TOT on

Sub-dermal Implants

Participant's Guide

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Course Schedule

Session Time	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
9.00 – 11.00	• Welcome and Opening • Pre-test • Present TOT agenda and syllabus • Counseling	• Introduction to Competency Based Training (CBT) • Coaching in clinical training • COACH Skill Inventory	• Norplant® insertion/removal (training on arm models)	• Clinical training • Model training	• Clinical training • Model training	• Clinical training • Model training
11.00 – 13.00	• Counseling	• Norplant® clinical profile • Norplant® Basic Learning Guides	• Implanon® insertion/removal (training on arm models)	• Clinical training	• Clinical training	• Clinical training
13.00 - 13.30	BREAK					
13.30 - 15.30	• Counseling	• Implanon® clinical profile • Implanon® Basic Learning Guides	• Videotape session • Discussion	• Model training	• Model Training	• Post test course evaluation • Closing

Course Syllabus

Course Description

This six-day clinical training course is designed to prepare participants to become competent clinical trainers able to train physician service providers in Norplant® and Implanon® use. Particular emphasis will be placed on Norplant® removal and Implanon® insertion/removal. It is mandatory that trainees attend and participate in all course sessions.

Course Goals

- To strengthen and improve clinical services of the national Family Planning/Reproductive Health (FP/RH) program.
- To develop a core of clinical trainers capable of delivering competency based training within the national FP/RH program.

Course Objectives

By the end of this training course, participants will be able to:

1. Define interpersonal communications
2. Explain why, how, and when to use counseling skills
3. Determine how to combat rumors, regarding sub-dermal implants
4. List and recognize audio/visual (A/V) materials
5. Define the term group discussion
6. Describe the counseling messages for Norplant® clients
7. Describe the counseling messages for Implanon® clients
8. List the principles of Competency-Based Training (CBT)
9. Explain the characteristics of an effective trainer/coach
10. Explain the essential elements of the COACH model
11. Assess a trainer's coaching skills
12. Explain the clinical profile of Norplant®
13. Explain the clinical profile of Implanon®
14. Demonstrate proficiency in Norplant® insertion and removal on arm models and in clients
15. Demonstrate proficiency in Implanon® insertion and removal on arm models and in clients
16. Demonstrate proficiency in recruiting eligible clients for Norplant® or Implanon® use

17. Demonstrate clinical training by using the Basic Learning Guides (BLG) successfully

Course Contents

- Interpersonal communications
- Counseling skills
- Rumors
- A/V materials
- Group discussion
- Counseling messages for Norplant®/Implanon® clients
- Competency Based Training (CBT)
- Coaching
- COACH Skill Inventory
- Clinical Profile of Norplant®/Implanon®
- Client assessment checklist for Norplant®/Implanon® use
- Basic Learning Guide for Norplant® Insertion Clinical Skills
- Basic Learning Guide for Norplant® Removal Clinical Skills
- Basic Learning Guide for Implanon® Insertion Clinical Skills
- Basic Learning Guide for Implanon® Removal Clinical Skills
- The use of the Basic Learning Guides

Training/Learning Methods

- Illustrated lectures and group discussions
- Demonstration and re-demonstration
- Role plays
- Simulated practice with the Norplant®/Implanon® training arm model
- Videotapes and discussion
- Guided clinical activities for Norplant®/Implanon® counseling, insertion and removal

Training Materials

- Reference material and relevant slides
- Infection prevention videotape (AVSC – JHPIEGO)
- Norplant® insertion/removal videotape
- Implanon® insertion/removal videotape

- Norplant®/Implanon® insertion and removal instrument kits and Norplant®/Implanon® sets
- Norplant®/Implanon® training arm models

Participant Selection Criteria

Course participants are being trained as master trainers who will conduct training of trainers (TOT) courses in Norplant®/Implanon® insertion and removal for clinical trainers in various Egyptian governorates.

These clinical trainers will subsequently conduct training and refresher courses for service providers, emphasizing Norplant® removal and Implanon® insertion and removal.

Evaluation Methods

The performance of participants in the TOT course will be evaluated using the following methods:

Coaching skills inventory	10%
Trainer's checklist for Norplant®/Implanon® insertion and removal	20%
Proper use of the Basic Learning Guides	20%
Pre-and post test questionnaires	40%
Course evaluation questionnaire	10%
TOTAL	100%

Criteria for Certification

- Participants should attend and participate in all training sessions
- Participants' performance levels should reach proficiency in Norplant®/Implanon® insertion and removal on arm models
- Participants should perform insertion and removal procedures using arm models the following number of times:
  - Norplant® removal 10 cases
  - Implanon® insertion 10 cases
  - Implanon® removal 10 cases
- Participants should perform insertion and removal procedures on women the following number of times:
  - Norplant® removal 5 cases
  - Implanon® insertion 5 cases
  - Implanon® removal 5 cases
- Participants should achieve a score of at least 80% score on the post-test

Course Duration

18 sessions, two hours each, over a period of six days

Suggested Course Composition

- 5 –10 participants
- 1 –2 clinical trainers

Unit 1. Counseling

This information is in Arabic and contained in Volume Two.

Unit 2. Competency-Based Training (CBT)

Introduction to Competency Based Training (CBT)

"What I hear I forget, what I see I remember, what I do, I understand."

For this reason, Competency Based Training (CBT) is based on learning by doing rather than simply knowledge acquisition. In this way, participants have an opportunity to learn and apply the required skills in less time, with lower costs and fewer clients required for training purposes.

To successfully conduct CBT the skill should first be broken down into its essential steps. Each step is then analyzed to determine the most efficient way to teach and learn the required information: this process is called standardization. Once, the skill (e.g. Norplant® removal) has been standardized, competency-based learning guidelines and checklists are developed and used to simplify learning and make evaluation more objective. This enables participants to have a self-directed learning experience with the clinical trainer serving as a facilitator.

With the CBT approach, a pre-course questionnaire is used as a knowledge assessment tool to assist both the clinical trainer and the participant as they begin the course. Mid-course questionnaires are used to assess the participants' learning progress.

Coaching involves the use of positive feedback, active listening, questioning and problem solving skills to ensure a positive training climate. The key characteristics of a skilled clinical trainer are, in many ways, the same as those of a good coach.

The essential elements of the coaching strategy can be described by the five concepts that form the acronym COACH. Clinical training courses should include these non-topic dependent elements that represent generic activities present in all clinical training programs.

When coaching is combined with other clinical training techniques, such as the use of anatomical models, slides sets and videotapes, it provides a highly efficient system for transferring skills and for providing counseling.

The performance levels of learned skills progress and can be measured as follows:

- Acquisition: the trainees have seen a procedure and acquire a mental picture of the sequence and steps but still need assistance to perform the procedure.
- Competency: the trainees know the steps and procedures and is comfortable performing them.
- Proficiency: the trainees can repeatedly perform a procedure efficiently.

Skills acquisition usually proceeds as follows:

- Clinical trainers demonstrate the required skill and client interaction several times using an anatomical model and appropriate slides and videotapes.
- The trainee practices the required skill and client interaction on a model first with, and then without, the Basic Learning Guides (BLGs). Trainees use the actual instruments in a setting that closely simulates the real situation under the supervision and coaching of clinical trainers. The trainee should talk to the model as if it were an actual client.
- Trainees evaluate each other's performance using the BLGs.

- Trainers discuss evaluation results with the trainees.
- The number of procedures observed and performed on models will vary depending on the trainee's background experience. Only when skill competency and a degree of skill proficiency have been demonstrated with models can trainees perform on humans.

