DELAWARE ACADEMY OF
FAMILY PHYSICIANS

Implantable Birth Control Workshop

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Disclosure

The presenters have nothing to disclose relevant to this presentation

Learning Objectives

- Discuss indications and contraindications for implantable birth control
- Review common side effects of implantable birth control
- Discuss the procedures for insertion and removal of implantable birth control
- Practice hands-on training for insertion and removal in small groups
- Provide information about how to become formally certified to insert and remove implantable birth control

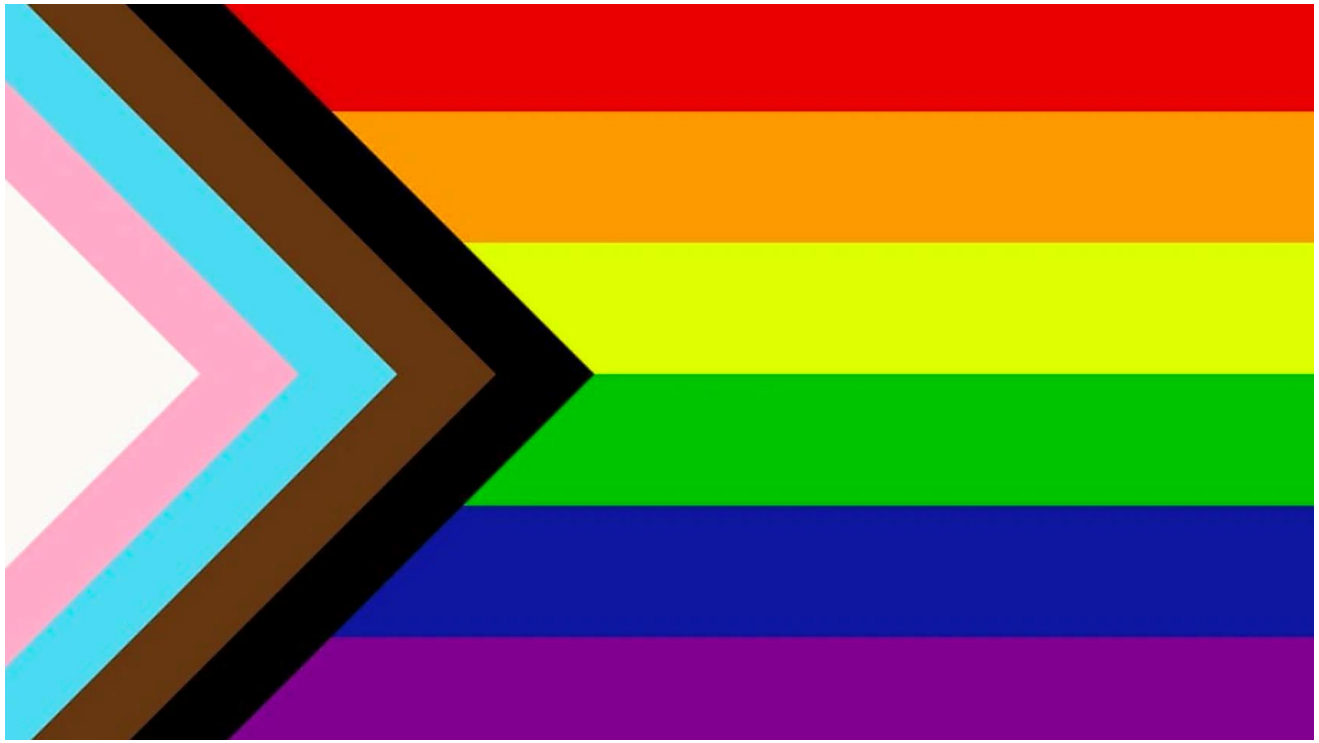
Agenda

- Overview
- Indications
- Contraindications
- Common Side Effects
- Billing Tips
- Insertion Procedure
- Removal Procedure
- Questions/Discussion

