

SUBDERMAL CONTRACEPTIVE IMPLANT

I. INTRODUCTION

The subdermal contraceptive implant (IMPLANON®/NEXPLANON®) is a long-acting, reversible, hormonal contraceptive that contains 68 mg etonogestrel (progesterone-only) and is effective for up to 3 years. The implant is a sterile, latex-free single-rod 4 cm in length and 2 mm wide. The rod initially releases between 60-70 mcg per day but declines slowly over time (etonogestrel blood levels inhibit ovulation for at least three years in most women).

In 2010 Implanon® was replaced by Nexplanon®. The hormone type and dose have not changed and the only difference in the implant itself was the addition of barium sulfate to allow x-ray location of the implant (Implanon® was not radio-opaque, making it difficult to locate when there was a question about implant location). The only other difference between the two products is the inserter.

The primary mechanisms of action of the subdermal contraceptive implant include suppression of ovulation, increased viscosity of cervical mucus and alterations in the endometrium.

In order to provide this contraceptive method, providers must undergo training for insertion and removal by a manufacturer-approved trainer.

II. CLIENT SELECTION

A. Indications:

1. Contraceptive implants and intrauterine devices (IUD) are top-tier contraceptive options and **should be highly encouraged for all women, especially adolescents.**
 - a. Implants and IUDs have lower failure (pregnancy) rates, higher continuation rates and improved safety when compared with other reversible hormonal or non-hormonal methods of contraception.
 - b. If patients decline the contraceptive implant or IUDs, alternate, less-effective contraceptive methods should be initiated.
2. Contraceptive implants and IUDs offer long-term, highly-effective, private contraception.

B. Contraindications (USMEC 3-- Risks outweigh advantages for method use; USMEC 4-- Unacceptable risk for method use):

C.

Absolute contraindication:

- a. 1. Breast Cancer – (current USMEC 4) (past USMEC 3)

Relative Contraindications:

1. Unexplained vaginal bleeding (USMEC 3 before evaluation)
2. Breast cancer (Past: no evidence of disease for > 5 years: USMEC 3)
3. History of myocardial infarction, ischemic heart disease or stroke (USMEC 3)
4. Cirrhosis (severe-decompensated) (USMEC 3)
5. Liver tumors – adenoma or hepatoma (USMEC 3)
6. Systemic Lupus Erythematosus –positive (or unknown) antiphospholipid antibodies(USMEC 3)

7. Rheumatoid Arthritis-Immunosuppressive therapy – (USMEC 3 for continuation)
8. Migraine with aura at any age (USMEC 3 for continuation)

Drug interactions

There is limited direct evidence regarding potential drug interactions between the subdermal implants (etonogestrel) and various medications. The best evidence indicates possible interactions with certain liver-enzyme inducing medications, including certain antiretroviral medications (ARV) and certain antiepileptic medications (AED), and rifampicin/rifabutin. It is possible for alterations in drug levels; typically a reduction in etonogestrel, which could increase failure of the subdermal implant.

For these patients, the subdermal implant is not contraindicated (USMEC 2 or 1). However, these patients should be encouraged to use dual-method contraception (condoms with the subdermal implant) in order to decrease risk of contraceptive failure. They should also be encouraged to notify their other health care providers of all contraceptives being used.

III. MEDICAL SCREENING AND EVALUATION

- A. An appropriate (targeted) history, height, weight, blood pressure measurement and laboratory testing as indicated should be completed prior to the provision of subdermal contraceptive implant.
- B. Patients should be encouraged to receive routine health maintenance, including annual examination. However, initiation or use of contraception should not be delayed or withheld due to a need for routine health maintenance.
- C. Written results of a physical exam done elsewhere within the last 12 months are acceptable (with the exception of history, height, weight and blood pressure - which must be taken and documented prior to providing implant).
- D. Pelvic exams are not required until age 21 years unless indicated (ACOG).
 - a. Pelvic examinations are not required prior to initiation of a subdermal implant for any patient.
 - b. Pelvic examinations should only be performed if needed as a part of preventative services (eg: annual exam) or if the patient has a medical complaint requiring evaluation.
- E. There is no time at which a pelvic exam is required for initiation or continued provision of the method as long as all eligibility requirements are met.
- F. Pap test screening according to current screening recommendations and site- approved protocols should be followed.
 - a. Contraceptive services, including initiation of a method, should not be delayed or withheld for patients who have not completed recommended screening, including pap smear or STI testing.
 - i. All patients should be encouraged to get age-appropriate screening and evaluation.

IV. WOMEN WITH SPECIAL CONDITIONS REQUIRING FURTHER EVALUATION

- A. Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral must be made based on protocols approved by the site

Medical Director. In addition, there should be consultation with the site Medical Director if needed.

