

# STANDARDIZED PROCEDURE

## Subcutaneous Medication Implant: Insertion (Adult, Peds)

### I. Definition Subcutaneous Implant Insertion

**A. Definition of Subcutaneous Implant:** an under-the-skin (subcutaneous) implantable device that contains medication which is slowly released over an extended period of time.

The most common classes of drugs for the subcutaneous implant procedure are:

**B. Etonogestrel implant:** a single rod, progestin-only subdermally implantable device that provides effective contraception for up to 3 years.

**C. Histrelin Acetate implant:** a single rod, histrelin acetate subdermally implantable device that provides effective suppression of LH/FSH for up to 1 year in children with central precocious puberty (CPP).

### II. Background Information

#### A. Setting:

The setting (inpatient vs outpatient) and population (pediatrics) for the Advanced Health Practitioner (AHP) is determined by the approval of the privileges requested on the AHP Privilege Request Form. If the procedure is being done on a Pediatric patient, make sure Child Life is involved and use age appropriate language and age appropriate developmental needs with care of children, as appropriate to the situation.

#### B. Training/Supervision:

All health care professionals, including AHPs, should receive instruction and training prior to performing insertion of the subcutaneous implant.

Nexplanon® (etonogestrel) requires completion of the clinical training program from Merck prior to performing insertion of the subcutaneous implant.

The necessity of this procedure will be determined by the Advanced Health Practitioner in collaboration with the supervising physician or his/her designee. Designee is defined as another attending physician who works directly with the supervising physician and is authorized to supervise the Advanced Health Practitioner.

Direct supervision will not be necessary once competency is determined, as provided for in the procedure. The Advanced Health Practitioner will notify the physician immediately upon being involved in any emergency or resuscitative events or under the following circumstances:

1. Patient decompensation or intolerance to the procedure
2. Bleeding that is not resolved
3. Outcome of the procedure other than expected

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**C. Indications**

1. Etonogestrel: Reproductive age women desiring long term contraception.  
Breastfeeding women may safely use etonogestrel.
2. Histrelin Acetate: children with central precocious puberty.

**D. Precautions/Contraindications of Etonogestrel**

1. Known or suspected pregnancy
2. Current or past history of thrombotic disease (consult MD)
3. Hepatic tumors, active liver disease
4. Undiagnosed abnormal genital bleeding
5. Hypersensitivity to any of the component of Implanon™
6. Not recommended for women who require chronic use of drugs that are potent inducers of hepatic enzymes because of potential for decreased efficacy, e.g. barbiturates, griseofulvin, rifampin, phenylbutazone, phenytoin, carbamazepine, felbamate, oxcarbazepine, topiramate, modafinil

**E. Precautions/Contraindications of Histrelin Acetate**

1. Patients who are hypersensitive to gonadotropin releasing hormone (GnRH) or GnRH agonist analogs.
2. Females who are or may become pregnant while receiving the drug. Histrelin acetate may cause fetal harm when administered to pregnant patients. The possibility exists that spontaneous abortion may occur.

**III. Counseling**

**A. Change in bleeding patterns after insertion of etonogestrel:**

1. Vaginal spotting and bleeding will be irregular and unpredictable
2. Bleeding can be light or heavy and can occur for just a few days or many days in a row
3. There may also be no bleeding for many days or weeks in a row
4. Patterns of bleeding can vary throughout the duration of use

**B. Initial agonistic action of histrelin acetate:**

1. Transient worsening of symptoms of puberty or onset of new symptoms may occur after insertion. Complete suppression of LH/FSH/gonadal steroids occurs within 4 weeks.

**C. Risks of insertion of etonogestrel:**

1. A small percentage of women experience pain, redness or swelling at the insertion site. Hematoma and expulsion are extremely rare.

