

## **Levonorgestrel-Releasing Intrauterine Devices (LNg IUDs)**

**Note:** Since many questions concerning LNg IUDs have the same answers as for non-hormonal IUDs, please see Copper-Bearing Intrauterine Devices for answers to the following questions:

What is an appropriate follow-up schedule after IUD insertion?

1. Is there a need for a routine pre-exam (a separate visit) before IUD insertion?
2. Is there a minimum or maximum age to receive IUDs?
3. Can nulliparous women receive IUDs?
4. Is there a need for a "rest period" with IUDs after a certain period of use?
5. If a woman is at low risk of sexually transmitted diseases (STDs) based on history, may IUDs be inserted without any lab tests if there is not mucopurulent endocervical discharge or clinically apparent pelvic inflammatory disease or cervicitis?
6. Should an IUD be removed if the partner complains about the string?
7. If the cervix is red due to eversion of the squamo-columnar junction (ectopy/ectropion), may the IUD be inserted without further investigation?
8. Can IUDs be safely inserted by trained nurses and midwives?
9. How much time should elapse between STD treatment and insertion? What about previous STD incidence?
10. Should IUDs be provided if infection prevention measures cannot be followed?
11. Following removal of an LNg IUD (for reasons of partial expulsion without infection, or expiration of IUD), should one wait to insert another?

## **Lng - IUD: Levonorgestrel-20 IUDs**

The levonorgestrel-20 IUD (LNg IUD) releases about 20 micrograms of levonorgestrel into the uterine cavity daily, leading to:

1. highly effective contraception rates (comparable to female sterilization) for five to seven years;
2. decreased blood loss compared to other IUDs, and decreased blood loss for women with a history of heavy menses (although the mean number of bleeding days is higher than normal for the first few months, it becomes lower than normal by six to eight months of using the levonorgestrel IUD, with improvement in anemia due to menstrual blood loss);
3. improvement in dysmenorrhea in most women;
4. decreased risk for ectopic pregnancy; and
5. possible use as the progestin necessary for a menopausal woman on estrogen replacement therapy.

The levonorgestrel IUD works in at least three ways:

1. by causing a thick cervical mucus which inhibits the passage of sperm through the cervical canal;
2. by causing anovulation in about 25% women; and
3. by causing high levonorgestrel levels in the uterine cavity, which suppress estradiol receptors and produce an atrophic endometrium, and inhibit passage of sperm through the uterine cavity.

Serum levonorgestrel levels are low, thus reports of hormonal side effects are few; no difference between LNg IUDs versus other IUDs has been reported concerning weight, blood pressure or lipid or carbohydrate metabolism. Because pituitary suppression is not strong, the LNg IUD does **not** cause a hypoestrogenic state.

### **Citations:**

- 1) Luukkainen T, Toivonen J. Levonorgestrel-releasing IUD as a method of contraception with therapeutic properties. *Contraception* 1995;52:269-76.
- 2) Andersson K, Odling V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. *Contraception* 1994;49:56-72.
- 3) Intrauterine progestagen for effective contraception. *IPPF Medical Bulletin* 1992;26(4).
- 4) Hatcher RA. *The levonorgestrel-20 IUD (monograph)*. Atlanta: Emory University 1997.

## Q.1. When can an LNG IUD be inserted?

Recommendations	Rationale
<p>a) <b>In general?</b></p> <p>The LNG IUD may be inserted anytime during the menstrual cycle, at the user's convenience, when one can be reasonably sure the woman is not pregnant.</p> <p>b) <b>Postpartum for breastfeeding women?</b></p> <p>The insertion of the LNG IUD is not usually recommended in the first six weeks postpartum in breastfeeding women (WHO Category 3).</p>	<p>a) All IUDs are effective immediately and prevent pregnancy if inserted before implantation.</p> <p>1) Guillebaud J. Contraception: your questions answered. New York: Churchill Livingstone, 1993:293-366.</p> <p>b) The WHO Medical Eligibility Criteria list the use of LNG IUDs prior to four weeks postpartum as a Category 3 classification ("use of the method [is] not usually recommended unless other more appropriate methods are not available or acceptable"). Little research has been done on women initiating IUDs before six weeks. There is concern that breastfeeding infants may be at risk due to exposure to steroid hormones during the first six weeks postpartum. Levonorgestrel in maternal serum is low and infants receive only 0.1% of the maternal daily dose. Since there is virtually no risk of ovulating during the first six weeks postpartum in breastfeeding women, LNG IUDs may safely be begun after six weeks postpartum.</p> <p>1) World Health Organization. Improving access to quality care: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.</p> <p>2) Heikkila M, Haukkamaa M, Luukkainen T. Levonorgestrel in milk and plasma of breast-feeding women with a levonorgestrel-releasing IUD. Contraception 1982;25(1):41-9.</p> <p>3) Heikkila M, Luukkainen T. Duration of breast-feeding and development of children after insertion of a levonorgestrel-releasing intrauterine contraceptive device. Contraception 1982;25(3):279-92.</p> <p>4) Shikary ZK, Betrabet SS, Patel ZM, Patel S, Joshi JV, Toddywala VS, et al. Transfer of levonorgestrel (LNg) administered through different drug delivery systems from the maternal circulation into the newborn infant's circulation via breast milk. Contraception 1987;35(5):477-86.</p>