- B. Consultation should be conducted when a client develops migraine with aura during use of contraceptive implant use (USMEC 3).
- C. Consultation may be appropriate to discuss possible use of a subdermal implant in women with comorbid conditions resulting in a USMEC 3 rating. For some of these patients, use of the subdermal implant may be appropriate.
- D. Data has not shown a significant change in effectiveness in overweight or obese women.
 - Use of the subdermal implant in overweight / obese women is USMEC Cat 1.

V. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a subdermal contraceptive implant should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to hormonal contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues.
- C. Information that implant does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- D. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same upon request.
- E. If implant is being provided/prescribed to a client with risk factors, then a Request for Contraception in Women with Risk Factors form should be reviewed and signed.
- F. A copy of the FDA approved Patient Package Insert (PPI).
- G. User card in the implant kit (write in insertion date, lot #, removal date).
- H. Instruction/counseling on importance of reading the Patient Package Insert (PPI).
- I. Emergency, 24-hour telephone number and location where emergency services can be obtained.
- J. Clinic access information.

VI. SUBDERMAL CONTRACEPTIVE IMPLANT INITIATION

- A. Follow manufacturers instructions for insertion and removal.
- B. Pregnancy must be excluded before insertion.
- C. Emergency procedure must be in place to manage vaso-vagal fainting episodes.
- D. Timing of Initiation - the table below should be followed when initiating the contraceptive implant. Alternative timings must be individualized to ensure contraceptive protection.

Current Method	IMPLANON®/NEXPLANON® Insertion	Back-Up
None (in the past month)	Days 1 thru 5 of the menstrual cycle	If more than 5 days since menstrual bleeding started, backup for 7 days
Combination Hormonal Contraceptive a. COC	Can insert anytime in cycle if R/O pregnancy OR a. Anytime within 7 days of the last active COC pill	None

b. Ring c. Patch Progestin Only Pill d. POP	b. Anytime during the 7 day ring-free period c. Anytime during the 7 day patch-free period d. Any day of the month (do not skip any days between the last POP pill and insertion of IMPLANON®/NEXPLANON®)	
IMPLANON®/ NEXPLANON®	On same day implant is removed	None
DMPA	On the day the next injection is due	None
IUCs	Any time in cycle (assure not pregnant) Within first 5 days of menses (remove IUC same day) Beyond first 5 days of menses (admits to sexual intercourse this cycle)---Delay removal of IUC until next menses Beyond first 5 days of menses (admits to no sexual intercourse this cycle)	None Delay removal of IUC until next menses Back-up for 7 days
1st trimester abortion or miscarriage	a. Within first 5 days following a complete first trimester abortion b. If beyond 5 days following complete first trimester abortion, follow instructions for “No hormonal contraceptive use in past month”	None
Post partum or 2 nd trimester abortion	a. Between 21-28 days post-partum (if not exclusively breast feeding) b. Between 21-28 days following 2 nd trimester abortion (no intercourse) c. If >4 weeks post-partum (and exclusively breastfeeding) assure client is not pregnant	None Back-up for 7 days Back-up for 7 days with non-hormonal method

VII. MANAGEMENT OF SIDE-EFFECTS AND COMPLICATIONS

A. Irregular Bleeding Patterns:

1. Clients are likely to have changes in their vaginal bleeding patterns. The unpredictable changes include frequency or duration or amenorrhea. An average of 17.7 days of bleeding or spotting every 90 days.
2. Obtain/perform the following:
 - a. Interval history with focus on the possibility of pregnancy or genital tract infection.
 - b. Pelvic examination, as indicated, to exclude pregnancy, infection, or an anatomic lesion.
 - c. Return for a repeat pregnancy test in 2 weeks. If the repeat pregnancy test is negative and the client has no signs of pregnancy (i.e. nausea, breast tenderness), continue the method.
 - d. Laboratory tests:
 - i. Highly sensitive pregnancy test, if indicated.
 - ii. Hemoglobin, if history suggests prolonged or heavy bleeding. If <10, refer for medical evaluation.