Coaching in Clinical Training

Learning Objectives

Upon completion of this session, participants will be able to use coaching as an effective clinical training strategy. To demonstrate this objective, participants will be able to:

- Identify the characteristics of an effective trainer/coach
- Interpret the COACH model
- Provide a clear performance model
- Create an environment open to learning
- Assess learning during the coaching process
- Communicate during learning

Characteristics of an Effective Trainer/Coach

Clinical trainers continuously change their roles and functions. They act as instructors when presenting illustrated lectures or class room demonstrations; as facilitators when conducting small group discussions or using role plays; as coaches after demonstrating a clinical procedure when the participants begin to practice; and as evaluators when assessing trainee performance. To perform these roles effectively, the clinical trainer should:

- Be proficient and interested in the skills s/he teaches and in training
- Encourage participants to learn the new skill
- Promote open, two-way communication
- Provide immediate feedback to participants:
  - Are they meeting the set objectives?
  - Give positive feedback as often as possible
  - Offer specific suggestions for improvement instead of negative feedback
- Recognize that training can be stressful and therefore:
  - Use appropriate humor
  - Observe participants for signs of stress
  - Provide regular breaks
  - Adapt agenda in response to participants' innovative ideas and suggestions when appropriate
- Use a variety of instructional methods such as:
  - Illustrated lectures

  - Demonstrations
  - Brain storming
  - Group discussion and individual or small group problem solving exercises
  - Role plays
- Involve participants as much as possible at all stages
- Plan all sessions in advance and provide participants with the course schedule and handouts
- Be patient and supportive
- Correct participants' errors while maintaining participants' self-esteem.
- Be a good listener and observant

An Effective Coach	An Ineffective Coach
Focuses on the practical work	Focuses on the theoretical
Reduces stress	Creates stress
Fosters two-way communication	Uses one-way communication
Encourages a working together attitude	Maintains a status above participants

The COACH Model

Five concepts that form the acronym COACH describe the essential elements of the coaching methodology used to implement clinical training strategy. These five concepts are listed and described as follows:

C Clear performance model

O Openness to learning

A Assess performance

C Communication

H Help and follow-up

Clear Performance Model

Performance models should be:

- Consistent among clinical trainers
- Practical and applicable in ordinary working circumstances
- Simple to learn
- Observational learning takes place in three stages:
- Acquisition: the trainees have seen a procedure and acquire a mental picture of the sequence and steps but still need assistance to perform the procedure.

- Competency: the trainees know the steps and procedures and are comfortable performing them.
- Proficiency: the trainees can efficiently perform a procedure repeatedly

It is important to establish agreed upon standards for effective performance to be followed by all trainers so that participants will have a clear picture of the expected performance.

Openness to Learning

New skills are most easily learned when the participant is highly motivated, particularly within a training context that is pleasant, supportive and enhances self-esteem. Such an atmosphere is essential for participants to progress through the predictable stages of competence, namely:

- Unconscious incompetence when participants lack certain skills and are unaware of their deficiencies
- Conscious incompetence when participants become aware of the deficiency but have not yet acquired the new skill
- Conscious competence when participants are learning the new skill but must concentrate to perform it correctly
- Unconscious competence when participants are comfortable performing the skill

The clinical trainer must guide the participants through these learning stages in a way that maintains and enhances self-esteem.

Assessing Performance during the Coaching Process

The accompanying Basic Learning Guides provide a simple way to monitor participant's progress in mastering Norplant®/Implanon® insertion and removal. Providing performance feedback enhances learning.

Before practice

Review participants' performance in previous session by referring to the Basic Learning guide.

During practice

Trainers should complete the Trainers Evaluation Checklist during observation of the participants and immediately provide positive feedback. Limit negative feedback to errors that can harm the client if practicing on a human being.

After the practice session is completed, trainers should complete the Trainers Evaluation Checklist again for final assessment and certification.

After practice

A post-practice feedback session should follow immediately. Firstly, request participants to perform self-assessments using the Basic Learning Guide. Concentrate on positive feedback before pointing out ways to improve performance.

Communication Methods Used during Coaching

Active listening

Active listening is a communication technique that enables trainers to establish trust with participants and stimulates exploration of ideas. The clinical trainer first accepts what is being said without passing judgment, then clarifies the ideas and lastly reflects these ideas back to the participants. When practicing active listening you should:

- Stop talking, listen to speaker
- Restate the speaker's exact words or paraphrase them into your own words
- Reflect your feeling and state the implication
- Do not include probing questions

Remember

- Every one likes to be heard and appreciated.
- Supportive comments strengthen and reinforce the desired behavior.

Questioning

Questioning can be used to assess participants' knowledge and skill or to teach problem solving. Questioning can take the form of closed or open-ended questions to assess additional knowledge, to challenge ideas, to explore new situations or to assess decision-making skills.

Problem solving

Problem solving helps participants gain confidence and become independent problem solvers. Increasingly, this method is becoming more acceptable and is replacing many lecture-based classes. Problem solving uses, as a method of learning, different formats to present and analyze possible causes, to identify additional information needed to formulate possible and effective solutions, and to implement and evaluate solutions. Possible problem solving formats include:

- Written case studies
- Videotaped situations (to trigger discussion)
- Case presentations by participants based on their personal past experiences
- Discussion of participants' practice cases between trainer and participants. (This has been found to be the most effective way to teach problem solving).

Help and Follow-up after Clinical Training

New skills and activities, such as infection prevention practices or implant insertion and removal, need to be reinforced through practice shortly after training, or they will be lost. On-the-job application of these acquired skills to the job is not only the participant's responsibility. Clinical trainers should ensure that training is effective and that knowledge retained and applied on the job by:

1. Ensuring that all resources required to perform the newly acquired skills are available at the trainee's home institution prior to commencing training (e.g. the modified no-scalped vasectomy clamps are available)
2. Using training practices that promote self-confidence such as practicing skills with real clients, problem solving discussions, role plays, etc., and focusing on ways to deal with difficult situations once trainees return to their home institutions
3. Providing participants with problem solving reference manuals, handouts and learning guides that summarize the key steps of Norplant®/Implanon® insertion and removal
4. Training in teams with counselors, nurses, and physicians together to facilitate skill transfer and application
5. Scheduling future consultations between trainees and trainers after the trainee performs a certain number of Norplant® removals or after reporting difficult cases to his/her trainer. The trainer should respond to the consultation request and provide guidance in overcoming the barriers. When possible, arrangements for trainers' visits to service units to monitor progress can be very helpful.
6. Trainee follow-up is critical. The relapse rate for participants to revert to their pre-training methods can be as high as 90%. Follow-up activities can include:
    a. Sending relevant articles to participants and exchanging correspondence
    b. Encouraging networking among participants
    c. Collecting data on newly introduced skills for evaluation or research
    d. Personal visits to consult on problems
    e. Providing refresher training to renew and extend skills. Meeting with training groups to share experiences and discuss mutual problems is very effective.

Summary

- Effective clinical trainers should assume different roles during different training phases, acting as demonstrators, instructors, facilitators, coaches and evaluators.

- Always remember the five elements of the COACH model of clinical training.
- Master the art of active listening and questioning to help participants become effective problem solvers.
- Help participants transfer the skills and knowledge gained during the training to their work place.

Coaching Skills Inventory

To what degrees are the following statements true of your actions or behavior when teaching or coaching new skills to participants? Circle the number that applies to each statement.