Note on Gender Diversity

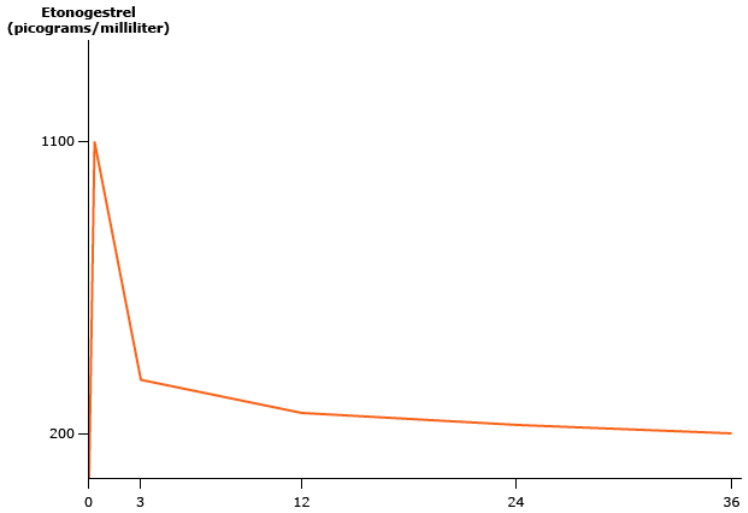
We will use the term "woman" in this presentation to refer to people with female anatomy, though we are aware that female anatomy is not equivalent to female gender.

Please ensure your patient counseling and contraceptive access is inclusive of cis-gendered, transgendered, gender nonconforming, gender nonbinary, and intersex people!



What is Implantable Birth Control?

- 68mg Etonogestrel single-rod implant
- Provides long-acting reversible progesterone-only birth control
- Bioequivalent to predecessor etonogestrel implant (Implanon)
- Implanted subdermally into inner upper arm
- 3-year duration of action per package insert
  - Up to 5-year duration of action shown to be reliable
- Releases 60-70 micrograms/day of etonogestrel initially
  - Release rate declines to ~ 30 micrograms daily by the end of 3 years
  - Levels remain high enough to prevent pregnancy for up to 5 years
- Radio-opaque and visible on x-ray, MRI, and ultrasound



Serum concentration over 3 years

Data from: NEXPLANON: Highlights of prescribing information. MSD Oss B.V., a subsidiary of Merck & Co., Inc., Whitehouse Station, New Jersey, USA.Graphic 85783 Version 1.0
Nexplanon image: https://www.change.org/p/nhs-nexplanon-side-effects-risks-not-being-fully-explained-to-female-patients

Indications

Pregnancy prevention

- Mechanism of Action: thickened cervical mucus, decreased tubal motility, inhibition of gonadotropin secretion to prevent ovulation, decreased endometrial thickness, endometrial atrophy
- Efficacy: 0.38 pregnancies in 100 women-years of use (similar to IUD efficacy)
  - medroxyprogesterone acetate (Depo): 4 pregnancies per 100 women-years of use
  - Pill: 8 pregnancies per 100 women-years of use
  - Barrier methods/fertility awareness/withdrawal: 13-28 pregnancies per 100 women-years of use

Menorrhagia/Dysmenorrhea/Endometriosis Pain/

- Mechanism of Action: decreased endometrial thickness, prevention of ovulation

Contraindications

- Allergies to device components
- Known or suspected pregnancy
- Liver tumors or severe liver disease
- Undiagnosed abnormal uterine bleeding
- Known or suspected breast cancer
- History of any progestin sensitive cancer
- Inability to tolerate unscheduled/breakthrough bleeding
  - More common with implantable birth control compared to progestin IUDs
- Cannot tolerate the risk of increased headaches
- Need birth control to be completely secret – implant can be palpated in arm
- Desires hormonal contraception specifically to reduce acne, hirsutism, irregular periods, PMS

Notable Side Effects

- Amenorrhea 20%
- Headaches 16%
- Weight gain 12%
  - 2kg greater weight gain over 36mo compared to intrauterine copper contraceptive (Paragard)
- Acne 12%
- Irregular bleeding 11%
  - Longer or shorter period duration
  - Decreased period volume/flow
  - Unscheduled spotting
  - Primary reason for discontinuation, most common in first 3mo
- Temporary insertion site irritation - 9%
  - Erythema 3% Hematoma 3% Bruising 2% Pain 1% Swelling 0.7%
- Breast tenderness 10%
- Emotional lability 6%
- Abdominal pain 5%

So many options, how to choose?

