Nexplanon®
(etonogestrel implant) 68mg
Radiopaque

Clinical Training Program

Insertion and Removal

This document contains the instructions for insertion and removal of NEXPLANON® (etonogestrel implant) 68 mg Radiopaque and a summary of key points. It is not intended to be a substitute for consulting the Prescribing Information or any of the training materials. **Please read the accompanying Prescribing Information carefully before inserting or removing NEXPLANON.**

NEXPLANON should be inserted and removed only by a healthcare professional who has completed a clinical training program.

Insertion of NEXPLANON® (etonogestrel implant) 68 mg Radiopaque

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. Information concerning the insertion and removal of NEXPLANON will be sent upon request free of charge (1-844-674-3200).

Preparation

Before inserting NEXPLANON, carefully read the instructions for insertion as well as the full Prescribing Information.

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 the packaging.
- The woman does not have allergies to the antiseptic and anesthetic to be used during insertion.

Insert NEXPLANON under aseptic conditions.

The following equipment is needed for the implant insertion:

- An examination table for the woman to lie on
- Sterile surgical drapes, sterile gloves, antiseptic solution, surgical marker
- Local anesthetic, needles, and syringe
- Sterile gauze, adhesive bandage, pressure bandage

To report SUSPECTED ADVERSE REACTIONS, contact the Organon Service Center at 1-844-674-3200 or FDA at 1-888-INFO-FDA (1-888-463-6332) or www.fda.gov/medwatch.

Insertion Procedure

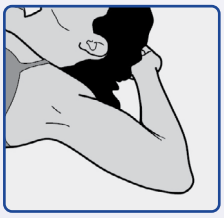

Figure 1

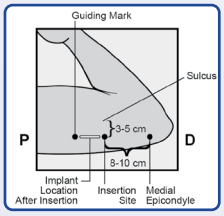

Figure 2a

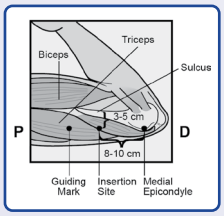

Figure 2b

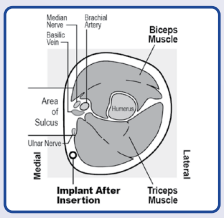

Figure 2c

Cross-section of the upper left arm, as viewed from the elbow Medial (inner side of the arm) Lateral (outer side of the arm)

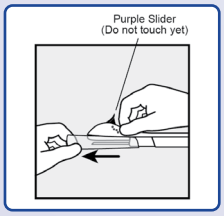

Figure 3

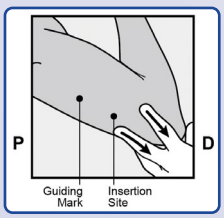

Figure 4

Step 1.

Have the woman 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) ***(Figure 1)***.

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 ***(Figures 2a, 2b, and 2c)***. 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 (eg, 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: first, mark the spot where the etonogestrel implant will be inserted, and second, mark a spot at 5 centimeters (2 inches) proximal (toward the shoulder) to the first mark ***(Figures 2a and 2b)***. 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 (for example, with anesthetic spray or by injecting 2 mL of 1% lidocaine just under the skin along the planned insertion tunnel).

Step 7.

Remove the sterile preloaded disposable NEXPLANON® (etonogestrel implant) 68 mg Radiopaque applicator containing the implant from its blister packaging. Prior to use, visually inspect the packaging for breaches of integrity or damage (e.g., torn, punctured, etc.). If the packaging has any visual damage that could compromise sterility, do not use the product.

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 ***(Figure 3)***. 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 subdermally, 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 ***(Figure 4)***.

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Note: Figure numbers correspond to figures in Prescribing Information.
For illustrative purposes, figures depict the left inner arm.
P – Proximal (toward the shoulder); D – Distal (toward the elbow).

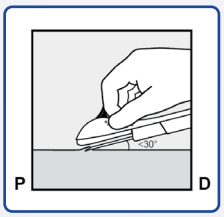

Figure 5a

Step 11.

The implant should be inserted subdermally under the skin. 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 *(Figure 6)*, you can clearly see the insertion site and the movement of the needle just under the skin.

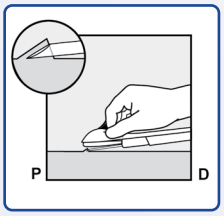

Figure 5b

Step 12.

Puncture the skin with the tip of the needle slightly angled less than 30° ***(Figure 5a)***.

Step 13. ⚠

Insert the needle until the bevel (slanted opening of the tip) is just under the skin (and no further) ***(Figure 5b)***. If you inserted the needle deeper than the bevel, withdraw the needle until only the bevel is beneath the skin.

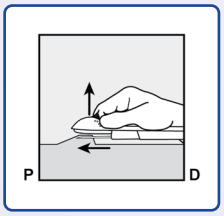

Figure 6

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 ***(Figure 6)***. 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.**

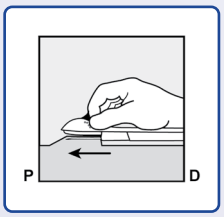

Figure 7

Step 15.