5	4	3	2	1
Always	Often	Sometimes	Occasionally	Never

Clear Performance Model					
1. I demonstrate the new skill myself before asking participants to do it.	5	4	3	2	1
2. I am careful that my demonstration is performed according to approved standards.	5	4	3	2	1
3. I verbally explain each step in the process while I demonstrate it.	5	4	3	2	1
4. I demonstrate the skill in a role-play or by using models before demonstrating with clients.	5	4	3	2	1
5. I make sure that all participants are in a position to see the demonstration clearly.	5	4	3	2	1
6. In my demonstration, I use materials, equipment and a setting similar to what is available to my participants at their home institutes.	5	4	3	2	1
7. During my demonstration, I encourage participants to ask questions.	5	4	3	2	1
8. I ask participants questions such as "What should I do next?" or "What would happen if...?" to keep their interest and test their understanding.	5	4	3	2	1
Clear Performance Model - Total Score =					

To what degrees are the following statements true of your actions or behavior when teaching or coaching new skills to participants? Circle the number that applies to each statement.

5	4	3	2	1
Always	Often	Sometimes	Occasionally	Never

Openness to Learning	
1. I help participants relax by getting to know them informally before introducing new skills	5 4 3 2 1
2. I make it easy for participants to acknowledge that they lack knowledge or skill.	5 4 3 2 1
3. I encourage participants to be helpful and supportive of each other.	5 4 3 2 1
4. Before asking participants to practice a new skill, I familiarize them with the staff and setting where they are going to practice.	5 4 3 2 1
5. I show sensitivity to participants' natural feelings of fear and anxiety when learning new skills.	5 4 3 2 1
6. Before each participant practice session, I meet with him/her to answer questions, and set expectations and learning objectives.	5 4 3 2 1
7. I do not belittle or ridicule participants when they make a mistake.	5 4 3 2 1
8. I acknowledge that I am still learning and trying to improve my skills	5 4 3 2 1
Openness to Learning - Total Score =	

To what degrees are the following statements true of your actions or behavior when teaching or coaching new skills to participants? Circle the number that applies to each statement.

5	4	3	2	1
Always	Often	Sometimes	Occasionally	Never

Assessing Performance during the Coaching Process	
1. I ask participants to assess their own strengths and identify areas for improvement in performing the skill.	5 4 3 2 1
2. I use the checklist or observation guide to give feedback on participant performance.	5 4 3 2 1
3. I clearly state what I expect of participants before they practice a new skill.	5 4 3 2 1
4. When giving feedback, I point out things participants are doing well and offer suggestions for improvement.	5 4 3 2 1
5. My feedback to participants is specific and is given as soon as possible after I have observed them.	5 4 3 2 1
6. Following each participant practice session I meet with each participant to discuss his/her strengths first and then areas where improvement could be made.	5 4 3 2 1
7. I make sure that participants do not practice incorrect procedures.	5 4 3 2 1
8. I encourage participants to take personal responsibility for problems and never to blame the client or others.	5 4 3 2 1
Assessing Performance- Total Score =	

To what degrees are the following statements true of your actions or behavior when teaching or coaching new skills to participants? Circle the number that applies to each statement.

5	4	3	2	1
Always	Often	Sometimes	Occasionally	Never

Communication Methods Used during Coaching	
1. I encourage mutual, two-way communication with participants.	5 4 3 2 1
2. I initiate conversations and ask questions to help participants resolve their concerns.	5 4 3 2 1
3. I develop a full understanding of the problems before helping to solve them.	5 4 3 2 1
4. I request participant opinions before expressing mine.	5 4 3 2 1
5. I emphasize solving problems rather than blaming people.	5 4 3 2 1
6. I help participants find their own solution to the problems.	5 4 3 2 1
7. I encourage participants to suggest better ways of doing things.	5 4 3 2 1
8. At least once each training day, I ask participants to evaluate the training and suggest improvements.	5 4 3 2 1
Communication Methods Used- Total Score =	

To what degrees are the following statements true of your actions or behavior when teaching or coaching new skills to participants? Circle the number that applies to each statement.

5	4	3	2	1
Always	Often	Sometimes	Occasionally	Never

Help and Follow-up after Clinical Training	
1. At the end of training, I ask each participant to identify the skills s/he needs to practice further.	5 4 3 2 1
2. I make sure each participant has a plan for continuing to practice and apply the skills after training.	5 4 3 2 1
3. I arrange for each participant to be visited at his/her work site soon after training to see that skills are being practiced properly.	5 4 3 2 1
4. I get feedback from participants about how well they are performing the skills.	5 4 3 2 1
5. I take steps to insure that participants have the necessary equipment and supplies in their home institute to apply the skills they were taught.	5 4 3 2 1
6. I set up ways for participants to contact me or other skilled persons to get help if they need it.	5 4 3 2 1
7. I assist the participant in obtaining handouts, books, and materials for procedures I teach.	5 4 3 2 1
Help and Follow-up - Total Score =	
TOTAL COACH Score	

Unit 3. Clinical Profile for Norplant®

Clinical Profile for Norplant®

Norplant® Implant

Norplant® is an effective progestagen–only long acting reversible contraceptive that consists of six flexible capsules made of soft silicone and filled with a synthetic hormone. Each capsule is 34 mm long, 2.4 mm in diameter and contains 216 mgm of crystalline levonorgestrel, a synthetic second generation progestagen. One third of the drug load is released over a period of five years.

After insertion, levonorgestrel is slowly released through the polydimethyl-siloxane tubing at a rate of 85 micrograms daily during the first 12 months of use, which diminishes to 50 micrograms daily for the following six months before stabilizing at 25-30 micrograms daily for the rest of the five years. The plasma level of the hormone sufficient to prevent conception is reached within 8-24 hours after insertion. The system supplies a steady, very low dose of levonorgestrel. After removal, the plasma level drops very rapidly and become immeasurable in a few days with almost immediate return to fertility.

Mode of Action

Norplant® prevents pregnancy through a combination of mechanisms. The most important mode of action is by changing the characters of the cervical mucus so that it becomes thick and scanty making it difficult for sperm to pass through it. The second mode of action is by inhibition of ovulation (by inhibiting the secretion of pituitary LH and FSH). After the first year of use, inhibition of ovulation occurs in about 50% of the menstrual cycles. Even in ovulatory cycles, there is poor production of progesterone and endometrial growth is suppressed.

Efficacy

Norplant® is a highly effective contraceptive. The failure rate during the first year of use is 0.2 per 100 women per year and the cumulative rate over the 5-year period is 1.6. Norplant® should be removed in cases where pregnancies occur. Babies born after continuation during pregnancy show no increased incidence of congenital malformations.

Return to Fertility

Within a few days of Norplant® removal, levonorgestrel levels become undetectable in the blood and fertility returns rapidly. Of those who desired to become pregnant after removal, 63% became pregnant within 6 months, 76% after one year and 90% after 24 months. These rates are similar for women using no contraception.

Indications

Being long acting, Norplant® suits women who desire to space pregnancies for many years. It is also suitable for those who want to end their reproductive career after

having the desired number of children by a long acting reliable but yet reversible method of contraception.