Particularly useful for patients who:

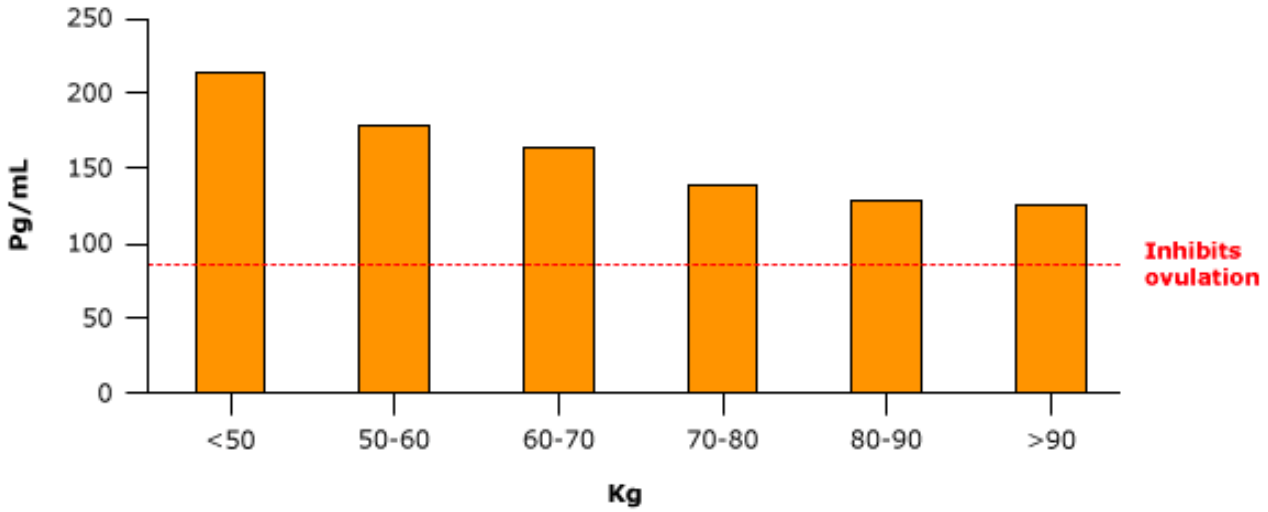
- Desire longer-term birth control (adolescents, patients near menopause)
- Cannot use estrogen-containing birth control
- Desire lighter or less painful periods
- Struggle to take birth control pills reliably
- Dislike scheduling q3mo injections for medroxyprogesterone acetate (Depo Provera) use
- Desire immediate reversibility of birth control
- Feel nervous about the procedure required for IUD insertion
- Should avoid bone loss related to medroxyprogesterone acetate (Depo Provera) use (prolonged steroid use, known low bone density)
- Are postpartum and desire healthy interpregnancy intervals (safe for insertion immediately postpartum and while breastfeeding)

Obesity

No dosing changes based on body weight

Increased chance of breakthrough bleeding

Not recommended to exceed the 3 year package insert duration of use if more than 70kg body weight



