Rancho Los Amigos National Rehabilitation Center
OUTPATIENT SERVICES: MOBILE CLINIC POLICY AND PROCEDURE

SUBJECT:	**Women's Health Procedure: Insertion and Removal of Nexplanon**	**Policy No.:**	**404.1**
		Supersedes:	**New**
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1. **PURPOSE**

1.1 To provide guidance and describe the workflow process in insertion and removal of Nexplanon Procedure in the mobile clinic.

2. **POLICY**

2.1 Medical Provider will perform the Nexplanon procedure with a chaperone.
2.2 UCG test will be perform prior to insertion of Nexplanon procedure.
2.3 Provide instructions and answers all patients' questions before the procedure is perform.
2.4 RN, LVN & CMA can help set-up and assist the medical provider in Nexplanon procedure.
2.5 Provide & maintain patient privacy while Nexplanon procedure is perform.
2.6 A signed consent from the patient will be secured before the commencement of the procedure.

3. DEFINITION

3.1 NEXPLANON is the birth control implant that goes in the arm. It's just as effective as the pill, but without the daily hassle. This small, thin, and flexible arm implant is placed discreetly under the skin of the inner, non-dominant upper arm by your medical healthcare provider.

4. **INDICATION:** ***NEXPLANON is indicated for use by women to prevent pregnancy.***

5. **CONTRAINDICATION**

5.1 Absolute
  5.1.1 Pregnancy is an absolute contraindication.
5.2 Relative
  5.2.1 Thromboembolism (current or past).
  5.2.2 Breast cancer (known or suspected), or other progestin sensitive cancer (past or present).
  5.2.3 Hepatic disorders (benign or malignant liver tumors, or active liver disease).
  5.2.4 Unexplained abnormal vaginal bleeding.
  5.2.5 Hypersensitivity (allergic) to components of the product.
  5.2.6 A detailed discussion of relative risks is available in the complete prescribing information at: www.implanon-usa.com/hcp.

6. **DOSE & ADMINISTRATION**

6.1 NEXPLANON (etonogestrel implant) 68mg radiopaque subdermal use only.

6.2 Single, white/off-white, soft, radiopaque, flexible, ethylene vinyl acetate (EVA) copolymer implant, 4 cm in length and 2 mm in diameter containing 68 mg etonogestrel, 15 mg of barium sulfate and 0.1 mg of magnesium stearate.

6.3 The efficacy of NEXPLANON does not depend on daily, weekly or monthly administration.

6.4 NEXPLANON must be inserted by the expiration date stated on the packaging.

6.5 NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive method. The implant must be removed by the end of the third year and may be replaced by a new implant at the time of removal, if continued contraceptive protection is desired.

6.6 A single NEXPLANON implant is inserted sub dermally just under the skin at the inner side of the non-dominant upper arm. The insertion site is overlying the triceps muscle about 8-10 cm (3-4 inches) from the medial epicondyle of the humerus and 3-5 cm (1.25-2 inches) posterior to (below) the sulcus (groove) between the biceps and triceps muscles. This location is intended to avoid the large blood vessels and nerves lying within and surrounding the sulcus. An implant inserted more deeply than sub dermally (deep insertion) may not be palpable and the localization and/or removal can be difficult or impossible [see Dosage and Warnings and Precautions].

* *All health care providers performing insertions and/or removals of NEXPLANON should receive instructions and training prior to inserting or removing the implant.*

The Clinical Training Program for NEXPLANON is offered to all eligible health care providers in a live, 2-hour, hands-on workshop. The training is open only to MD/DO, NP, PA or CNMs, and Residents authorized to perform the procedures entailed in the insertion and removal of NEXPLANON in the jurisdiction where they practice. Additionally, NPs, PAs, and CNMs must attest that they have met all specific state conditions and requirements, including but not limited to signing a collaborative agreement with an MD/DO. Residents must understand that they can only administer NEXPLANON under the supervision of an attending physician who has also been trained on the procedures to insert and remove NEXPLANON.

To request clinical training, contact a representative at 1-877-467-5266 or visit
https://www.nexplanontraining.com/request-clinical-training/in-person-training/

7. INITIATING CONTRACEPTION WITH NEXPLANON

IMPORTANT: Rule out pregnancy before inserting the implant.

Timing of insertion depends on the woman's recent contraceptive history, as follows:

7.1 No preceding hormonal contraceptive use in the past month NEXPLANON should be inserted between Day 1 (first day of menstrual bleeding) and Day 5 of the menstrual cycle, even if the woman is still bleeding. If inserted as recommended, back-up contraception is not necessary. If deviating from the recommended timing of insertion, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded.