Contraindications

Women with the following conditions should not use Norplant® except after careful clinical judgment. In such cases, the theoretical or proven risks usually outweigh the advantages of the method. They are classified as Category 3 according to the *WHO Medical Eligibility Criteria for Starting Contraceptive Methods:*

- Current or past thromboembolic disorders
- Past history of breast cancer with no evidence of disease in the past 5 years
- Active viral hepatitis
- Severe liver cirrhosis
- Benign or malignant liver tumors
- Concomitant administration of Rifampin, Griseofolvin, and anti-convulsant drugs except vaproic acid
- Breast-feeding women within 6 weeks after childbirth

The following conditions represent unacceptable health risks if the method is used. Women with these conditions should never use Norplant® as they are classified under Category 4 according to the *WHO Eligibility Criteria for Starting Contraceptive Methods:*

- Pregnancy
- Unexplained abnormal vaginal bleeding
- Active breast cancer

Side-effects

As with all progestagen–only contraceptives, menstrual irregularities are the most commonly encountered side effects. In a clinical trial conducted on Egyptian women, menstrual problems were the reason for discontinuation in 13.8% of the women who discontinued.

Menstrual irregularities

- Amenorrhea occurred among 22.9% of users during the first 3 months of use and diminished gradually to become only 1.7 % by the end of 5 years.
- Spotting/bleeding was observed among 14.2% of users during the first 3 months and diminished gradually to reach 1.1% by the end of 5 years.
- Dysmenorrhea was observed in only 5% of users during the first 3 months and diminished gradually to reach 0.8% by the end of 5 years.

Menstrual irregularities due to Norplant® use diminish over time with an increasing proportion of regularly menstruating women. Norplant® provides a

cure for dysmenorrhea and very few women complain from painful menstruation during its use.

Subjective symptoms

Subjective symptoms such as headache, nausea, breast pain and mood changes were reported by Norplant® users.

Weight gain

Weight gain is frequently observed among Norplant® users. Among Egyptian women there was a mean increase of 3.5% of the original body weight after the first year and 4.6%, 5.8%, 6.9% and 9.5% after years 2, 3, 4 and 5 respectively.

Local complications

Local complications at the insertion site such as pain, itching, infection and expulsion are very rarely reported.

Metabolic complications

Norplant® induces minimal or no changes in carbohydrate metabolism, lipoproteins, blood clotting factors, blood pressure, liver functions or bone mineral density.

Ectopic pregnancy

Ectopic pregnancy very rarely occurs with Norplant® use. However, the possibility should be considered when establishing a differential diagnosis in a case of amenorrhea and acute abdominal pain.

Acceptability

Overall, most women are satisfied with Norplant® use. In the Egyptian study, the cumulative discontinuation rates were 6.85%, 17.62%, 25.72%, 32.49% and 38.74% for the years 1, 2, 3, 4, and 5 respectively.

Insertion of Norplant®

- Norplant® insertion should not be attempted unless the physician is trained and certified to perform the procedure.
- Appropriate infection prevention, aseptic and antiseptic precautions should be adopted throughout the procedure.
- On the whole, the insertion procedure takes about 10-15 minutes.
- Proper and superficial placement of the capsules is an important requisite for trouble–free removal.

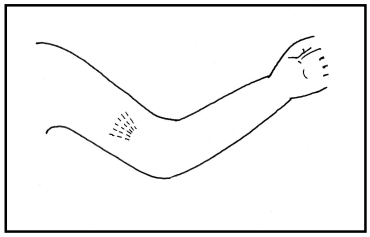
Timing of Insertion

- In menstruating women, Norplant® should be inserted on day 1-5 of the menstrual cycle while the client is still menstruating
- It can be inserted immediately or within one week after a first or second trimester abortion

- In postpartum women
  - Non-breastfeeding women can use Norplant® immediately or within 6 weeks after labor
  - Breastfeeding women should not use Norplant® within 6 weeks after labor

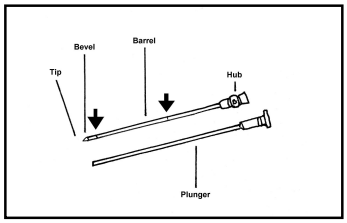
Norplant® Insertion Technique

- Make sure that all instruments needed for insertion are available and properly sterilized or high level disinfected (HLD). The following basic equipment should be available:
  - Arm support
  - Sterile set of six Norplant® capsules
  - Number 10-gauge trocar with plunger
  - Surgical cloths and bowl
  - Talc free sterile (or HLD) gloves, as talc make the capsules more apt to cause adhesions and scarring
  - Antiseptic e.g., Betadine®
  - 1% lidocaine solution without epinephrine
  - Sterile 5 or 10 ml syringe and Number 22 gauge needle
  - Scalpel with number 11 blades
  - Ordinary band-aid
  - Sterile gauze and compresses
  - Epinephrine ampoules for emergency treatment of anaphylactic shoc
- The capsules are to be inserted in a fan-shaped manner under the skin of the inner (medial) side of the non-dominant upper arm, 6-8 cm above the elbow where they are usually not visible.

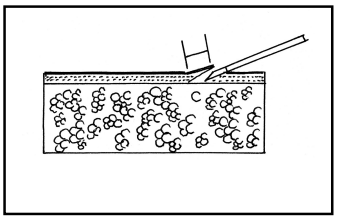


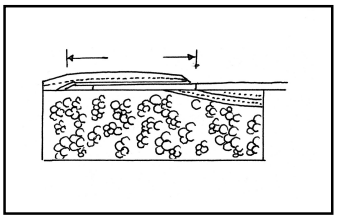
- Ask the woman to lie down on the table with her arm comfortably extended or slightly bent and supported by the armrest. Place, a clean dry cloth under her arm.
- Assure the woman that she will not feel pain during insertion.
- Prepare the instrument tray without touching the instruments or other items.

- Open the sterile pouch containing the Norplant® capsules and allow the six capsules to drop into a sterile bowl. If a capsule falls on the ground, open another package. Never attempt to re-sterilize the contaminated capsules.
- Wash your hands and apply a pair of talc-free sterile gloves.
- Disinfect the skin of the inner side of the upper arm by a suitable antiseptic, e.g. povidone-iodine (Betadine)
- Cover the arm with sterile towels leaving clear the proposed area for insertion.
- Fill the syringe with 3 ml of the local anesthetic and insert the needle just under the skin of the incision site (point closest to the elbow) and inject a very small amount to raise a small wheal under the skin. Gently advance the needle under the skin for 4 cm. Then slowly withdraw the needle while pushing the plunger of the syringe to lay a "track" of anesthetic. Three equally spaced tracks in a fan–shaped manner provide adequate anesthesia and 1 ml is sufficient in each track. Lastly, gently massage the site to ensure uniform distribution of the anesthetic so as to maximize its effectiveness. The total amount of injected anesthetic should not exceed 10 ml.
- Hold the scalpel and gently touch the skin with its tip to ensure that the anesthetic had worked, then make a 2 mm transverse shallow incision 6-8 cm above the elbow. Do not make a deep or a long incision. Some providers pierce the skin by the trocar if it is sharp enough instead of an incision with a scalpel. They claim no significant difference in pain, edema or bruising and it prevents making an incision longer than needed.
- Hold the trocar that has two marks: a proximal one near the hub and a distal one close to the tip (bevel)



- The proximal one indicate how far the trocar should be introduced before loading each capsule, and the distal one indicate how much of the trocar should be left under the skin after withdrawal following the insertion of each capsule.
- Keep the plunger in place and with the bevel up, introduce the tip of the trocar inside the wound at a shallow angle. Start at either the extreme right or left side of the proposed fan-like pattern, push the trocar forward and stop when the distal mark is completely under the skin. Never force the trocar. If resistance is met, try another angle.