Implantable Birth Control (NEXPLANON): Highlights of prescribing information

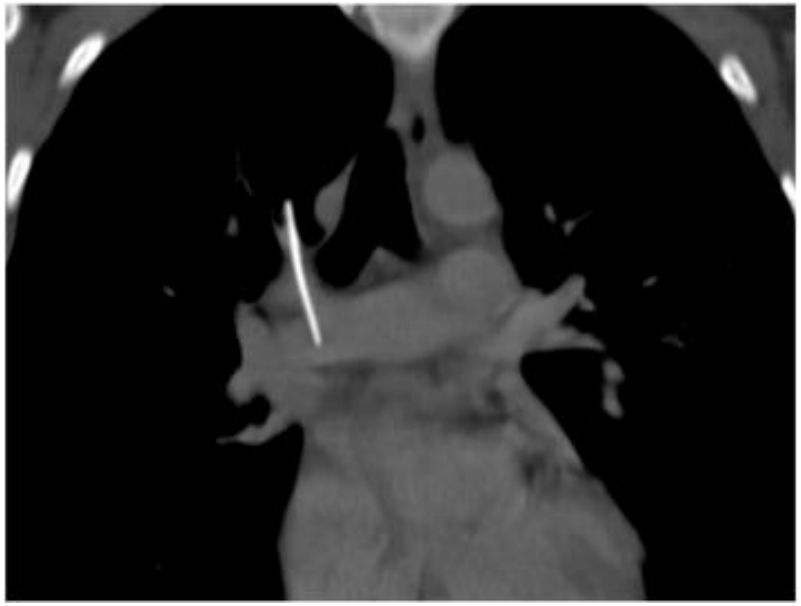
Device Migration

There have been several case reports of device migration into the pulmonary vasculature, requiring IR removal of the migrated device

Less common now that insertion is recommended BELOW the neurovascular bundle instead of directly over it

Also thought to be less common since the device trochar was re-designed to prevent excessively deep insertion

Implantable birth control is still thought to migrate up to 2cm from original location over several years



Pierre-Marie Heudes, Valerie Laigle Querat, Eric Darnis, Claire Defrance, Frederic Douane, Eric Frampas, Migration of a contraceptive subcutaneous device into the pulmonary artery. Report of a case, Case Reports in Women's Health, Volume 8, 2015, Pages 6-8, ISSN 2214-9112, https://doi.org/10.1016/j.crwh.2015.09.002. (https://www.sciencedirect.com/science/article/pii/S2214911215300072)

Drug Interactions

- Contraceptive efficacy and etonogestrel serum concentrations are decreased in patients taking certain antiretrovirals including:
  - Antiretrovirals: Efavirenz, Fosamprenavir, Ritonavir boosted therapies
  - Antiseizure Medications: phenytoin, carbamazepine, topiramate, oxcarbazepine, primidone, barbiturates

Billing Tips

E&M coding

- 99214 for counseling appointment
  - ICD 10 Diagnosis Codes:
    - Menorrhagia N92.0
    - Dysmenorrhea N94.6
    - Irregular Periods N92.6
    - Encounter for Birth Control Counseling Z30.9 (general) or Z30.46 (Implantable Birth Control (Nexplanon) specific)

J Code to charge for device itself: J7307

CPT code for insertion and/or removal procedure

- Insertion 11981 (1.14 RVUs)
- Removal 11982 (1.34 RVUs)
- Removal and Reinsertion 11983 (1.91 RVUs)

Be sure to get a prior authorization prior to insertion procedure!

Insertion Procedure

No imaging or laboratory examinations are needed prior to insertion

Providers must ensure they are "reasonably certain" that the patient is not pregnant. You can be "reasonably certain" if one of these criteria is met:

