

ADPH Family Planning Protocol: Updates & Changes

**Satellite Conference and Live Webcast
Monday September 24, 2007
2:00 - 4:00 p.m. (Central Time)**

Produced by the Alabama Department of Public Health
Video Communications and Distance Learning Division

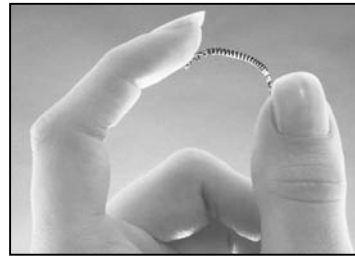
Objectives

- Describe the clinical application and function of the Essure sterilization procedure
- Describe the appropriate candidates for the Essure sterilization procedure

Objectives

- Describe the clinical application and function of the contraceptive implant, Implanon
- Complete the newly revised Adolescent/Adult Assessment Record known as the CHR-12 A & B

Essure®



**Lance Thrash, BSN, RN
Essure Representative**

What is the *Essure* Procedure?

- First and only FDA-approved transcervical sterilization procedure
- Hysteroscopically placed micro-inserts illicit a benign occlusive tissue response
 - Does not contain silicone or release hormones
 - Micro-insert anchors in tube while tissue occlusion develops

What is the *Essure* Procedure?

- Direct visualization upon deployment of each micro- insert to confirm deployment
- Three months post procedure, confirmation of correct placement and occlusion by the *Essure* confirmation test (slow, low pressure HSG)

Essure Procedure Benefits

- Quick – minimal scope in/out time; patient recovery measured in hours not days for majority of patients
- Simple – hysteroscopic approach placing a micro insert into each fallopian tube

Essure Procedure Benefits

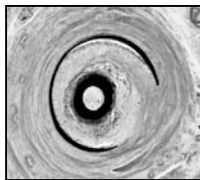
- Safe – transcervical approach eliminates risks of traditional tubal ligation; no general anesthesia, no trocars/incisions, no CO2, no burning, no tissue destruction or trauma, no adhesion stimulus

Essure Procedure Benefits

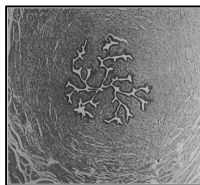
- Clinically Proven – 99.74% effective –Based on 5 years of clinical data in a small portion of women undergoing clinical studies
- Zero pregnancies in the clinical trials.
- Essure procedure is 99.80% effective after four years of follow-up
- Five year follow-up of all patients in clinical trials is ongoing

Mechanism of Action

- Dynamic expansion of super elastic outer coil for acute anchoring –Direct visualization of device deployment and placement – outer proximal coils
- Tubal occlusion by tissue in-growth (elicited by PET fibers) into and around the micro-insert over a 3 month period; as verified by the *Essure* confirmation test (HSG)

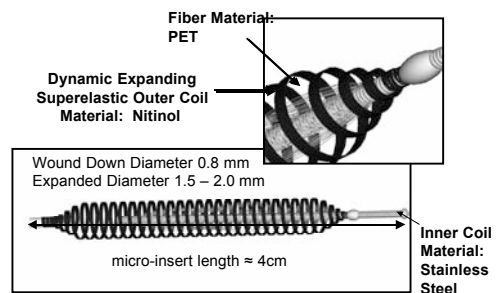


- Cross section of tubal occlusion
- 13 weeks of wearing

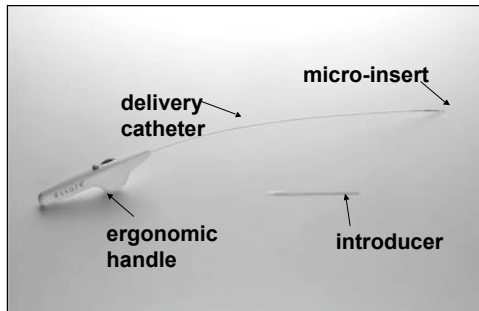


- Normal tubal architecture 5mm distal to micro-insert

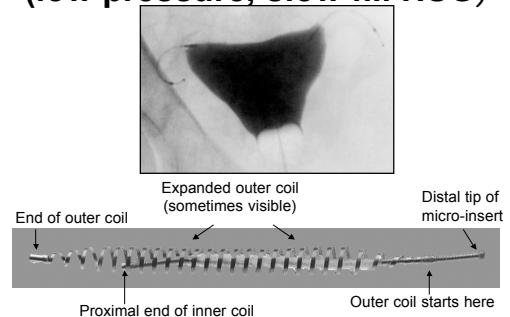
Micro-Insert Design



Essure System



Essure Confirmation Test (low pressure, slow fill HSG)



Essure Confirmation Test

- Current US labeling requires
 - HSG at 3 months post placement
- HSG must demonstrate proper placement *and* bilateral tubal occlusion
 - Essure micro-inserts are visible on x-ray due to radiopacity

Essure Confirmation Test

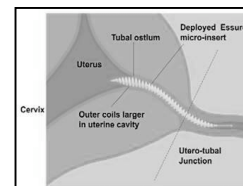
- To date based on information received, there have been no reported failures when HSG demonstrated satisfactory device placement and tubal occlusion

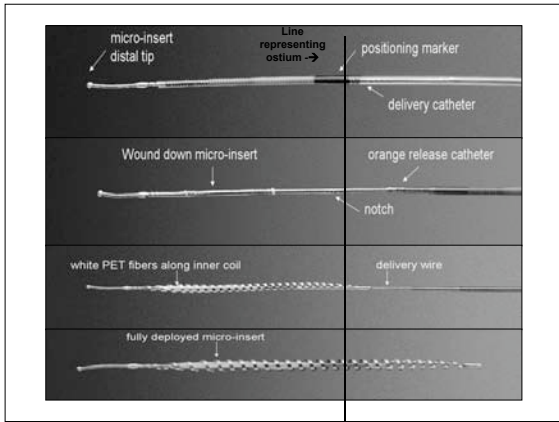
Post Essure Confirmation Test (HSG)

