Overview of the IMPLANON NXT® checklist and consent form

This document, comprising a doctor checklist and patient consent form for the insertion of IMPLANON NXT®, has been developed by the RACGP’s National Standing Committee – GP Advocacy & Support and National Standing Committee – Quality Care to assist General Practitioners maintain a high level of quality and safety in the insertion of IMPLANON NXT®. This document:

(a) does not imply a recommendation of the product itself; and

(b) The information set out in this document is current at the date of first publication and is intended for use as a guide of a general nature only and may or may not be relevant to particular patients or circumstances. Nor is this publication exhaustive of the subject matter. Persons implementing any recommendations contained in this publication must exercise their own independent skill or judgement or seek appropriate professional advice relevant to their 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. Whilst the text is directed to health professionals possessing appropriate qualifications and skills in ascertaining and discharging their professional (including legal) duties, it is not to be regarded as clinical advice and, in particular, is no substitute for a full examination and consideration of medical history in reaching a diagnosis and treatment based on accepted clinical practices. Accordingly The Royal Australian College of General Practitioners and its employees and agents shall have no liability (including without limitation liability by reason of negligence) to any users of the information contained in this publication for any loss or damage (consequential or otherwise), cost or expense incurred or arising by reason of any person using or relying on the information contained in this publication and whether caused by reason of any error, negligent act, omission or misrepresentation in the information.

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

Medical Indemnity Insurers (MIIs) 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 1 – Initial Consultation

Doctor
- Tick and date the Pre-insertion Section
- Explain the Pre-insertion Section in the ‘Patient Consent Form’
- Ask Patient to tick, date and sign the Pre-insertion Section in the ‘Patient Consent Form’ and return it prior to insertion.

Stage 2 – Insertion

Doctor
- Sight and record the Patient's completed Pre-insertion Section of the ‘Patient Consent Form’
- Tick off 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’.

Stage 3 – Removal

Doctor
- Tick and date the Removal Section of the ‘Doctors’ Checklist’.

Consider:
- having a reminder system as a service for regular patients
- scanning the Patient Consent form if you require an electronic record.
**Doctors’ Checklist for the Insertion of IMPLANON NXT®**

### 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 or any of the active or inactive ingredients or excipients contained in IMPLANON NXT® |
| ✔️ | Implant planned for day 1-5 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 1-5 in cycle, or as per Manufacturer’s instructions |
| ✔️ | If inserted later than day 5, I have advised of the importance of using additional contraceptive cover for 7 days |
| ✔️ | I have adequately excluded pregnancy / I am satisfied that the woman is not pregnant |
| ✔️ | I have followed the Manufacturer’s instructions on the correct method of insertion |
| ✔️ | Needle fully retracted into the body of the applicator |
| ✔️ | Implant is palpable after insertion, or |
| ✔️ | The implant is not palpable (see manufacturer’s notes on management plan) |
| ✔️ | 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 she has any concerns |
| ✔️ | Post-insertion Section of Patient Consent Form completed and copy provided to patient and record |
| ✔️ | Insertion adequately documented in record |

Doctor’s signature: [ ] Date: [ ]

### Removal Section

| ✔️ | Removal documented in record |

Doctor’s signature: [ ] Date: [ ]
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

Benefits and risks

I have discussed the benefits, risks and side effects of using IMPLANON NXT® with my doctor. Side effects may include:

• irregular bleeding, no bleeding, headaches, weight gain and breast symptoms
• bruising and discomfort for up to one week after insertion
• the possibility of allergic reactions
• the implant moving from its original position, which could make removal more difficult.

Effectiveness of contraception

I am aware of the effectiveness of IMPLANON NXT® as well as its relative effectiveness compared with other birth control methods. I am aware no birth control method is completely reliable so I could have a small chance of becoming pregnant.

Removal after three years

I understand that the IMPLANON NXT® implant must be removed by three years since leaving it in place for longer may increase the chances of an ectopic pregnancy (pregnancy in the tube). I am aware it is my responsibility to arrange removal.

Scarring

The insertion and removal of the Implant may leave a small scar on the skin. I am aware that some people are predisposed to develop a thickened scar. A larger scar is likely if the IMPLANON NXT® implant is difficult to remove.

Insertion and removal

I understand that to reduce discomfort, my doctor will use a local anaesthetic when inserting and removing the IMPLANON NXT® implant.

Allergic reactions

I have advised my doctor of any known allergies, especially allergies to a local anaesthetic, sex hormones, plastics, metals, latex or any of the active or inactive ingredients or excipients contained in IMPLANON NXT®.

Acknowledgement

I have understood the information concerning IMPLANON NXT®. I will contact my doctor should I require further advice.

Interactions

I understand that I must advise my doctor of any medication I am taking, as well as advise any other doctors I see, that I have an IMPLANON NXT® implant, as these can reduce the effectiveness of IMPLANON NXT®.

Based on the information above, I ___________________________ willingly consent for my doctor to insert an IMPLANON NXT® implant for use as a contraceptive in my Left/Right arm. By ticking off each of the items above, I acknowledge that these are understood by me and have been discussed with my doctor.

Signed by patient ___________________________ Date ___/___/______

Post Insertion Section

Outcome

1. I can feel the inserted implant.
2. I have a copy of the Consumer Medicine Information and the post-insertion care instructions
3. I should return to see my doctor if I have any concerns or questions
4. I should have an annual check up while the implant is inserted.
5. I need to have the implant removed in 3 years time.

_____________________ Date ___/___/______
Signed by Patient

_____________________ Date ___/___/______
Signed by Doctor