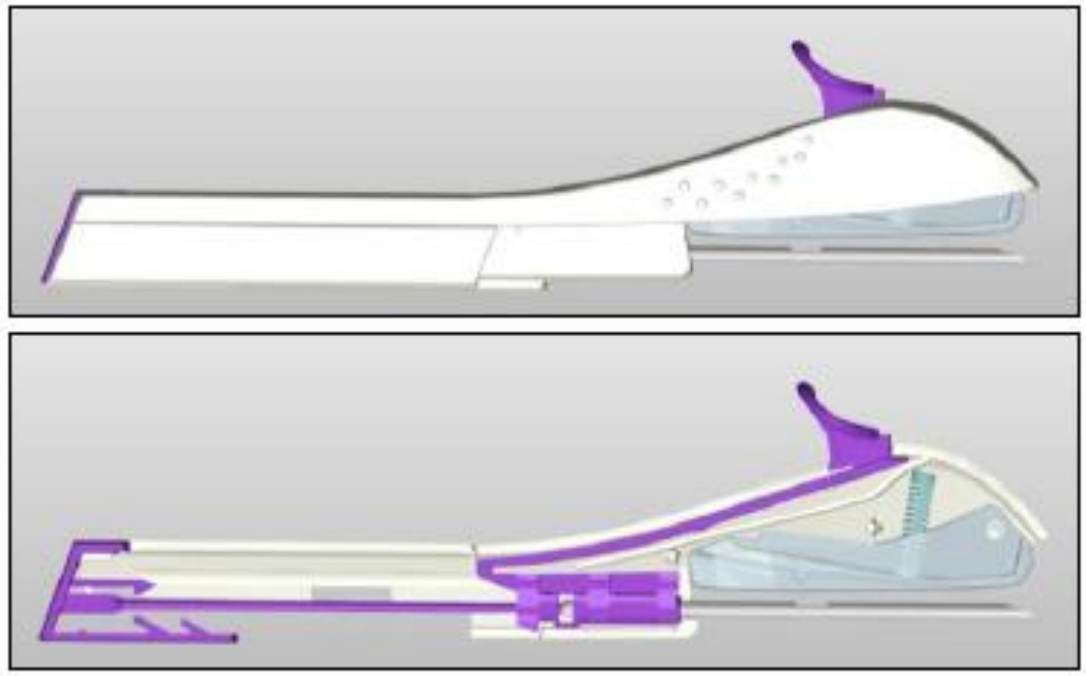
- Patient has had no sex since their last period
- Patient has a negative urine pregnancy test AND has had no unprotected sex in the last 7 days
- Patient has been consistently and correctly using a reliable method of birth control
- Patient is within 7d of the first day of their last period (assuming regular periods)
- Patient is within 7d of miscarriage or pregnancy termination
- Pt is within 4w post partum

Note: Implantable Birth Control (Nexplanon) can be inserted at any time during the menstrual cycle

Insertion procedure

Equipment list

- 25 gauge needle
- 3cc or 5cc syringe
- 1% lidocaine with epinephrine
- Alcohol swabs and chlorhexidine/iodine swabs
- Sterile and nonsterile gloves
- Sterile fenestrated drape
- Nexplanon device
- Sterile gauze pack
- Ace wrap or Keflex wrap and Band-Aid



Implanon NXT/Nexplanon applicator.

Insertion Procedure

Counsel thoroughly on indications, contraindications, side effects

Check to be "reasonably sure" the patient is not pregnant and document negative urine pregnancy test as appropriate

Patient and provider sign procedure consent form

Insertion Complications

- Bleeding
- Infection
- Pain during insertion
- Soreness after insertion
- Bruising/hematoma
- Scarring
- Paresthesia
- Excessively deep insertion increases risk of damage to nearby structures (nerves, muscles and blood vessels)

Insertion Procedure

Position patient

- Lying supine on exam table, arm raised above head as during a clinical breast exam

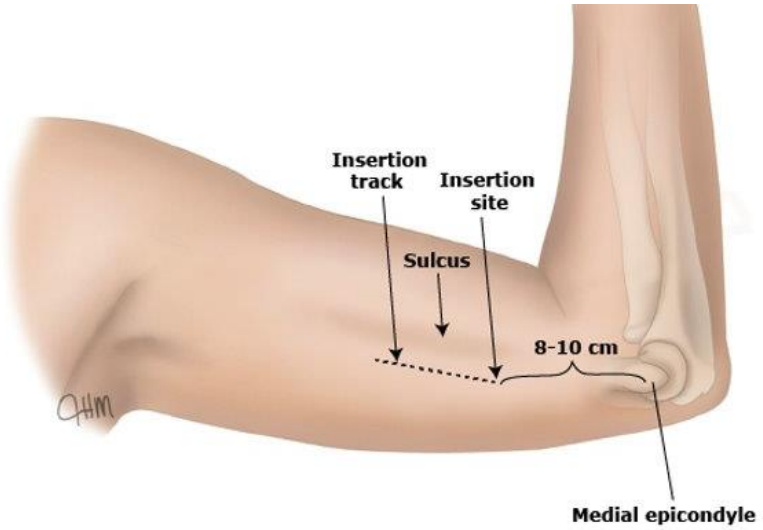
Identify Procedure Site - mark (1) insertion entry point and (2) a "guide" mark

- 8-10cm proximal to the medial epicondyle of the humerus
- 3-5cm below the groove between the bicep and tricep muscles
- AVOID the neurovascular bundle lying in the intermuscular groove!