- Radiology report must specifically document
 - number of micro-inserts
 - specific location of micro-inserts
 - description of any unusual findings
 - assessment of tubal occlusion bilaterally

Placement: Spanning the Utero-Tubal Junction

- 3-8 expanded coils visible in uterine cavity



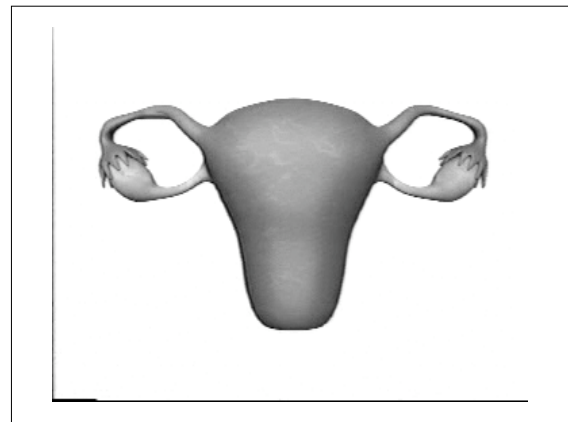


Essure Simple Procedure Steps

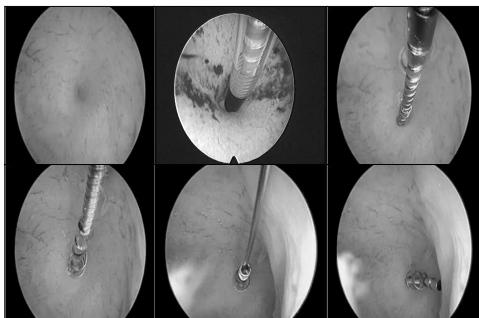
- Insert *Essure* system through hysteroscope
- Advance into ostium to black positioning marker
- Retract catheter to uncover device while stabilized

Essure Simple Procedure Steps

- Confirm markers, press button and roll thumbwheel back, device will deploy, wait for device to seat itself (10 seconds)
- Rotate handle counter clockwise for disengagement, remove delivery system



Micro-Insert Placement



Clinical Trials Summary

FDA approval November 2002

Pivotal Trial Objectives

- Evaluate
 - Safety and participants' tolerance of and recovery from Essure procedure
 - Safety and participants' tolerance to implanted micro-inserts

Pivotal Trial Objectives

- Tubal occlusion by *Essure* Confirmation Test at 3 months (HSG)
- Effectiveness in preventing pregnancy
 - Primary endpoint at 1 year

Pivotal Trial Adverse Events Preventing Reliance on Essure for Permanent Contraception

Events	Number	Percent
Expulsion	14/476	2.9%*
Perforation	5/476	1.1%
Other unsatisfactory micro-insert location	3/476	0.6%
Initial tubal patency	16/456	3.5%**

- *14 women experienced an expulsion, however 9 of these 14 women chose to undergo a second micro-insert placement procedure, which was successful in all nine cases
- **Tubal patency was demonstrated in 16 women at the 3 month HSG, but all 16 women were shown to have tubal occlusion at a repeat HSG performed 6-7 months after Essure placement

Safety of Placement Procedure

- Adverse events reported in 3% of women
 - All resolved prior to discharge
 - None required major surgery
 - No hospitalizations except one woman who was observed overnight due to a reaction to pain medication*

Safety of Placement Procedure

- Micro-insert perforation rate of 1%
 - No symptoms
- Mild to no pain reported in majority of women
 - adverse reaction to pain medication

Patient Satisfaction (Clinical Trials)

- 99% of women rated their tolerance of wearing as “Good” to “Excellent”
- 97% of women rated their satisfaction with their experience as “Somewhat” to “Very Satisfied”
- 88% of women rated tolerance of procedure as “Excellent” to “Good”

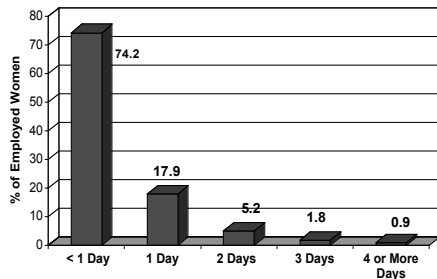
Post-procedure Recovery

- Procedure time (data from pivotal trial)
 - Total – 35 minute average
 - Hysteroscopy –13 minute average
- Post procedure events reported: 42%
 - Cramping
 - Pain
 - Nausea

Post-procedure Recovery

- No post-procedure analgesia required: 75%
- Average time to discharge: 45 minutes

Days of Work Missed for Employed Women



* Does not include day of procedure

Results

Comparison of Cumulative Risk of Pregnancy in "CREST Study" vs. Essure Sterilization

Method	Year of follow-up				
	1	2	3	4	5
Bipolar	2.3	4.6	6.7	13.1	16.5
Unipolar	0.7	2.3	2.3	2.3	2.3
Silicone band	5.9	7.6	8.3	9.0	10.0
Spring clip (Hulka)	18.2	23.8	29.1	30.7	31.7
Interval salpingectomy	7.3	15.1	15.1	15.1	15.1
Postpartum salpingectomy	0.6	3.9	4.6	5.4	6.3
All "CREST" average	5.5	8.4	9.9	11.8	13.1
Essure®, posterior mean	0.5	1.0	1.6	2.0	2.6**

*Cumulative number of pregnancies/ 1000 women

** Represents 75 Phase II patients who have completed 5 year follow-up. No patients in the Pivotal Study have reached the 5 year follow-up visit.