Keep the applicator in the same position with the needle inserted to its full length ***(Figure 7)***. If needed you may use your free hand to stabilize the applicator. Unlock the purple slider by pushing it slightly down ***(Figure 8a)***. Move the slider fully back until it stops. **Do not move the applicator while moving the purple slider *(Figure 8b)*.** 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 ***(Figure 8c)***. **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**.

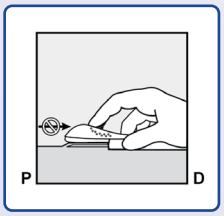

Figure 8a

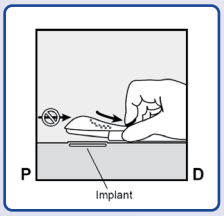

Figure 8b

Step 16.

Apply a small adhesive bandage over the insertion site.

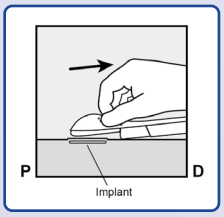

Figure 8c

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Note: Figure numbers correspond to figures in Prescribing Information.
For illustrative purposes, figures depict the left inner arm.
P – Proximal (toward the shoulder); D – Distal (toward the elbow).

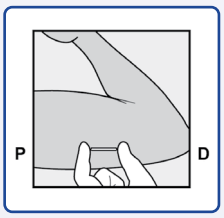

Figure 9

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 ***(Figure 9)***. 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 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.

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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) or 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.

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.

Removal of NEXPLANON® (etonogestrel implant) 68 mg Radiopaque

Preparation ⚠

Removal of the implant should only be performed under aseptic conditions by a healthcare professional who is familiar with the removal technique. **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 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. Removal of non-palpable implants should only be performed by a healthcare professional experienced in removing deeply placed implants and familiar with localizing the implant and the anatomy of the arm. Call 1-844-674-3200 for further information.

Procedure for Removal of an Implant That Is Palpable

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.

The following equipment is needed for removal of the implant:

- An examination table for the woman to lie on
- Sterile surgical drapes, sterile gloves, antiseptic solution, surgical marker
- Local anesthetic, needles, and syringe
- Sterile scalpel, forceps (straight and curved mosquito)
- Skin closure, sterile gauze, and pressure bandage

Removal Procedure

Figure 1

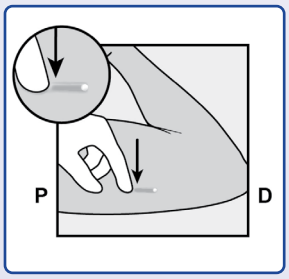

Figure 10

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) ***(Figure 1)***.

Step 2. ⚠
Locate the implant by palpation. Push down the end of the implant closest to the shoulder ***(Figure 10)*** 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.

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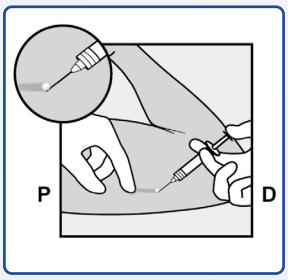

Figure 11

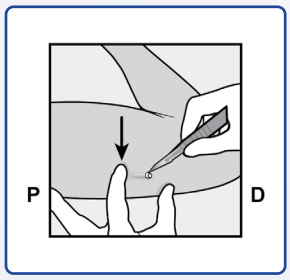

Figure 12

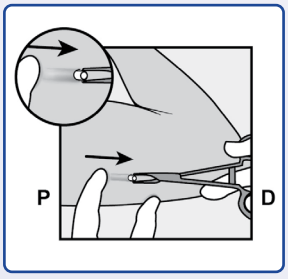

Figure 13

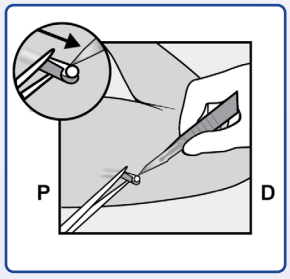

Figure 14

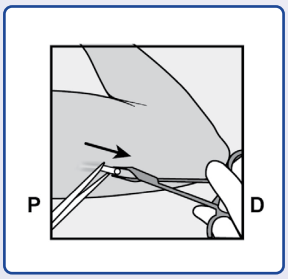

Figure 15

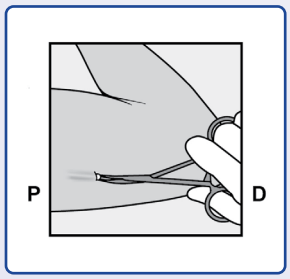

Figure 16

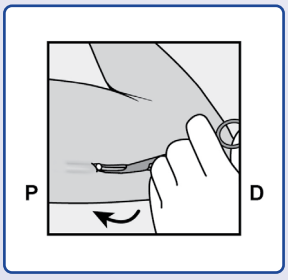

Figure 17

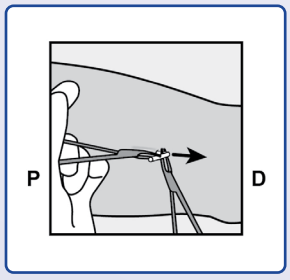

Figure 18

Note: Figure numbers correspond to figures in Prescribing Information.
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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 ***(Figure 11)***. Be sure to inject the local anesthetic **under** the implant to keep it 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 ***(Figure 12)*** 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 mm towards the elbow. 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 and, if possible, remove the implant ***(Figure 13)***. 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 ***(Figures 14 and 15)***.

