Implanon NXT® (etonogestrel) Subdermal Implant Training Recommendations for Healthcare Professionals (HCPs) in Australia

Table of Contents

Definitions	2
Introduction	3
Implanon NXT training recommendations for HCPs	4
Competencies for the insertion and removal of Implanon NXT	4
Criteria for Implanon NXT Trainers	8
Recommendations for Training Implanon NXT Trainers	9
Resources available for Implanon NXT Trainers	10
Endorsement	12
Review Date	12
References	12

Definitions

Implanon NXT Trainee (Trainee): HCP who undertakes training on the appropriate use, insertion and removal of Implanon NXT.

Implanon NXT Future Trainer (Future Trainer): HCP who meets the recommended criteria (see page 8) and is undertaking training and assessment to become an Implanon NXT Trainer.

Implanon NXT Trainer (Trainer): HCP who meets the recommended criteria (see page 8) and has completed the appropriate training to become a Trainer.

Introduction

Implanon NXT is an etonogestrel single rod subdermal implant, which provides long-acting reversible contraception.¹

To ensure the appropriate use and effective insertion and removal of Implanon NXT in Australian clinical practice, this document has been developed in consultation with experts in family planning and reproductive health. The following factors were taken into consideration during the development of the document:

- The Implanon NXT Approved Product Information (PI)
- Procedures in Australia and overseas for training in subdermal contraceptive implant techniques
- The experience of current Trainers
- Current Implanon NXT Train the Trainer programs
- Australia's National Women's Health Strategy 2020-2030 goal of increasing availability and uptake of long acting reversable contraceptive options
- A need for sustainable reproductive and sexual health care in Australia through a flexible health workforce and innovative models of care

This document provides guidance on the following components of Implanon NXT training:

- Recommended Implanon NXT training for HCPs
- The competencies required by HCPs to insert and remove Implanon NXT appropriately and safely
- Criteria for Trainers
- Recommendations for training Trainers
- Resources available for Trainers

The recommendations provided relate to Implanon NXT theory and simulation training only, and do not specifically address criteria for clinical training on live patients.

Completion of any online training in isolation is not considered sufficient for assessment of competency for either Future Trainers or Trainees. It is strongly recommended that Implanon NXT training includes both theory and simulation components (either face to face or virtually).

Implanon NXT training recommendations for HCPs*

HCPs wishing to perform contraceptive implant procedures are strongly recommended to participate in a training session to understand the theoretical aspects of Implanon NXT, familiarise themselves with the Implanon NXT applicator, the techniques for insertion and removal of Implanon NXT and where appropriate, request supervision prior to inserting or removing the implant.¹

Training of HCPs on the appropriate and safe use of Implanon NXT and the correct insertion and/or removal of Implanon NXT should be undertaken either in person or virtually. During training, the Trainer must be able to demonstrate and describe the insertion and removal of Implanon NXT to the Trainee. Subsequently, the Trainee should be given the opportunity to practise correct insertion and removal of the implant using a model arm and placebos.

It is recommended that Trainers use the competencies for the insertion and removal of Implanon NXT outlined below, to assess the Trainee. Once the Trainee completes the training and meets the competencies described, the Trainer should provide a training certificate to the HCP.

Upon completion of training, it is highly recommended that the HCP performs insertion and removal of Implanon NXT in a patient, within a reasonable timeframe to consolidate skills learnt. It is recommended that trainees who have not performed insertion or removal of Implanon NXT on live patients should seek suitable supervision within their workplace, where possible.

*HCPs who will only conduct Implanon NXT insertions in future are not required to complete training or simulation of Implanon NXT removal. The training certificate provided to these HCPs should state they have completed Implanon NXT insertion training only.