<b>Recommendations</b>	<b>Rationale</b>
<p><b>Postpartum for non-breastfeeding women?</b></p> <p>The insertion of the LNG IUD is not usually recommended in the first four weeks postpartum for non-breastfeeding women (WHO Category 3).</p> <p>The LNG IUD may be inserted at four weeks postpartum or any time beyond that when you can be reasonably sure the woman is not pregnant.</p> <p><b>c) Postabortion?</b></p> <p>The LNG IUD may be inserted immediately after a safe first-trimester abortion, in the absence of infection.</p>	<p>There is an increased risk of perforation for IUD insertions done after 48 hours and up to four weeks postpartum. The risk varies by the experience of the provider. There is little data on the local effects of LNG IUD on uterine involution.</p> <ol style="list-style-type: none"><li>1) Chi I, Farr G. Postpartum IUD contraception-a review of an international experience. <i>Advances in Contraception</i> 1989;5:127-46.</li><li>2) O'Hanley K, Huber D. Postpartum IUDs: keys for success. <i>Contraception</i> 1992;45:351-61.</li></ol> <p><b>c) Data exists only for first trimester legal abortions with no or treated cervical infections. The LNG IUD may be inserted immediately postabortion; however, as with any IUD insertion, the woman must be evaluated for the presence of infection.</b></p> <ol style="list-style-type: none"><li>1) Heikkila M, Lahteenmaki P, Luukkainen T. Immediate postabortal insertion of a levonorgestrel-releasing IUD. <i>Contraception</i> 1982;26(3):245-59.</li></ol>

## Q.2. Should the LNG IUD be discontinued because of extended amenorrhea or steroidal effects?

Recommendations	Rationale
<p>a) <b>Extended amenorrhea?</b></p> <p>No. Amenorrhea is expected and is not a medical reason for removal. Emphasis should be on counseling, including reassurance that amenorrhea with LNG IUDs is to be expected and is safe, as well as counseling on the benefits of amenorrhea.</p> <p>However, if the woman does wish to have the LNG IUD removed, her wishes should be respected.</p>	<p>a) The intrauterine release of levonorgestrel converts the endometrium to a nonproliferative stage, which is insensitive to ovarian estradiol. The result of this complete suppression of the endometrium is a sharp reduction of the duration of bleeding and menstrual blood loss. The reduction of bleeding is so intensive that in about 20% of women there is no bleeding at all in spite of completely normal ovarian function; therefore, amenorrhea is common and normal for women using LNG IUDs.</p> <p>Women who are well informed about the possibility of amenorrhea may consider it to be a convenience/advantage. Also, hemoglobin levels increase with LNG IUD use, thereby benefiting women with anemia.</p> <ol style="list-style-type: none"> <li>1) Andersson K, Odland V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. <i>Contraception</i> 1994;49(1):56-72.</li> <li>2) Xiao B, Zeng T, Wu S, Sun H, Xiao N. Effect of levonorgestrel-releasing intrauterine device on hormonal profile and menstrual pattern after long-term use. <i>Contraception</i> 1995;51(6):359-65.</li> <li>3) Sivin I, Stern J, Coutinho E, Mattos CE, el Mahgoub S, Diaz S, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNG 20) and the copper T 380 Ag IUDs. <i>Contraception</i> 1991;44(5):473-80.</li> </ol>
<p>b) <b>Steroidal effects?</b></p> <p>No. However, the LNG IUD should be removed if the client experiences intolerable or unacceptable side effects, attributable either to the IUD or to systemic steroidal effects.</p>	<p>b) Steroidal side effects such as acne, weight change, nausea, headache, have been found to be prevalent in Nordic countries. However, the gross discontinuation rate due to all of these side effects was only 2.7 per 100 women in a European multicenter study.</p> <ol style="list-style-type: none"> <li>1) Luukkainen, T, Allonen H, Haukkamaa M, Holma P, Pyoralala T, Terho J, et al. Effective contraception with the levonorgestrel-releasing intrauterine device: a 12-month report of a European multicenter study. <i>Contraception</i> 1987;36(2):169-79.</li> </ol>

