RACGP

Implanon NXT®

Overview, GP checklist, and patient consent form

Overview

This document, comprising a doctor checklist and patient consent form for the insertion of Implanon NXT®, has been developed by The Royal Australian College of General Practitioners (RACGP) Expert Committee – Quality Care (REC–QC) and RACGP Specific Interests Sexual Health Medicine to assist general practitioners (GPs) maintain a high level of quality and safety when inserting Implanon NXT®.

The information in this document:

- does not imply a recommendation of the product
- is current at the date of first publication and is intended for use as a guide of a general nature only and may or maynot be relevant to all patients or in all circumstances.
- is not exhaustive. When implementing any recommendations contained in this publication you must exercise your own independent skill and judgement, or seek appropriate professional advice relevant to your own particular circumstances when so doing. Compliance with any recommendations cannot of itself guarantee discharge of the duty of care owed to patients and others coming into contact with the health professional and the premises from which the health professional operates.
- is directed at health professionals possessing appropriate qualifications and skills in ascertaining and discharging their professional (including legal) duties
- is not to be regarded as clinical advice and is not a substitute for a full examination and consideration of medical history in reaching a diagnosis and treatment based on accepted clinical practices.

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The forms are designed for use in a three-stage process – an initial consultation followed by the insertion and removal of the implant.

Your medical indemnity insurer may have requirements regarding Implanon NXT®. It is important to be aware of these and complete appropriate training that meets the educational requirements prior to inserting Implanon NXT®.

This checklist and consent form is not a substitute for reading the approved product information and for being familiar with the insertion and removal technique.

Stage one – Initial consultation

Doctor:

- Explain the pre-insertion section in the ‘patient consent form’
- Ask your patient to initial, sign, and date, the pre-insertion section in the ‘patient consent form’ and return it to you before the insertion
- Sign and date the pre-insertion section of the ‘patient consent form’.

Patient:

- Initial, sign, and date the pre-insertion section in the ‘patient consent form’ and return it to your doctor before the insertion.

Stage two – Insertion

Doctor:

- Sight and record the patient’s completed pre-insertion section of the ‘patient consent form’
- Tick, sign, and date the insertion section in the ‘doctors’ checklist’
- Sign and date the post-insertion section of the ‘patient consent form’
- Ask patient to sign and date the post-insertion section of the ‘patient consent form’.

Patient:

- Initial, sign, and date the post-insertion section of the ‘patient consent form’.

Stage three – Removal

Doctor:

- Tick, sign, and date the removal section of the ‘doctors’ checklist’.

Also consider:

- Having a reminder system as a service for regular patients
- Scanning the 'patient consent form' if you require an electronic record
- For further information on the insertion and localisation of Implanon NXT®, contact Organon, the manufacturer of Implanon NXT®:
    - P: 1800 023 135
    - E: dpoc.anz@organon.com

Further reading and resources

- Implanon NXT® insertion and removal videos

- Implanon NXT® product information

- Implanon NXT® patient booklet – Available in English and eight other languages

- Implanon NXT® patient booklet – For Aboriginal and Torres Strait Islander patients

- Centres of experience for deeply inserted implants

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Doctors' checklist – For the insertion of Implanon NXT®

Medical rec no: _____

Patient name: _____

_____

DOB: _____

Pre-insertion section

☐	No contraindication according to the manufacturer's product information, particularly medications which can decrease the effectiveness of Implanon NXT®.
☐	Confirmation that there are no known allergies to local anaesthetics, sex hormones, plastics, metals, latex.
☐	No known allergies to any of the active or inactive ingredients or excipients of Implanon NXT®.
☐	Implant planned for day one to five in cycle, or as per manufacturer's instructions.
☐	If previously using another method of contraception, I have discussed the importance of using effective contraception prior to insertion of Implanon NXT®.
☐	I have discussed the benefits, risks, and side effects of Implanon NXT®.
☐	I have discussed the insertion and removal process of Implanon NXT®.

Doctor's signature:	Date:

Insertion section

☐	Pre-insertion section of 'patient consent form' completed and returned.
☐	Implant present in cannula pre-insertion.
☐	Implant inserted between day one to five in cycle, or as per manufacturer's instructions.
☐	If inserted later than day five, I have advised of the importance of using additional contraceptive cover for seven days.
☐	I have adequately excluded pregnancy and I am satisfied that the patient is not pregnant.
☐	I acknowledge the implant insertion site is at the inner side of the non-dominant upper arm, overlaying the triceps muscle, approximately 8–10 cm from the medial epicondyle of the humerus and 3–5 cm posterior to (below) the sulcus (groove) between the biceps and triceps muscles – Refer to figure 1.
☐	I acknowledge the implant should be inserted subdermally. The skin should be punctured with the tip of the needle, angled < 30°. The needle should be inserted until the bevel (slanted opening of the tip) is just under the skin (and no further) – Refer to figure 2 and 3.

☐	Needle fully retracted into the body of the applicator
☐	Implant is palpable after insertion.
☐	The implant is not palpable – Refer to manufacturer guidance. **Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged.**
☐	Procedure completed, batch number sticker affixed to consent form and date of insertion / removal of implant recorded on appropriate credit card slip for patient.
☐	Side-effects explained and patient advised to attend for review if they have any concerns
☐	Post-insertion section of 'patient consent form' completed and copy provided to patient and recorded.
☐	Insertion adequately documented in record.