7.2 Switching contraceptive method to NEXPLANON Combination hormonal contraceptives: NEXPLANON should preferably be inserted on the day after the last active tablet of the previous combined oral contraceptive or on the day of removal of the vaginal ring or transdermal patch. At the latest, NEXPLANON should be inserted on the day following the usual tablet-free, ring-free, patch-free or placebo tablet interval of the previous combined hormonal contraceptive. If inserted as recommended, back-up contraception is not necessary.

If deviating from the recommended timing of insertion, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded. Progestin-only contraceptives: There are several types of progestin-only methods. NEXPLANON should be inserted as follows: 3

7.3 Injectable Contraceptives: Insert NEXPLANON on the day the next injection is due.

7.4 Minipill: A woman may switch to NEXPLANON on any day of the month. NEXPLANON should be inserted within 24 hours after taking the last tablet.

7.5 Contraceptive implant or intrauterine system (IUS): Insert NEXPLANON on the same day the previous contraceptive implant or IUS is removed. If inserted as recommended, back-up contraception is not necessary. If deviating from the recommended timing of insertion, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded.

7.6 Following abortion or miscarriage

7.7 First Trimester: NEXPLANON should be inserted within 5 days following a first trimester abortion or miscarriage.

7.8 Second Trimester: Insert NEXPLANON between 21 to 28 days following second trimester abortion or miscarriage. If inserted as recommended, back-up contraception is not necessary. If deviating from the recommended timing of insertion, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded.

7.9 Postpartum

7.10 Not Breastfeeding: NEXPLANON should be inserted between 21 to 28 days postpartum. If inserted as recommended, back-up contraception is not necessary. If deviating from the recommended timing of insertion, the woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded.

7.11 Breastfeeding: NEXPLANON should not be inserted until after the fourth postpartum week. The woman should be advised to use a barrier method until 7 days after insertion. If intercourse has already occurred, pregnancy should be excluded. 2.2 Insertion of NEXPLANON the basis for successful use and subsequent removal of NEXPLANON is a correct and carefully performed subdermal insertion of the single, rod-shaped implant in accordance with the instructions. Both the healthcare professional and the woman should be able to feel the implant under the skin after placement. All healthcare professionals performing insertions and/or removals of NEXPLANON should receive instructions and training prior to inserting or removing the implant. Preparation Before inserting NEXPLANON, carefully read the instructions for insertion as well as the full prescribing information. If you are unsure of the necessary steps to safely insert and/or remove NEXPLANON, do not attempt the procedure.

Call the Organon Service Center at 1-844-674-3200 if you have any questions. Videos demonstrating insertion and removal are available online for trained healthcare professionals at https://www.nexplanontraining.com/

* Before insertion of NEXPLANON, the healthcare professional should confirm that:

- The woman is not pregnant and has no other contraindication for the use of NEXPLANON
- The woman has had a medical history and physical examination, including a gynecologic
- examination, performed.
- The woman understands the benefits and risks of NEXPLANON.
- The woman has received a copy of the Patient Labeling included in packaging.

- The woman has reviewed and completed a consent form to be maintained with the woman's chart.
- The woman does not have allergies to the antiseptic and anesthetic to be used during insertion.
- Insert NEXPLANON under aseptic conditions.

8. EQUIPMENT: NEXPLANON INSERTION PROCEDURE

8.1 Upon patient arrival:
8.1.1 UCG test

8.2 In procedure room:
8.2.1 An examination table for the woman to lie on.
8.2.2 Sterile surgical drapes, sterile gloves, antiseptic solution, surgical marker.
8.2.3 Gauze 4" x 4" (sterile), adhesive bandage (like Coban), pressure bandage.
8.2.4 Implant insertion and consent forms.
8.2.5 Local anesthetic.
8.2.6 Povidone-iodine or chlorhexidine in cup with swabs Anesthesia for insertion site.
8.2.7 Spray-on anesthesia or
8.2.8 2 cc of 1% lidocaine (without epinephrine), 3ml syringes, and 25-gauge x 1.5" needles.
8.2.9 NEXPLANON package kit (no. 11 blade, straight and curved mosquito clamps, and forceps are needed for removal)

Insertion Procedure

Technique **(Placement of NEXPLANON)** To help make sure the implant is inserted just under the skin, the healthcare professionals should be positioned to see the advancement of the needle by viewing the applicator from the side and not from above the arm. From the side view, the insertion site and the movement of the needle just under the skin can be clearly visualized.

