

## NORPLANT<sup>®</sup> Implants

### Q.1. When can NORPLANT<sup>®</sup> Implants be inserted (interval)? How soon after the insertion are NORPLANT<sup>®</sup> Implants effective? Is there a need for a back-up method?

Recommendations	Rationales
a) NORPLANT <sup>®</sup> Implants may be inserted any time you can be reasonably sure the woman is not pregnant, for example, during the 7 days which begin with the onset of menses (days 1 through 7 of the menstrual cycle).	a) Blood levels of levonorgestrel rise to a level sufficient to prevent conception within 24 hours of insertion.  1) <i>NORPLANT<sup>®</sup> Levonorgestrel Implants: A Summary of Scientific Data</i> . Monograph. New York, The Population Council, 1990, p 2.  Although ovulation can occur as early as day 10 of the menstrual cycle, this is rare <sup>4</sup> . Fertile ovulation is very uncommon before day 12 <sup>1</sup> . Intercourse 5 days before ovulation may have as much as a 5% chance of resulting in pregnancy <sup>2</sup> ; however, since experts believe there are few fertile ovulations before day 13, there is only a very small chance that intercourse on day 7 of the cycle could result in pregnancy <sup>1</sup> .  In general, use of NORPLANT <sup>®</sup> Implants within the first 7 days after the woman's normal menses would assure that the probability of the woman already being pregnant, or becoming pregnant, is extremely low <sup>3</sup> .  1) The Technical Guidance Working Group has reached this conclusion after a thorough review of the available literature and consultation with the following experts: William Collins, PhD, DSc, Department of Obstetrics and Gynecology, Kings College, UK Jeffrey Spieler, MSc, Research Division, Office of Population, USAID. 2) Dixon GW, Schlesselman JJ, Ory HW, Blye RP. Ethinyl estradiol and conjugated estrogens as postcoital contraceptives. <i>Journal of the American Medical Association</i> 1980;244:1336-1339. 3) Gray RH, Pardthaisong T, McDaniel EB, Doyle P. The timing of the first insertion of Depo Provera. <i>IPPF Medical Bulletin</i> 1975;9(3):3-4. 4) Schiphorst LE, Collins WP, Roystar JP. An estrogen test to determine The times of potential fertility in women. <i>Fertility and Sterility</i> 1985;44:328-334.

Recommendations	Rationales
<p>b) For women having menstrual cycles, no back-up method is needed if she is in the first 7 days of her menstrual cycle and is still menstruating. If she is in the first 7 days of her cycle, but is not menstruating, some programs may recommend use of a back-up method for 1 week. NORPLANT® Implants may be inserted anytime you can be reasonable sure the woman is not pregnant. However, if insertion is done after day 7 of a regular cycle, a back-up method (or abstinence) may be needed (see c., below).</p>	<p>b) It is probable that NORPLANT® Implants effectively thicken cervical mucus within 24 hours. Consistent with this theory, progestin-only pills have been shown to produce a thickened mucus with low sperm penetration within 3 to 4 hours after pill ingestion. Natural progesterones also cause cervical mucus to become scant, thick and sticky decreasing or inhibiting sperm penetration, within 24 hours, but sometimes within 48 hours. Clinical judgement is also consistent with this theory.</p>
<p>c) Although there is good reason to believe the effect on cervical mucus will promptly provide contraceptive protection within 24 hours, it may be prudent to consider a back-up method for up to 7 days.</p> <p>(See Q.2. for postpartum insertion and Q.3. for post-abortion insertion.)</p>	<ol style="list-style-type: none"><li>1) The Technical Guidance Working Group (GWG) has reached this conclusion after a thorough review of the literature and consultation with the following experts: Gary Grubb, MD, MPH, The RW Johnson Pharmaceutical Research Institute, Raritan, NJ, USA Michael Orme, Professor of Clinical Pharmacology, The University of Liverpool, UK.</li><li>2) Wright SW, Fotherby K, Fairweather F. Effect of daily small doses of Norgestrel on ovarian function. <i>Journal of Obstetrics and Gynecology of the British Commonwealth</i> 1970;77:65-68.</li><li>3) Tsibris JCM. Cervical mucus, in Gould JJ, Josimovich JB (eds). <i>Gynecologic Endocrinology</i>. New York, Plenum Medical Book Company, 1987, pp 175-183.</li><li>4) Insler V, Melmed H, Eichenbrenner I, Serr D, Lunenfeld B. The cervical score: A simple semiquantitative method for monitoring of the menstrual cycle. <i>International Journal of Gynaecology and Obstetrics</i> 1972;10(6): 223-228.</li><li>5) Flynn AM, Lynch SS. Cervical mucus and identification of the fertile phase of the menstrual cycle. <i>British Journal of Obstetrics and Gynaecology</i> 1976(83):656-659.</li><li>6) Moghissi KS, Syner FN, Evans TN. A composite picture of the menstrual cycle. <i>American Journal of Obstetrics and Gynecology</i> 1972;114(3):405-418.</li></ol> <p>c) Some programs might recommend a back-up method for women who are not menstruating at the time of NORPLANT® Implants initiation because there is a very slight risk of conception from unprotected intercourse on day 7 of the cycle.</p>