Effectiveness

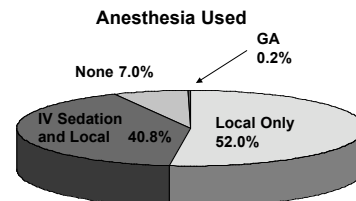
Age-adjusted Posterior Cumulative Bayesian Effectiveness Rates (Posterior Means) for Essure: Phase II and Pivotal Trials Combined

1 year	2 years	3 years	4 years	5 years
99.95%	99.90 %	99.84 %	99.80 %	99.74 %**

- * Age-adjustments are for comparison to CREST as a reference population
- **Represents 75 Phase II patients who have completed 5 year follow-up. No patients in the Pivotal Study have reached the 5 year follow-up visit.

Pain Management

82% received NSAIDS prior to procedure



Micro-insert Placement Rate in First Attempt in the Commercial Setting

Post Approval Study for Newly Trained Physicians

Placement Status	Number	Percent
Bilateral	350/370*	94.6%
Unilateral **	15/370	4.0%
* No devices placed	5/370	1.4%

Micro-Insert Placement Rate in First Attempt in the Commercial Setting

- Excludes 194 placement attempts using a previous generation Essure delivery catheter design that is no longer marketed and 21 placement procedure non-attempts

Micro-insert Placement Rate in first attempt in the Commercial Setting

- Includes 6 women with known prior tubal surgery (tubal removal), 1 with known proximal tubal occlusion, 1 planned contralateral salpingo-oophorectomy, and 1 unicornuate uterus

Identifying Patients within your Practice

- Women over 35
- Women with 2 or more children
- Women age 35-45 whose last child was born > 5 years prior

Identifying Patients within your Practice

- Patients seeking endometrial ablation
- Women dissatisfied with their current method of contraception
- Couples whose husband is considering vasectomy

Scheduling the Essure Procedure

- During the early proliferative phase
 - Eliminates undiagnosed luteal phase pregnancy
 - Enhanced visualization of fallopian tube ostia
- Post-Partum – 6-8 weeks

Pre- Procedure Counseling

- Discuss patient options if bilateral placement is not achieved
- Alternative contraception for 3 months
 - Alternative contraception excluding the use of an IUD
 - Compliance is critical due to the theoretical increased risk of ectopic pregnancy

Pre- Procedure Counseling

- 3 month follow-up appointment with HSG
- No protection against HIV or other STDs
- Essure is irreversible
- Success with IVF is unknown

Counseling/Contraindications

- Reconfirm patient's decision for permanent birth control–Essure is irreversible
- Conduct pregnancy test 24 hours prior to or immediately preceding procedure

Counseling/Contraindications

- Do not attempt if
 - Previously undergone a tubal ligation
 - Only one micro-insert can be placed

Contraindications

- *Essure* should not be used by patients with any of the following conditions
 - Pregnancy or suspected pregnancy
 - Delivery or termination of pregnancy less than 6 weeks before Essure placement
 - Active or recent upper or lower pelvic infection

Contraindications

- Known allergy to contrast media
- Known hypersensitivity to nickel confirmed by skin test
- See complete Instructions for Use in packaging
- Patients with suspected hypersensitivity to nickel should undergo a skin test to assess hypersensitivity prior to an Essure placement procedure

Immunosuppressive Therapy

- Placement discouraged in women undergoing immunosuppressive therapy
 - Systemic corticosteroids
 - Chemotherapy
- Therapy may negatively affect tissue response that leads to tubal occlusion

Pre-procedure Medications

- NSAIDs - strongly recommended
1-2 hours before procedure
 - Oral
 - Suppositories
 - IM or IV
- Anxiolytic agent (if needed)

Recommended Anesthesia

- Local anesthesia
 - Paracervical block or topical
 - Wait at least 5 minutes

Post-Placement Warnings

- Intrauterine procedures
 - Diagnostic procedures
 - Use direct visualization
 - Blind insertion of instruments
 - With caution
 - Electrosurgery
 - Avoid contact with micro-inserts
 - MRI safe, but will obscure imaging of local tissue

Post Procedure Documentation

- Number of coils visible at ostium
- Scope time and/or fluid deficit
- Unusual anatomy or placement
- Patient counseling

Benefits

- Safe and effective office procedure
- No incisions
- Avoidance of general anesthesia
- No abdominal scars
- Rapid return to normal activities
- Contains no hormones or silicone

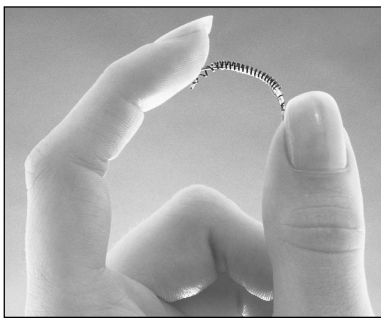
Success:

- Over 100,000 procedures have been performed world wide since 1998
- Zero pregnancies have been reported among patients in the clinical trials

Resources

- Healthcare Professional Web site
www.essureMD.com
- Consumer/Patient Web site
www.essure.com
- *Essure* Information and Scheduling Center
1-877-377-8732 health care professionals
1-877-377-8731 consumers

Thank You



Candidates for Essure

1. All sterilization candidates (male or female) must be 21 years of age, mentally competent, and completely sure that they do not want any more children
2. Women who are eligible to receive a surgical procedure are to be offered a bilateral tubal ligation

Candidates for Essure

3. Women who meet the following criteria can be offered Essure
 - For Medicaid recipients, the physician performing the procedure must obtain prior approval from Medicaid based on one of these criteria)

Candidates for Essure

1. Morbid Obesity (BMI of 45 or greater), OR
2. Abdominal mesh that mechanically interferes with laparoscopic tubal ligation sterilization procedures, OR
3. Permanent colostomy with documented adhesions, OR