- The implant rod and inserter should remain sterile throughout the procedure. If at any time sterility is compromised, a new device should be used.

Step 1. Have the patient lie on her back on the examination table with her non-dominant arm flexed at the elbow and externally rotated so that her hand is underneath her head (or as close as possible).

Step 2. Identify the insertion site, which is at the inner side of the non-dominant upper arm. The insertion site
is overlying the triceps muscle about 8-10 cm (3-4 inches) from the medial epicondyle of the humerus and 3-5 cm (1.25-2 inches) posterior to (below) the sulcus (groove) between the biceps and triceps muscles. This location is intended to avoid the large blood vessels and nerves lying within and surrounding the sulcus. If it is not possible to insert the implant in this location (e.g., in women with thin arms), it should be inserted as far posterior from the sulcus as possible.

Step 3. Make two marks with a surgical marker:
1. Mark the spot where the etonogestrel implant will be inserted (6-8cm above the elbow crease of nondominant arm). *The site should be on the medial aspect of the arm, between the biceps and triceps.*

2. *A second mark should be made on the same arm 6 to 8 cm proximal (farther up the arm) to the first mark (2 inches proximal (toward shoulder) to first mark).* This second mark (guiding mark) will later serve as a direction guide during insertion.

Step 4. After marking the arm, confirm the site is in the correct location on the inner side of the arm.

Step 5. Clean the skin from the insertion site to the guiding mark with an antiseptic solution.

Step 6. Anesthetize the insertion area locally with anesthetic spray or by injecting 1-3ml of 1% to 2% lidocaine with or without epinephrine (see Local Anesthesia protocol) just under the skin along the planned insertion tunnel.

Step 7. Remove the sterile preloaded inserter device (without the contraceptive rod in the needle/cannula) from the packaging. The applicator should not be used if sterility is in question. Keep the shield on the needle, identify the white rod inside the needle tip (If not visible, tap the side of the device, with needle pointing down, to slide the rod into the needle tip). It is now possible for the rod to fall out of the needle so keeps the applicator in the upright position until insertion to minimize this risk.

Step 8. Hold the applicator just above the needle at the textured surface area. Remove the transparent protection cap by sliding it horizontally in the direction of the arrow away from the needle. If the cap does not come off easily, the applicator should not be used. You should see the white colored implant by looking into the tip of the needle. Do not touch the purple slider until you have fully inserted the needle sub dermally, as doing so will retract the needle and prematurely release the implant from the applicator.

Step 9. If the purple slider is released prematurely, restart the procedure with a new applicator.

Step 10. With your free hand, stretch the skin around the insertion site towards the elbow.

Step 11. The implant should be inserted sub dermally just under the skin [see Warnings and Precautions]. To help make sure the implant is inserted just under the skin; you should position yourself to see the advancement of the needle by viewing the applicator from the side and not from above the arm. From the side view, you can clearly see the insertion site and the movement of the needle just under the skin.

Step 12. While applying countertraction to the skin, puncture the skin with the needle bevel up into the skin, slightly angled less than 20°

Step 13. Insert the needle until the bevel (slanted opening of the tip) is just under the skin (and no further). If you inserted the needle deeper than the bevel, withdraw the needle until only the bevel is beneath the skin.

Step 14. Lower the applicator to a nearly horizontal position. To facilitate subdermal placement, lift the skin with the needle while sliding the needle to its full length. You may feel slight resistance but do not exert excessive force. If the needle is not inserted to its full length, the implant will not be inserted properly. If the needle tip emerges from the skin before needle insertion is complete, the needle should be pulled back and be readjusted to subdermal position before completing the insertion

procedure.

Step 15. Break the applicator seal by pressing the support for the obturator. Keep the applicator in the same position with the needle inserted to its full length. If needed, you may use your free hand to stabilize the applicator. Unlock the purple slider by pushing it slightly down (turn obturator 90 degrees in either direction) or retract the cannula (move the slider fully back until it stops). Do not move the applicator while moving the purple slider (do not push or pull on the obturator). Slide the cannula off the device, allowing the insert to "fall in place" and be implanted into the patient. The implant is now in its final subdermal position, and the needle is locked inside the body of the applicator. The applicator can now be removed. Check the needle to make sure the device is not in it:

- If the applicator is not kept in the same position during this procedure or if the purple slider is not moved fully back until it stops, the implant will not be inserted properly and may protrude from the insertion site.
- If the implant is protruding from the insertion site, remove the implant and perform a new procedure at the same insertion site using a new applicator. Do not push the protruding implant back into the incision.

