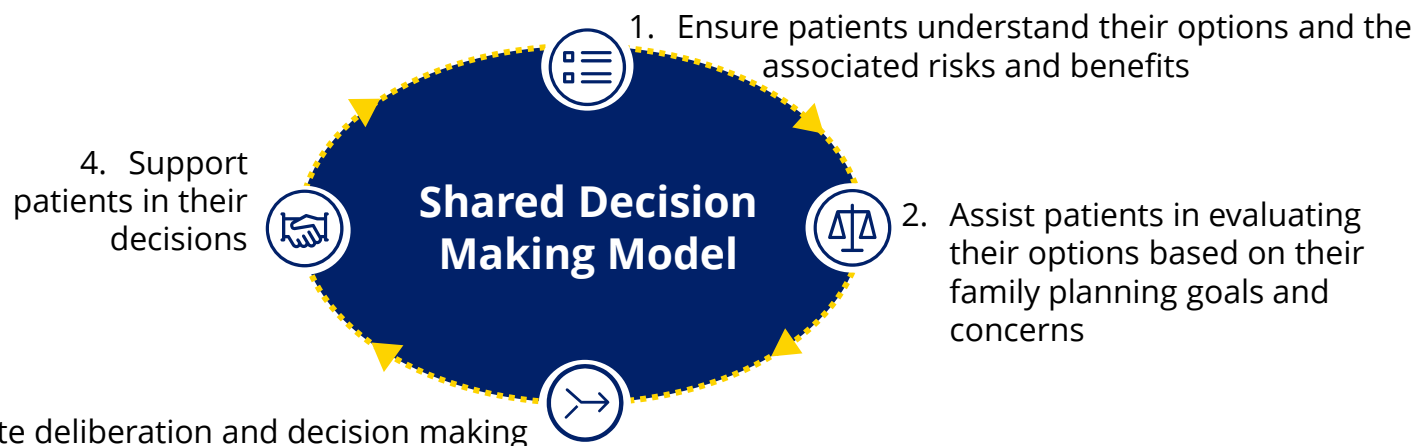
BENEFITS

- Patient gains additional time before needing to remove device through intrauterine procedure
- Cost-saving
- Prolongation of contraception

RISKS

- Progestin levels slightly decline over time
- Increasing likelihood of spotting and breakthrough bleeding

SHARED DECISION MAKING: Make the decision for extended use in partnership with the patient using a shared decision making model:



¹ Practice bulletin number 186, November 2017 "Long-Acting Reversible Contraception: Implants and Intrauterine Devices" ²UpToDate



Extended LARC Use: Guidance Continued

3. Clinical Background on Extended LARC Use

Extended Use: Levonorgestrel (LNg) IUDs

LNg-releasing IUDs are available in three different formulations in the United States.

Commercial Name	Mirena®	Liletta®	Kyleena®	Skyla®
Amount of LNg	52 mg	52 mg	19.5 mg	13.5 mg
Release Rate	20 mcg/day, declines to 10 mcg/day at 5 years	20 mcg/day, declines to 8.6 mcg/day at 6 years	17.5 mcg/day, declines to 7.4 mcg/day at 5 years	14 mcg/day, declines to 5 mcg/day at 3 years
FDA-Approved Duration	5 years	6 years	5 years	3 years

After five years of use, both the Liletta® and Mirena® IUDs release approximately double the amount of levonorgestrel as the Skyla® IUD releases after three years, which suggests that **both the Mirena® and Liletta® IUDs can be used beyond five years.**²

- In a prospective cohort study of nearly 500 women with extended use of 52 mg LNg IUDs, two pregnancies were reported during the two year extended observation, for six- and seven-year cumulative failure rates of 0.25 and 0.43 per 100 woman-years.²
- A different chart review of 766 women who used Mirena® or Liletta® IUDs beyond five years reported no pregnancies after a mean of 73 months of use (range 61 to 184 months).²
- According to clinical research, Mirena® is effective for at least 7 years, with a 7 year pregnancy rate of 0.5 per 100 women.¹

Kyleena® and Skyla® have a lower LNg dose, and there is no evidence supporting extended use of these IUDs.²

Extended Use: Copper IUD

The copper IUD is **approved by the FDA to remain in place for 10 years**; however, **some clinicians use the copper IUD for more than 10 years**. Extended use of the copper IUD is supported by several studies.

- In two studies of 314 women who used the copper IUD for an additional two years (10 to 12 years from insertion), no pregnancies were reported.²
- Additionally, no pregnancies were reported in the subgroup of eight women who used the device for up to 16 years.²

Extended Use: Etonogestrel (ENG) Implant

In clinical studies, extended use of the one-rod ENG-releasing subdermal contraceptive implant (commercial name NEXPLANON®) showed **100% efficacy in years 4 and 5.**³

- Serum ENG levels indicate the implant contains adequate hormone for ovulation suppression at the end of both 3 and 4 years of use.³
- In one study with 123 women using the ENG implant for 4 years and 34 using it for 5 years, zero pregnancies were documented, for a failure rate of 0 (one-sided 97.5% confidence interval [CI] 0-1.61) per 100 women-years.³