- iii. Gonorrhea and Chlamydia tests, if a cervical or upper tract infection is suspected.
- 3. If no obvious cause of bleeding is found, reassure the client that bleeding patterns are not dangerous and may improve with time.
- 4. If inter-menstrual bleeding becomes problematic, the client may try over the counter (OTC) medication such as Ibuprofen 800 mg PO TID for 5 days.
- 5. Instruct the client that treatment may temporarily improve bleeding pattern, but there is substantial possibility that the irregular pattern will return after discontinuation of treatment.
- 6. Discontinuation may be required if the client continues to find the bleeding intolerable.
- B. Possible Pregnancy:
 - 1. In the rare event of a failure of the contraceptive device, there may be an increased risk of ectopic pregnancy.
 - 2. Obtain/perform the following:
 - a. Interim history update, focusing on pregnancy signs and symptoms.
 - b. Pelvic examination, as indicated, to evaluate uterine softening or enlargement, adnexal tenderness or mass.
 - c. Highly sensitive urine pregnancy test.
 - i. If positive, evaluate for symptoms and signs of ectopic pregnancy; begin workup or refer immediately if suspected.
- C. Headache: (NOTE: migraine with aura any age is a "USMEC 3" for continuation on implant)
 - 1. In clinical trials, 24.9% of IMPLANON® users reported headache as an adverse event.
 - 2. Obtain a headache history in an attempt to differentiate tension headache from migraine.
 - 3. If the headaches seem to be of the tension variety, explain that discontinuation of the subdermal implant is unlikely to change the pattern.
 - 4. For mild headaches without neurological symptoms, attempt treatment with ibuprofen or other analgesic.
 - 5. If analgesics fail or signs of migraine aura are present, weigh the risks and benefits of continuing the subdermal implant.
- D. Weight Change:
 - 1. All progestin-only methods may have a side effect of stimulating patient appetite. This effect appears to be most pronounced with DMPA, but can occur with other methods.
 - a. No progestin-containing contraceptive cause weight gain.
 - i. Changes in patient behavior (increased caloric intake) may result in weight gain.
 - 2. In clinical trials of the subdermal implant, 6.4% gained weight with an average of 2.8 pounds after 1 year and 3.7 pounds after 2 years.
 - 3. Patients may avoid or limit weight changes through monitoring and/or modification of their diet and activity.
 - 4. If these measures fail and weight gain becomes problematic, discontinuing implant may be useful.
- E. Carbohydrate and Lipid Metabolic Effects: implant may induce mild insulin resistance and small changes in glucose concentrations. Women with diabetes or impaired glucose tolerance must be observed by the provider managing the diabetes.
 - a. Subdermal implant use is appropriate for women with hyperlipidemias (USMEC Cat 2) and diabetes (USMEC Cat 1/2).

- F. Liver Function: If jaundice develops using implant removal is recommended as the hormone in IMPLANON®/NEXPLANON® may be poorly metabolized in clients with impaired liver function.
- G. Depression: Clients with a history of depression should be monitored. It is uncommon for progestin-containing contraceptives to have a significant impact on mood; however, in rare circumstances, patients may require removal of a subdermal implant for this reason.
- H. Contact Lens Users: Clients who develop visual changes or changes in lens tolerance should be referred to an ophthalmologist for assessment.

VIII. FOLLOW-UP

- A. Post-insertion site check is not indicated unless the client has signs of infection at the site (red, inflamed, discharge) or other implant related complications.
- B. Advise client to report any of the following:
 1. Unable to palpate rod
 2. Heavy vaginal bleeding (lasting 14 days or longer)
 3. Delayed menses after a long interval of regular cycles
 4. Concern about possible pregnancy
 5. Arm pain, redness, bleeding/discharge at the insertion site
 6. Onset/worsening of migraine, aura, or severe headache
 7. Desire for removal
- C. Annual exams are to be scheduled by the client.
- D. Removal:
 1. Implant should be removed when method change desired, pregnancy desired or implant has reached expiration date (3 years from insertion).
 2. Removal should be conducted only by clinicians who have completed the manufacturer-approved implant insertion and removal training.
 3. Follow removal guidelines in the manufacturer's package insert
 4. Removal consent is needed.
 5. Counsel the client as indicated on alternate contraceptive methods or provide preconception health information if pregnancy is desired.
 6. If client desires another implant, insertion may occur immediately upon removal of the current implant.

IX. DOCUMENTATION

- A. Order must be written in medical record
- B. Document on the medical record and the client's user card:
 1. Date of the insertion
 2. Type and amount of topical anesthetic
 3. 3 year removal date
 4. Location (left or right arm)
 5. Client identification (ID) number
 6. Client and provider palpated inserted rod
 7. Lot number
 8. Expiration date of implant
 9. Full Name of inserter
- C. Removal Documentation
 1. Reason for removal
 2. Type and amount of topical anesthetic

3. Length of incision
 4. Length of time to remove
 5. Any problems encountered
 6. Site care instructions provided
 7. Full Name of remover
- D. All education/counseling must be documented

REFERENCES

1. Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 59, No. RR-4, June 18, 2010
2. Manufacturers FDA approved Patient Package Insert (PPI)

CLIENT EDUCATION FOR CONTRACEPTIVE IMPLANT

(May use the information provided by the manufacturer)

I understand the Patient Labeling for IMPLANON®/NEXPLANON®. I have discussed the implant with my healthcare provider who has answered all my questions. I understand that there are benefits as well as risks from using the implant. I understand that there are other birth control methods and that each has its own benefits and risks.

