1. Purpose
This guideline outlines the requirements at the Women’s for clinicians undertaking a clinical assessment of a woman’s request for an Implanon NXT® and the procedure for inserting or removing an Implanon NXT® in the Choices clinic.

2. Definitions
TGA Therapeutic Goods Administration
RANZCOG Royal Australian and New Zealand College of Obstetrics and Gynaecology
MSD Merck Sharp & Dohme
LH luteinizing hormone
VTE Venous Thromboembolism
IUD Intrauterine Device

3. Responsibilities
Certified clinicians: counselling, inserting and removing Implanon NXT®.

4. Guideline
Implanon NXT® is a single, flexible sub-dermal implant 4cm x 2mm which contains 68mg of a synthetic progestogen, etonogestrel. It is designed to be inserted, under local anaesthetic, directly under the skin of the inner aspect of the non-dominant upper arm. Unlike Implanon®, Implanon NXT® is radiopaque and can be identified by Xray and CT as well as ultrasound and MRI.

The implant releases approximately 40micrograms of etonogestrel/day which inhibits ovulation by suppressing the LH surge, increases viscosity of cervical mucus, reducing sperm penetration and motility and provides effective contraception for 3 years.

After removal etonogestrel levels fall rapidly and are undetectable after a week and the majority of women will ovulate in the first month.

It is a highly effective, convenient contraceptive method with a Pearl Index of <0.07 per 100 woman years, provided it is inserted correctly at the correct time of the menstrual cycle.

It is a recommendation of the TGA, RANZCOG and medical defence organizations that clinicians prescribing Implanon NXT® have attended a training session in patient selection, counselling and Implanon NXT® insertion and removal techniques arranged by the manufacturer . Wherever possible, it is also recommended that an experienced practitioner supervise the first insertion. A correctly inserted Implanon NXT® is easily palpable. Removal of Implanon NXT® after correct insertion is a simple procedure under local anaesthetic.

Inquiries regarding training sessions, please contact: MSD- Tel: 1800 818553.

4.1 Advantages of method
- Highly effective, long acting contraception for up to 3 years
- convenience
- rapid reversibility
- available at low cost through the PBS system for Australian residents
- suitable for women with a contraindication to oestrogen
4.2 Contraindications

Absolute:
- pregnancy
- undiagnosed vaginal bleeding
- active thromboembolic disease
- present or history of severe liver disease (abnormal LFT's)
- Progestogen dependent tumours
- current breast cancer
- hypersensitivity to components of Implanon®

Relative:
- Long term use of liver enzyme inducing drugs can reduce efficacy
- Severe cirrhosis or any malignant liver tumour
- SLE with positive or unknown antiphospholipid antibodies
- Women diagnosed with breast cancer within 5 years
- Continuing use in women who develop ischaemic heart disease
- Women for whom regular periods are important.
- Use in breast feeding has not been demonstrated to have adverse effects on infants to 6 months of age.
- PH/FH thromboembolic disease - clinical trial data shows no adverse effects of Implanon® on clotting parameters, likely that like other progestogen only methods i.e risk of VTE is minimal (compared with the oral contraceptive pill) but data on VTE events limited.

4.3 Side effects

Disturbance of menstrual pattern is usual, so the method will only be acceptable to women who can tolerate this.

Side effects include the following:
- bleeding approximating normal 35%
- infrequent bleeding 26%
- amenorrhea 21%
- frequent and or prolonged bleeding 18%

Menstrual disturbance is the most common reason for removal. There is no proven method of treatment. NSAID'S e.g. mefenamic acid or oestrogen supplementation could be tried based on varying anecdotal results only.

NB: Implanon NXT® is not recommended to control pre-existing menstrual bleeding problems.

Other side effects (5-10%):
- breast tenderness, fluid retention
- weight gain
- skin disorders (note: pre-existing acne may improve with Implanon®)
- mood changes
4.4 Insertion

Women wishing to have Implanon NXT® inserted can be referred to the Choices Clinic if their General Practitioner has not attended the training course. Correct insertion technique and timing is essential as most failures since introduction to Australia have been due to the woman already being pregnant at the time of insertion or non-insertion (faulty insertion technique and position not checked post insertion).

Implanon NXT® is effective immediately if inserted during day 1-5 of the patient's menstrual cycle. At any other time in the cycle it is important to be certain the patient could not be pregnant and alternative contraception should be used for seven days after insertion.

It can be inserted with immediate effectiveness in women:

- on combined oral contraceptive (pref. pill free interval to minimize bleeding irregularities)
- on Depo Provera® before next injection due
- after termination of pregnancy

NB: in IUD users, if insertion of Implanon NXT® is not done day 1-5 of cycle, IUD should be left in situ for 7 days post insertion as a pre-ovulatory follicle may be present.

Insertion technique: refer to manufacturer's instructions/training course.

Post insertion dressing and pressure bandage to minimize bruising for 48 hours and review in 3 months.

4.5 Removal

Women requesting removal of Implanon NXT® rod should be referred to their General Practitioner or to Choices Clinic call Outpatient Clinic Appointments - 8345 3032 or Clinic Nurse Coordinator - 8345 2191). Implanon NXT® should generally not be removed in the Emergency Department, unless the attending doctor has attended a training course and the Implanon NXT® is easily palpable and alternative contraception can be provided if required.

No clinician should incise the skin with a view to removing Implanon® unless they can feel the rod clearly and they are sufficiently confident of their technique to be certain that they can remove it. Removal of a correctly inserted Implanon® should be a simple procedure performed through a 2-3mm incision under local anaesthetic.

Removal technique - refer to manufacturer's instructions/training course.

4.6 Management of women in whom Implanon NXT® is not palpable

If Implanon NXT® is not palpable either:

- it is not present (i.e. insertion failure) OR
- it has been inserted too deeply

The woman should be advised to use alternative contraception until the situation is clarified.

Implanon NXT® is usually identifiable by ultrasound examination by a sonographer with experience of the ultrasound appearance of Implanon® - available through the Women's Pauline Gandel Imaging Centre. Implanon NXT® is also identifiable on Xray or CT.

Further management if removal required can be most efficiently arranged through Choices Clinic Nurse Coordinator. If Implanon® is visible on ultrasound, removal can be arranged through the clinic either under local anaesthetic, through the Women's Pauline Gandel Imaging Centre for removal under ultrasound control or under general anaesthetic by hospital general surgeon if required.

If Implanon NXT® cannot be visualised on ultrasound, depending on the clinical situation:

- presumptive evidence of non insertion can be based on progesterone levels consistent with ovulation
- further imaging of arm by MRI will be arranged through Choices clinic
- serum level of etonogestrel can be estimated (requires blood to be sent to the Netherlands by MSD- Tel: 1800 818553 for authorization). This measure is rarely required
Evaluation, monitoring and reporting of compliance to this guideline

Compliance to this guideline or procedure will be monitored, evaluated and reported through annual review of incidents associated with Implanon NXT®.

5. References

Royal College of Obstetricians and Gynaecologists (RCOG), Faculty of Sexual and Reproductive Healthcare, Clinical Effectiveness Unit provide regular updates on all methods available at: www.fsrh.org

Sexual Health and Family Planning Australia, Contraception: an Australian Clinical Practice Handbook, 4th Ed, 2016 (contact FPV [03] 9257 0100)


6. Legislation/Regulations related to this guideline or procedure

Nil applicable

7. Appendices

Appendix 1: Contraceptive Implants

Appendix 2: Contraception - Your Choices

Appendix 3: Intra Uterine Device (IUD)

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