### Q.3. Can an LNG IUD be used as a method of contraception for women with heavy menstrual bleeding?

Recommendations	Rationale
<p>Yes. The LNG IUDs can be used for treatment of women with heavy menstrual bleeding.</p>	<p>Lng IUDs decrease the menstrual blood loss (MBL) by about 80% at three months of use and by more than 95% at one year. With correct insertion, the LNG IUD does not cause prolonged or heavy bleeding. However, women should be told that in the first three months of use they may experience many days of spotting and bleeding.</p> <ol style="list-style-type: none"> <li>1) Luukkainen T, Allonen H, Haukkamaa M, Holma P, Pyorala T, Terho J, et al. Effective contraception with the levonorgestrel-releasing intrauterine device: a 12-month report of a European multicenter study. <i>Contraception</i> 1987;36(2):169-79.</li> <li>2) Andersson JK, Rybo G. Levonorgestrel-releasing intrauterine device in the treatment of menorrhagia. <i>British Journal of Obstetrics and Gynaecology</i> 1990;97(8):690-4.</li> <li>3) Milsom I, Andersson K, Andersch B, Rybo G. A comparison of flurbiprofen, tranexamic acid, and a levonorgestrel-releasing intrauterine device in the treatment of idiopathic menorrhagia. <i>American Journal of Obstetrics and Gynecology</i> 1991;164(3):879-83.</li> </ol> <p>The LNG IUD has also been used in treatment of menorrhagia. Reduction of MBL gives clients better iron balance and less anemia. The reduced bleeding can also relieve the symptoms of dysmenorrhea.</p> <ol style="list-style-type: none"> <li>1) Andersson JK, Rybo G. Levonorgestrel-releasing intrauterine device in the treatment of menorrhagia. <i>British Journal of Obstetrics and Gynaecology</i> 1990;97(8):690-4.</li> <li>2) Milsom I, Andersson K, Andersch B, Rybo G. A comparison of flurbiprofen, tranexamic acid, and a levonorgestrel-releasing intrauterine device in the treatment of idiopathic menorrhagia. <i>American Journal of Obstetrics and Gynecology</i> 1991;164(3):879-83.</li> <li>3) Faundes A, Alvarez F, Brache V, Tejada AS. The role of the levonorgestrel intrauterine device in the prevention and treatment of iron deficiency anemia during fertility regulation. <i>International Journal of Gynaecology and Obstetrics</i> 1988;26(3):429-33.</li> </ol>

**Q.4. Because LNG IUDs might protect against pelvic inflammatory disease (PID), does this change the IUD eligibility of women at risk of sexually transmitted diseases (STDs)?**

<b>Recommendations</b>	<b>Rationale</b>
<p>No. The evidence that LNG IUDs may protect against PID is not conclusive.</p> <p>The insertion of the LNG IUD is not usually recommended for women at increased risk of STDs or HIV, unless more appropriate methods are not available or are not acceptable. The LNG IUD should not be used in women with a current (or within the last three months) pelvic or sexually transmitted disease (STD). When there is a risk of STD or HIV, condoms should be recommended.</p>	<p>Evidence is conflicting as to a protective effect. One major study suggests that women using LNG IUDs have a lower risk of progression from STDs to PID, compared to users of copper IUDs. However, other major studies have not demonstrated a significant protection by LNG IUDs against PID. The preventive effect of LNG IUDs against PID is probably similar to the prevention provided by oral contraceptives (OCs).</p> <ol style="list-style-type: none"><li>1) Toivonen J, Luukkainen T, Allonen H. Protective effect of intrauterine release of levonorgestrel on pelvic infection: three years' comparative experience of levonorgestrel- and copper-releasing intrauterine devices. <i>Obstetrics and Gynecology</i> 1991;77(2):261-4.</li><li>2) Andersson K, Odland V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. <i>Contraception</i> 1994;49(1):56-72.</li><li>3) Sivin I, Stern J, Coutinho E, Mattos CE, el Mahgoub S, Diaz S, et al. Prolonged intrauterine contraception: A seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the Copper T380 Ag IUDs. <i>Contraception</i> 1991;44(5):473-80.</li></ol> <p>No hormonal method prevents the transmission of STDs; however, the possible prevention of the progression of infection is a safety feature of this method of contraception in young women, compared to IUDs without progestin, or to use of no method at all.</p>