Competencies for the insertion and removal of Implanon NXT

1. The appropriate use and insertion of Implanon NXT requires that HCPs must be able to:

- 1.1 Assess an individual's suitability for Implanon NXT, including:
- Determining any contraindications to Implanon NXT¹
- Determining any contraindications to the use of antiseptic solution and use of local anaesthetic
- Review the patients' concurrent medicines, and any potential interactions with etonogestrel
- Determining the appropriate timing of Implanon NXT initiation, including exclusion of pregnancy prior to insertion and switching from another contraceptive method¹
- Provide informed consent for the procedure and document this in the patient records

- 1.2 Provide advice about possible side effects and management options, including:
- Bleeding patterns and other side effects of Implanon NXT¹
- Follow up and management of adverse bleeding patterns and side effects²
- Consider providing patients with copies of/access to the Implanon NXT Consumer Medicines
 Information (CMI) leaflet. Available at:

1.3 Set-up the environment for the insertion, including:

- The time that should be allowed, light requirements and equipment required for performing the procedure¹
- Requirement for hand hygiene, gloves and correct skin disinfection prior to procedure
- Other equipment required for sterile/aseptic technique

1.4 Position for insertion, including:

- Position the individual in accordance with the Implanon NXT PI instructions¹
- Position themselves in relation to the individual in accordance with Implanon NXT PI instructions¹

1.5 Prepare the insertion site, including:

- Identifying the insertion site in accordance with the Implanon NXT PI instructions¹
- Describing cleaning of site via use of appropriate skin preparation (such as antiseptic to sterilise the site)
- Identifying and administering appropriate local anaesthetic¹
- Demonstrating the correct application of anaesthesia at the insertion site using a model arm (or live person as appropriate)

1.6 Insert the implant, including:

- Appropriate technique for implant insertion in accordance with the Implanon NXT PI instructions¹
- Demonstrating that the implant is visible in the cannula prior to insertion
- Demonstrating correct implant insertion using a model arm (or live person as appropriate)
- Demonstrating palpation of both ends of implant after insertion to confirm its presence using a model arm (or live person as appropriate)¹
- Determining appropriate positioning of the implant, additional local anaesthetic requirements, and other considerations outlined in the Implanon NXT PI instructions if replacing an existing etonogestrel implant with a new etonogestrel Implant¹

- 1.7 Dress the insertion site, including:
- Appropriate use of dressing and pressure bandages
- 1.8 Provide advice to individual on self-care relating to insertion, including:
- Instructions on self-palpation¹
- Ongoing care required for dressing and pressure bandage
- Documentation detailing insertion site, insertion date and date for removal
- 1.9 Describe the appropriate steps to take in case of non-palpable implant following insertion including:
- Knowledge of suitable methods for localisation such as two-dimensional X-ray, Computerised Tomography (CT) scanning, Ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater) or Magnetic Resonance Imaging (MRI)
- In case these imaging methods fail to locate the implant, it is advised to verify the presence of the implant by measuring the etonogestrel level in a blood sample from the individual. In this case it is recommended to consult Organon for the appropriate protocol
- Knowledge of the need to inform the individual to use a non-hormonal contraceptive method until the presence of the implant has been verified
- Knowledge that deeply placed implants need to be localised and removed as soon as possible to avoid the potential for distant migration

2. The appropriate removal of Implanon NXT requires that HCPs must be able to:

- 2.1 Assess an individual's suitability for Implanon NXT removal, including:
- Palpation of the implant prior to initiating removal using a model arm (or live person as appropriate)
- Understanding of how impalpable, misplaced, migrated and deep implants may occur and steps to take when implant is not palpable, including referral pathways and imaging
- Ensuring requirements for ongoing contraception are met¹
- 2.2 Set-up the environment for the removal, including:
- The time that should be allowed, light requirements and equipment required for performing the removal
- Appropriate hand hygiene, gloves and correct skin disinfection prior to procedure¹
 - Other equipment required for sterile/aseptic technique

2.3 Position for removal, including:

- Position the individual in accordance with the Implanon NXT PI instructions¹
- Position themselves in relation to the individual in accordance with Implanon NXT PI Instructions¹

2.4 Prepare the site for removal, including:

- Use of recommended antiseptic to sterilise and clean the site¹
- Demonstrating correct application of anaesthesia at the removal site using a model arm (or live person as appropriate)

2.5 Remove the implant, including:

- Incision and removal technique in accordance with the Implanon NXT PI instructions¹
- Demonstrating correct incision and removal of the implant using a model arm (or live person as appropriate)
- Confirmation that the entire 4cm long implant has been removed by measuring its length

2.6 Dress the insertion site, including:

Use of dressing and pressure bandages¹

2.7 Provide advice to individual on self-care relating to removal, including:

- Instructions on using another reliable contraceptive method on the same day that Implanon NXT is removed, if the individual does not wish to get pregnant³
- Ongoing care required for dressing and pressure¹