- Next, advance the trocar slowly and smoothly until the proximal mark is at the skin incision. While advancing the trocar, it should be lifted up, tenting the skin and visibly raising it all the time. Passage of the trocar will be smooth if it is passed in a proper superficial plane. Then remove the plunger from the trocar.
- Load the first capsule into the trocar holding it by two fingers or gently by a forceps and then insert the plunger. It is wise enough to keep your other hand below the capsule during this procedure to hold it if it falls. Push the plunger gently to advance the capsule towards the tip of the trocar until you feel resistance (usually felt when it is about half–way into the trocar). Never use force to advance the plunger.
- Hold the plunger firmly with one hand and slide the trocar back with the other until the distal mark is seen at the incision and the hub touches the handle of the plunger. Now the capsule should be under the skin and free from the trocar. It is important to keep the plunger steady and not to push it in order to avoid pushing the capsule into the tissue. Feel the capsule with a finger and ensure that it is free from the tip of the trocar.
- Without completely removing the trocar, slide it to the side for about 15 degrees. Fix the first capsule with one finger and advance the trocar in a similar way along the side of your finger. This will ensure a suitable distance between the capsules and will prevent the trocar from puncturing the previously inserted capsules. Advance the trocar until the proximal mark is at the skin incision and load the next capsule after removing the plunger proceeding as before. Repeat the process until you insert the six capsules and then remove the trocar from the wound.
- At the end, the capsules should fan out, about 15 degrees apart so that the angle between the first and the last capsule is about 75 degrees. During the whole process, avoid touching the part of the trocar between the bevel and the proximal mark and do not remove the trocar from the incision to reduce the chance of infection and inflicting trauma.
- Palpate the capsules and check that their proximal tips are about 5 mm from the incision. If one capsule protrudes from the incision or its tip is close to it, remove the capsule and insert it again properly.
- Lastly press on the incision with a gauzed finger for one minute or more to stop any bleeding, clean the skin around the incision and bring the edges of the incision together with a band–aid. Sutures are not necessary. Cover the insertion area with a pressure dressing and wrap gauze around the arm using slight pressure to minimize bruising.
- Before taking off the gloves, decontaminate the instruments, dispose of contaminated objects, then take off the gloves and wash your hands with soap and water.

- Observe the woman for at least 5 minutes for bleeding from the incision or any adverse effect and provide her with post–insertion care instructions before sending her home.

Care of the Wound

- Keep the area dry and clean for at least 48 hours.
- Tenderness, bruising and swelling at the insertion site is usual for a few days.
- The woman can return to work immediately but must avoid bumping the area.
- The pressure bandage and gauze is to be removed after 48 hours and the band-aid after 3-5 days, after which she can wash.
- The woman should return to the clinic if she experiences fever, persistent pain or redness at the insertion site, or expulsion of a capsule. Other reasons to return to the clinic include problems with the method, if she wants to remove the capsules, or if she thinks she might be pregnant.
- The client should be instructed to report to the clinic immediately if she experiences symptoms such as:
  - Severe lower abdominal pain
  - Heavy vaginal bleeding
  - Migraine or blurred vision
  - Delayed menstruation after a long interval of regular menses

Norplant® Removal

- Unlike insertion, Norplant® removal:
  - Does not have to be timed to the menses
  - Needs patience
  - Takes an average of 15-30 minutes to remove. Maximum removal time should not exceed 45-60 minutes.
  - Is more difficult to perform than insertion. In the Egyptian trial where physicians were adequately trained for both insertion and removal, difficulties were encountered in 4% of removals.
  - Needs more experience than insertion
  - Causes more bleeding that can be controlled by pressure

As previously stated, the ease of removal depends to a great extent on proper and superficial insertion of the capsules. If it is not possible to remove all the capsules at one session, the procedure should be stopped. The woman should be advised that she is no longer protected against pregnancy.

The remaining capsules may be removed after the incision heals in 4-6 weeks and preferably by a more experienced operator. Difficult to locate capsules can be detected by x-ray or ultrasound.

Strict infection prevention measures should be adhered to in performing removals.

- Check that all instruments and other items are available and properly sterilized or HLD. The instruments needed are those used for insertion plus:
  - 2 mosquito forceps
  - A modified no-scalpel vasectomy forceps
- Ask the woman to lie on the table, her arm straight or slightly bent and supported on the armrest. Put a clean dry cloth under her arm.
- Locate the capsules first with ungloved fingers. Some providers prefer to mark the positions with a ballpoint pen.
- Wash your hands and wear sterilized or HLD gloves
- Swab the area with an antiseptic e.g. Betadine®
- Cover the arm with sterile towels leaving clear the skin area on the capsules.
- Fill the syringe with 3 ml of the anesthetic solution and insert the needle under the ends of the capsules near the elbow (do not inject the anesthetic over the capsules so as not to obscure them). Advance the needle gently about one third the length of the capsule (about 1 cm) and then inject the anesthetic (about 0.5 ml) while withdrawing it to lay a track of anesthetic. Next, slide the tip of the needle sideways without removing it and repeat the process under the six capsules. The injection will raise the ends of the capsules. During removal, additional small amounts of the anesthetic may be added if needed. The total dose should not exceed 10 ml.

Standard Capsule Removal Method

- Choose the site of the incision about 5mm below and equidistant from the ends of all capsules
- Touch the site with the tip of the scalpel to ensure that the anesthetic is working
- Make a small 4 mm skin incision with the scalpel and begin by removing the capsule closest to the surface and/or nearest to the incision
- Push the capsule gently towards the incision until its tip becomes visible
- Insert the open tips of the mosquito forceps under the end of the capsule so as not to push it away from the incision and grasp the end of the capsule with the forceps
- If a fibrous tissue envelope surrounds the capsule, rub it with a piece of sterile gauze to expose the tip of the capsule. If this fails, carefully use the scalpel to open the fibrous sheath and free the capsule.

- Grasp the freed end of the capsule with the second mosquito forceps, release the first forceps holding the tip and remove the capsule with the second forceps. Usually the capsules slip easily out of the fibrous capsule, as tissue does not adhere to silicon rubber. If the capsules do not come out easily, gently scrape away any adherent tissue with the scalpel.
- Continue with removal of other capsules using additional anesthetic if needed
- Ensure that all six capsules are removed and show them to the client
- Clean the skin and apply pressure with a piece of gauze for 1-2 minutes to control any bleeding
- Bring the edges of the incision together with a band aid (sutures are not necessary)
- Cover the wound with a pressure dressing and wrap gauze snugly around the arm to ensure hemostasis and to minimize bruising
- Remove the gloves and wash your hands with soap and water.
- Watch the woman for at least 5 minutes and give her the following instructions:
  - If she feels intolerable pain after the effect of the anesthetic wears off, she can take a tablet of paracetamol or any other suitable analgesic
  - Keep the area clean and dry and remove the gauze pressure bandage after 48 hours. Some subcutaneous bruises are normal.
  - Instruct her to remove the band aid after 3-5 days and then she can wash
  - She should come to the clinic if she experience fever, persistent pain and/or local redness
  - Upon removal the contraceptive effect is lost immediately and she must use another contraceptive if she does not want to become pregnant

Three Alternative Methods for Norplant® Capsule Removal

The "Pop-out" technique

This process does not involve the use of forceps thus the capsules can be removed through a smaller incision with less discomfort, trauma, and/or bleeding and with less risk of breaking the capsules. The only disadvantage is that the method may not work if the capsules are poorly aligned or are too deeply inserted.