Clean the site with 3x alcohol swabs

Administer anesthesia

- Inject ~3cc of 1% lidocaine with epinephrine along the track of the insertion site
- Test anesthesia with a gentle tap to the anesthetized skin using a needle



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Insertion Procedure

- Reclean site with chlorhexidine swabs
- Place fenestrated drape over insertion site
- Insertion
  - Position yourself to see the entire length of the intended insertion site
  - Check the device expiration date and look to confirm product is inside the delivery needle
  - Insert the device just under the skin as superficially as possible
- Provider and patient both palpate device to ensure it is beneath the skin
- Place a ban daid and Keflex bandage
- Fill out patient card with insertion and removal dates
- Discuss after-care instructions
  - How long to use backup birth control after insertion
  - Keep bandage in place for 24 hours
  - Acetaminophen/ibuprofen/ice for procedural site pain

Sample Insertion Procedure Note

INSERTION PROCEDURE NOTE:

PRE-OP DIAGNOSIS: Desire for Birth Control/Menorrhagia/Dysmenorrhea/other

POST-OP DIAGNOSIS: Same

PROCEDURE: Implantable Birth Control placement

Performing Physician:

Supervising Physician:

CHECK LIST:

Pregnancy test negative today [ ]

No unprotected sex x7d prior to procedure [ ]

Consent form signed and scanned into chart [ ]

----> No contraindications to placement (liver dz, breast CA, allergies, pregnancy).

-----> Risks of procedure discussed including bleeding, pain, infection, damage to nearby structures, malplacement.

-----> Side effects discussed including irregular bleeding (11%), headaches (16%), weight gain (12%), Acne (12%), breast tenderness (10%).

------> Duration of action 3 years

------> Need for backup contraception x7d after insertion discussed

PROCEDURE DESCRIPTION

Site: Right/Left Upper Arm

Device Lot #:

Device Exp Date:

Insertion site selected 8 - 10 cm from Left medial epicondyle and marked.

Procedure area cleaned with 3x alcohol pads. XmL of 1% lidocaine w epi injected for anesthesia.

Procedure area cleaned with 3x iodine swabs and draped with a fenestrated drape.

Device was inserted subcutaneously without difficulty. The insertion needle was retracted, leaving the device beneath the skin.

Device palpated by provider and patient to assure satisfactory placement.

Estimated blood loss of 1 mL

Dressings applied: Band-Aid and Coban

FOLLOW UP:

The patient tolerated the procedure well.

Standard post-procedure care explained including acetaminophen/l/ibuprofen for soreness

Return precautions given for signs of infection, bleeding, device displacement, etc

Backup birth control

- Backup birth control/abstinence is **NOT** needed if the device is placed:
  - Within 5d of the beginning of the patient's last period
  - Within 21 days postpartum
  - Within 6mo postpartum if the patient is (1) amenorrhoeic AND (2) exclusively breastfeeding
  - Within 15 weeks of most recent medroxyprogesterone acetate (Depo Provera) shot
  - On the same day as a miscarriage or pregnancy termination
  - On the same day as implantable birth control removal (assuming prior device was placed within 5 years)

Backup birth control

- Backup birth control/abstinence **IS** needed for 7 days if:
  - Patient was not previously consistently using reliable birth control
  - Switching from barrier method/fertility awareness
  - Switching from the pill
    - Alternative: continue pill for 4 days after placement
  - Switching from hormonal or copper IUD
    - Alternative: remove IUD 4 days after placement
  - Switching from the patch/ring
    - Alternative: continue patch/ring for 4 days after placement

Removal Procedure

Device can be removed at any time due to side effects or desire for pregnancy

Return to fertility occurs theoretically occurs within ~1 day of removal

- Undetectable etonogestrel levels within 1 week
- 90% of people ovulate within 3-4 weeks of removal