I also understand that this Patient Consent Form is important. I understand that I need to sign this form to show that I am making an informed and careful decision to use IMPLANON®/NEXPLANON®, and that I have read and understand the following points:

- The implant helps to keep me from getting pregnant.
- No contraceptive method is 100% effective, including the implant.
- IMPLANON®/NEXPLANON® is made of a hormone mixed in a plastic rod.
- It is important to have IMPLANON®/NEXPLANON® inserted at the right time of my menstrual cycle.
- After IMPLANON®/NEXPLANON® is inserted, I should check that it is in place by gently pressing my fingertips over the skin in my arm where it was inserted. I should be able to feel the small rod.
- IMPLANON®/NEXPLANON® must be removed at the end of three years, but can be removed sooner if I want.
- If I have trouble finding a healthcare provider to remove IMPLANON®/NEXPLANON®, I can call 1-877- IMPLANON® (1-877-467-5266) for help.
- The implant is placed under the skin of my arm during a procedure done in my healthcare provider's office. There is a slight risk of getting a scar or an infection from this procedure.
- Removal is usually a small office procedure. However, removal may be difficult. Rarely, the implant cannot be located when it is time to remove it. Special procedures, including surgery in the hospital may be needed. Difficult removals may cause pain and scarring. If IMPLANON®/NEXPLANON® cannot be found/removed its effects may continue while it is still in place, even beyond the three years.
- Most women have changes in their menstrual bleeding while using IMPLANON®/NEXPLANON®. My bleeding may be irregular, lighter or heavier, or my bleeding may completely stop. If I think I am pregnant, I should see my healthcare provider as soon as possible.
- I understand the warning signs for problems with IMPLANON®/NEXPLANON®. I understand that I should seek medical attention if any warning signs appear.
- I should tell all my healthcare providers that I am using IMPLANON®/NEXPLANON®
- I need to have a medical checkup regularly and at any time I am having problems.
- IMPLANON®/NEXPLANON® does not protect me from HIV infection (AIDS) or any other sexually transmitted disease.

**CONSENT FOR SUBDERMAL CONTRACEPTIVE IMPLANT
(OR USE MANUFACTURERS CONSENT FORM)**

I, (print or type name) _____, request subdermal contraceptive implant (IMPLANON®/NEXPLANON®) as my family planning method.

I understand the implant is good for 3 years and I have received information about the benefits, risks, side effects, and the use of a subdermal contraceptive implant as my method of birth control.

I understand that no birth control method is perfect and that some women have gotten pregnant while using the implant (1 out of every 1000 women during the first year of use).

I understand the implant will not protect me from HIV infection or other sexually transmitted infections and I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the implant to decrease the effectiveness of the implant as a contraceptive. I know it is important to tell all my health care providers that I am using an implant for birth control.

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using a subdermal contraceptive implant:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that it is important to tell my health care provider if I have ever had any of the following conditions so my health care provider can explain problems that could happen if I use a subdermal contraceptive implant:

- Diabetes
- High cholesterol
- Headaches
- Seizures or epilepsy
- Gall bladder or kidney disease
- Depression
- HIV / AIDS

I understand that side effects sometimes associated with the subdermal contraceptive implant include:

- Changes in menstrual bleeding pattern, or even no periods
- Spotting or bleeding between periods
- Weight gain
- Headaches
- Acne

- Depression, mood swings, nervousness

I understand that certain problems can be related to the insertion or removal of the implant:

- Pain, irritation, swelling, or bruising at the insertion/removal site on the arm
- Thick scar tissue around the implant making it difficult to remove
- Infection at the insertion/removal site
- Need for hospitalization to remove the implant (the cost is your responsibility)
- IMPLANON®/NEXPLANON® must be removed at the end of three years, but can be removed sooner if I want.
- If I have trouble finding a healthcare provider to remove IMPLANON®/NEXPLANON®, I can call **1-877- IMPLANON® (1-877-467-5266)** for help.

I know to watch for “A.C.H.E.S.” as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Please complete the following if interpretation of informed consent was required:

- An interpreter was offered to the client. Yes No
- This form has been read to the client in the client’s spoken language. Yes No
- Patient’s Language (specify): _____
- Interpreter Name: _____
(print or type name of interpreter)
- Interpreter Services provided by (agency): _____
- Date: _____ Interpreter Signature: _____

Staff Use only:

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____