SECTION 2.7
IMPLANON®/NEXPLANON®

Implanon® is a progestin only single implant which contains 68 mg of etonogestral. Implanon is 99% effective at preventing pregnancy.

I. Subjective Data

A. Refrain from providing in the following conditions

1. Undiagnosed, abnormal vaginal bleeding.
2. Progestin-dependent tumor.
3. Active venous thromboembolic disorder.
4. Hypersensitivity to the active substance or to any of the excipients of Implanon.
5. Breast cancer – current or within the last 5 years.
6. Sustained hypertension that develops during the use of Implanon – discontinue use.

B. Exercise caution in the following situations and carefully monitor for adverse effects. Conditions for which the theoretical or proven risks usually outweigh the advantages of using the method (Category 3**).** (Based on Centers for Disease Control (CDC) U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 (USMEC) MMWR Early Release 2010; 59 May 28, 2010**).** Women in this category who choose to use Implanon, where the clinician/physician determines that Implanon can be used, must be provided with information regarding the way in which these conditions may add a health risk for her. This discussion must be documented.

1. Pre-existing breast cancer and no recurrence in the last 5 years.
2. Systemic lupus erythematosus (SLE) with positive (or unknown) antiphosphlipid antibodies.
3. Use of certain medications may make Implanon less effective, specifically those that induce cytochrome P450 enzymes resulting in an increased clearance of sex hormones in the liver. Some examples are: phenytoin, carbamazepine, phenylbutazone, barbiturates, the herbal remedy St. John's Wort, rifampin/rifampicin, griseofulvin. Women in long-term treatment with these drugs should consider another method of birth control. Please see package insert for complete list. Recommend concomitant use of a barrier method if use of these medications is short term.
4. Severe decompensated cirrhosis of the liver, hepatocellular adenoma, malignant hepatoma.
5. The development of ischemic heart disease, stroke, or migraine headaches with aura at any age while using Implanon. Discontinue use.

C. Advantages outweigh theoretical or proven disadvantages

1. Severe headaches including migraine with and without focal neurologic symptoms.
2. Diabetes with or without vascular disease, nephropathy, retinopathy, neuropathy – carefully monitor during first few months.

II. Objective Data

A. Physical exam as per Title X regulations (follow package insert). (See Section 1.4 - Health Care Services)

B. Laboratory testing as per Title X regulations. (See Section 1.4 - Health Care Services)

III. Assessment/Plan

A. Client Education/Informed Consent

1. Client must sign the Implanon insertion consent and information sheet.
2. Client will be informed that Implanon offers no protection against sexually transmitted infections; she should be advised to use condoms if she has concerns about potential exposure. There will be documentation of this in the client record.
3. Certain medications may make Implanon less effective, specifically those that induce cytochrome P450 enzymes resulting in an increased clearance of sex hormones in the liver. Some examples are: phenytoin, carbamazepine, phenylbutazone, barbiturates, the herbal remedy St. John's Wort, rifampin/rifampicin, griseofulvin (see package insert for complete list). Women in long-term treatment with these drugs should consider another method of birth control.
4. **Antiretroviral (ARV) drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data suggest potential drug interactions between many ARV drugs (particularly some NNRTIs and ritonavir-boosted protease inhibitors) and hormonal contraceptives. These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended to both prevent HIV transmission and compensate for any possible reduction in the effectiveness of the hormonal contraceptive. (USMEC 2010)**
5. Client will be informed that if she wishes to discontinue the Implanon, she should make an appointment at the clinic for removal. If she does not wish to become pregnant she must start using another method on the day of removal.

B. Insertion of Implants

Implanon may be inserted:

1. within the first 1 - 5 days of a regular menses;
2. at any time, if the client is currently and consistently using a highly effective method of birth control;
3. immediately post-abortion;

4. Post partum and breastfeeding

    a. Less than one month post partum: category 2, advantages of using the method generally outweigh the theoretical or proven risks. Greater than one month post partum: category 1, no restrictions.