Candidates for Essure

4. Multiple abdominal/pelvic surgeries with documented severe adhesions, OR
5. Artificial heart valve requiring continuous anticoagulation, OR
6. Other severe medical problems that would be a contraindication to laparoscopic tubal ligation procedures based on medical documentation submitted

Requesting Sterilization Funds

- Title X funds may be requested for sterilizations in the usual manner
 - This will now include Essure if the Title X (non-Medicaid) patient is not eligible for a tubal based on established criteria

Requesting Sterilization Funds

- Referral provider must be under contract with the health department in order to perform a Title X procedure
 - NOTE - If the patient is covered by Plan First, the referral provider must be enrolled through Medicaid

Requesting Sterilization Funds

- Procedures and Title X Fees for sterilizations
 - Surgical tubal ligation
 - \$1,000 (covers physician + hospital)
 - Nonsurgical tubal (Essure)
 - Procedure must be done in a hospital outpatient facility
 - \$1,570 (physician reimbursement to cover procedure, follow-up tests and device)

Requesting Sterilization Funds

- \$590 (hospital reimbursement)
 - Vasectomy
 - \$300
- Patient will need her Initial or Annual exam done within the previous 12 months
 - consent must be signed 30 days prior to procedure
 - patient has been informed that she/he can change her mind at any time and she will not endure any cost from the procedure

Sterilization Consent

- There are actually two sterilization consent forms available from
 1. Medicaid
 2. Title X
- Both consent forms are acceptable to use, however, if the patient is a known Medicaid recipient, utilize the Medicaid consent form

Sterilization Consent

- Title X recently updated their consent
 - There is an expiration date on the top right corner of 11/30/2009
- Copies of both consent forms are being sent to counties now
- Medicaid and ADPH policy requires that sterilization counseling and completion of the applicable consent form be performed by a nurse, nurse practitioner, physician, or certified nurse midwife

Sterilization Patient Education Materials

- New PT+3 fact sheet developed for Essure
 - “Facts About Sterilization for Women” – ADPH-FHS-535
- Can continue to use information packets for tubals and vasectomies
 - “Information for Women – Your Sterilization Operation”
 - “Information for Men – Your Sterilization Operation”

Sterilization Patient Education Materials

- Can be ordered through ADPH Warehouse Operations
- Important counseling point
 - Patient will need ongoing birth control for at least 3 months pending confirmation of tubal occlusion

IMPLANON (etonogestrel implant) 65mg Clinical Data

Christine Donahue, MSN, CRNP
Senior Medical Science Manager
Organon USA

IMPLANON™

- A single rod, progestin-only subdermal implant effective for up to 3 years
- Clinical trials in over 17 countries, including the US
- Supplied in a sterile and disposable preloaded applicator

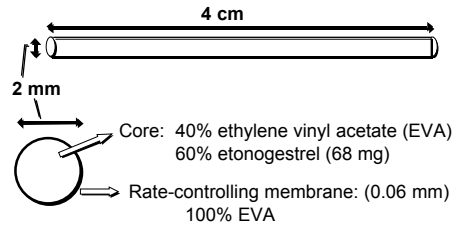
IMPLANON™

- Inserted subdermally in the groove between the biceps and triceps muscles
- Must be inserted and removed only by clinicians completing this training program

IMPLANON™ Worldwide Availability

- United Kingdom
 - Ireland
 - The Netherlands
 - Belgium
 - France
 - Spain
 - Portugal
 - Norway
 - Germany
 - Austria
 - Switzerland
 - Denmark
 - Sweden
 - Finland
 - Czech Republic
 - Slovak Republic
 - Mexico
 - Brazil
 - Chile
 - Turkey
 - Venezuela
 - Australia
 - Indonesia
 - Vietnam
 - Thailand
 - Malaysia
 - Peru
 - South Korea
 - Iceland
 - Kenya
 - Lebanon
 - Luxembourg
 - Singapore
 - Tunisia
- **Approximately 2.5 million implants prescribed since 1998**

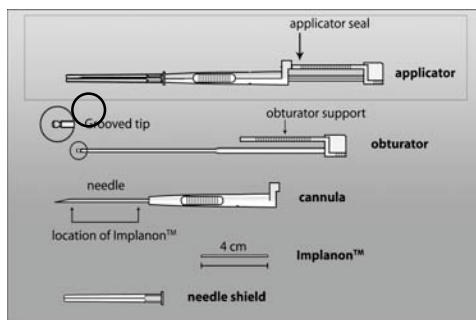
IMPLANON™



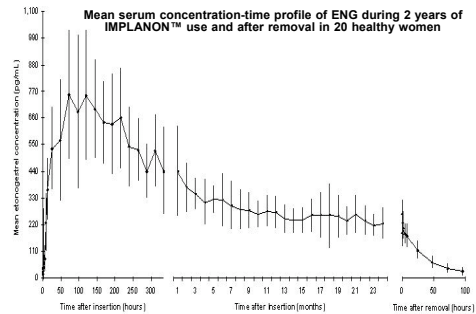
Release Rate: 60 µg/day to 70 µg/d initially then decreases to 25 µg/d to 30 µg/d by end of third year

- **IMPLANON™ is not radio-opaque**

IMPLANON™ Applicator



Pharmacokinetics



Efficacy

- 6 pregnancies reported in 20,648 cycles
- Each conception was likely to have occurred shortly before or within two weeks after IMPLANON™ removal
- With these pregnancies cumulative pearl index = 0.38

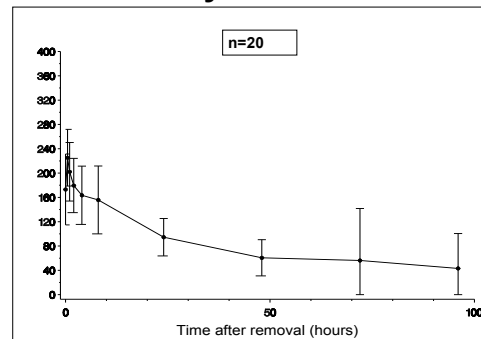
Efficacy in Overweight Women

- No clinical trial data
- Women who weighed more than 130% ideal body weight were excluded from the clinical trials
- It is possible that with time IMPLANON™ may be less effective in overweight women
- Clinical judgment required