- Prepare and inject the anesthetic following the standard removal method
- Select one capsule and press on its proximal end (closest to the shoulder) with a finger until its distal tip become clearly visible under the skin
- Make a small incision (2-3 mm) on the tip with the scalpel

- Apply further pressure on the proximal end of the capsule to bring the tip into better position under the incision
- While still holding the capsule, insert the tip of the scalpel into the wound and feel the tip of the capsule and if necessary, cut the fibrous tissue around it
- Induce further pressure on the proximal end of the capsule until the tip "pops out" of the incision. Gently grasp it with the forceps and pull it out.
- "Pop out" the remaining capsules using the same method. If you encounter difficulty with any capsule, remove it with the standard technique using the forceps. Take all precautions not to break the capsules as once they are damaged, they may break again with each attempt to grasp them with the forceps.

The "U" technique

This procedure was initially developed to deal with difficult Norplant® removals. Some providers use it as the removal method of choice instead of the standard technique, because it is more rapid, needs a smaller incision, has less tissue trauma, capsule breakage is less likely and it is easier to learn by the inexperienced.

The technique requires the use of a special Norplant® holding forceps that is a modified version of the no–scalpel vasectomy clamp with a tip diameter of 2.2 mm.

- Locate the capsules by palpation (some providers mark their positions with a ballpoint pen)
- Inject the anesthetic as with the standard method
- Make a 4 mm longitudinal incision between capsules 3 and 4, 0.5 cm above the distal tip.
- Introduce the Norplant® holding forceps through the incision and advance them until they touch the nearest capsule. Stabilize the capsule by placing the index finger lateral and parallel to the longitudinal axis of the capsule.
- Grasp the capsule with the Norplant® holding forceps at right angle to its longitudinal axis and within 5 mm from its distal tip.
- Pull the capsule gently towards the incision while rotating the handle of the forceps towards the client's shoulder so as to bring the tip of the capsule into the incision.
- Clean and open the soft tissue surrounding the exposed part of the capsule with sterile gauze (or alternatively by using the scalpel).
- Grasp the exposed part of the freed capsule with a mosquito forceps and pull it out.
- Compared with the standard technique, the method has the following advantages:
- The physician can easily deal with capsules more than 1 (one) cm away from the incision site.

- The Norplant® holding forceps hold the capsules better than the mosquito forceps with capsules less likely to slip or to break.
- The procedure avoids cutting through the dense fibrous tissue that sometimes forms at the tip of the capsules

The Emory method

The Emory method for Norplant® removal is claimed to speed up the procedure. Compared to the standard technique, the Emory method:

- Uses 6-8 ml of local anesthetic instead of 3 ml
- Requires an 8 mm -1 cm long incision rather than the standard 4 mm
- Gently disrupts the adhesions before attempting removal of the Norplant® capsules by repeatedly opening and closing a small curved hemostat in the tissue near the end of the implants for 30 seconds

Key Counseling Topics for Norplant® Users

- Safety and efficacy
- How Norplant® works
- Initiation and discontinuation involves minor surgical procedures
- Advantages and disadvantages
- Possible side effects with emphasis on menstrual irregularities
- Provider can discontinue Norplant® at the client's request by removing the capsules
- The capsules should be removed after 5 years
- The method provides no protection against sexually transmitted infections (STIs) including HIV

Basic Learning Guides (BLG) for Norplant®

Basic Learning Guides do not include the steps involved in counseling clients.

BLGs are designed to be used primarily during the early phases of learning (i.e. skill acquisition) when trainees are practicing on models.

Before using the BLG, the clinical trainer will review the entire insertion/removal activity with the trainees using slides, videotapes, and arm models. The trainees can use the BLGs to follow the steps as the clinical trainer demonstrates the insertion/removal procedures.

Subsequently, BLGs serve as step-by-step guides for trainees as he/she performs the skill in arm model.

The clinical trainer circulates to each trainee to observe how his/her learning is progressing and checks to see that he/she is following the steps outlined in the BLG.

As the trainee progress through the course and gains experience, dependence on the detailed BLG decreases.

Once skills are acquired, trainees can use the BLG to rate each other's performance. This exercise can be used as a basis for discussion during a small group discussion before the trainees provide service to clients.

Basic Learning Guide for Norplant® Insertion Clinical Skills

Using the Checklist to Be Used by Participants

Rate the performance of each step or task observed using the following rating scale:

A Needs Improvement: Step or task not performed correctly, is out of sequence or is omitted

B Competently Performed: Step or task performed correctly in proper sequence but participant does not progress from step to step efficiently

C Proficiently Performed: Step or task efficiently and precisely performed in the proper sequence

Participant Name _____Course Dates_____

TASK/ACTIVITY	CASE				
	1	2	3	4	5
Getting Ready					
1. Determine that client has been counseled for insertion procedure.					
2. Review "Client Assessment Checklist" and further evaluate client, if indicated.					
3. Ask client about allergies to anesthetic agents.					
4. Check to be sure client has thoroughly washed her entire arm and hand with soap and water and completely rinsed to remove all soap.					
5. Help client get on table, position her non-dominant arm.					
6. Select and position woman's arm and place clean, dry cloth under her arm.					
7. Determine insertion site by measuring 6-8 cm above the elbow fold on medial side of arm.					
8. Mark points on arm for insertion and the fan pattern for the six implants.					
9. Open sterile instrument pack.					
10. Determine that required sterile or HLD instruments are present.					

11. Open sterile Norplant® package by pulling apart sheets of the pouch and dropping capsules into a sterile bowl (or leave in package if bowl not available).					
Pre-Insertion Tasks					
1. Wash hands thoroughly with soap and water and dry with sterile cloth.					
2. Put sterile or HLD gloves on both hands; if gloves are powdered, wipe talc off glove fingers with gauze soaked in sterile or HLD water.					
3. Arrange instruments and supplies.					
4. Count to make sure that there are six (6) capsules.					
5. Prepare insertion site by swabbing area with antiseptic solution, moving outward in a circular motion; allow to air dry.					
6. Place sterile or HLD surgical drape over arm.					
Insertion of Capsules					
1. Assure woman she will not feel pain.					
2. Inject local anesthetic just under the skin (intradermally) at the incision site to raise a small wheal (raised area).					
3. Advance needle about 4 cm and inject 1 ml of local anesthetic in each of 3 sub-dermal tracks.					
4. Check for anesthetic effect before making skin incision.					
5. Make a shallow, 2 mm incision with a scalpel just through the skin at insertion site (alternatively, insert trocar directly subdermally).					
6. Insert trocar and plunger through the incision at a shallow angle (tenting the skin).					
7. While tenting the skin, advance trocar and plunger just under the skin to mark (1) near hub of trocar.					
8. Remove plunger.					
9. Load first capsule into trocar using either gloved thumb and finger or forceps, keeping one hand beneath the capsule in order to catch it if it falls.					
10. Reinsert plunger and push capsule toward tip of trocar just until resistance is felt.					