2.8 Reinsertion of Implanon NXT as appropriate in line with updated PI recommendations:

- Ensure reinsertion is in line with the Implanon NXT PI instructions¹
- 2.9 Describe the appropriate steps to take in case of non-palpable implant at time of removal
- Demonstrate knowledge of suitable methods for localisation such as two-dimensional X-ray, Computerised Tomography (CT) scanning, Ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater) or Magnetic Resonance Imaging (MRI)
- In case these imaging methods fail to locate the implant, it is advised to verify the presence of
 the implant by measuring the etonogestrel level in a blood sample from the individual. In this
 case it is recommended to consult Organon for the appropriate protocol

In cases of misplaced, deep, or difficult to retrieve etonogestrel implants; HCPs should be familiar with referral pathways to surgical services and/or interventional radiology, where conventional methods would not suffice.

Note: In the event of misplaced, faulty, or broken implants, or any other adverse event or possible adverse event involving Organon products, please forward the details to Organon either by email: dpoc.anz@organon.com or by phone: 1800 023 135. Adverse events can be directly reported to the Therapeutic Goods Administration (TGA). Please refer to the TGA website for further details www.tga.gov.au/reporting-problems.

Criteria for Implanon NXT Trainers

The recommended and desirable criteria for Trainers are outlined below.*

Recommended criteria for Trainers:

The training of HCPs on the appropriate use, insertion, and removal of Implanon NXT should be undertaken by a registered doctor, nurse practitioner, midwife, or nurse who:

- Has completed training (both theory and simulation), on the insertion and removal of Implanon NXT (see Implanon NXT training recommendations for HCPs)*
- Has clinical experience with the insertion and removal of Implanon NXT (≥10 insertions and ≥10 removals)*
- Agrees to teach the standard Implanon NXT insertion and removal technique and comply with relevant applicable professional standards and the Implanon NXT PI¹
- Possesses current evidenced-based knowledge in contraception
- Agrees, at a minimum, to provide training that delivers the learning outcomes outlined above in this document
- Agrees to include a theory component and allow time for discussion and questions
- Agrees to provide evidence of training (e.g., certificate) to HCPs who achieve the competencies outlined in this document

*HCPs who will only conduct training on Implanon NXT insertions are not required to complete Implanon NXT removal simulation training or have clinical experience with removal of Implanon NXT. They must agree to teach the standard Implanon NXT insertion technique but are not permitted to teach the removal technique. The certificate they receive upon completion of a Trainer course will be for Implanon NXT Trainer insertion only. Any certificates they provide as Trainers, must also state the training provided was Implanon NXT insertion training.

Note: It is highly recommended that all Trainers register with Organon, to receive updates to the PI and access available resources. Trainers can register via the Organon website www.implanonnxt.com.au

Desirable additional criteria for Trainers

- Current clinical practice in etonogestrel implant insertions and removals and more broadly contraception in a clinical setting
- Current or recent past supervision of training in etonogestrel insertions and removals in a clinical setting
- Current or recent past clinical education experience
- Evidence of professional development and/or qualification in the field of reproductive and sexual health e.g., FPAA National Certificate in Reproductive & Sexual Health for Doctors or an accredited reproductive and sexual health course for nurses or midwives, depending on professional group

Recommendations for Training Implanon NXT Trainers

The following recommendations have been developed for Trainers, to use as the basis for instructing and training Future Trainers on the appropriate use, insertion, and removal of Implanon NXT.

Prior to initiating training, the Trainer will need to confirm that the Future Trainer meets the recommended criteria (and preferably the desirable additional criteria) for Trainers and has a current AHPRA registration.

The training of Future Trainers, should include the following#:

- A theoretical component covering how to discuss with Trainees all relevant aspects of Implanon NXT (including clinical information, insertion and removal, guidance re: management of unfavourable bleeding, reference to clinical guidelines, etc.) – see Resources available for Implanon NXT Trainers
- Assessment of the Future Trainer's ability to correctly demonstrate and explain to Trainees the Implanon NXT insertion and removal techniques
- Frequently Asked Questions (FAQs), based on clinical experience and expertise of the Trainer
- Opportunity to answer any questions the Future Trainer may have
- Discussion of referral pathways to surgical services and/or interventional radiology, where conventional methods are not sufficient for cases of misplaced, deep or difficult to retrieve etonogestrel implants
- Provision of resources for the Future Trainer to use in simulation e.g., dummy arm, placebos, etc.
- Adverse Event reporting requirements: In the event of misplaced, faulty, or broken implants, or
 any other adverse event or possible adverse event involving Organon products, please report
 the details to Organon (email: dpoc.anz@organon.com or phone: 1800 023 135). Adverse events
 can be reported directly to the TGA (please refer to the TGA website for further details
 www.tga.gov.au/reporting-problems).
- Provision of a certificate or similar documentation upon successful completion of training