## Q.5. What is the duration of use for LNG IUDs?

Recommendations	Rationale
<p>Currently, the LNG-20 IUD is technically approved for five years of use; however, evidence indicates that it actually will last for seven years.</p>	<p>It has been approved for five years of use in Europe. However, it has been shown to have low pregnancy rates through seven years. Studies are on-going.</p> <ol style="list-style-type: none"><li data-bbox="824 485 1414 604">1) Sivin I, Stern J, Coutinho E, Mattos CE, el Mahgoub S, Diaz S, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the copper T 380 Ag IUDs. <i>Contraception</i> 1991;44(5):473-480.</li></ol>

## Classification of Selected Procedures for Levonorgestrel IUDs (LNg IUDs)

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	A	Bimanual and speculum exams are essential and mandatory before IUD use, to rule out contraindications (pregnancy, Pelvic inflammatory disease (PID) and endocervical infection, cervical lesions) and to determine uterine position in order to avoid perforation. If the woman is pregnant, presence of the IUD will lead to spontaneous abortion (miscarriage) in about half of all pregnancies, and there is significant risk of septic abortion <sup>1</sup> . If a purulent endocervical discharge is present at the time the IUD is inserted through the cervical canal, bacteria in the canal may be introduced into the sterile uterine cavity and lead to PID <sup>2</sup> .
Blood pressure	C	The use of this method does not affect blood pressure.
Breast examination	C	There is no evidence linking the LNg IUD to breast cancer. The LNg IUD provides a very low dose of progestin.
Sexually transmitted disease (STD) screening by risk assessment	A	Assessment of STD risk by personal history and socio-demographic risk factors is an essential procedure for identifying women at risk of PID.
STD screening by lab tests (for asymptomatic persons)	B	<ul style="list-style-type: none"> <li>Assessment of STD risk by personal history and socio-demographic risk factors may be the most practical method of identifying women at risk for PID. The speculum and bimanual exam may also detect some STDs. When feasible, negative test results provide reassurance to corroborate the woman's history.</li> </ul> <p>For those clients with a personal history or with socio-demographic risk factors which suggest high risk, the clients who still make an informed choice of an IUD must understand they may have an STD without any signs or symptoms. While negative STD lab tests would be somewhat reassuring in this circumstance, they will not alter the clients' future STD risk.</p>

Procedure	Class	Rationale
Cervical cancer screening	C	<p>IUD insertions and continued IUD use have no known relation to the risk of acquiring cervical carcinoma<sup>3</sup>.</p> <p>Although WHO considers cervical cancer for IUD insertion to be Class 4 (a condition which represents an unacceptable health risk), clinically apparent cervical lesions are detectable from observation during a pelvic exam<sup>1</sup>.</p>
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	C	These tests are not necessary to perform before insertion.
Proper infection prevention procedures.	A	Proper infection prevention procedures are essential and mandatory to minimize the risk of infection to clients and providers.
<p>Specific counseling points for LNG IUDs:                      efficacy                      common side effects, including change in menses (irregular or absent menstrual bleeding)                      correct use of method                      signs and symptoms for which to see a health provider                      STD protection (when/as appropriate), and counseling about condom use for women who are at high risk for STDs.</p> <p><b>Note:</b> <i>Women currently at high risk for STDs, in general, should not receive IUDs.</i></p> <p>Benefits (anemia and dysmenorrhea improved)</p>	A	<p>Accurate client education is essential for maximum quality of family planning (FP) services. Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation.</p> <p>Women at risk should be counseled on high risk behavior for contracting STDs and potential complications from IUD use.</p> <p>The woman should be encouraged to return if she has any problems or at any time she has questions or concerns.</p>

**KEY:**

**Class A** = essential and mandatory or otherwise important in all circumstances, for safe and effective use of the contraceptive method

**Class B** = medically/epidemiologically rational in some circumstances to optimize the safe and effective use of the contraceptive method, but may not be appropriate for all clients in all settings

**Class C** = may be appropriate for good preventive health care, but not materially related to safe and effective use of the contraceptive method

**Class D** = not materially related to either good routine preventive health care or safe and effective use of the contraceptive method

**Citations for Procedures Table:**

- 1) World Health Organization. Improving access to quality care in family planning: medical eligibility criteria for contraceptive use. Geneva: WHO, 1996.
- 2) Mishell DR, Jr. Contraception, sterilization and pregnancy termination. In: Herbst AL, Mishell DR Jr., Stenchever MA, Droegemueller W, editors. Comprehensive Gynecology, second edition. St. Louis: Mosby Year Book, 1992: 295-362.
- 3) Lassise DL, Savitz DA, Hamman RF, Baron AE, Brinton LA, Levines RS. Invasive cervical cancer and intrauterine device use. International Journal of Epidemiology 1991;20(4):865-70.