**D. Risks of insertion of histrelin acetate:**

1. Some children will experience pain, redness, or swelling at the insertion site. Hematoma and expulsion are rare.

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**IV. Patient Preparation**

**A. Etonogestrel:**

1. If no preceding hormonal contraceptive use in the past month, insert on days 1-5 of the menstrual cycle.
2. If switching from combined contraceptive pills/estrogen+progestin methods, can insert anytime with 7 days of last active dose/exposure
3. Progestin only pill: do not skip dose, insert any time
4. IUD: same day as removal
5. DMPA: when next injection is due
6. Post 1st trimester abortion: with 5 days of procedure
7. Childbirth or 2<sup>nd</sup> trimester abortion: 3-4 weeks post
8. Exclusively breastfeeding: 4<sup>th</sup> postpartum week
9. **Back up contraception is not needed if the above recommendations are followed: if deviating from recommended insertion times, rule out pregnancy and use non-hormonal back up method for 7 days following insertion**

**B. Pre-insertion Preparation:**

1. The patient should be positioned on his/her back with the non-dominant arm positioned either bent or extended, so that the provider has access to the inner aspect of the upper arm.
2. Propping the arm with pillows may help the patient more easily hold the position.
3. The optimum site for the subcutaneous insertion is approximately midway between the shoulder and elbow, in line with the bicipital groove.

**V. Materials**

The necessary supplies to insert the implant, including the insertion tool and local anesthetic, are provided in the implantation kit. This kit is separate from the implant.

Insertion of the subcutaneous implant is a surgical procedure. Sterile gloves and aseptic technique must be used in order to minimize the chance of infection.

1. Mayo stand
2. sterile gloves
3. Sterile marker (optional)
4. sterile drape
5. antiseptic swabs
6. local anesthesia (e.g. 1% lidocaine with 1:100,000 epinephrine. This may be buffered with a 1:5 admixture of sodium bicarbonate to anesthetic solution,)

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7. Syringe for injection of local anesthesia
8. 25 or 27 gauge needle or spinal needle
9. Sterile adhesive surgical strips
10. Sterile gauze pads
11. Absorbable sutures
12. Benzoin tincture antiseptic
13. Insertion tool
14. Adhesive bandage
15. Scalpel
16. Forceps

**VI. Insertion Procedure**

**A. Counsel patient re: procedure and obtain signed informed consent**

**B. Pre-treatment evaluation**

Rule out allergies to antiseptic and anesthetic.

**C. Set up**

1. Examination table for the patient to lie on
2. Mayo table for equipment set up
3. Sterile surgical drapes, sterile gloves, antiseptic solution, sterile marker (optional), and sterile scalpel
4. Local anesthetic, needles, and syringe
5. Sterile gauze, adhesive bandage, and pressure bandage
6. Subcutaneous implant

**D. Etonogestrel Subcutaneous Implant Procedure**

1. Place patient in supine position with non-dominant arm flexed at the elbow and externally rotated. Complete a time out with the appropriate steps.
2. Insertion site is 8-10 cm above the medial epicondyle of the humerus in the bicipital groove. *The implant should be inserted sub-dermally just under the skin to avoid the large blood vessels and nerves that lie deeper in the subcutaneous tissue in the sulcus between the biceps and triceps.*
3. Make two marks with a sterile marker, one for the insertion site and one for a guide during insertion.
4. Prep the site using an antiseptic solution.
5. Infuse 2 ml of local anesthesia (1% lidocaine) along the intended site of insertion.

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6. Remove the sterile preloaded disposable insertion tool carrying the implant from its blister, and remove the transparent protection cap by sliding it horizontally in the direction of the arrow away from the needle.
7. Stretch the skin around the insertion site, and puncture the skin with the tip of the needle angled about 30 degrees.
8. Lower the insertion tool to a horizontal position. While lifting the skin with the tip of the cannula, slide the cannula to its full length.
9. Unlock the slider by pushing down and retract the slider until it stops. The implant is now in its final sub-dermal position.
10. The insertion tool can now be removed.
11. Palpate insertion site to assure placement of implant.
12. Apply sterile adhesive surgical strips and pressure dressing.