11. Hold plunger firmly in place with one hand and slide trocar out of incision until it reaches plunger handle.					
12. Withdraw trocar and plunger together until mark (2) near tip is seen at the incision.					
13. Hold the previously-placed capsule with one finger and slide insertion trocar and plunger to mark (1).					
14. After each capsule is inserted, trocar is redirected about 15 degrees to distribute capsules in fan pattern.					
15. Hold previously placed capsules to avoid damage while advancing the trocar to the next position.					
16. Trocar tip not removed from incision until all capsules have been inserted.					
17. Capsules palpated to check that all have been inserted in a fan shaped distribution.					
18. Incision palpated to be sure that all capsules are well clear of incision.					
Post-Insertion Tasks					
1. Press on incision with gauzed finger to stop bleeding.					
2. Bring edges of incision together and close it with band-aid.					
3. Apply pressure dressing to insertion area and wrap gauze bandage snugly around the arm.					
4. Instruct client regarding wound care, when to remove bandage, washing, and symptoms that necessitate immediate reporting to clinic.					
5. Fill needle and syringe with chlorine solution and soak for ten minutes.					
6. Place all instruments in chlorine solution for 10 minutes after separating plunger from trocar.					
7. Dispose of contaminated waste materials according to guidelines.					
8. If using reusable gloves, briefly immerse gloved hands in chlorine solution, then remove gloves and soak them in chlorine solution for 10 minutes.					
9. Wash hands thoroughly with soap and water and dry with clean cloth.					

10. Draw location of capsules in the client record and note anything unusual.					
11. Observe client for at least 5 minutes before sending her home with post-insertion instructions.					

Basic Learning Guide for Norplant® Removal Clinical Skills

Using the Checklist - To Be Used by Participants

Rate the performance of each step or task observed using the following rating scale:

A Needs Improvement: Step or task not performed correctly, is out of sequence or is omitted

B Competently Performed: Step or task performed correctly in proper sequence but participant does not progress from step to step efficiently

C Proficiently Performed: Step or task efficiently and precisely performed in the proper sequence

Participant Name _____Course Dates_____

TASK/ACTIVITY	CASES				
	1	2	3	4	5
Getting Ready					
1. Ask client the reason for removal.					
2. Ensure that client understands the removal procedure.					
3. Assure that she will feel little or no pain.					
4. Ask client about previous allergies to anesthetic agents.					
5. Check to be sure client has thoroughly washed her entire arm and hand with soap and water and completely rinsed it to remove all soap.					
6. Help client get on the table, position arm and place clean, dry cloth under her arm.					
7. Palpate capsules to locate point for removal incision equidistant from the ends of all the capsules.					
8. Open sterile instrument pack.					
9. Determine that all required sterile or HLD instruments are present.					
Pre-Removal Tasks					
1. Wash hands thoroughly with soap and water and dry with sterile cloth.					

2. Put sterile or HLD gloves on both hands; if gloves are powdered, wipe talc off glove fingers with gauze soaked in sterile or HLD water.					
3. Arrange instruments and supplies.					
4. Prepare removal site by swabbing with antiseptic solution, beginning at incision site and moving outward in a circular motion; allow to air dry.					
5. Place sterile or HLD surgical drape over arm.					
Removal of the Capsules					
Standard Technique					
1. Inject a small amount (2-3 ml) of local anesthetic at the incision site and under the ends of the six (6) capsules.					
2. Check for anesthetic effect before making incision.					
3. Make small (4 mm) incision with scalpel about 5 mm below and equidistant from the ends of the capsules.					
4. Locate easiest capsule to remove and gently push it towards the incision until tip is visible.					
5. Grasp end of capsule with mosquito forceps and gently bring it into the incision.					
6. Clean off and open fibrous sheath surrounding capsule with sterile gauze (or scalpel).					
7. Grasp freed end of the capsule with the second mosquito forceps, remove the first forceps and then pull the seen capsule with the second forceps.					
8. Use additional anesthesia if necessary.					
9. Ensure that the six capsules were removed.					
Pop-out Technique					
1. Inject a small amount (2-3 ml) of local anesthetic at the incision site and under the ends of the six capsules.					
2. Check for anesthetic effect before making incision.					
3. Push on proximal end of one capsule (nearest the shoulder) with a finger.					
4. When the distal tip (nearest the elbow) pushes up under the skin, make a small (2-3 mm) incision over the tip with the scalpel.					

5. Apply further pressure on the proximal end of the capsule to bring the tip in better position in the wound.					
6. While still holding the capsule, insert the scalpel blade into the incision to feel the tip of the capsule and if necessary cut the fibrous tissue surrounding the tip of the capsule.					
7. Introduce further pressure on the proximal end of the capsule until it pops-out of the incision.					
8. Pop-out the remaining capsules using the same method and remove them using the forceps.					
"U"-Technique					
1. Locate capsules by palpation.					
2. Inject small amount of local anesthetic at the incision site and under the ends of the six (6) capsules.					
3. Check for the anesthetic effect before making incision.					
4. Make a longitudinal incision, 4 mm long, between capsules 3 and 4, 0.5 cm above the distal tip.					
5. Stabilize the nearest capsule by index finger, lateral and parallel to its longitudinal axis.					
6. Introduce the Norplant® holding forceps in the incision.					
7. Grasp the capsule with the forceps at right angle to its longitudinal axis and within 5 mm from its distal tip.					
8. Pull capsule while rotating handle of forceps towards client's shoulder to bring the tip of the capsule into the incision.					
9. Clean and open soft tissue round the tip of the capsule by gauze or scalpel.					
10. Grasp tip of capsule with mosquito forceps and pull it.					
11. Place capsule in bowl containing 0.5% chlorine solution.					
Post-Removal Tasks					
1. Count the six capsules.					
2. Show six capsules to client.					
3. Clean the wound, bring edges of incision together and close it with a band-aid.					
4. Apply pressure dressing and wrap gauze bandage snugly around the arm.					

5. Instruct client about wound care, when to remove the band-aid, washing, and symptoms that necessitate immediate reporting to clinic.					
6. Fill needle and syringe with chlorine solution and soak for 10 minutes.					
7. Place all instruments in chlorine solution for 10 minutes.					
8. Dispose of contaminated waste materials and Norplant® capsules according to guidelines.					
9. If using reusable gloves, briefly immerse gloved hands in chlorine solution, then remove gloves and soak them in chlorine solution for 10 minutes.					
10. Wash hands thoroughly with soap and water.					
11. Observe client for at least 5 minutes before sending her home.					

Unit 4. Clinical Profile for Implanon®

Clinical Profile for Implanon®

Implanon® is a progestagen-only sub-dermal contraceptive implant. It is a single rod system, preloaded in a sterile disposable applicator to facilitate easy and rapid insertion. The ethylene-vinyl-acetate rod is 4 cm long and 2 mm in diameter and contains 68 mgm of crystalline etonogestrel (3-Keto-desogestrel), the active metabolite of the third generation progestagen "desogestrel" that has been used in combined oral contraceptives.

As with Norplant®, Implanon® is inserted in the inner side of the upper non-dominant arm. A daily release rate of 30 micrograms of Etonogestrel inhibits ovulation completely in most women. The daily release rate is 60-70 mcg in week 5-6 after insertion, and 35-45 mcg, 30-40 mcg, and 25-30 mcg at the end of the first, second, and third year. Within 24 hours after insertion, serum levels rapidly increase to a concentration that inhibit ovulation and after removal of the implant it declines to levels below the detection limit within one week, indicating the potential for rapid return to fertility after removal.

Mode of Action

Implanon® prevents pregnancy mainly by ovulation inhibition due to suppression of gonadotrophins (LH and FSH) secretion. In studies where the occurrence of ovulation was monitored, no ovulations were detected at all in the first two years post-insertion. A second mode of action is its effect on cervical mucus.

Etonogestrel increases the viscosity of the cervical mucus that contributes to its contraceptive effectiveness by inhibiting sperm penetration. A decrease in endometrial thickening is also observed during the use of Implanon®.