Main Mechanisms of Action

- Primarily inhibits ovulation
 - No ovulation was observed for 30 months
 - Only 2 out of 31 (6.5%) subjects ovulated in year 3, with no resulting pregnancies
 - Subject 1 = 69.5 kg and ovulated only at month 30
 - Subject 2 = 57.5 kg and ovulated months 30, 33, and 36
- Secondarily increases viscosity of cervical mucus

Quickly Reversible



Return to Ovulation

- 41 women were followed for return to ovulatory cycles after removal
- Ovulation was determined by serial Progesterone measurements ($(P) > 16\text{nmol/L}$) and serial ultrasounds
- >90% subjects ovulated well within 3 months post removal

Contraindications

- Known or suspected pregnancy
- Current or past history of thrombotic disease
- Hepatic tumors, active liver disease
- Undiagnosed abnormal genital bleeding
- Known, suspected or history of breast cancer
- Hypersensitivity to any of the components of IMPLANON™

Drug Interactions

- IMPLANON™ is not recommended for women who require chronic use of drugs that are potent inducers of hepatic enzymes because of potential for decreased efficacy and unintended pregnancy

Drug Interactions

- Examples
 - Barbiturates
 - Carbamazepine
 - Griseofulvin
 - Felbamate
 - Rifampin
 - Oxcarbazepine
 - Phenylbutazone
 - Topiramate
 - Phenytoin
 - Modafinil

Drug Interactions

- Anti-HIV Protease Inhibitors
 - Studies have been done with COCs
 - Unknown if same risks apply to IMPLANON™
 - Refer to labeling of the individual inhibitors for drug-drug interactions

Drug Interactions

- Herbal Products
 - St. John's Wort (*Hypericum perforatum*) may induce hepatic enzymes and may reduce the effectiveness of contraceptive steroids

IMPLANON™ Bleeding Patterns

- All hormonal contraceptive bleeding patterns are categorized by:
 - Frequency
 - Duration of bleeding
- Some women may have a more favorable pattern while others may not and this is impossible to predict

IMPLANON™ Bleeding Patterns

- Bleeding can be light or heavy
- Can be for just a few days or many days in a row
- Can have many consecutive days or weeks of no bleeding
- Patients should be prepared to experience any of these patterns
- Patterns can vary throughout the duration of use

IMPLANON™ Bleeding Patterns

- On average, the total amount of bleeding/spotting days is similar to or slightly better than a normal menstruating woman
- The key difference is the irregularity and unpredictability of the bleeding
- Some women may have a slight trend towards lighter and infrequent bleeding or no bleeding at all

Mean Bleeding Days and Episodes per 90-Day Reference Period

Spotting (S) Days	10.44
Bleeding (B) Days	7.25
(B)/(S) Episodes	2.35

Mean of 90-day reference periods 2-6
Number of patients =780

Hemoglobin Levels

n=504

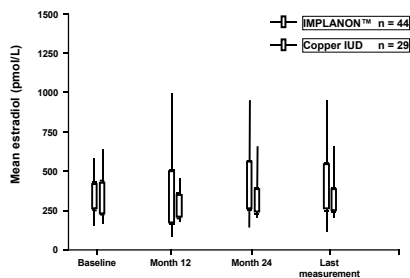
	Mean Hgb (g/dl)
Baseline	13.3
12 months	13.4
24 months	13.2
36 months	12.9

Bleeding Patterns During the First 2 Years

Bleeding Patterns	Definitions	%*
Infrequent	Less than three bleeding and/or spotting episodes in 90 days (excluding amenorrhea)	33.6
Amenorrhea	No bleeding and/or spotting in 90 days	22.2
Prolonged	Any bleeding and/or spotting episode lasting more than 14 days in 90 days	17.7
Frequent	More than 5 bleeding and/or spotting episodes in 90 days	6.7

- * % = Percentage of 90 day intervals with this pattern
- Based on 3,315 reference periods by 780 women, excluding the first 90 days after insertion

Estradiol Levels During Treatment



IMPLANON™ Use While Breastfeeding

- ~ 0.2% of estimated absolute maternal dose is excreted in breast milk
- Non-randomized group comparative study with copper-IUD and IMPLANON™ (n = 80)
- Inserted 4 weeks post-partum
- Breast-fed for mean duration of 14 months and followed up to 36 months of age

IMPLANON™ Use While Breastfeeding

Results

- No significant effects and no differences were observed in the physical and psychomotor development of the infants
- No differences in the production and quality of breast milk were detected

Discontinuation Rates ($\geq 1\%$) due to Adverse Events

n = 942

Bleeding Irregularities*	11.0%	(104/942)
Weight Gain	2.3%	(22/942)
Emotion Liability	2.3 %	(22/942)
Headache	1.6 %	(15/942)
Acne	1.3 %	(12/942)
Depression	1.0 %	(9/942)

* includes frequent, heavy, prolonged, spotting and other patterns of bleeding irregularity

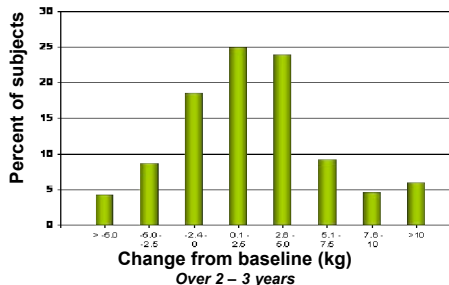
Mean Weight Gain

U.S. Clinical Study n=330

One Year	2.8 lbs
Two Years	3.7 lbs

Weight Changes in Clinical Trials

n = 936



Implant Site Condition

n=942

Condition	n	%
Pain	27	2.9
Redness	3	0.3
Swelling	3	0.3
Hematoma	1	0.1
Expulsion*	0	0.0