 Reminder to Future Trainers to contact the Implanon NXT help desk upon completion of training and provide the help desk with a copy of their certificate of training. They will then be added to the list of Trainers and will be able to request practical resources (e.g., dummy arm, placebos, etc), to assist them with future training they provide.

Implanon NXT help desk:

Ph: 1800 230 330 Fax: 1800 227 126

Email: implanonnxt@blackgroup.com.au

*These may be conducted in person and/or virtually.

To remain credentialled it is suggested that Trainers:

- Provide etonogestrel implant training regularly to maintain currency of practice (at least 1 session per year)
- Maintain knowledge, clinical practice and professional development in contraception practice and contraceptive implants

Resources available for Implanon NXT Trainers

- Implanon NXT Training Platform. Available at www.implanonnxt.com.au HCPs can register to access the Implanon NXT training slide deck, online learning modules, insertion and removal videos, template certificate, etc.
- **Implanon NXT videos.** Videos detailing insertion and removal techniques are also available at: www.implanonnxtvideos.com
- Implanon NXT PI. Available at: pdf (tga.gov.au)
- Implanon NXT CMI. Available at: www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-CMI-02694-3
- Implanon NXT Patient Booklet. Please scan the following QR code to download a copy:



Australian and International Guidelines:

- Therapeutic Guidelines eTG Sexual and Reproductive guidelines. Available at www.tg.org.au (Subscription required to access)
- The Faculty of Sexual and Reproductive Healthcare of the Royal College of Gynaecologists and Obstetricians Guidelines and Statements Progesterone-only Implants. Available at: <u>FSRH Clinical Guideline: Progestogen-only Implant (February 2021) - Faculty of Sexual</u> and Reproductive Healthcare

- Medical Eligibility Criteria for Contraceptive Use. 5th ed. Geneva: World Health Organization;
 2015. PMID: 26447268. Available at: Medical eligibility criteria for contraceptive use (who.int)
- The Faculty of Sexual and Reproductive Healthcare UK Medical Eligibility Criteria for Contraceptive Use. UKMEC 2016 (Amended September 2019). Available at: www.fsrh.org/documents/ukmec-2016/fsrh-ukmec-full-book-2019.pdf

Other resources:

- Join the AusCAPPS Network: A community of practice to support the provision of long acting reversible contraception and medical termination of pregnancy in primary care (AusCAPPS | Medcast)
- Australian College of Rural and Remote Medicine Resources. Available at: <u>Resources</u> (acrrm.org.au)
- o Family Planning Alliance Australia Resources. Available at: <u>Resources</u> (familyplanningallianceaustralia.org.au)
- Family Planning NSW Health Professional Resources. Available at: <u>Resources | Family Planning NSW (fpnsw.org.au)</u>
- Family Planning Victoria Clinical Resources. Available at: Clinical Resources https://www.fpv.org.au/professional-learning-support/clinical-support
- o SHINE SA Clinical Resources for Doctors and Nurses. Available at: <u>SHINE SA | Sexual Health Information Networking & Education</u>
- The Royal Australian College of General Practitioners Overview of the Implanon NXT checklist and consent form. Available at: www.racgp.org.au/download/Documents/PracticeSupport/201105implanonchecklist.pdf

Endorsement

This document has been endorsed by the following organisations:

















Review Date

This document should be reviewed in the event of significant changes to clinical practice, or yearly. The sponsor company will coordinate reviews with the endorsing bodies and other relevant stakeholders.

References

- 1. IMPLANON NXT Approved Product Information
- 2. Mansour D et al. Eur J Contracept Reprod Health Care. 2008;13(suppl 1):13–28.
- 3. IMPLANON NXT Consumer Medicines Information

The document uses individual as an inclusive and broad term that refers to and acknowledges the diversity in needs and experiences of all people who may access and use Implanon NXT

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