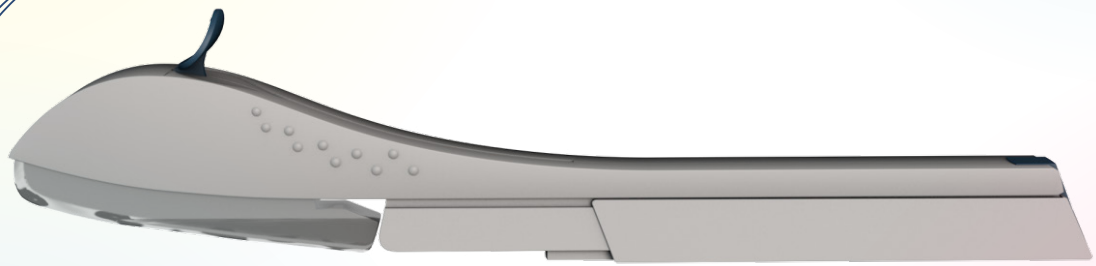
NEXPLANON®
(etonogestrel implant) 68 mg
Radiopaque



(Applicator not actual size)

Removal Instructions

INDICATION AND SELECTED SAFETY INFORMATION

INDICATION
NEXPLANON® is indicated for prevention of pregnancy in women of reproductive potential for up to 5 years.

SELECTED SAFETY INFORMATION

WARNING: RISK OF COMPLICATIONS DUE TO IMPROPER INSERTION and REMOVAL
Improper insertion of NEXPLANON increases the risk of complications.
Proper training prior to first use of NEXPLANON can minimize the risk of improper NEXPLANON insertion.
Because of the risk of complications due to improper insertion and removal NEXPLANON is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the NEXPLANON REMS.

Selected Safety Information continued on next page.
Before prescribing NEXPLANON, please read the Prescribing Information, including Boxed Warning.

REMOVAL OF *NEXPLANON*

NEXPLANON is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the NEXPLANON REMS program to ensure healthcare providers are trained on the proper insertion and removal of NEXPLANON prior to first use. To enroll and become certified, visit www.NEXPLANONREMS.com.

All healthcare professionals must receive instruction and training prior to performing insertion and/or removal of NEXPLANON.

⚠ 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.
[For instructions on localization and removal of non-palpable implant, see page 5.]

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

SELECTED SAFETY INFORMATION (*continued*)

CONTRAINDICATIONS

- NEXPLANON should not be used in women who have known or suspected pregnancy; current or past history of thrombosis or thromboembolic disorders; liver tumors or active liver disease; undiagnosed abnormal uterine bleeding; known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past; or allergy to any component of NEXPLANON.

WARNINGS AND PRECAUTIONS
Risk of Complications Due to Improper Insertion and Removal

Complications of insertion and removal

- Palpate immediately after insertion to ensure proper placement. Undetected failure to insert the implant may lead to unintended pregnancy.
- Insertion and removal-related complications that may occur include pain, paresthesia, bleeding, hematoma, scarring, or infection. If NEXPLANON is inserted too deeply (intramuscular or intrafascial), neural or vascular injury may occur.
- There have been postmarketing reports of implants located within the vessels of the arm and the pulmonary artery; in these cases, endovascular or surgical procedures may be needed for removal.
- Implant removal may be difficult or impossible if the implant is not inserted correctly, 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.

Selected Safety Information continued on next page.

REMOVAL PROCEDURE

For illustrative purposes, Figures depict the left inner arm.

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). (See Figure 1.)

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

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 3). 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 (Figure 4) 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.