## Q.2. When can NORPLANT® Implants be inserted postpartum?

Recommendations	Rationales
<p><b>For Breastfeeding Women:</b></p> <p>a) If the woman chooses to rely on the Lactational Amenorrhea Method (LAM), insert NORPLANT® Implants when her menses* return, or when the woman is no longer fully or nearly fully breastfeeding or at 6 months postpartum, whichever comes first (see "Relying on Lactational Amenorrhea Method" in Appendix A).</p> <p>* <b>NOTE:</b> In breastfeeding women, bleeding in the first 56 days (8 weeks) postpartum is NOT considered "menstrual" bleeding, because it is not preceded by ovulation.</p> <p>b) If the woman is fully breastfeeding, but does not want to rely on LAM, ideally wait until at least 6 weeks postpartum to initiate NORPLANT® Implants. If she is only partially breastfeeding and does not want to rely on LAM, it is still advisable to wait at least until 6 weeks postpartum before initiating NORPLANT® Implants.</p>	<p>a) Risk of pregnancy during lactational amenorrhea is very low: less than 2% in first 6 months postpartum if fully breastfeeding; less than or equal to 7% in first 12 months. If the fully or nearly-fully breastfeeding woman remains amenorrheic, her risk of pregnancy is about the same as her risk with other modern contraceptive methods.</p> <ol style="list-style-type: none"> <li>1) Bellagio Consensus Conference on Lactational Infertility. Bellagio consensus statement on the use of breastfeeding as a family planning method. <i>Contraception</i> 1989;39(5):477-496.</li> <li>2) Kennedy KI, Visness CM. Contraceptive efficacy of lactational amenorrhea. <i>The Lancet</i> 1992;339:227-230.</li> <li>3) Perez A, Labbok MH, Queenan JT. Clinical study of The lactational amenorrhea method for family planning. <i>The Lancet</i> 1992;339:968-970.</li> </ol> <p>b) Based on animal studies and observed fluctuations of human sex hormones in the first 6 weeks of life, plus the immaturity of the neonatal liver for the metabolism of exogenous steroids, it is considered prudent to wait to initiate progestin-only contraceptives until a breastfeeding woman is at least 6 weeks postpartum.</p> <ol style="list-style-type: none"> <li>1) Harlap S. Exposure to contraceptive hormones through breast milk — Are there long-term health consequences? <i>International Journal of Gynaecology and Obstetrics</i> 1987;25(Suppl):47-55.</li> <li>2) Ward RM. Pharmacologic principles and practicalities, in Taeusch HW, Ballard RA, Avery ME (eds). <i>Diseases of the Newborn</i>. Philadelphia, WB Saunders Company, 1991.</li> </ol>

**Recommendations**

**Rationales**

Most studies<sup>1-5</sup> have not detected clinically measurable effects on the health or growth of breastfed babies of women who begin using NORPLANT<sup>®</sup> Implants after 6 weeks postpartum, although not all studies report consistent findings<sup>6,7</sup>. Based on current literature including studies with other progestin-only methods<sup>2,3,8,11</sup>, it is unlikely that there is a significant effect on growth of breastfeeding infants whose mothers initiate NORPLANT<sup>®</sup> Implants after the sixth postpartum week.

- 1) Affandi B, Karmadibrata S, Prihartono J, Lubis F, Samil RS. Effect of NORPLANT<sup>®</sup> on mothers and infants in the postpartum period. *Advances in Contraception* 1986;2:371-380.
- 2) WHO Task Force on Oral Contraceptives. Effects of hormonal contraceptives on milk volume and infant growth. *Contraception* 1984;30(6):505-521.
- 3) WHO Task Force on Oral Contraceptives. Special Programme of Research, Development, and Research Training in Human Reproduction. Effects of hormonal contraceptives on breast milk composition and infant growth. *Studies in Family Planning* 1988;19(6):361-369.
- 4) Diaz S, Peralta O, Juez G, Herreros C, Casado M, Salvatierra A, Miranda P, Croxatto H. Fertility regulation in nursing women. VI. Contraceptive effectiveness of a subdermal progesterone implant. *Contraception* 1984;30(4):311-325.
- 5) Shaaban MM. Contraception with progestogens and progesterone during lactation. *Journal of Steroid Biochemistry and Molecular Biology* 1991;40:705-710.
- 6) Diaz S, Herreros C, Juez G, Casado ME, Salvatierra AM, Miranda P, Peralta O, Croxatto HB. Fertility regulation in nursing women: VII. Influence of NORPLANT<sup>®</sup> Levonorgestrel implants upon lactation and infant growth. *Contraception* 1985;32(1):53-74.
- 7) Shaaban M, Salem H, Abdullah K. Influence of Levonorgestrel contraceptive implants, Norplant, initiated early postpartum upon lactation and infant growth. *Contraception* 1985;32(6):623-635.
- 8) Karim M, Ammar R, El Mahgoub S, El Ganzoury B, Fikri F, Abdou I. Injected progestogen and lactation. *British Medical Journal* 1971;1:200-203.
- 9) Pardthaisong T, Yencht C, Gray R. The long-term growth and development of children exposed to Depo-Provera during pregnancy or lactation. *Contraception* 1992; 45:313-324.
- 10) Zacharias S, Aguilera E, Assenzo JR, Zanartu J. Effects of hormonal and non-hormonal contraceptives on lactation and incidence of pregnancy. *Contraception* 1986;33(3):203-213.
- 11) McCann MF, Moggia AV, Higgins JE, Potts M, Beeker C. The effects of a progestin-only oral contraceptive (Levonorgestrel 0.03 mg) on breastfeeding. *Contraception* 1989;40(6):635-648.

Recommendations	Rationales
<p>c) Programs that wish to give clients the option of NORPLANT® Implant insertion immediately postpartum should also give clients the option of returning after 6 weeks to receive NORPLANT® Implants.</p>	<p>c) In some service delivery settings, access to NORPLANT® Implants insertion may be difficult for clients to obtain outside of immediate postpartum services.</p>
<p><b>For Non-Breastfeeding Women:</b></p>	
<p>a) NORPLANT® Implants can be inserted immediately postpartum and whenever you can be reasonably sure the woman is not pregnant.</p>	<p>a) While there may be a theoretical concern of increased thrombogenic effect with combined oral contraceptive use in the first week postpartum, there is no known clinical thrombogenic effect of progestin-only contraceptives; therefore NORPLANT® Implants can be safely inserted immediately postpartum, for non-breastfeeding women.</p>
	<ol style="list-style-type: none"><li>1) <i>Injectable Contraceptives: Their Role in Family Planning Care</i>. Geneva, World Health Organization, 1990.</li><li>2) Fotherby K. The progestin-only pill and thrombosis. <i>The British Journal of Family Planning</i> 1989;15:83-85.</li><li>3) Chi I. The safety and efficacy of progestin-only oral contraceptives — An epidemiological perspective. <i>Contraception</i> 1993;47:1-21.</li></ol>