5. Post partum, not breastfeeding

    a. Category 1, no restrictions. (USMEC 2010)

IV. Follow-Up

A. The client may return for an insertion site check if she has concerns about the Implanon site.

B. Client should return to clinic at three months to have an evaluation of her satisfaction with the method. At this visit client should fill in the Hormonal Evaluation form (see the sample at the end of this section). She may have her blood pressure checked, and be weighed if she wishes.

C. Clients should be advised to call the clinic for an appointment for any of the following:

1. arm pain; pus or bleeding at the insertion site; expulsion of the rod;
2. heavy vaginal bleeding that is unusual for this client;
3. concern that she might be pregnant, including delayed menstrual cycles after a long interval of regular cycles;
4. onset or worsening of migraine headaches, repeated very painful headaches or blurred vision;
5. severe lower abdominal pain (rule out ectopic pregnancy).

D. Management of Post-Insertion Side Effects/ Complications

1. Arm pain, pus, or bleeding at insertion site

    a. Management

        (1) Advise the client to apply ice packs to the area for bruising, swelling, bleeding; moist heat for signs of infection.

        (2) Advise to take Ibuprofen or other non-steroidal ant-inflammatory medication to relieve the discomfort.

        (3) In case of infection of the insertion site, consultation with medical back-up may be indicated to select a therapeutic treatment drug.

    b. Follow-up

        Consider contacting the client within 48-72 hours to confirm improvement.

    c. Education

        (1) Client is instructed to keep wound site clean and dry for 24 hours.

(2) The client should be informed that there might be irritation of a superficial nerve from the implants; paresthesia or paresthesia-like events may occur.

(3) Expulsion or migration of Implanon might be possible.

2. The implants appears to be coming out

Assessment/management - If the actual implant is protruding from the incision site, the implant should be removed and a new implant inserted at a different site.

3. Heavy or prolonged vaginal bleeding

a. Assessment

(1) Review client history, including sexual history, other symptoms, contact to STIs.

(2) Physical examination and appropriate lab work should be done (according to Title X Guidelines) to rule out STIs.

b. Management

(1) Any low-dose combination birth control pill for one or more cycles, if no contraindications to estrogen, or

(2) Ibuprofen 800 mg p.o. tid for 5-10 days, or

(3) Premarin 0.625 or 1.25 mg or 2.5 mg p.o. qd for 20 days if no contraindications to estrogen.

4. Amenorrhea from the time of Implanon insertion, or after a pattern of regular periods

a. Assessment

Evaluate for pregnancy

b. Management

(1) If pregnancy test is positive:

(a) Remove Implanon if client wishes to continue the pregnancy.

(b) Refer for immediate follow-up if ectopic pregnancy is suspected.

(c) Leave the Implanon in if the client plans an abortion.

(2) If the pregnancy test is negative:

(a) Discuss amenorrhea with client and reassure her that amenorrhea is a normal side effect of Implanon use.

(b) Implanon may be removed if client desires.

5. Severe lower abdominal pain

a. Assessment

(1) Client should be seen immediately to rule out pregnancy

vs. pelvic inflammatory disease (PID) vs. follicular cyst.

(2) Physical examination and appropriate lab work should be done (according to Title X Guidelines) to rule out pregnancy vs. PID vs. follicular cyst.

b. Management

(1) Rule out pregnancy, PID, and/or follicular cyst.

(2) If unable to determine pathology, must be referred to physician for further evaluation.

6. Headache

a. Assessment

(1) Review headache history.

(2) Take blood pressure.

b. Management

(1) Refer to physician for further evaluation, if indicated.

(2) If a client develops migraine headaches with aura or other neurological symptoms while using Implanon, the theoretical or proven risk of continuing Implanon usually outweigh the advantages of using the method. (USMEC 2010). Implanon should be removed.

7. Development of ischemic heart disease or stroke while using Implanon.

The theoretical or proven risk of continuing Implanon usually outweigh the advantages of using the method (USMEC 2010). Implanon should be removed.

E. Client shall be advised to have an annual exam and Pap test, based on the current Pap test screening guidelines in use.

V. For Clients Desiring Removal

A. Subjective

If the client desires removal before three years, investigate the user's reasons for desiring removal. If, after counseling, the client still desires removal, the procedure should be scheduled.