Figure 1

Figure 2

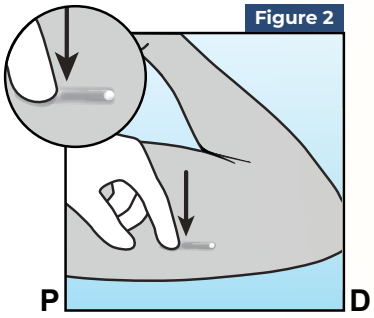


Figure 3

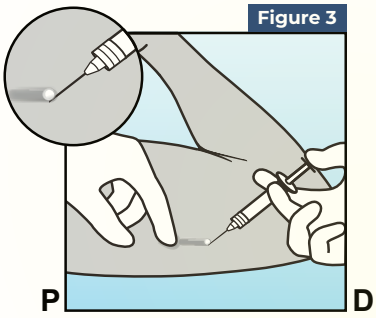
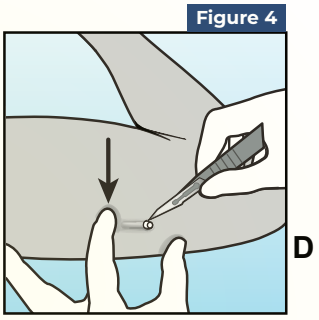


Figure 4



P – Proximal (toward the shoulder)
D – Distal (toward the elbow)

SELECTED SAFETY INFORMATION (*continued*)

Complications of insertion and removal (*continued*)

- 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.

NEXPLANON REMS

- NEXPLANON is only available through a restricted program under a REMS called NEXPLANON REMS because of the risk of complications due to improper insertion and removal.

  Notable requirements of the NEXPLANON REMS include the following:
  - Healthcare providers must be certified with the program by enrolling and completing training on the proper insertion and removal of NEXPLANON prior to first use.
  - Pharmacies must be certified with the program and must only dispense NEXPLANON to certified healthcare providers who dispense NEXPLANON for insertion.

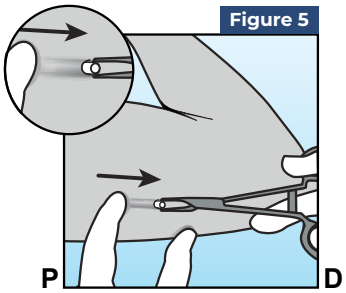
Selected Safety Information continued on next page.

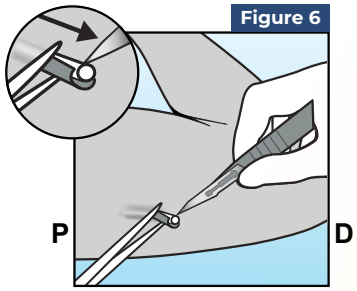
REMOVAL PROCEDURE (*continued*)

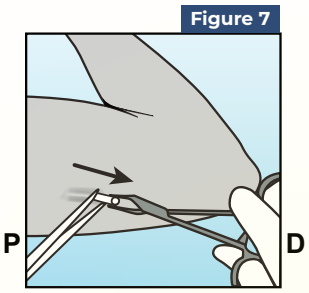
STEP 6. The tip of the implant should pop out of the incision. If it does not, gently push the implant towards the incision until the tip is visible. Grasp the implant with forceps and, if possible, remove the implant (Figure 5). If needed, gently remove adherent tissue from the tip of the implant using 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 6 and 7).

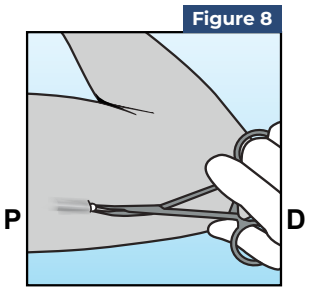
STEP 7. If the tip of the implant does not become visible in the incision, insert forceps (preferably curved mosquito forceps, with the tips pointed up) superficially into the incision (Figure 8). Gently grasp the implant and then flip the forceps over into your other hand (Figure 9).

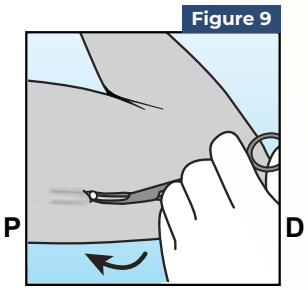
STEP 8. With a second pair of forceps carefully dissect the tissue around the implant and grasp the implant (Figure 10). The implant can then be removed. STOP **If the implant cannot be grasped, stop the procedure and refer the woman to a healthcare professional experienced with complex removals or call 1-844-674-3200.**

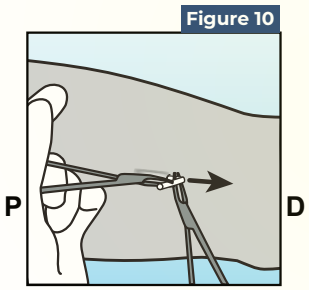












SELECTED SAFETY INFORMATION (*continued*)

NEXPLANON REMS (*continued*)

- Wholesalers and distributors must be registered with the program and must only distribute to certified pharmacies and certified healthcare providers.