### Q.3. Are NORPLANT® Implants appropriate for use immediately post-abortion?

Recommendations	Rationales
a) Yes, NORPLANT® Implants are appropriate for use immediately post-abortion (spontaneous or induced), in any trimester, and should be inserted within the first seven days post-abortion (or anytime you can be reasonably sure the woman is not pregnant).	a) Fertility returns almost immediately post-abortion (spontaneous or induced): within 2 weeks for first trimester abortion and within 4 weeks for second trimester abortion. Within 6 weeks of abortion, 75% of women have ovulated.  <ol style="list-style-type: none"><li>1) Lähteenmaki P, Ylöstalo P, Sipinen S, Toivonen J, Ruusuvaara L, Pikkola P, Nilsson CG, Luukkainen T. Return of ovulation after abortion and after discontinuation of oral contraceptives. <i>Fertility and Sterility</i> 1980;34(3):246-249.</li><li>2) Ostimehin BD, Otolorin ED, Ladipo OA. Sequential hormone measurements after first trimester abortion for normal Nigerian women. <i>Advances in Contraception</i> 1985;1(1):83-90.</li></ol> <p>While there may be a theoretical concern of increased thrombogenic effect with combined oral contraceptive use in the first week post-abortion, there is no known clinical thrombogenic effect of progestin-only contraceptives; therefore NORPLANT® Implants can be safely used immediately post-abortion (spontaneous or induced).</p> <ol style="list-style-type: none"><li>1) <i>Injectable Contraceptives: Their Role in Family Planning Care.</i> Geneva, World Health Organization, 1990.</li><li>2) Fotherby K. The progestin-only pill and thrombosis. <i>The British Journal of Family Planning</i> 1989;15:83-85.</li><li>3) Chi I. The safety and efficacy of progestin-only oral contraceptives — An epidemiological perspective. <i>Contraception</i> 1993;47:1-21.</li></ol>

## Q.4. Are there any age/parity restrictions on NORPLANT® Implants?

Recommendations	Rationales
<p>a) No. NORPLANT® Implants may be used at any age at which the woman is at risk for pregnancy (e.g., past menarche and through menopause).</p>	<p>a) The contraceptive effect of NORPLANT® Implants ceases within 24 hours of removal and return to fertility is comparable to that of women who have not used contraception; 40 to 50% of women become pregnant after three months and 75 to 95% of women are pregnant by 12 months post-removal.</p> <ol style="list-style-type: none"><li>1) Noerpramana N-P. The Norplant removal training and service at Dr. Kariadi Hospital, Semarang, Indonesia. <i>Advances in Contraception</i> December 1991; 7(4):389-401.</li><li>2) Sivin I, Diaz S, Holma P, Alvarez-Saneuez F, Robertson DN. A four-year clinical study of Norplants. <i>Studies in Family Planning</i> 1983;14(6-7):184-191.</li><li>3) Singh K, Viegas OAC, Ratnam SS. A three-year evaluation of Norplant in Singaporean acceptors. <i>Advances in Contraception</i> 1990;6:1-9.</li></ol>
<p><b>Older Women:</b></p> <p>b) NORPLANT® Implants may be used by women through menopause.</p>	<p>b) Many providers consider NORPLANT® Implants to be an especially appropriate method for older women, since they contain no estrogen.</p> <ol style="list-style-type: none"><li>1) <i>Norplant Contraceptive Subdermal Implants: Managerial and Technical Guidelines</i>. Geneva, World Health Organization, 1990.</li></ol> <p>Because women greater than 35 years of age are at increasing risk for endometrial (and ovarian) cancer, it is particularly important to:</p> <ul style="list-style-type: none"><li>● carefully evaluate irregular bleeding before inserting NORPLANT® Implants and</li><li>● more carefully consider cancer as a possible cause if the woman returns with irregular bleeding after prolonged amenorrhea.</li></ul> <ol style="list-style-type: none"><li>1) Herbst AL, Mishell DR, Stenchever MA, Droegmueller W. <i>Comprehensive Gynecology</i>, 2nd edition. St. Louis, Mosby Year Book, 1992, pp 1082-1083.</li><li>2) Parazzini F, La Vecchia C, Bocciolone L, Franceschi S. The epidemiology of endometrial cancer. <i>Gynecologic Oncology</i> 1991;41:1-16.</li></ol>