Step 16. Apply a small adhesive bandage over the insertion site.

Step 17. Always verify the presence of the implant in the woman's arm immediately after insertion by palpation. By palpating both ends of the implant, you should be able to confirm the presence of the 4 cm rod. See "If the rod is not palpable after insertion" below.

Step 18. Request that the woman palpate the implant.

Step 19. Apply a pressure bandage with sterile gauze to minimize bruising. The woman may remove the pressure bandage in 24 hours and the small adhesive bandage over the insertion site after 3 to 5 days.

Step 20. Complete the USER CARD and give it to the woman to keep. Also, complete the PATIENT CHART LABEL and affix it to the woman's medical record.

Step 21. The applicator is for single use only and should be disposed in accordance with the Center for Disease Control and Prevention guidelines for handling of hazardous waste.

- **If the rod is not palpable after insertion**: If you cannot feel the implant or are in doubt of its presence, the implant may not have been inserted or it may have been inserted deeply:
- Check the applicator. The needle should be fully retracted and only the purple tip of the obturator should be visible.
- Use other methods to confirm the presence of the implant. Given the radiopaque nature of the implant, suitable methods for localization are:
    - Two-dimensional X-ray and X-ray computerized tomography (CT scan).
    - Ultrasound Scanning (USS) with a high frequency linear array transducer (10 MHz or greater)
    - Magnetic Resonance Imaging (MRI) may be used.

** If this method fails, call the Organon Service Center at 1-844-674-3200 for information on the procedure for measuring etonogestrel blood levels which can be used for verification of the presence of the implant.*

- Until the presence of the implant has been verified, the woman should be advised to use a non-hormonal contraceptive method, such as condoms.
- Deeply placed implants should be localized and removed as soon as possible to avoid the potential for distant migration [see Warnings and Precautions].

9. EQUIPMENT: NEXPLANON REMOVAL PROCEDURE

9.1 In Procedure Room

- An examination table for the woman to lie on.
- Sterile drapes, sterile gloves, antiseptic solution, surgical marker.
- Gauze 4" x 4" (sterile)
- Butterfly closure or steri-strips, pressure bandage.
- Local anesthetic.
    - Povidone-iodine or chlorhexidine in cup with swabs Anesthesia for insertion site:
    - Spray-on-anesthesia or
    - 2 cc of 1% lidocaine (without epinephrine), 3mll syringes, and 25-gauge x 0.5" or 1.5" needles.
- Scalpel (sterile 15 blade)
- Straight and curved mosquito forceps (sterile)

Procedure for Removal of an Implant that is Palpable

Preparation Removal of the implant should only be performed under aseptic conditions by a healthcare professional who is familiar with the removal technique and familiar with localizing the implant and the anatomy of the arm. If you are unfamiliar with the removal technique, call 1-844-674-3200 for further information.

- Before initiating the removal procedure, the healthcare professional should assess the location of the implant and carefully read the instructions for removal. The exact location of the implant in the arm should be verified by palpation.
- If the implant is not palpable, consult the User Card or medical record to verify the arm which contains the implant. If the implant cannot be palpated, it may be deeply located or have migrated. Consider that it may lie close to vessels and nerves.

Before removal of the implant, the healthcare professional should confirm that:

- The woman does not have allergies to the antiseptic or anesthetic to be used.
- Prepare proper equipment (see above)

Technique **(Removal of NEXPLANON)**

Step 1. Have the woman lie on her back on the table. The arm should be positioned with the elbow flexed and the hand underneath the head (or as close as possible).

Step 2. Locate the implant by palpation. Push down the end of the implant closest to the shoulder to stabilize it; a bulge should appear indicating the tip of the implant that is closest to the elbow. If the tip does not pop up; removal of the implant may be more challenging and should be performed by professionals experienced with removing deeper implants. Call 1-844-674- 3200 for further information. Mark the distal end (end closest to the elbow), for example, with a surgical marker. P – Proximal (toward the shoulder) D - Distal (toward the elbow)

Step 3. Clean the site with an antiseptic solution.

Step 4. Anesthetize the site, for example, with 0.5 to 1 mL 1% lidocaine, where the incision will be made. Be sure to inject the local anesthetic under the implant to keep the implant close to the skin surface. Injection of local anesthetic over the implant may make removal more difficult.

