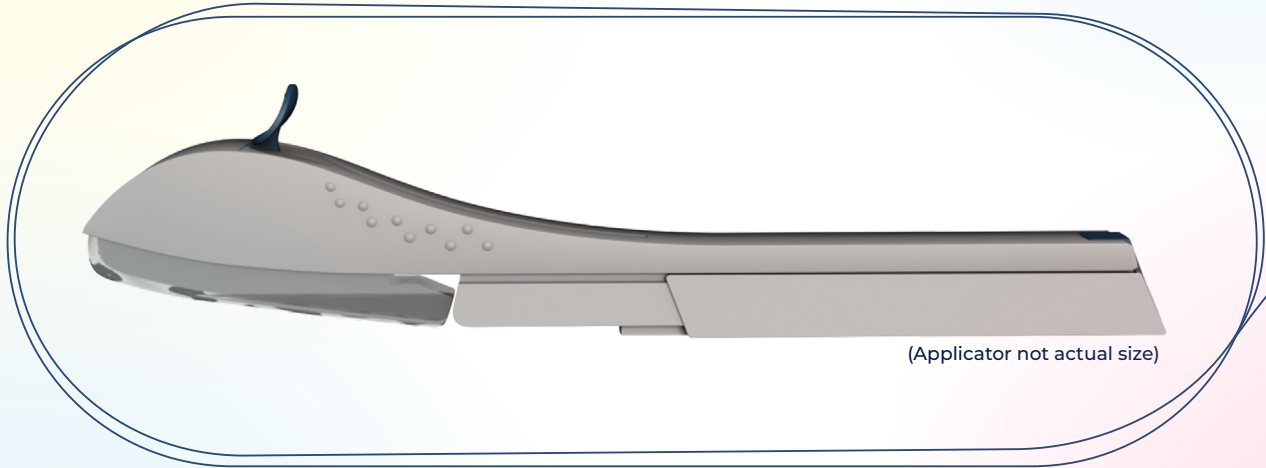


NEXPLANON[®]
(etonogestrel implant) 68 mg
Radiopaque



Insertion 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.

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Radiopaque

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.

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

Before inserting NEXPLANON, carefully read the instructions for insertion as well as the full prescribing information, including Boxed Warning. 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 (www.NEXPLANONREMS.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
[For a complete list of contraindications, see NEXPLANON Prescribing Information, Contraindications (4)]
- 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 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

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.

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INSERTION PROCEDURE

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.

For illustrative purposes, figures depict the left inner arm.

- 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 (e.g., in women with thin arms), it should be inserted as far posterior from the sulcus as possible. [For additional information, see NEXPLANON Prescribing Information, Warnings and Precautions (5.1).]
- 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 (Figure 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 applicator containing the implant from its blister packaging. Prior to use, visually inspect the packaging for breaches of integrity or damage (eg, torn, punctured). If the packaging has any visual damage that could compromise sterility, do not use the product.

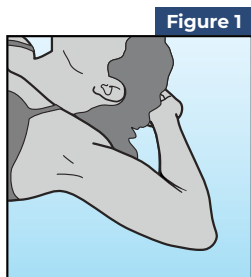


Figure 1

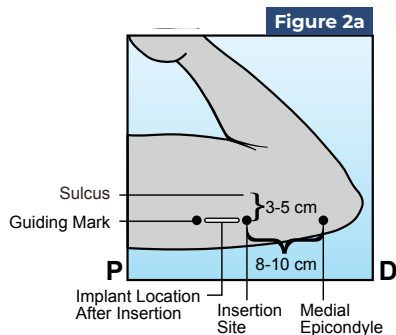


Figure 2a

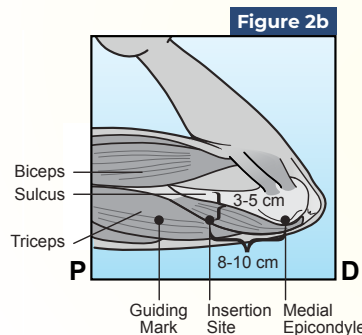


Figure 2b

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

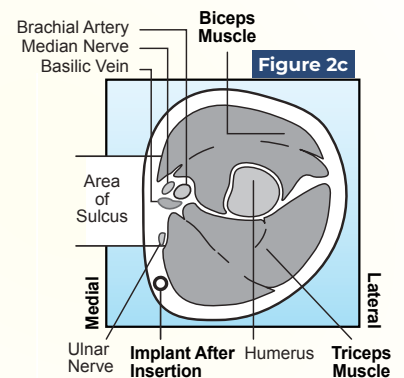


Figure 2c

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

SELECTED SAFETY INFORMATION (continued)

Complications of insertion and removal (continued)

- 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.
- 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.