* Expulsions have been reported post-marketing outside the US

IMPLANON™ Removal (From Clinical Trials)

1.7% of Women Experienced Problems at Removal
(n = 15 women out of 900)

Implant Not Palpable
Broken or Damaged Implant
Formation of Fibrosis
Difficult Localization
Slight Migration
Difficult Removal due to Deep Insertion

When to Insert IMPLANON™

- Timing of insertion should be followed exactly as described in the Package Insert
- If no preceding hormonal contraceptive use in the past month:
 - days 1 to 5 of the menstrual cycle

When to Insert IMPLANON™

- If switching from Combination Methods:
 - anytime within 7 days of the last active combined dose
- If switching from a progestin-only method:
 - Any day when switching from POP (do not skip any dose)

When to Insert IMPLANON™

- Same day as implant or IUS removal
- On the day when the next contraceptive injection would be due
- Within 5 days following 1st trimester abortion
- Between 3-4 weeks following childbirth or 2nd trimester abortion

When to Insert IMPLANON™

- After the 4th post-partum week if exclusively breastfeeding
- Backup is not needed if insertion occurs as recommended
- If deviating from the recommended timing of insertion, rule out pregnancy and use back-up non-hormonal method of contraception for 7 days after IMPLANON™ insertion

Key Point on Insertion

- Careful and correct subdermal insertion is one of the keys to successful placement and will facilitate removal

IMPLANON™ Summary

- Single-rod implantable contraceptive
- Duration of action up to 3 years
- Extensive history of use
- Highly effective
- Rapid onset of action
- Quickly reversible
- Patient Counseling is very important

IMPLANON™ Summary

- Most common side effect associated with discontinuation is irregular and unpredictable bleeding
- Rare pregnancies have been reported post-marketing which were predominantly due to failure to strictly adhere to labeling instructions and more rarely due to method failure
- Occasional removal complications have occurred

Insertion Steps and Techniques

Pre-Insertion Preparation

- Thoroughly counsel the patient
 - Provide patient education materials
 - Patient Package Insert (Patient Labeling) with Consent Form
 - Patient Education Video
- Provide the patient adequate time for full consideration
- Obtain patient consent

Pre-Insertion Preparation

- Prior to inserting IMPLANON™ carefully read the Full Prescribing Information
- Confirm correct timing of insertion
- *Aseptic* conditions are required
- IMPLANON™ must be inserted by the expiration date stated on the package

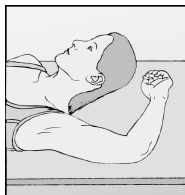
Materials for IMPLANON Insertion

- Table Drape
- Sterile Talc Free Gloves
- Aseptic Solution (Betadine, Hibiclens)
- Optional Sterile Marker
- Local Anesthetic (*draw up @2 cc of 1% Lidocaine*)
- Needles
- Syringe
- Sterile Gauze
- Adhesive Bandage
- Pressure Bandage

Materials for IMPLANON Insertion

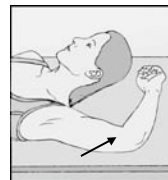
- All materials needed for IMPLANON insertion and removal are referenced in the package insert
- Insertion/Removal supplies are not shipped with the product and will have to be ordered in advance

Pre-Insertion Preparation



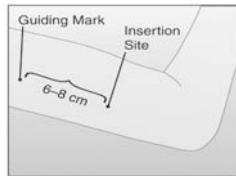
- Place patient in supine position with nondominant arm flexed at the elbow and externally rotated

Pre-Insertion Preparation



- Identify insertion site → 6-8 cm above the elbow crease at the inner side of the upper arm overlying the groove between the biceps and triceps

Pre-Insertion Preparation



- Mark the insertion site
- Make a second mark 6 – 8 cm above the first

Pre-Insertion Preparation

- Rule out allergies to antiseptic and anesthetic
- Clean the insertion site with an antiseptic
- Inject sufficient anesthetic (e.g. ~ 2 cc of 1% Lidocaine) just under the skin along the planned insertion canal
- Carefully remove the IMPLANON™ sterile applicator from its blister pack
- Keep the applicator sterile

IMPLANON™ Insertion

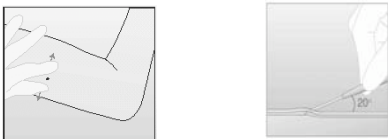
- Visually verify the presence of IMPLANON™ inside the needle with the needle cap in place
 - The rod is seen as a white body inside the needle tip
 - If the implant is not visible, turn the applicator needle down and gently tap on a surface with the needle cap in place until it is seen

IMPLANON™ Insertion

- Note that IMPLANON™ can fall out of the needle prior to insertion
- After the needle cap is removed, the applicator must always be held in the upright position until the moment of insertion

IMPLANON™ Insertion

- Stretch the skin at the insertion site with thumb and index finger



- Insert the needle tip beveled side up no greater than a 20° angle just until the skin has been penetrated

IMPLANON™ Insertion

- Lower the applicator so that it is parallel to the arm



- To minimize chance of deep insertion, lift or tent the skin with the tip of the needle while inserting
- Gently insert the needle to its full length

IMPLANON™ Insertion

- Break the seal of the applicator by pressing the obturator support



- Turn the obturator 90° in either direction with respect to the cannula

IMPLANON™ Insertion

- Fix the obturator in place on the arm with one hand
- With the other hand, slowly and fully retract the needle (cannula) back along the full length of the obturator