B. Client Education

1. The client needs to know that removal may take more time and may be more difficult than the insertion.

2. This information should be included in a removal consent (see the sample at the end of this section).

3. The client should be counseled on all alternative contraceptive methods, and if she does not desire a pregnancy at this time, a method should be

provided, as appropriate.

C. Follow-Up

Client should be encouraged to return for annual exam and Pap test, based on the current Pap test screening guidelines in use.

*The following is a sample of an Implanon Insertion Consent Form. This form can be downloaded from the **CDPHE Family Planning Program** website at:*
http://www.colorado.gov/cs/Satellite/CDPHE-PSD/CBON/1251618366665

NEXPLANON / IMPLANON INSERTION CONSENT/ CLIENT INFORMATION SHEET

I understand that Nexplanon / Implanon is a kind of birth control implant that consists of one small flexible rod, containing a form of the hormone progestin. It will be implanted just under the skin of my upper arm. I realize that Nexplanon / Implanon will keep me from getting pregnant for 3 years. After three years, Nexplanon / Implanon is no longer effective and must be taken out. I can have another Nexplanon / Implanon inserted at that time or start using another method of birth control. I also know that I can have Nexplanon / Implanon removed at any time and for any reason.

I understand that Nexplanon / Implanon is more effective in preventing pregnancy than the Pill. Nexplanon / Implanon is not permanent. I can get pregnant after it is taken out. I understand that Nexplanon / Implanon might not be as effective if I take certain medications (mainly medications for seizures) or the herbal remedy called St. John's Wort.

I am aware that women who use Nexplanon / Implanon have changes in their menstrual periods. Some women spot or bleed more often and some women bleed less or not at all. Spotting between periods is common. I understand that some women might also have a little weight gain, headaches or depression. I understand that Nexplanon / Implanon does not protect me from sexually transmitted diseases, including the virus that causes AIDS (HIV). I need to use condoms, as well, to get protection from infections.

I have been told what to expect when Nexplanon / Implanon is put in and taken out. I am aware that I might feel some discomfort during and after these procedures. I have been told about the problems that might occur when putting in or taking out Nexplanon / Implanon such as: allergic response to anesthetic; bruising or soreness around the insertion site; or infection. After Nexplanon / Implanon is put in, it could accidentally come out. When Nexplanon / Implanon is taken out, it could break.

Removing Nexplanon / Implanon may be slightly more difficult than putting it in. Sometimes it takes two clinic visits before the Nexplanon / Implanon rod can be taken out.

I know to call the clinic if I:

- Want my Nexplanon / Implanon taken out
- Have heavy bright red bleeding from the vagina that is more than a period
- Have a late period after my periods have been on time
- Have pain, pus, bleeding, or red skin where the Nexplanon / Implanon was put in or if my Nexplanon / Implanon capsule comes out
- Have very bad pain in the lower stomach or abdomen
- Have very bad headaches or problems with my vision

Based on my knowledge of the above, I consent to having Nexplanon / Implanon inserted.

Client Signature	Date	Staff Signature	Date

INTERPRETER'S STATEMENT

I have interpreted the information and advice presented orally to the client who has chosen to use Nexplanon / Implanon. I have also read to her the consent form in a language she understands and explained its content to her. To the best of my knowledge and belief, she understands this explanation and voluntarily consents to the insertion of Nexplanon / Implanon.

Interpreter's signature	Date

*The following is a sample of Post Implanon Insertion Instructions. This form can be downloaded from the **CDPHE Family Planning Program** website at:*
http://www.colorado.gov/cs/Satellite/CDPHE-PSD/CBON/1251618366665

POST IMPLANON INSERTION INSTRUCTIONS

You can go back to normal daily activities immediately after the Implanon has been put in. After the numbness in your arm wears off, you may have some soreness for a day or two where the Implanon was inserted. There also may be some swelling, bruising, or discoloration for up to two weeks. This is how to care for your arm after Implanon is inserted. Please be aware of signs of infection and know how, when, and where to get medical care if needed.

1. Try not to bump the place where the Implanon was put in for a few days.
2. To make sure you don't get an infection where the Implanon was put in, keep the large gauze bandage on for 24 - 48 hours and keep it dry. Remove the large bandage after 24-48 hours.
3. Keep the little bandage strip on for 3 days, and keep it dry.
4. **If** you have any redness or oozing, or anything that concerns you, return to the clinic to have the insertion site checked.