Step 5. Push down the end of the implant closest to the shoulder to stabilize it throughout the procedure. Starting over the tip of the implant closest to the elbow, make a longitudinal (parallel to the implant) incision of 2-3 mm towards the elbow using a no. 11 blade. Take care not to cut the tip of the implant.

Step 6. The tip of the implant should pop out of the incision. If it does not, gently push the implant towards the incision until the tip is visible. Grasp the implant with forceps (hemostat) and remove the implant. If needed, gently remove adherent tissue from the tip of the implant using blunt dissection. If the implant tip is not exposed following blunt dissection, make an incision into the tissue sheath and then remove the implant with the forceps.

Step 7. If the tip of the implant does not become visible in the incision, insert forceps (preferably curved mosquito forceps, with the tips pointed up) superficially into the incision. Gently grasp the implant and then flip the forceps over into your other hand.

Step 8. With a second pair of forceps carefully dissect the tissue around the implant and grasp the implant. The implant can then be removed. If the implant cannot be grasped, stop the procedure and refer the woman to a healthcare professional experienced with complex removals or call 1-844-674 3200.

Step 9. Ensure that the entire device has been removed by measuring it (length is 4 cm). There have been reports of broken implants while in the patient's arm. In some cases, difficult removal of the broken implant has been reported. If a partial implant (less than 4 cm) is removed, the remaining piece should be removed. If the woman would like to continue using NEXPLANON, a new implant may be inserted immediately after the old implant is removed using the same incision as long as the site is in the correct location, or in the opposite arm if desired.

Step 10. After removing the implant, close the incision with a sterile adhesive wound closure.

Step 11. Apply a pressure bandage with sterile gauze to minimize bruising. The woman may remove the pressure bandage in 24 hours and the sterile adhesive wound closure in 3 to 5 days. After

removal, Steri-Strips should be left in place until they "fall off." The wound should be treated as a simple laceration.

10. Localization and Removal of a Non-Palpable Implant

10.1 There have been reports of migration of the implant; usually this involves minor movement relative to the original position [see Warnings and Precautions] but may lead to the implant not being palpable at the location in which it was placed.

10.2 An implant that has been deeply inserted or has migrated may not be palpable and therefore imaging procedures, as described below, may be required for localization. A non-palpable implant should always be located prior to attempting removal.

10.3 Given the radiopaque nature of the implant, suitable methods for localization are:

- two-dimensional X-ray and X-ray computerized tomography (CT scan).
- Ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater)
- magnetic resonance imaging (MRI) may be used.
- If these methods fail, call the Organon Service Center at 1-844-674-3200 for information on the procedure for measuring etonogestrel blood levels which can be used for verification of the presence of the implant.

10.4 Once the implant has been localized in the arm, the implant should be removed by a healthcare professional experienced in removing deeply placed implants and familiar with the anatomy of the arm.

10.5 The use of ultrasound guidance during the removal should be considered.

10.6 If the implant cannot be found in the arm after comprehensive localization attempts, consider applying imaging techniques to the chest as events of migration to the pulmonary vasculature have been reported.

- If the implant is located in the chest, surgical or endovascular procedures may be needed for removal; healthcare professionals familiar with the anatomy of the chest should be consulted.
- If at any time these imaging methods fail to locate the implant, etonogestrel blood level determination can be used for verification of the presence of the implant. For details on etonogestrel blood level determination, call 1-844-674-3200 for further instructions.
- If the implant migrates within the arm, removal may require a minor surgical procedure with a larger incision or a surgical procedure in an operating room.

10.7 Removal of deeply inserted implants should be conducted with caution in order to help prevent injury to deeper neural or vascular structures in the arm.

10.8 Non-palpable and deeply inserted implants should be removed by healthcare professionals familiar with the anatomy of the arm and removal of deeply inserted implants. Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged.

Replacing NEXPLANON

Immediate replacement can be done after removal of the previous implant and is similar to the insertion procedure described in section "Insertion Procedure" above. The new implant may be inserted in the same arm, and through the same incision from which the previous implant was removed, as long as the site is in the correct location, i.e., 8-10 cm from the medial epicondyle of the humerus and 3-5 cm posterior to (below) the sulcus. If the same incision is being used to insert a new implant, anesthetize the insertion site [for example, 2 mL lidocaine (1%)] applying it just under the skin along the 'insertion canal.' Follow the subsequent steps in the insertion instructions [see Insertion Procedure].

For WARNINGS AND PRECAUTIONS, visit:
https://www.organonconnect.com/nexplanon/professional-resources/

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