Confirmation Immediately After Insertion

- Look for the grooved tip of the obturator visible inside the needle
- Palpate the implant to verify correct subdermal insertion. IMPLANON™ feels like a 4 cm long flexible rod

Confirmation Immediately After Insertion

- If the implant is not palpable, confirm its presence in the arm with high-frequency, linear array transducer (≥ 10 MHz) US or, if necessary, MRI
- Patient must use a non-hormonal method until the presence of IMPLANON™ has been confirmed

IMPLANON™ Post-insertion Steps

- Place small adhesive bandage over the insertion site
- Place pressure bandage with sterile gauze
- After palpation and confirmed insertion, fill out the User Card and Patient Chart Label

IMPLANON™ Post-insertion Steps

- Give the User Card to the patient for her records
- Give the Personal Calendar (Bleeding Diary) to the patient and instruct her how to use it
- Place Patient Chart Label in patient's record
- Properly dispose of applicator

Removal Steps and Techniques

IMPLANON™ Removal

- Indications for removal
 - Patient request
 - Medical indication
 - Desired pregnancy
 - At the end of 3 years of use
- Should be performed only by clinicians completing this training program
- Prior to removal carefully read the Full Prescribing Information

IMPLANON™ Removal

- Counsel patients about removal
- Consult the Patient User Card and/or Patient Chart Label
- **Do Not** attempt removal until the location of the implant has been verified by palpation or imaging
- Confirm that there are no allergies to antiseptic and anesthetic
- Place patient in same position as for insertion
- Maintain aseptic conditions

Materials for IMPLANON™ Removal

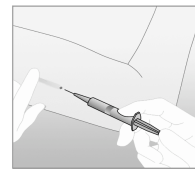
- Table Drape
- Sterile Talc Free Gloves
- Aseptic Solution (Betadine, Hibiclens)
- Optional Sterile Marker
- Local Anesthetic (about 0.5 -1 cc of 1% Lidocaine)
- Needles
- Syringe
- Sterile Scalpel
- Straight or Curved Mosquito Forceps
- Sterile Gauze
- Adhesive Bandage (Butterfly closure)
- Pressure Bandage

IMPLANON™ Removal



- Locate the implant by palpation and mark the end closest to the elbow with a sterile marker
- Clean the area and apply an antiseptic

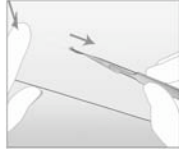
IMPLANON™ Removal



- Inject sufficient anesthetic (e.g. 0.5 to 1 cc of 1% lidocaine) just underneath the end of the implant closest to the elbow*

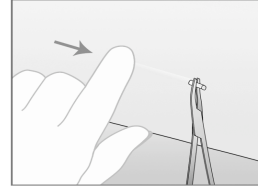
*It is important to inject under the implant in order to prevent obscuring or displacing it.

IMPLANON™ Removal



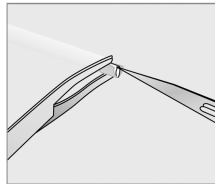
- Press down on the end of the implant closest to the axilla
- Make a 2-3 mm incision in the longitudinal direction of the arm at the tip of the implant closest to the elbow

IMPLANON™ Removal



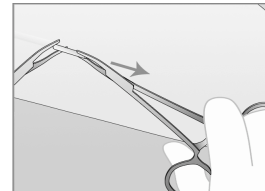
- Gently push the implant toward the incision until the tip is visible

IMPLANON™ Removal



- Grasp the implant with sterile mosquito forceps and gently remove

IMPLANON™ Removal



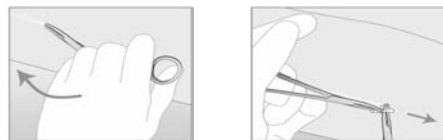
- If encapsulated, gently remove the capsule with sharp or blunt dissection

IMPLANON™ Removal



- If the tip of the implant is still not visible after gently pushing it towards the incision, gently insert a sterile forceps into the incision and grasp the implant

IMPLANON™ Removal



- Flip the forceps over and use a second pair of sterile forceps to localize the implant and dissect the fibrotic capsule
- Remove the entire 4 cm implant

IMPLANON™ Removal

- Close the incision with a butterfly closure and apply an adhesive bandage
- Apply a sterile gauze with a pressure bandage

Questions

Implanon

- Currently, Implanon will be a referral-only method
- We are looking at the possibility of our Nurse Practitioners being trained, however, this is still in the review process with the Alabama Board of Nursing
- Medicaid recipients are to be referred to an enrolled provider trained to insert Implanon

Implanon

- Title X funds may be requested for non-Medicaid patients
- Referral provider must be under contract with the Health Department
- The procedures and Title X fees include
 - Implant insertion only – \$150
 - Implant removal & reinsertion – \$150
 - Implant removal only – \$80
 - The Implant (rod) is to be requested through the central office

Implanon Bleeding Concerns

- NP may use her discretion with the following treatment options for heavy or prolonged menses or BTB in women using Implanon
 - Overlap with up to 3 packs of low dose combined oral contraceptives
 - 20 mcg pill preferred, if available
 - Patient must have no contraindication to estrogen use

Implanon Bleeding Concerns

- Conjugated estrogen
 - Premarin 0.625 or 1.25 mg tid x 1 week
 - Patient must have no contraindication to estrogen use
- NSAIDs
 - Nonsteroidal anti-inflammatory drug such as ibuprofen (e.g. Advil, Motrin) 800 mg every 8 hours for up to 3 days
 - No more than 2400 mg in a 24 hour period

Implanon Consent Form and Fact Sheet

- Newly developed method consent form for Implanon – CHR-7G
 - Must be completed when making arrangements for insertion
 - Form will be available October 1 to print through PHALCON

