**(insert AGENCY name)**

Reproductive Health Program

Clinical Practice Standard

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| **Subject:** Subdermal Implant | **No.** |
| **Approved by:**  |  | **Effective Date:**  |
| **Revised Date:** January 2018; January 2019, January 2021, **October 2022** |
| **References:** U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC), 2016; U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR), 2016; Managing Contraception, 11th Ed |

**POLICY:** This Clinical Practice Standard follows the recommendations of the U.S. MEC, 2016; U.S. SPR, 2016; Managing Contraception, 11th Ed, and the Society of Family Planning, 2022.

**PURPOSE:** This Clinical Practice Standard provides direction for reproductive health clinics to assist clients in their use of the subdermal implant.

Implants are controlled contraceptive release systems, implanted into subcutaneous tissue to deliver a synthetic progestin hormone directly to the circulation. There is currently only one contraceptive implant available in the United States; other implants are available abroad. The information in this CPS pertains only to Nexplanon®. Nexplanon® is a single rod implant containing 68 mg of etonogestrel (ENG) which is released slowly from the device/polymer matrix. The Nexplanon® rod is polymer, 4 cm long with a 2-mm diameter. It is non-biodegradable, does not contain latex and is radio-opaque. The contraceptive effect is achieved by suppression of ovulation, increased viscosity of the cervical mucus and alterations in the endometrium. Although Nexplanon® is FDA-approved for use up to 3 years, there is evidence to support its effectiveness through 5 years. Clients may be counseled on extended use of the implant, centering their priorities and preferences.

The implant is very effective, with less than 1 out of 100 people who use the implant become pregnant in the first year of typical use. The implant is long-acting, is reversible, and can be used by clients of all ages, including adolescents.

The implant does not protect against sexually transmitted infections (STIs).

**STANDARD:**

(**insert AGENCY name**) MDs, NPs, PAs, DOs, and NDs may provide the implant to any client who requests this method and has no U.S. MEC category 4 risk conditions. RNs may provide counseling and education related to the implant.

**PROCEDURE:**

1. Follow [*Core Reproductive Health Services Clinical Practice Standard.*](https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/REPRODUCTIVESEXUALHEALTH/RESOURCES/Documents/Clinical-Practice-Standards/CPS-Core_RH.docx)
2. Follow the [U.S. MEC](https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/appendixc.html) guidelines to determine client eligibility for use of the implant.
	1. If client has any MEC category 3 conditions, an NP, PA, DO, ND or MD *may* provide the method according to their clinical judgement, if requested by the client. Documentation must show that the client understands the risks of the method and finds other, lower-risk methods unacceptable.
	2. Clients requesting a method for which they have a category 4 risk condition will be offered lower risk method and referred to an OB/GYN or specialist provider.
3. Provide education on warning signs, common side effects, risks, method of use, alternative methods, use of secondary method, and clinic follow-up schedule. Document client’s education and understanding of the method.
4. Obtain written consent for the procedure and for use of the device.

**PLAN:**

* + - 1. Initiation of the implant:
1. The implant can be inserted at any time if it is reasonably certain that the client is not pregnant:
* If the implant is inserted within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.
* If the implant is inserted >5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
	+ - 1. Special insertion considerations:

Amenorrhea (Not Postpartum):

* The implant can be inserted at any time if it reasonably certain that the client is not pregnant.
* The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postpartum (breastfeeding):

* The implant can be inserted at any time (U.S. MEC 2 if < 1 month postpartum and U.S. MEC 1 if ≥ 1 month postpartum), if it is reasonably certain that the client is not pregnant.
* If the client is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or vast majority [85%] of feeds are breastfeeds) no additional contraceptive protection is needed.
* A client who is ≥21 days postpartum and has not experienced return of their menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
* If a client’s menstrual cycles have returned and it has been > 5 days since menstrual bleeding started, they need to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postpartum (not breastfeeding):

* The implant can be inserted at any time, including immediately postpartum (U.S. MEC 1) if it is reasonably certain that the client is not pregnant.
* A client who is < 21 days postpartum, no additional contraceptive protection is needed.
* A client who is ≥21 days postpartum and has not experienced return of their menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
* If a client’s menstrual cycles have returned and it has been > 5 days since menstrual bleeding started, they need to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

Postabortion (spontaneous or induced):

* The implant can be inserted within the first 7 days, including immediately after the abortion (U.S. MEC 1).
* The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless the implant is inserted at the time of a surgical abortion.
	+ - 1. Switching from another contraceptive method
1. The implant can be inserted immediately if it is reasonably certain that the client is not pregnant. Waiting for their next menstrual period is unnecessary.
* If it has been >5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days after insertion.
1. Switching from an IUD/IUS:
* If the client has had sexual intercourse since the start of their current menstrual cycle and it has been >5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract. A healthcare provider may consider any of the following options:

Advise the client to retain the IUD/IUS for at least 7 days after the implant is inserted and return for IUD/IUS removal;

Advise the client to abstain from sexual intercourse or use barrier contraception for 7 days before removing the IUD/IUS and switching to the new method; or

If the client cannot return for IUD removal and has not abstained from sexual intercourse or used barrier contraception for 7 days, advise the client to use EC pills (with the exception of Ella®) at the time of IUD/IUS removal.