Further information is available at **www.NEXPLANONREMS.com** and 1-833-697-7367.

Changes in Menstrual Bleeding Patterns

- After starting NEXPLANON, women are likely to have changes in their menstrual bleeding patterns, which can include changes in frequency, intensity, or duration. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy. In clinical studies of the non-radiopaque etonogestrel implant, the most common reason for discontinuation was changes in bleeding patterns (11.1%).

Ectopic Pregnancies

- Be alert to the possibility of an ectopic pregnancy in women using NEXPLANON who become pregnant or complain of lower abdominal pain.

Selected Safety Information continued on next page.

REMOVAL PROCEDURE (*continued*)

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 Removal of NEXPLANON, above. 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. *[For information on Replacing NEXPLANON, see page 6.]*

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.

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, but may lead to the implant not being palpable at the location in which it was placed. *[For more information on implant migration, see NEXPLANON Prescribing Information, Warnings and Precautions (5.1).]* 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.

SELECTED SAFETY INFORMATION (*continued*)

Thrombotic and Other Vascular Events

- There have been postmarketing reports of serious arterial thrombotic and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and strokes, in women using etonogestrel implants. Assess women with known risk factors. NEXPLANON should be removed if thrombosis occurs.
- NEXPLANON should not be used prior to 21 days postpartum due to risk of thromboembolism.
- Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence.
- In case of long-term immobilization, consider removing NEXPLANON.

ADDITIONAL WARNINGS & PRECAUTIONS AND ADVERSE REACTIONS

- Remove NEXPLANON if jaundice occurs or blood pressure rises significantly and becomes uncontrolled.
- Monitor prediabetic and diabetic women using NEXPLANON.
- Observe women with a history of depressed mood. Consider removing NEXPLANON in patients who become significantly depressed.

Selected Safety Information continued on next page.

Localization and Removal of a Non-Palpable Implant (*continued*)

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.

Replacing NEXPLANON

Immediate replacement can be done after removal of the previous implant and is similar to the insertion procedure described in NEXPLANON Insertion Instructions. [*Please see NEXPLANON Prescribing Information, Section 2.2.*]

The new implant may be inserted in the same arm, and through the same incision from which the previous implant was removed, if 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. [*For details, see NEXPLANON Prescribing Information, Dosage and Administration (2.2).*] *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 NEXPLANON Insertion Instructions. [*For details, see NEXPLANON Prescribing Information, Dosage and Administration (2.2).*]

SELECTED SAFETY INFORMATION (*continued*)

ADDITIONAL WARNINGS & PRECAUTIONS AND ADVERSE REACTIONS (*continued*)

- The most common adverse reactions (≥5%) reported in 3-year clinical trials were headache (24.9%), vaginitis (14.5%), weight increase (13.7%), acne (13.5%), breast pain (12.8%), abdominal pain (10.9%), and pharyngitis (10.5%). In a separate clinical trial to assess contraceptive efficacy and safety of NEXPLANON beyond 3 years, up to 5 years, a similar adverse reaction profile was observed as in Years 1 through 3. The most frequently reported adverse reaction >5% was intermenstrual bleeding (5.4%).

DRUG INTERACTIONS AND USE IN SPECIFIC POPULATIONS

- Drugs or herbal products that induce enzymes, including CYP3A4, may decrease the effectiveness of NEXPLANON or increase breakthrough bleeding.
- **Rule out pregnancy before inserting NEXPLANON.**
- NEXPLANON does not protect against HIV or other STDs.

Before prescribing NEXPLANON, please read the Prescribing Information, including Boxed Warning. The Patient Information also is available.

Manufactured for: Organon USA LLC, a subsidiary of Organon & Co., Jersey City, NJ 07302, USA
Manufactured by: N.V. Organon, Oss, The Netherlands, a subsidiary of Organon & Co., Jersey City, NJ 07302, USA
For patent information: www.organon.com/our-focus/patents/

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