Recommendations	Rationales
<p><b>Adolescents:</b></p> <p>c) Use of NORPLANT® Implants leads to amenorrhea in a small proportion of women, less than that for women using progestin-only injectables. Some evidence suggests that a hypogestrogenic state within the first two years after menarche may increase the risk of osteoporosis later in life, particularly for women with other risk factors for osteoporosis (i.e., women who are small-boned, underweight, white or Asian, smokers or malnourished). However, for those adolescents age 15 or under, for whom NORPLANT® Implants is the most appropriate method, the benefits of the method generally outweigh the risks.</p>	<p>c) Amenorrhea, while on progestin-only contraceptives, is generally evidence of lower estrogen levels (although not as low as menopausal levels). Estrogen is necessary for the development and maintenance of strong bones (to prevent osteoporosis). The peak strength (density) of spinal bone is reached by girls around age 16; the greatest increase in bone density occurs in the first two years post-menarche.</p> <ol style="list-style-type: none"> <li>1) Faúndes A, Alvarez-Sanchez F, Brache V, Jimenez E, Tejada AS. Hormonal changes associated with bleeding during low dose progestogen contraception delivered by Norplant subdermal implants. <i>Advances in Contraception</i> 1991;7(1):85-94.</li> <li>2) Shoupe D, Mishell DR, Bopp BL, Fielding M. The significance of bleeding patterns in Norplant implant users. <i>Obstetrics and Gynecology</i> 1991;77:256-260.</li> <li>3) Bonjour JP, Theintz G, Buchs B, Slosman D, Rizzoli R. Critical years and stages of puberty for spinal and femoral bone mass accumulation during adolescence. <i>Journal of Clinical Endocrinology and Metabolism</i> 1991; 73: 555-563.</li> <li>4) Theintz G, Buchs B, Rizzoli R, Slosman D, Clavien H, Sizonenko PC, Bonjour JP. Longitudinal monitoring of bone mass accumulation in healthy adolescents: Evidence for a marked reduction after 16 years of age at the levels of lumbar spine and femoral neck in female subjects. <i>Journal of Clinical Endocrinology and Metabolism</i> 1992;75:1060-1065.</li> <li>5) Dhuper S, Warren M, Brooks-Gunn J, Fox R. Effects of hormonal status on bone density in adolescent girls. <i>Journal of Clinical Endocrinology and Metabolism</i> 1990;71:1083-1088.</li> </ol>

**Q.5. Is there need for a routine pre-exam (a separate visit) before insertion?**

<b>Recommendations</b>	<b>Rationales</b>
a) No: <ul style="list-style-type: none"><li>● If possible, handle all counseling and screening on the same day as the insertion.</li><li>● A routine system of pre-exam visits is not necessary.</li></ul>	a) There is no medical need for a pre-exam (separate visit); it may be difficult for a woman to make two visits, and she may be at risk of unintended pregnancy during this interval.

**Q.6. What is the risk of an ectopic pregnancy while using NORPLANT® Implants?**

<b>Recommendations</b>	<b>Rationale</b>
<p>The risk of ectopic pregnancy during the first five years of use is reduced compared to noncontraceptive users since NORPLANT® Implants are a highly effective method of contraceptive protection. Although NORPLANT® Implants reduce the total number of ectopics by decreasing the number of pregnancies, any pregnancies which do occur have an increased risk of being ectopic when compared to the risk of pregnancies being ectopic when using most alternative methods of contraception. Therefore, a woman who becomes pregnant while using NORPLANT® Implants should be monitored for signs and symptoms of ectopic pregnancy.</p>	<p>Because NORPLANT® contraceptive implants provide a high level of protection against all pregnancies during the first five years, the number of ectopic pregnancies is reduced when compared with no contraceptive use. Data suggest that the ectopic pregnancy rate of NORPLANT® implants is similar to the ectopic pregnancy rates for some very effective alternative methods such as female sterilization. However, the percent of any pregnancies which do occur that are ectopic when using NORPLANT® Implants is somewhat higher than the percent of pregnancies which are ectopic when using most other contraceptive methods.</p> <ol style="list-style-type: none"><li>1) NORPLANT® Levonorgestrel Implants: a summary of scientific data. New York: The Population Council, 1990.</li><li>2) International collaborative surveillance of Norplant. Post-marketing surveillance report of NORPLANT®: collaborating agencies progress report. Geneva: WHO, 1996.</li><li>3) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of ectopic pregnancy after tubal sterilization. New England Journal of Medicine 1997;336:762-767.</li></ol>

**Q.7. What other methods can be used with NORPLANT® Implants? What are the recommendations for dual method use after five years of NORPLANT® Implants use?**

<b>Recommendations</b>	<b>Rationale</b>
<p>a) <b>During the First Five Years:</b></p> <p>During the first five years of use, NORPLANT® Implants are a highly effective contraceptive method. Therefore, no additional contraceptive method is required to provide pregnancy protection.</p> <p>b) <b>After the First Five Years of Using NORPLANT® Implants:</b></p> <p>Under some circumstances (for example, if immediate removal is not practical in a woman weighing more than 60 kg or if the client refuses removal), it is reasonable for the client (and provider) to consider choosing any of the contraceptive methods in addition to the implants after the first five years when levonorgestrel has diminished to low levels. However, there is theoretical concern that the combination of a copper or inert intrauterine device (IUD) with NORPLANT® Implants may result in an unacceptable increase in menstrual blood loss enhancing the risk of anemia.</p>	<p>a) The cumulative pregnancy rate of users of NORPLANT® Implants at the end of five years of use is 1%.</p> <p>1) Sivin I. Contraception with Norplant Implants. Human Reproduction 1994;9(10):1818-26.</p> <p>b) If NORPLANT® Implants removal is delayed beyond five years or if a woman refuses removal, the client and provider may consider using an additional contraceptive method to avoid an unwanted (and possibly ectopic) pregnancy, particularly for women heavier than 60 kgs using NORPLANT® Implants with hard tubing. Since the blood levels of levonorgestrel are very low to begin with and are especially low after five years of hard tubing use, it is unlikely that safety problems will occur when NORPLANT® Implants are used in combination with another contraceptive method, including other hormonal methods. No contraindications exist against such dual method use. However, since both IUDs and progestin-only methods are associated with increased menstrual bleeding, there is concern that combined use of an IUD with NORPLANT® Implants could result in an even higher loss of menstrual blood increasing the risk of anemia in at risk populations.</p>

<b>Recommendations</b>	<b>Rationale</b>
<p>c) <b>For sexually transmitted disease (STD) protection:</b></p> <p>At any time, for STD protection, condoms or other barrier methods may be used.</p>	<p>c) Like other hormonal methods, NORPLANT<sup>®</sup> Implants use does not protect against STDs. Therefore, using condoms in combination with NORPLANT<sup>®</sup> Implants will help protect against STDs, including human immunodeficiency virus (HIV).</p> <p>Supplemental use of contraceptive methods in women using NORPLANT<sup>®</sup> Implants may be important to provide protection from pregnancy (after five years of use) and from STDs/HIV. However, since current experience with dual method use is limited, supplemental use should be undertaken only after careful consideration. Furthermore, the short-term provision of supplemental contraception should not reduce programmatic efforts for removing NORPLANT<sup>®</sup> Implants at the end of year five in women desiring removal.</p>