Implanon Consent Form and Fact Sheet

- New PT+3 Fact Sheet developed for Implanon
 - “Facts about Implanon”, ADPH-FHS-268
 - Can be ordered through ADPH Warehouse Operations
- Currently both the consent form and fact sheet are only available in English
 - Spanish translation forthcoming

Forms Review

Laurie Stout, BSN, RN
Nurse Consultant
Bureau of Family Health Services
Alabama Department of Public Health

Family Planning Protocol Update

- Visit Standards
 - Revised CHR-12 A & B throughout
 - Nurse may use her discretion to obtain a height on a patient beyond the initial visit

Let’s Review the New Forms

Adolescent/Adult Assessment Record CHR-12A Changes – Side 1

- Patient History
 - Pap Smear Status
 - Included space for Pap smear history
 - Nurse is to document known Pap history, including abnormal results

Adolescent/Adult Assessment Record CHR-12A Changes – Side 1

- General Medical History
 - Omitted “Migraines” and added “Headaches”
 - Nurse is to document known or suspected migraines

**Adolescent/Adult Assessment Record
CHR-12A Changes – Side 1**

- **Family History**
 - Nurse is to indicate the applicable relative with the abnormal condition
 - Audits have shown that family history entries are often left blank

**Adolescent/Adult Assessment Record
CHR-12A Changes – Side 1**

- Examples include
 - Breast cancer and no family member named
 - “MGM, cancer” entered but it does not specify the type of cancer
 - Counseling section has been moved to the revised CHR-12B

**Adolescent/Adult Assessment Record
CHR-12A Changes – Side 1**

- **Signature Sections**
 - Nurse
 - Can document additional comments in this section if indicated
 - Sign and date indicating he/she obtained history

**Adolescent/Adult Assessment Record
CHR-12A Changes – Side 1**

- Provider
 - Can document additional history findings in this section if indicated
 - Check if obtained or reviewed history
 - Initial, sign and date the form
 - It is acceptable for the provider to initial a history item on the form if not previously identified

**Adolescent/Adult Assessment Record
CHR-12A Changes – Side 2**

- Additional room added at the top to describe abnormal menstrual cycles
- Revised the graphic on the breast
- **Assessment/Plan** (at the bottom)
 - Omitted section to document medications given (now on the CHR-12B)
 - More room available to document assessment and plan

**Adolescent/Adult Assessment Record
Continuation Notes CHR-12B Changes**

- Counseling Section has been moved from CHR-12A
 - Nurse and provider are to use this section
 - Each is to initial the applicable topic, then date, initial and sign in the space provided

Adolescent/Adult Assessment Record Continuation Notes CHR-12B Changes

- Use the notes section at the bottom of the form if needed for additional documentation
- PT+3 Section has moved from the CHR-12A
 - Complete in the usual manner

Adolescent/Adult Assessment Record Continuation Notes CHR-12B Changes

- Continuation Notes from Health Assessment
 - Nurse and provider are to use this section as a progress note to document information from the patient history and physical assessment OR if applicable for a problem focused visit requiring a physical exam

Adolescent/Adult Assessment Record Continuation Notes CHR-12B Changes

- Use this section to document medications given, additional counseling, referral information, etc.
- This form is not intended to be used to document routine contraceptive supply visits, counseling visits, etc.

Family Planning Protocol Update

- Tools/Forms section
 - ADPH Request Form for Title X Funding
 - Added Implanon (rod) insertion and removal to request form
 - Counties may order Implant (Implanon), Paragard or Mirena IUDs from the central office for a Title X patient if unable to obtain through a Patient Assistance program such as the ARCH Foundation

Family Planning Protocol Update

- Other Protocol Section
 - Common Diagnosis and Contraceptive Issues - Headaches/Migraines
 - If focal neurologic symptoms develop or worsen after initiating method, discontinue and refer to MD; offer a barrier method

Family Planning Protocol Update

- Combined Methods
 - If 35 years or older, do not initiate or continue a combined method; offer progestin only method (previous protocol required a consult with collaborating MD)

Family Planning Protocol Update

- **Other Protocol Section**
 - **Contraceptive Methods**
 - **Depo–Provera/Medroxyprogesterone Acetate**
 - Omitted active thrombophlebitis and current thromboembolic disorders from the list of contraindications

Family Planning Protocol Update

- **Implant (Implanon)**
 - New section added for Implanon
- **Combined OCs**
 - May provide to women up to the age of 55 years if they are healthy, non-smokers who have no additional risk factors such as obesity (current age is 50)
 - A 20 mcg pill formulation should be considered as a first option for any woman

Family Planning Protocol Update

- **Other Protocol Section**
 - **Contraceptive Methods**
 - **Progestin-only pills**
 - Quick start option added
 - Patient may start the pills on the date of service if pregnancy is ruled out and backup method is used for one week

Family Planning Protocol Update

- May be provided to women up to the age of 55 years
- **Sterilization**
 - Essure added to protocol

Faculty

**Laurie Stout, BSN, RN
Nurse Consultant
Bureau of Family Health Services
Alabama Department of Public Health**

**Annie Vosel, BSN, RN
Plan First Manager
Bureau of Family Health Services
Alabama Department of Public Health**

Faculty

**Christine Donahue, CRNP
Implanon Representative**

**Lance Thrash, BSN, RN
Essure Representative**

Upcoming Programs

Workplace Violence:

ADPH Policies & Prevention

Friday, September 28, 2007

9:00-11:00 a.m. (Central Time)

Short Term Birth Interval: Counseling

Family Planning Patients

Thursday October 4, 2007

2:00 - 4:00 p.m. (Central Time)

Upcoming Programs

Mosquito Abatement in Louisiana

Post Katrina and Rita

Thursday October 11, 2007

12:00 -1:30 p.m. (Central Time)

Collaboration: The Key to Public

Health System Improvement

Wednesday October 24, 2007

12:00 -1:30 p.m. (Central Time)