#### **E. Histrelin Acetate Subcutaneous Implant Procedure:**

1. Place patient in supine position with non-dominant arm flexed at the elbow and externally rotated. Complete a time out with the appropriate steps.
2. Insertion site is 8-10 cm above the medial epicondyle of the humerus in the bicipital groove. *The implant should be inserted sub-dermally just under the skin to avoid the large blood vessels and nerves that lie deeper in the subcutaneous tissue in the sulcus between the biceps and triceps.*
3. Make two marks with a sterile marker, one for the insertion site and one for a guide during insertion.
4. Prep the site using an antiseptic solution.
5. Infuse 2 ml of local anesthesia (1% lidocaine) along the intended site of insertion.
6. It may be easier if a “pocket” for the implant is first created by blunt dissection through the incision along the path of the anesthetic, using the insertion tool cannula or a sterile hemostatic clamp.
7. Insert the implant into the cannula of the insertion tool.
8. Make an incision using a sterile scalpel transverse to the long axis of the arm, and of a size adequate to allow the cannula of the insertion tool to be inserted into the subcutaneous tissue.
9. Lower the insertion tool to a horizontal position. While lifting the skin with the tip of the cannula, slide the cannula to its full length.
10. Unlock the slider by pushing down and retract the slider until it stops. The implant is now in its final subdermal position.
11. The insertion tool can now be removed.
12. Palpate insertion site to assure placement of implant.
13. Apply sterile adhesive surgical strips and pressure dressing.

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**F. Post-procedure**

1. Instruct the patient to leave the pressure dressing on for 24 hours and to keep the area dry for 72 hours. Steri-strip can be removed after 3-5 days.
2. Instruct the patient to observe the site for bleeding, discharge, redness or swelling. Call provider if any of these occur.
3. Place Patient Chart Label in medical record.

**G. Follow-up Treatment**

1. Etonogestrel: no follow up visit is required for uncomplicated insertion.
2. Histrelin acetate: LH, FSH, and estradiol or testosterone should be monitored at 1 month post implantation, and then every six months. Height and bone age imaging should be assessed every 6-12 months.

**VII. Documentation**

**A. Documentation is in the electronic medical record**

1. Document the pretreatment evaluation and any abnormal physical findings.
2. Record the time out, consent, indication for the procedure, EBL, the outcome, how the patient tolerated the procedure, medications (drug, dose, route, & time) administered, complications, and the plan in the note, as well as any teaching and discharge instructions.

**B. All abnormal or unexpected findings are reviewed** with the supervising physician.

**VIII. Competency Assessment**

**A. Initial Competence**

1. **AHPs must have completed mandated Merck training for insertion of Etonogestrel.**
2. The Advanced Health Practitioner will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.
3. The Advanced Health Practitioner will demonstrate knowledge of the following:
  - a. Medical indication and contraindications of implant
  - b. Risks and benefits of the procedure
  - c. Related anatomy and physiology
  - d. Consent process (if applicable)
  - e. Steps in performing the procedure
  - f. Documentation of the procedure
  - g. Ability to interpret results and implications in management

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4. Advanced Health Practitioner will perform the procedure **three** times under direct supervision.
5. Supervising physician will document Advanced Health Practitioner's competency prior to performing the procedure without direct supervision.
6. The Advanced Health Practitioner will ensure the completion of competency sign off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.

#### **B. Continued proficiency**

1. The Advanced Health Practitioner will demonstrate competence by successful completion of the initial competency.
2. Each candidate will be initially proctored and signed off by an attending physician. Advanced Health Practitioner must perform this procedure at least **three** times per year. In cases where this minimum is not met, the attending, must again sign off the procedure for the Advanced Health Practitioner. The Advanced Health Practitioner will be signed off after demonstrating 100% accuracy in completing the procedure.
3. Demonstration of continued proficiency shall be monitored through the annual evaluation.
4. A clinical practice outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted.

#### **VII. RESPONSIBILITY**

Questions about this procedure should be directed to the Chief Nursing and Patient Care Services Officer at 353-4380.

#### **VIII. HISTORY OF POLICY**

Revised April 2012 by Subcommittee of the Committee for Interdisciplinary Practice

Reviewed April 2012 by the Committee on Interdisciplinary Practice

Prior revision October 2008

Approved April 2012 by the Executive Medical Board and the Governance Advisory Council.

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