Placement:

1. Only clinicians who have received certification by undergoing approved training by the manufacturer and have demonstrated skill in successful Nexplanon insertion and removal shall insert the implant.
2. Review the implant placement procedure with the client.
3. Obtain written consent for the procedure.
4. Insert the device; the manufacturer’s instructions MUST be followed.
5. Apply a small adhesive bandage over the insertion site.
6. The clinician and client must be able to palpate the device under the skin immediately after the insertion. If it cannot be palpated, the client must be advised to use a non-hormonal contraceptive method until placement is verified.
7. Apply a pressure bandage with sterile gauze to minimize bruising.
8. Instruct the client to remove the pressure bandage in 24 hours and the small adhesive bandage over the insertion site in 3-5 days. Instruct the client to keep the area dry for 48 hours to prevent infection.
9. Document the procedure in the client’s medical record including:
10. Date of procedure;
11. Site of the procedure;
12. The lot number of the implant; and
13. The clinician and client confirmed placement by palpating the implant after insertion.
14. Complete the “User Card” supplied by the manufacturer and give it to the client to keep.
15. Because the device is inserted and retained, it is recommended that the lot number and expiration date is documented in the client’s medical record in addition to the pharmacy dispensing log.

Removal:

1. Only clinicians who have received certification by undergoing a training course approved by the manufacturer and have demonstrated skill in successful Nexplanoninsertion and removal shall remove implants.
2. Review the procedure with the client.
3. Obtain written consent for the procedure.
4. Remove the device per the manufacturer’s instructions, which MUST be followed.
5. If desired, another Nexplanon may be inserted immediately after removal through the same incision and in a track parallel to the one removed.
6. After removal, close the incision with a butterfly closure and apply an adhesive bandage.
7. Apply a pressure bandage with sterile gauze to minimize bruising.
8. Unless pregnancy is desired, an alternative method of contraception should be offered.
9. If pregnancy is desired, provide preconception counseling and advise client to begin taking a daily prenatal vitamin with 0.4 milligrams of folic acid at least 30 days before trying to become pregnant.

**ROUTINE FOLLOW-UP:**

1. The recommendations listed below address when routine follow-up is needed for safe and effective continued use of contraception for healthy clients. These recommendations refer to general situations and might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions may benefit from more frequent follow-up visits.
2. Advise client to return at any time to discuss side effects or other problems, if they want to change their method, or when it is time to remove or replace the implant. No routine follow-up is required.
3. At other routine visits, healthcare providers should do the following:
* Assess a client’s satisfaction with the implant and whether there any concerns about the method use;
* Assess any changes in health status, including medications that would change the appropriateness of the implant for safe and effective continued use based on U.S. MEC; and
* Consider assessing weight changes and counseling clients who are concerned about weight changes perceived to be due to contraceptive method.

Management of Bleeding Irregularities:

1. Prior to implant insertion, provide counseling about potential changes in bleeding patterns during implant use. Unscheduled spotting or light bleeding is common with implant use, and some clients experience amenorrhea. This bleeding is not harmful and may or may not decrease with continued use. Heavy or unusually prolonged bleeding is uncommon with implant use.
2. Irregular bleeding (spotting, light bleeding or heavy or prolonged bleeding):
3. If clinically indicated, consider underlying gynecological problem; such as interaction with other medications, STIs, pregnancy, or new pathologic uterine conditions.
* Refer to the prescribing provider/ PCP for evaluation.
1. If any underlying condition is not found and the client wants treatment, the following treatment options during days of bleeding can be considered:
* NSAIDS for short term treatment (5-7 days); or
* Hormonal treatment (if medically eligible) with low dose combined oral contraceptives or estrogen for short-term treatment (10-20 days) (U.S. SPR, 2013).
1. If irregular bleeding persists and the client finds it unacceptable, counsel on alternative methods, and offer another method if it is desired.
2. Amenorrhea:
3. Amenorrhea does not require any medical treatment. Provide reassurance.
* If a client’s regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.
* If amenorrhea persists and the client finds it unacceptable, counsel on alternative contraceptive methods, and offer another method if it is desired.

**CLIENT EDUCATION:**

1. Review care of insertion or removal site.
2. Instruct client to return to clinic if a significant Nexplanon related problem is suspected and/or if any of the following occur:
3. Unable to palpate rod (use back-up contraception until evaluated);
4. Expulsion (use back-up contraception until they can return to the clinic);
5. Very heavy vaginal bleeding or bleeding that lasts longer than 14 days;
6. Delayed menses after a long interval of regular cycles;
7. Concern about a possible pregnancy;
8. Arm pain; pus, redness, or bleeding at the insertion site;
9. Onset or worsening of episodes of migraine, aura, or severe headache; or
10. Client decides they want the implant removed.
11. Advise the client to contact the clinic whenever they have questions about their contraceptive method.
12. Client shall be informed that any signs or symptoms of complications should be reported to the clinic; if the clinic is not open, clients should call 911 or go to the emergency room.

**REFERENCES:**

Centers for Disease Control and Prevention. 2016. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf>

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FDA Biologics Circular (8/2015) for Nexplanon® <https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021529s011lbl.pdf>

Merck. 2011. Prescribing information. Retrieved October 3, 2014 from <http://www.merck.com/product/usa/pi_circulars/n/nexplanon/nexplanon_pi.pdf>

Zieman, M., Hatcher, R. 2013. Implants: Nexplanon or Implanon- The Single Etonogestrel Implant. *Managing Contraception.* Pg. 128-133. Tiger, Georgia: Bridging the Gap Foundation.

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