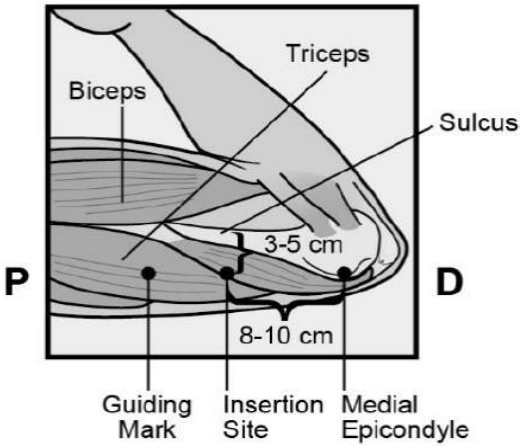
Doctor's signature:	Date:

Removal section

☐	Removal adequately documented in record.

Doctor's signature:	Date:

Figure 1



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

Figure 2

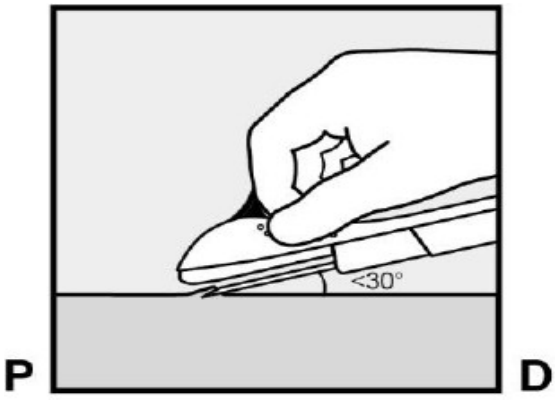
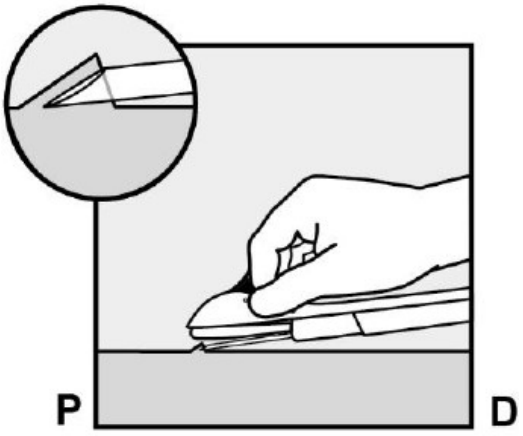


Figure 3



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Medical rec no: _____

Patient name: _____

_____

DOB: _____

Patient consent form – For the insertion of Implanon NXT®

Overview of treatment

The insertion of Implanon NXT® involves a small plastic implant containing the hormone progestogen being inserted underneath the skin of the upper inner arm to act as a contraceptive against pregnancy for up to three years.

Pre-insertion section

		Patient initials
Risks	I have discussed the risks and side effects of using Implanon NXT® with my doctor. I understand the following risks: • Small chance of failure to prevent pregnancy (less than 1 in 1000). • Disturbance of the menstrual cycle including irregular bleeding, no bleeding or prolonged bleeding. • Other possible hormonal side effects such as acne, headaches, weight gain and breast symptoms. These can improve over first 3 months. • There is a small increased risk of breast cancer during the use of Implanon NXT® but this risk appears to decrease with time after discontinuation. • Bruising or discomfort for up to one week after insertion or removal. • Scarring from the insertion/removal procedure. • Implant being inserted deeply or moving from its original position, which could make removal more difficult and may require referral to a specialist for removal.	
Removal	• I understand that the implant must be removed or replaced within three years from today. • I am aware that it is my responsibility to arrange removal.	
Pregnancy excluded – Refer table 1	• I understand that I will/will not need to use another method of contraception or abstain from sexual intercourse for the next seven days.	
Pregnancy not excluded – Refer table 2	• I understand there is a chance of pregnancy even if today's pregnancy test is negative • I understand that I will need to use another method of contraception or abstain from • sexual intercourse for the next 7 days • I understand the importance of a follow up pregnancy test (4 weeks from today) and discussed how results will be communicated to the clinic.	

Based on the information above, I (print name) _____ willingly consent for my doctor to insert an Implanon NXT® implant for use as a contraceptive in my left arm / right arm and the use of local anaesthetic to reduce the discomfort of insertion. By initialing each of the items above, I acknowledge that these are understood by me and have been discussed with my doctor.

Patient signature:	Date:
Doctor name:	Position:
Doctor's signature:	Date:

Post-insertion section

		Patient initials
Post-insertion	• I can feel the inserted implant. • I have a copy of the Consumer Medicine Information and the post insertion care instructions • I should return to see my health professional if I have any concerns or questions	

Patient signature:	Date:
Doctor name:	Position:
Doctor's signature:	Date:

Table 1 – Pregnancy excluded checklist

• Day one to five of normal menstrual cycle • Up to 21 days post-partum • Up to five days post-abortion or miscarriage	Effective immediately
Negative pregnancy test on day of insertion **and** either: • No unprotected sexual intercourse in last three weeks • No unprotected sexual intercourse since last menstrual period • Correct and consistent use of reliable contraception	Effective in seven days

Table 2 – Pregnancy not excluded checklist

Negative urine pregnancy test on day of insertion. Discuss the following: • Importance of testing for undiagnosed early pregnancy regardless of bleeding pattern post insertion • No known increased teratogenesis risk • Follow-up urine pregnancy test four weeks from day of insertion • Add to recall system for follow-up pregnancy test.	Effective in seven days