Step 7.

If the tip of the implant does not become visible in the incision, insert a forceps (preferably curved mosquito forceps, with the tips pointed up) superficially into the incision ***(Figure 16)***. Gently grasp the implant and then flip the forceps over into your other hand ***(Figure 17)***.

Step 8.

With a second pair of forceps carefully dissect the tissue around the implant and grasp the implant ***(Figure 18)***. 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.

Confirm that the entire implant, which is 4 cm long, has been removed by measuring its length. 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 by following the instructions in section 2.3 (of the Prescribing Information for NEXPLANON® (etonogestrel implant) 68 mg Radiopaque). 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.

Continued on next page.

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.

The woman should restart contraception immediately after removal of the implant if continued contraceptive protection is desired.

Localization and Removal of a Non-Palpable Implant

There have been reports of migration of the implant; usually this involves minor movement relative to the original position *[see Warnings and Precautions (5.1)]*, but may lead to the implant not being palpable at the location in which it was placed. 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. Given the radiopaque nature of the implant, suitable methods for localization include two-dimensional X-ray and X-ray computer tomography (CT). Ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater) or magnetic resonance imaging (MRI) may be used. 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. The use of ultrasound guidance during the removal should be considered.

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

Localization Methods

If NEXPLANON® (etonogestrel implant) 68 mg Radiopaque is not palpable, you may use other methods to confirm the presence of the implant. Suitable methods are: two-dimensional X-ray, ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater), X-ray computerized tomography (CT scan), or magnetic resonance imaging (MRI).

If these methods fail, call 1-844-674-3200 for information on the procedure for measuring etonogestrel blood levels.

To report SUSPECTED ADVERSE REACTIONS, contact the Organon Service Center at 1-844-674-3200 or FDA at 1-888-INFO-FDA (1-888-463-6332) or www.fda.gov/medwatch.

Complications of Insertion/Removal and Broken/Bent Implants

NEXPLANON® (etonogestrel implant) 68 mg Radiopaque should be inserted subdermally so that it will be palpable after insertion, and this should be confirmed by palpation immediately after insertion. Failure to insert NEXPLANON properly may go unnoticed unless it is palpated immediately after insertion. Undetected failure to insert the implant may lead to an unintended pregnancy. Complications related to insertion and removal procedures may occur, e.g., pain, paresthesia, bleeding, hematoma, scarring, or infection.

If NEXPLANON is inserted deeply (intramuscular or intrafascial), neural or vascular injury may occur. To help reduce the risk of neural or vascular injury, NEXPLANON should be inserted subdermally just under the skin at the inner side of the non-dominant upper arm 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 nerves and blood vessels lying within and surrounding the sulcus. Deep insertions of NEXPLANON have been associated with paraesthesia (due to neural injury), migration of the implant (due to intramuscular or fascial insertion), and intravascular insertion. If infection develops at the insertion site, start suitable treatment. If the infection persists, the implant should be removed. Incomplete insertions or infections may lead to expulsion.

Reports of implant migration within the arm may have been related to deep insertion. Postmarketing reports of implants located within the vessels of the arm and the pulmonary artery also may have been related to deep insertions or intravascular insertions. Some cases of implants found within the pulmonary artery were associated with chest pain and/or respiratory disorders (such as dyspnea, cough, or hemoptysis); others were asymptomatic. In cases where the implant has migrated to the pulmonary artery, endovascular or surgical procedures may be needed for removal.

Implant removal may be difficult or impossible if the implant is not inserted correctly, is inserted too deeply, not palpable, encased in fibrous tissue, or has migrated. If at any time the implant cannot be palpated, it should be localized and removal is recommended. When an implant is removed, it is important to remove it in its entirety.

Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged. Removal of deeply inserted implants should be conducted with caution in order to prevent injury to deeper neural or vascular structures in the arm and be performed by healthcare professionals familiar with the anatomy of the arm. If the implant is located in the chest, healthcare professionals familiar with the anatomy of the chest should be consulted. Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.

Broken or Bent Implants:
Cases of breakage or bending of implants while inserted within a patient's arm have been reported. Cases of migration of a broken implant fragment within the arm have also occurred. These cases may be related to external forces, e.g., manipulation of the implant or contact sports. The release rate of etonogestrel may be slightly increased in a broken or bent implant, based on *in vitro* data. As noted previously, when an implant is removed, it is important to remove it in its entirety.

To report SUSPECTED ADVERSE REACTIONS, contact the Organon Service Center at 1-844-674-3200 or FDA at 1-888-INFO-FDA (1-888-463-6332) or www.fda.gov/medwatch.

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Nexplanon®
(etonogestrel implant) 68mg
Radiopaque