## Q.8. What should the routine follow-up schedule be?

Recommendations	Rationales
<p>a) <b>Encourage</b> the client to call or return to local provider if problems arise.</p> <p>b) A visit within the first 1 to 3 months may be advised if additional counseling is necessary or to check the insertion site.</p> <p>c) Inform the woman when removal will be necessary (in 5 years or sooner if she desires) and provide her with a means of remembering this date.</p> <p>d) Visits are encouraged for other preventive reproductive health care as available, including provision of condoms, when appropriate.</p>	<p>a-d) The client should be encouraged to return to the clinic if she has any problems or questions, after 5 years or when she desires removal, and for general reproductive health care. If women have no complaints, there is no need for routine contraceptive clinic visits before the end of the 5 years.</p> <ol style="list-style-type: none"><li>1) <i>Norplant Contraceptive Subdermal Implants: Managerial and Technical Guidelines</i>. Geneva, World Health Organization, 1990.</li><li>2) <i>NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data</i>. Monograph. New York, The Population Council, 1990.</li><li>3) Emerling JM, Palozzi P, Lelva J, Collins U. Subdermal contraceptive implants in nurse-midwifery practice. <i>Journal of Nurse-Midwifery</i> 1993; 38(2):809-875.</li></ol>

**Q.9. If a woman complains of heavier menses and/or prolonged bleeding, is there a medical basis for removing NORPLANT® Implants?**

Recommendations	Rationales
<p>Not usually. Irregular and even prolonged bleeding episodes are common and expected especially in the first 3 to 6 months of NORPLANT® Implant use.</p> <p>a) For <b>prolonged spotting or moderate bleeding</b> (equivalent to normal menstruation but longer in duration), the first approach should be counseling and reassurance. It should be explained that in the absence of evidence for other diseases, irregular bleeding commonly occurs with NORPLANT® Implants.</p> <p>If counseling and reassurance are not sufficient for the woman and the woman wishes to continue NORPLANT® Implants use, the following management approaches may be tried:</p> <ul style="list-style-type: none"> <li>● short term (for 7 to 21 days) combined oral contraceptives (COCs) or estrogen or</li> <li>● ibuprofen (or similar non-steroidal anti-inflammatories other than aspirin).</li> </ul> <p>b) <b>Heavy bleeding</b> (greater than normal menstruation) is very uncommon with NORPLANT® Implants; it can usually be controlled by administration of increased doses of COCs or estrogen.</p>	<p>a) NORPLANT® Implants may cause increased bleeding in some women and decreased bleeding in others, and changes in bleeding patterns tend to decrease over time.</p> <ol style="list-style-type: none"> <li>1) <i>NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data</i>. Monograph. New York, The Population Council, 1990.</li> <li>2) Croxatto HB. Norplant: Levonorgestrel-releasing contraceptive implant. <i>Annals of Medicine</i> 1993;25:155-160.</li> <li>3) Wang SC, Wu SC, Xin XM, Chen JH, Gao J. Three years' experience with levonorgestrel-releasing intrauterine device and Norplant-2 implants: a randomized comparative study. <i>Advances in Contraception</i> 1992;8(2):105-111.</li> </ol> <p>a-b) Bleeding is managed by rebuilding the endometrium with COCs, or by taking ibuprofen* which blocks prostaglandin synthesis and thus decreases uterine contractions. (COCs are preferred over estrogen because NORPLANT® Implants deliver such a low dose of progesterone that the contraceptive effect on the cervical mucus may be reduced by the addition of estrogen only.)</p> <ol style="list-style-type: none"> <li>1) <i>Injectable Contraceptives: Their Role in Family Planning Care</i>. Geneva, World Health Organization, 1990.</li> <li>2) Diaz S, Croxatto HB, Davez M, Belhadj H, Stern J, Sivin I. Clinical assessment of treatments for prolonged bleeding in users of NORPLANT® Implants. <i>Contraception</i> 1990;42(1):97-109.</li> </ol> <p>* <b>NOTE:</b> Nonsteroidal anti-inflammatory drugs (e.g., ibuprofen) should be used instead of aspirin because of aspirin's stronger and longer-lasting inhibitory effects on platelet aggregation (aspirin promotes bleeding).</p> <ol style="list-style-type: none"> <li>1) <i>American Hospital Formulary Service Drug Information</i>. Bethesda, MD, American Society of Hospital Pharmacists, 1994, p 1208.</li> </ol>

Recommendations	Rationales
<ul style="list-style-type: none"><li>c) If suspected, abnormal conditions which cause prolonged or heavy bleeding should be evaluated and treated as appropriate.</li><li>d) Some prolonged or heavy bleeding may fail to be corrected. Some women will require removal of NORPLANT<sup>®</sup> implants due to medical reasons for excessive bleeding or due to client's preference.</li><li>e) Evaluate and address anemia, as appropriate. Give nutritional advice on the need to increase the intake of iron containing foods.</li><li>f) <b>Do not</b> perform uterine evacuation unless another medical condition is suspected (vacuum aspiration is generally the preferred method of uterine evacuation).</li></ul>	<p>2) Field CS. Dysfunctional uterine bleeding. <i>Primary Care</i> 1988;15(3):561-574.</p>

**Q.10. Are NORPLANT® Implants less effective in heavier women? Is there a weight limit for the use of NORPLANT® Implants?**