Device should be removed and replaced every 3-5 years for continued efficacy

Removal Procedure

Equipment list

- 25-gauge needle
- 3cc or 5cc syringe
- 1% lidocaine with epinephrine
- Alcohol swabs and chlorhexidine/iodine swabs
- Sterile and nonsterile gloves
- Sterile fenestrated drape
- Nexplanon device (if immediately replacing)
- Sterile gauze pack
- Hemostats
- 11 blade
- Ace wrap or Keflex wrap and Band-Aid

Removal Procedure

Identify device and assess depth

- if not palpable, imaging is indicated

Clean the site with 3x alcohol swabs

Administer anesthesia

- Push down on the proximal end of the rod to elevate the distal end
- Inject ~1cc of 1% lidocaine with epinephrine deep to the elevated distal tip of the rod
  - Note: excessive anesthesia can make it challenging to find the rod again
- Test anesthesia with a gentle tap to the anesthetized skin using a needle

Reclean the site with chlorhexidine swabs x3 and don sterile gloves

1. Place sterile fenestrated drape
2. Press on the proximal end of the rod to elevated the distal tip as much as possible
3. Use a #11 blade to make a 3mm incision parallel to the device
4. Continue to elevated the tip through the incision and clamp with hemostats
5. If the rod does not pop easily from the surrounding tissue, use the blade to lyse any fibrous adhesions
6. Measure the removed rod to ensure no part of the device remains (40mm length)
7. Close the incision with steri strips, cover with a Band-Aid and Keflex wrap
8. Aftercare Instructions
   - Ice, Acetaminophen, ibuprofen/for soreness
   - Use of backup birth control as indicated
   - Keep bandage in place for **24H**

Removal Procedure

REMOVAL COMPLICATIONS

- Bleeding
- Infection
- Pain during insertion
- Soreness after insertion
- Bruising/hematoma
- Scarring
- Inability to find device

How to switch to another birth control

Backup birth control IS needed for 7 days after removing the device when:

- Switching to a Pill/Patch/Ring
  - Alternative: Start pill/patch/ring 7 days prior to device removal
- Switching to medroxyprogesterone acetate (Depo Provera)
  - Alternative: first injection 7 days prior to device removal
- Switching to a Hormonal IUD
  - Alternative: insert IUD 7 days prior to device removal

Backup birth control is NOT needed when:

- Switching to the copper IUD up to 5 days after device removal
  - Note: this uses the copper IUD's emergency contraception mechanism of action

Sample Removal Procedure Note

NEXPLANON REMOVAL PROCEDURE NOTE

Procedure: implant removal

Location: Right/Left Upper arm

Pre-Op Diagnosis: device in place, desire for device removal

Post Op Diagnosis: same

Performing Physician:

Supervising Physician:

CHECKLIST

[ ] Consent obtained and scanned into chart - Risks discussed including pain, bleeding, infection, damage to nearby structures, poor cosmesis.

[ ] Alternative birth control plan discussed - patient will use ***

PROCEDURE DESCRIPTION

The area was identified and marked.

The area was cleaned with alcohol swabs x3 and Xcc of 1% lidocaine with epinephrine was infiltrated using a 25 gauge needle.

The area was then prepped with 3x iodine swabs and draped with a sterile drape.

An 11 blade was used to incise the skin parallel to the device Incision length Xmm.

The device was identified and grasped with straight hemostats and removed without difficulty after adhesive scar tissue was lysed.

The incision was dressed with sterile gauze and coban.

The patient tolerated the procedure well.

EBL<1cc

FOLLOW UP:

Pt will follow up PRN

Return precautions provided

Patient will use backup birth control ***, as they are switching to *** birth control

How to Become a Provider

- Complete a 3 hour in person training provided by the manufacturer
  - More information at www.nexplanontraining.com
  - Note: model arms and dummy devices are available from the manufacturer
- Note: providers who completed their training prior to 2018 must re-train using updated device and updated placement location

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QUESTIONS?

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