Selected Safety Information continued on next page.

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INSERTION PROCEDURE (*continued*)

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).

STEP 11. **The implant should be inserted subdermally just under the skin.** [For additional information, see NEXPLANON Prescribing Information, Warnings and Precautions (5.1).]

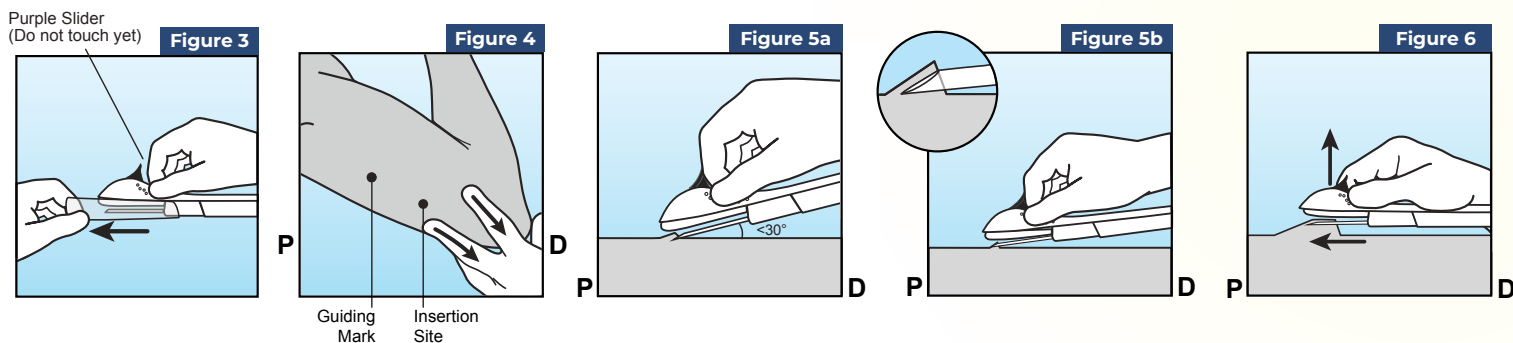
To help ensure the implant is inserted just under the skin, you should position yourself to see the advancement of the needle by viewing the applicator from the side and not from above the arm. From the side view (see Figure 6), you can clearly see the insertion site and the movement of the needle just under the skin.

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.

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.



SELECTED SAFETY INFORMATION (*continued*)

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.

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INSERTION PROCEDURE (*continued*)

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.**

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

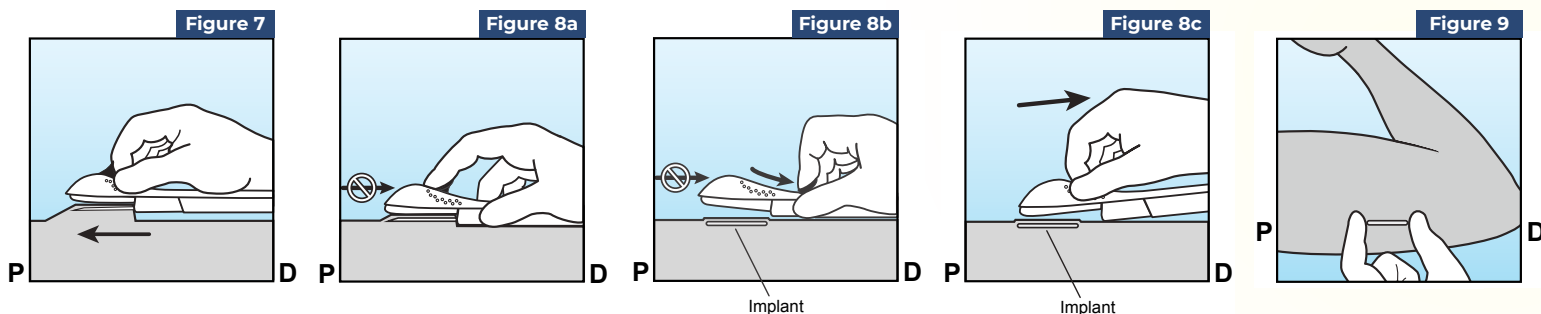
STEP 17. **Always verify the presence of the implant in the woman's arm immediately after insertion by palpation.** By palpating both ends of the implant, you should be able to confirm the presence of the 4 cm rod (Figure 9). [*If you cannot feel the implant, see page 6 for instructions.*]

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.



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.

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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.

[For additional information, see NEXPLANON Prescribing Information, Warnings and Precautions (5.1).]

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.
- 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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