<b>Recommendations</b>	<b>Rationale</b>
<p>Increased weight does not appear to substantially diminish the effectiveness of soft tubing NORPLANT® Implants. In contrast, NORPLANT® Implants made with older hard tubing are less effective in women weighing more than 60 kg. However, hard tubing NORPLANT® Implants have not been manufactured since 1992.</p>	<p>There is not a significant effect of user's weight on the contraceptive effectiveness of soft tubing NORPLANT® Implants, the only kind of implants now being manufactured. Heavy women using hard tubing NORPLANT® Implants experience a higher pregnancy risk than women using soft tubing because less hormone diffuses out through the hard tubing. NORPLANT® Implants made with hard tubing demonstrated a cumulative five year failure rate of 4.5% in women who weighed 60 to 69 kg. In contrast, NORPLANT® Implants made with soft tubing demonstrated a cumulative five year failure rate of 1.5% in women who weighed 60 to 69 kg. This difference between hard and soft tubing is more pronounced for heavier women. Women who weighed more than 70 kg had a five year cumulative failure rate of 9.3% for hard tubing NORPLANT® Implants and 2.4% for soft tubing use.</p> <p>Although recent data from China reported cumulative five year failure rates for hard tubing use which were lower than the failure rates reported above, an increased number of pregnancies was still associated with increasing weight – 1.46 pregnancies (over five years) per 100 women weighing 50 to 59 kg, 2.08 pregnancies (over five years) per 100 women weighing 60 to 69 kg, and 4.58 pregnancies (over five years) for women weighing 70 kg or more.</p>

Recommendations	Rationale
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**Cumulative Five Year Failure Rate for NORPLANT® Implants**

User's Weight	Pooled Data from Clinical Trials, 1988 <sup>1</sup>		Data from China, 1995 <sup>2</sup>
	Soft Tubing	Hard Tubing	Hard Tubing
60 to 69 kg	1.5%	4.5%	2.08%
70 kg or more	2.4%	9.3%	4.58%

b) There are no known weight limits for NORPLANT® Implants use.

- 1) Sivin I. International experience with NORPLANT and NORPLANT-2 contraceptives. *Studies in Family Planning* 1988;19(2):81-94.
- 2) Gu S, Sivin I, Du M, Zhang L, Ying L, Meng F, et al. Effectiveness of Norplant Implants through seven years: a large-scale study in China. *Contraception* 1995;52(2):99-103.

b) Previous concerns about a 70 kg weight limit apply only to the older, harder tubing. Currently, only the new softer tubing is in use.

**Q.11. Should a client with keloids or a history of keloids be eligible for insertion or removal of NORPLANT<sup>®</sup>?**

<b>Recommendations</b>	<b>Rationale</b>
<p>Yes. History of keloids is not a reason to restrict NORPLANT<sup>®</sup> Implants insertion or removal. However, a woman with previous keloid formation or a family history of keloids should be informed (during the counseling on risks and benefits of the method) that keloid formation at the insertion site is generally rare, but she may be at increased risk of keloid formation.</p>	<p>Keloid formation resulting from NORPLANT<sup>®</sup> Implants insertion is a rare event. However, some women are at greater risk of keloids following any surgical procedures. In general, the degree of risk of keloid formation can be evaluated according to the following factors: history of keloids, family history of keloids, and deeper skin pigmentation (of any race). The potential for keloid formation at the insertion site should be discussed with women at increased risk of keloids to allow them to make an informed decision about use of this method.</p> <p>1) Nuovo J, Sweha A. Keloid formation from levonorgestrel implant (Norplant system) insertion. <i>Journal of the American Board of Family Practice</i> 1994;7(2):152-4.</p>

## Q.12. What may happen if the NORPLANT® Implants are removed later than five years<sup>1</sup>?

Recommendations	Rationale
<p>There is no risk from the NORPLANT® Implants themselves after five years. However, since the hormone levels released by NORPLANT® Implants decrease with time, after five years of use NORPLANT® Implants do not prevent pregnancy as well as during the first five years of use. Available evidence suggests that, as the rate of pregnancy increases, so will the rate of ectopic pregnancy. Because of the increased risk of pregnancy, current recommendations (which apply to all women regardless of weight or age) is that these implants be removed at the end of five years. Providers and women should be aware, however, that recent data suggest that for women who weigh less than 60 kg and/or are over 30 years of age at implant insertion, good protection still exists in years six and seven after placement, although the protection is somewhat less than that provided in the first five years. As stated above, there may be an increasing risk of intrauterine and ectopic pregnancy, but this risk tends to fall with age.</p> <p>A woman may refuse to have her NORPLANT® Implants removed after five years. In such cases, the woman should be counseled on the potential risks (including pregnancy) and contraceptive benefits. If the woman still refuses to have the removal, she should be encouraged to use an additional method of contraception.</p>	<p>NORPLANT® Implants are a very highly effective method of protection against pregnancies for up to five years after placement. Also, in the first five years of use, the risk of ectopic pregnancy is also reduced (compared to use of no method). The blood levels of the hormone released by the implants decrease with time. Thus, it is assumed that pregnancy and ectopic pregnancy rates will both rise after five years. For these reasons, it is recommended that NORPLANT® Implants be removed after five years of use.</p> <p>Recent data from a very large Chinese study clarify some of the issues. Women who weighed less than 60 kg and women over age 30 at implant insertion did not experience marked increases in pregnancy rates in years six and seven of use as compared with rates in year five, and the pregnancy rates were still quite low. A second, much smaller study in Chile found that the pregnancy rate during implant use increased to four per 100 woman years in years six through eight, but that no ectopic pregnancies occurred after the fifth year. These data perhaps suggest that although the blood levels of the drug are reduced after five years of use, this reduction is somewhat offset by the aging of the women, a factor that may principally affect women over the age of 30 who participated in the study.</p>

<sup>1</sup> Currently NORPLANT® Implants are approved for only five years, however, if approval is extended beyond five years, the recommendations included here would have to be modified accordingly.