After the incision has healed, you don't have to worry about bumping it or putting pressure on it. You can hold your child, carry books, do housework, or do whatever you usually do.

The Implanon is effective within 3 days if it was put in within 5 days of the first day of your period. You should use a back up method for _____ days.

The following is a sample of an Implanon Removal Consent Form. This form can be downloaded from the ***CDPHE Family Planning Program*** *website at:*
http://www.colorado.gov/cs/Satellite/CDPHE-PSD/CBON/1251618366665

NEXPLANON / IMPLANON REMOVAL CONSENT/ CLIENT INFORMATION

Client Name ______________________________________

I am aware that if I don't want to get pregnant after Nexplanon / Implanon is taken out, I can have a new Nexplanon / Implanon put in or choose a different method of birth control today.

I understand that it could take up to 30 minutes to take out Nexplanon / Implanon. First, the skin over the implant will be cleaned and numbed. Next, a small cut will be made close to the tip of the implant so that it can be removed. I am aware that I might feel some discomfort during this procedure.

I am aware of the possible problems that might occur when taking out Nexplanon / Implanon such as: an allergic reaction to the anesthetic; bruising or soreness where the implant was removed; infection; the implant could break; a second cut could be needed to take out the implant; or a second visit could be needed to take out the implant.

Based on my knowledge of the above, I consent to the removal of Nexplanon / Implanon.

____

Client signature **Date** **Staff Signature** **Date**

INTERPRETER'S STATEMENT

I have interpreted the information and advice presented orally to the client who has chosen to use Nexplanon / Implanon. I have also read to her the consent form in a language she understands and explained its content to her. To the best of my knowledge and belief she understands this explanation and voluntarily consents to the removal of Nexplanon / Implanon.

____

Interpreter's signature **Date**

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NEXPLANON / IMPLANON POST REMOVAL INSTRUCTIONS

I am aware that I can go back to my normal daily activities right away after the Nexplanon / Implanon has been removed. I might have some soreness for a day or two where the Nexplanon / Implanon was removed. There also might be some swelling, bruising, or discoloration for a few days.

1. Try not to bump the place where the Nexplanon / Implanon was removed for a few days.
2. Keep the large gauze bandage on for 24 - 48 hours and keep it dry to avoid an infection.
3. Keep the little bandage strip on for 3 days, and keep it dry.
4. If there is any redness or oozing, or anything that concerns you, return to the clinic to have the removal site checked.

*The following is a sample of a Hormonal Evaluation Form. This form can be downloaded from the **CDPHE Family Planning Program** website at:*
http://www.colorado.gov/cs/Satellite/CDPHE-PSD/CBON/1251618366665

HORMONAL METHOD EVALUATION
ORAL CONTRACEPTIVES (Combined and POP),
EVRA PATCH, NUVARING, IMPLANON (rod implant)

Name _____ Today's date _____

Date of birth _____ Age _____

First day of last period _____

1. **Please check your current method:**

   ☐ Birth control pill (Combined)
   ☐ Evra
   ☐ Implanon
   ☐ Birth control pill (Progesterone only)
   ☐ Nuvaring

2. **Are you having any problems with your method?** ☐ No ☐ Yes
   Explain: _____

3. **Do you have any questions?** ☐ No ☐ Yes
   Explain: _____

4. **Have you had any health problems or seen a physician since your last visit?**
   ☐ No ☐ Yes Explain: _____

5. **Are you taking any other medications?** ☐ No ☐ Yes
   List: _____

6. **Check if you have had any of the following since you started your method:**

   ☐ Severe headaches
   ☐ Dizziness
   ☐ Vision changes
   ☐ Chest pain
   ☐ Severe leg pain
   ☐ Severe abdominal pain
   ☐ Depression
   ☐ Nausea or vomiting
   ☐ Heavy bleeding
   ☐ Weight gain

_____
Client Signature **Date**

TO BE COMPLETED BY STAFF

S:

O: B/P____ WT____

A:

P:

_____
Staff signature **Date**