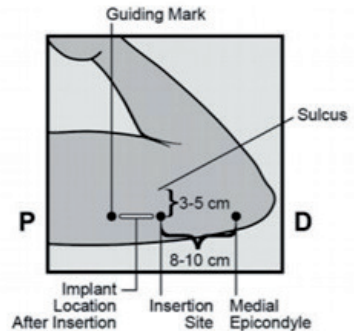


Implanon NXT (etonogestrel implant) – Updated insertion and removal instructions due to risk of neurovascular injury and implant migration

Implanon NXT* is a non-biodegradable, single-rod, long-acting, etonogestrel-containing hormonal contraceptive implant, which is inserted subdermally. There have been reports of migration of the implant within the arm from the insertion site, which may be related to deep insertion or external forces (e.g. manipulation of the implant or contact sports). There also have been rare post-marketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion. Existing warnings and recommendations for insertion (site and position of the arm during insertion) and removal of Implanon NXT implant have recently been updated to further minimise the risk of neurovascular injury and implant migration, based on the advice of relevant experts. A Direct Healthcare Professional Communication (DHPC), with full details of the changes, was recently circulated to healthcare professionals (HCPs) by the marketing authorisation holder (MAH i.e. the company which holds the licence for a product), and is available on the HPRA website. A summary of key aspects is provided below.

Advice to Healthcare Professionals

- **Updated position of the arm:** The woman's arm should be flexed at the elbow with her hand underneath her head (or as close as possible) during insertion and removal of the implant.
- **Updated implant insertion site:** The implant should be inserted subdermally just under the skin at the inner side of the **non-dominant upper arm**. The updated insertion site is overlying the triceps muscle about 8-10 cm from the medial epicondyle of the humerus and 3-5 cm posterior to the sulcus (groove) between the biceps and triceps muscles.
- The correct location of the implant (subdermally) should be confirmed by palpation by both the HCP and the woman at the time of insertion. Deeply-placed implants should be localised and removed as soon as possible to avoid the potential for distant migration.
- Ensure women are supplied with a Patient Alert Card** and instructed to show the card to the HCP at any visits related to the use of the implant.
- Palpate the implant at each check-up visit and instruct the woman to contact her doctor as soon as possible if she cannot feel the implant at any time between check-ups.
- In case of an implant that is not palpable, consult the Patient Alert Card or medical record to verify the arm that 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. Non-palpable implants should only be removed by a HCP experienced in removing deeply placed implants and who is familiar with localising the implant and the anatomy of the arm.
- Videos demonstrating the insertion and removal of Implanon NXT are available at www.implanonnxtvideos.eu.
- The Product Information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)) and Patient Alert Card for Implanon NXT have been updated accordingly, and **should be consulted for detailed usage instructions.**



- It remains a strong recommendation that Implanon NXT be inserted and removed only by healthcare professionals (HCPs) who have completed training in the use of the Implanon NXT applicator and the techniques for insertion and removal of the implant, and, where appropriate, that supervision be requested prior to inserting or removing the implant.
- Similarly, the recommendation that the woman returns for a medical check-up three months after insertion of the implant remains unchanged.

Key Message

- Cases of neurovascular injury and migration of the Implanon NXT implant from the insertion site within the arm, or in rare cases into the pulmonary artery, have been reported.
- To further minimise the risk of neurovascular injury and implant migration, **the instructions for insertion and removal of the implant have been updated.** Further information can be found on the HPRA website in a Direct Healthcare Professional Communication or in the updated product information.
- It is strongly recommended that Implanon NXT be inserted and removed only by HCPs who have completed training in the use of the Implanon NXT applicator and the techniques for insertion and removal of the implant. Non-palpable implants should only be removed by a HCP experienced in removing deeply placed implants and who is familiar with localising the implant and the anatomy of the arm.
- Videos demonstrating the insertion and removal of Implanon NXT are available at www.implanonnxtvideos.eu.
- Ensure women are supplied with a Patient Alert Card and instructed to show the card to the HCP at any visits related to the use of the implant.
- Suspected adverse reactions should be reported to the HPRA via the available methods (www.hpra.ie/report).

**Further details on Implanon NXT are available at www.hpra.ie.*

***The Implanon NXT package contains a Patient Alert Card intended for the woman, which records the batch number of the implant. HCPs are requested to record the date of insertion, the arm of insertion and the intended date of removal on the Patient Alert Card. Patients should be instructed to keep the Patient Alert Card in a safe place and show the card at any visits related to the use of her implant. The Patient Alert Card also contains instructions for the patient to occasionally gently palpate the implant to be sure that she knows its location. Patients should be instructed to contact their doctor as soon as possible if at any time they cannot feel the implant. The package also includes adhesive labels intended for HCP records showing the batch number. This information should be included in the electronic medical records of the patient if such are used.*

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