<b>Recommendations</b>	<b>Rationale</b>
	<p>Although the general recommendation to remove NORPLANT® Implants after five years pertains to all women, the Chinese and Chilean data suggest some leeway to organize and implement removal services at five years for populations where a large proportion of women weigh less than 60 kg or are over 35 years of age at the end of five years of implant use.</p> <p>High priority should be placed on linking women who desire removal with providers trained with the skills necessary to perform such removals. However, if a woman does not want her NORPLANT® Implants removed, she should be informed of the risks (and contraceptive benefits) associated with use of NORPLANT® Implants beyond five years, particularly decreasing effectiveness and the possibility of ectopic pregnancy.</p> <p>In additional method of contraception, and be advised about the signs and symptoms that occur with pregnancy or with ectopic pregnancy. She should further be advised to return to the clinic or facility at any time that she experiences signs or symptoms of a pregnancy or ectopic pregnancy.</p> <ol style="list-style-type: none"><li>1) NORPLANT® Levonorgestrel Implants: a summary of scientific data. New York: The Population Council, 1990.</li><li>2) Gu S, Sivin I, Du M, Zhang L, Ying L, Meng F, et al. Effectiveness of Norplant Implants through seven years: a large-scale study in China. <i>Contraception</i> 1995;52(2):99-103.</li><li>3) Diaz S, Pavez M, Miranda P, Johansson ED, Croxatto HB. Long-term follow-up of women treated with Norplant Implants. <i>Contraception</i> 1987;35(6):551-67.</li><li>4) Meeting Report: NORPLANT® Implants issues related to removal and quality of care. Washington, DC: USAID, June 6, 1995.</li></ol>

**Q.13. Is hard tubing still being used in the manufacturing of NORPLANT® Implants? Should the removal technique be handled differently in women with hard tubing?**

<b>Recommendations</b>	<b>Rationale</b>
a) No. Hard tubing is no longer being used to manufacture NORPLANT® Implants.  b) No. The removal procedure for women with hard tubing NORPLANT® Implants is identical to the removal of soft tubing NORPLANT® Implants.	a) NORPLANT® Implants manufactured with hard tubing are no longer manufactured or distributed. They were provided through 1992, however, and are still used by many women.  b) The clinical parameters of NORPLANT® Implants differ between these two types of tubing. Heavy women using hard tubing NORPLANT® Implants experience a higher pregnancy risk than women using soft tubing because less hormone diffuses out through the hard tubing (see Question 4). However, the physical removal procedure is the same for both hard and soft tubing NORPLANT® Implants.

## Q.14. Should NORPLANT® Implants be provided if infection prevention measures cannot be followed?

Recommendations	Rationales
<p>a) No.</p> <p>All centers inserting and/or removing NORPLANT® Implants should follow basic infection prevention measures, including:</p> <ul style="list-style-type: none"><li>● careful aseptic technique (including appropriate handwashing by the provider and thorough cleaning of the insertion site),</li><li>● proper decontamination of reusable sharps and other instruments,</li><li>● sterilization (or, at a minimum, high-level disinfection) of all equipment, and</li><li>● safe disposal of contaminated sharps, and other disposables.</li></ul>	<p>a) Although insertion and removal of NORPLANT® Implants are minor surgical procedures, careful aseptic technique, including good surgical technique, must be followed to prevent an increase in infections at the insertion site. Infection may result in early removal or spontaneous expulsion of the NORPLANT® Implants capsule.</p> <p>Another concern is the increasing problem of transmission of hepatitis B and AIDS viruses to clients, health care providers and clinic staff, especially cleaning personnel. To minimize this risk, blood contaminated waste must be properly disposed of, and soiled instruments, gloves and other items must be decontaminated, then thoroughly cleaned and then sterilized or high-level disinfected after every case.</p> <p>Sterilization (the destruction of all microorganisms, including endospores) is the preferred practice for processing instruments and other items that come in contact with the blood stream or touch tissue beneath the skin. When sterilization is not possible, high-level disinfection (which destroys all microorganisms <b>except</b> some endospores) is acceptable.</p> <p>Regardless of which method (sterilization or high level disinfection) is used for instruments and other items, thorough cleaning of the client's arm and hand to remove soil and organic material is also necessary to prevent infection. Appropriate dressing and instruction to clients on hygiene of the insertion site are also important.</p>

**Recommendations**

**Rationales**

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|  | <p>1) Tietjen L, Cronin W, McIntosh N. <i>Infection Prevention for Family Planning Service Programs: A Problem-Solving Reference Manual</i>. Durant, OK, Essential Medical Information Systems, Inc., 1992, pp 152-154.</p> |
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**Q.15. What kind of training in insertion and removal is needed for a provider to provide NORPLANT® Implants? Which category of professionals have been found to insert and remove NORPLANT® Implants with few complications?**

Recommendations	Rationale
<p>a) The training should include:</p> <ul style="list-style-type: none"> <li>● counseling of potential acceptors (including the fact that some removals may be difficult and may require more than one removal procedure),</li> <li>● counseling that removal should be entirely voluntary and at the option of the client,</li> <li>● infection prevention measures, and</li> <li>● techniques for inserting and removing implants (with an emphasis on removal training).</li> </ul> <p>Those programs that focus on removal training and correct insertion training should experience less difficulty in performing removals. Training programs require practical, hands-on experience in insertion and removal techniques, and use of models for practice before working with clients is advisable.</p> <p>b) Doctors, nurses, midwives, paramedics, and other health workers can perform insertion (including immediate postpartum and postabortion insertion) and removal procedures provided they are appropriately trained.</p>	<p>a) Training in counseling is just as important as technical training for providers who supply NORPLANT® Implants. Counseling training should help providers to effectively communicate the advantages and disadvantages of the method, possible side effects, the length of protection provided, the procedures for insertion and removal, reasons to return to the clinic, and information on follow-up care.</p> <p>Insertion and removal of NORPLANT® Implants are minor surgical procedures. Therefore, all centers inserting and removing NORPLANT® Implants need to follow basic infection prevention measures. Insertion and removal are relatively easy to learn, but formal training is needed to minimize the potential for difficult removals that may result from poor insertion techniques. An emphasis on removal training allows providers to understand the relationship between good insertion placement and ease of implant removal. Providers who have mastered insertion and removal skills on models before working with clients achieve competency in a shorter time.</p> <p>b) Any specially trained doctor, nurse, midwife, or other health worker can perform NORPLANT® Implants insertions and removals.</p> <ol style="list-style-type: none"> <li>1) Statement on NORPLANT® subdermal contraceptive implant system. IPPF Medical Bulletin 1995;29(5).</li> <li>2) McIntosh N, Blouse A, Schaefer L, editors. NORPLANT® Implants Guidelines for Family Planning Service Providers, second edition. Baltimore: JHPIEGO Corporation, 1995.</li> <li>3) NORPLANT® Levonorgestrel Implants: a summary of scientific data. New York: The Population Council, 1990.</li> </ol>

## Classification of Selected Procedures for NORPLANT<sup>®</sup> Implants

Procedure	Class	Rationale
Pelvic examination (speculum and bimanual)	C	<ul style="list-style-type: none"> <li>● Conditions which would restrict use of NORPLANT<sup>®</sup> Implants should be identified by history before method initiation.</li> <li>● A pelvic exam may reveal reproductive tract infections or reproductive tract malignancies which should be treated for optimal preventive care. Routine pelvic exam screening for asymptomatic women, in the absence of tests for cervical cancer, however, is a low yield procedure<sup>1</sup>.</li> <li>● In some cases, a pelvic exam may help evaluate the question of pregnancy beyond 6 weeks duration: in this case it is Class A.</li> <li>● A pelvic exam is not necessary to ensure safe use of NORPLANT<sup>®</sup> Implants as a contraceptive method.</li> </ul>
Blood pressure	C	<ul style="list-style-type: none"> <li>● Screening for high blood pressure is part of optimal preventive health care.</li> <li>● NORPLANT<sup>®</sup> Implants do <b>not</b> affect blood pressure<sup>2</sup>.</li> </ul>
Breast examination	C	<ul style="list-style-type: none"> <li>● For all women of reproductive age or beyond, a breast exam is recommended for optimal preventive health care.</li> <li>● NORPLANT<sup>®</sup> Implants do <b>not</b> cause breast cancer<sup>2</sup>. Lumps that are suspicious for cancer should be evaluated. While any hormonal treatment may, in theory, cause such lumps to grow, pregnancy causes much higher hormonal levels; therefore, potential malignancies of the breast should not be a reason to delay a woman's access to the use of this contraceptive method.</li> </ul>
Sexually transmitted disease (STD) screening by lab tests (for asymptomatic persons)	C	For optimal health care, clients at risk for STDs (by personal history or socio-demographic risk factors) should be offered STD screening where possible. However, presence of an STD will not affect the safe use of NORPLANT <sup>®</sup> Implants.

Procedure	Class	Rationale
Cervical cancer screening	C	<ul style="list-style-type: none"> <li>● Cervical cancer screening is indicated for women at risk of cervical carcinoma, and is recommended for optimal preventive health care for women of reproductive age or beyond (particularly women at risk of STDs).</li> </ul> <p><b>NOTE:</b> Cervical cancer screening is advised for optimal preventive care for all women at risk of cervical cancer (e.g., smokers, women with partners having multiple partners, women with young age at first intercourse, etc.). All women at risk should ideally have access to a practical method of cervical cancer screening, treatment and follow up.</p> <ul style="list-style-type: none"> <li>● NORPLANT<sup>®</sup> Implants use has no <b>known</b> relation to risk of cervical carcinoma<sup>2</sup>.</li> </ul>
Routine, mandatory lab tests (e.g., cholesterol, glucose, liver function tests)	D	The effects of NORPLANT <sup>®</sup> Implants on cholesterol, blood glucose and normal liver function are slight, and of <b>no</b> demonstrated clinical significance <sup>3</sup> .
Specific counseling points for NORPLANT <sup>®</sup> Implants use: <ul style="list-style-type: none"> <li>● efficacy</li> <li>● common side effects</li> <li>● correct use of method</li> <li>● signs and symptoms for which to return to the clinic</li> <li>● STD protection (when/as appropriate)</li> </ul>	A	<ul style="list-style-type: none"> <li>● Accurate client education is essential for maximum quality of family planning services.</li> <li>● Appropriate counseling about common contraceptive side effects at the time of method selection can lead to improved client satisfaction and contraceptive continuation<sup>4</sup>.</li> </ul>
Counseling concerning change in menses, including irregular or absent menstrual bleeding	A	NORPLANT <sup>®</sup> Implants may cause increased frequency of bleeding in some women and decreased bleeding in others; changes in bleeding patterns tend to decrease over time <sup>5</sup> . Bleeding pattern changes are the most common side effect of NORPLANT <sup>®</sup> Implants and the most common cause of discontinuation <sup>5</sup> .

**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 to the safe and effective use of the contraceptive method

**Citations:**

- 1) Huber DH, Huber SC. Screening oral contraceptive candidates and inconsequential pelvic examinations. *Studies in Family Planning* 1975;6(2):49-51.
- 2) *NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data*. New York, The Population Council 1990, p 11.
- 3) Singh K, Viegas OAC, Loke DFM, Ratnam SS. Effect of NORPLANT® Implants on liver, lipid and carbohydrate, metabolism. *Contraception* 1992;45(2):141-153.
- 4) Cotten N, Standback J, Maidouka H, Taylor-Thomas JT, Turk T. Early discontinuation of contraceptive use in Niger and The Gambia. *International Family Planning Perspectives* 1992;18(4):145-149.
- 5) *NORPLANT® Levonorgestrel Implants: A Summary of Scientific Data*. New York, The Population Council 1990, pp 9-11.