Efficacy

Implanon® is a highly effective contraceptive. No pregnancies were observed among users. Its high contraceptive effectiveness is labeled as being maintained for three years after insertion. However, the woman should be informed that she can request removal of Implanon® at any time.

The contraceptive effect is related to the plasma levels of etonogestrel, which is inversely related to body weight and decreases with time after insertion. Clinical experience with Implanon® effectiveness among obese women during the third year of use is limited. Thus, it cannot be ruled out that the contraceptive effect in such cases may be lower than for women of normal weight. Therefore earlier replacement of Implanon® in heavier women may be considered.

Return to Fertility

After removal of Implanon®, return to fertility is achieved rapidly. If protection against pregnancy is needed for more than three years, another Implanon® implant can be inserted immediately after removal.

Indications

Implanon® may be used to postpone the first pregnancy, to space pregnancies or to provide long-term contraception when the desired family size is reached. As with all other progestagen only contraceptives, Implanon® is particularly suitable for women in whom estrogen intake is contraindicated.

Although the World Health Organization has not formulated medical eligibility criteria for starting Implanon® use, it is widely assumed to be the same as for Norplant®. Therefore, it can be assumed that women with the following conditions should not use Implanon® except after careful clinical judgment. In such cases, the theoretical or proven risks usually outweigh the advantages of the method.

Women with the following conditions should not use Implanon® except after careful clinical judgment. In such cases, the theoretical or proven risks usually outweigh the advantages of the method. They are classified as Category 3 according to the *WHO Medical Eligibility Criteria for Starting Contraceptive Methods:*

- Current or past thromboembolic disorders
- Past history of breast cancer with no evidence of disease in the past 5 years
- Active viral hepatitis
- Severe liver cirrhosis
- Benign or malignant liver tumors
- Concomitant administration of Rifampin, Griseofolvin, and anti-convulsant drugs except vaproic acid
- Breastfeeding women less than 6 weeks after childbirth

The following conditions represent unacceptable health risks for Norplant®. It is therefore assumed that they should also never use Implanon® as they are classified under Category 4 according to the *WHO Eligibility Criteria for Starting Contraceptive Methods:*

- Pregnancy
- Unexplained abnormal vaginal bleeding
- Active breast cancer

As all progestagen–only contraceptives, menstrual irregularities are the most commonly encountered side effects.

Menstrual irregularities

- Amenorrhea is more frequently encountered than with Norplant® users
- Infrequent bleeding/spotting episodes, (less than three episodes in 90 days) occurred among 26.1% of users
- Frequent bleeding/spotting episodes, (more than five episodes in 90 days) is less common than with Norplant® users and was observed in 6% of the users

- Prolonged bleeding/spotting episodes, (more than 14 consecutive bleeding days in 90 days) is more common than among Norplant® users, occurring in 11.8% of the users.
- Compared to Norplant®, the bleeding pattern during Implanon® use is characterized by less bleeding, but also by a more variable pattern. There is a slight overall increase in hemoglobin concentration during Implanon® use.

Subjective symptoms

Subjective symptoms such as headache, nausea, breast pain and mood changes were reported by Implanon® users.

Weight gain

Gradual mean increases in body weight of 1.5-2% annually occur during the use of Implanon®.

Local complications

Local complications at the insertion site such as pain, itching, infection and expulsion are very rarely reported.

Metabolic complications

Implanon® induces minimal or no changes in carbohydrate metabolism, lipoproteins, blood clotting factors, blood pressure, liver functions or bone mineral density.

Ectopic pregnancy

Ectopic pregnancy very rarely occurs with Implanon® use as it consistently inhibits ovulation. However, the possibility should be considered when establishing a differential diagnosis in a case of amenorrhea and acute abdominal pain.

Venous thromboembolism

Some epidemiological studies have observed increased risk and incidence of venous thromboembolism among users of contraceptives containing third generation compared to second generation progestagens. Other studies that corrected for newly recognized confounders reported no such increase.

Other side effects

Acne and chloasma

Acceptability

Factors affecting the acceptability of Implanon® include the surgical nature of its insertion and removal, the duration for which contraceptives are desired and the presence of side effects including changes in the menstrual bleeding pattern. Assess to counseling is important with Implanon® use.

Insertion of Implanon®

- Implanon® insertion should not be attempted unless the physician is trained and certified to perform the procedure.
- Appropriate infection prevention, aseptic and antiseptic precautions should be adopted throughout the procedure.
- Insertion and removal is easier than with Norplant® and can be performed four times faster with less pain, bleeding, bruising or other complications.

Timing of Insertion

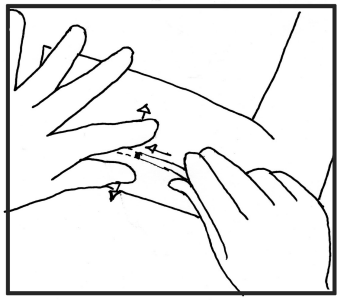
- In menstruating women, Implanon® should be inserted on day 1-5 of the menstrual cycle while the client is still menstruating
- It can be inserted immediately or within one week after a first or second trimester abortion
- In postpartum women
  - Non breast-feeding women can use Implanon® immediately or within 6 weeks after labor
  - Breast-feeding women should not use Implanon® before 6 weeks after labor

Implanon® Insertion Technique

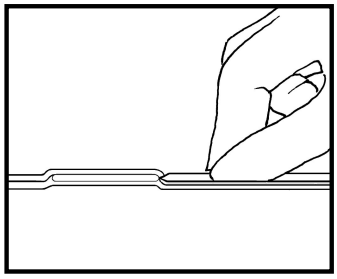
It is important that the Implanon® capsule be inserted correctly, directly under the skin so as to ensure easy uncomplicated removal.

- Make sure that all instruments needed for insertion are available and properly sterilized or high level disinfected (HLD). The following basic equipment should be available:
  - Arm support
  - Antiseptic e.g. Betadine®
  - 1% lidocaine solution or a surface spray anesthetic
  - Sterile 5 or 10 ml syringe and Number 22 gauge needle
  - Ordinary band-aid
  - Sterile gauze and compresses
  - Epinephrine ampoules for emergency treatment of anaphylactic shock
- The capsules are to be inserted under the skin of the inner (medial) side of the non-dominant upper arm, 6-8 above the elbow in the groove between the biceps and the triceps
- Ask the woman to lie down on the table with her arm comfortably extended or slightly bent and supported by the armrest. Place, a clean dry cloth under her arm.

- Assure the woman that she will not feel pain during insertion.
- Prepare the instrument tray without touching the instruments or other items.
- Wash your hands and apply a pair of talc-free sterile gloves.
- Disinfect the skin of the inner side of the upper arm by a suitable antiseptic e.g. povidone iodine (Betadine)
- Cover the arm with sterile towels leaving clear the proposed area for insertion.
- Anesthetize the insertion site with an anesthetic spray or by injecting 2 ml of 1% lidocaine under the skin along the insertion channel.
- Ask the assistant to open the sealed envelope. Remove the sterile disposable applicator carrying the Implanon®.
- Keep the needle and the implant sterile. If contamination occurs, change them. Always hold the applicator with the needle pointing up prior to insertion to prevent the Implanon® implant from dropping out of the needle. Be sure that the implant is inside the metal canula. If it protrudes tap against the plastic part of the canula until it returns inside the canula.
- Stretch the skin at the insertion site (the medial side of the upper arm at the sulcus between the biceps and the triceps muscle, 6-8 cm above the elbow).

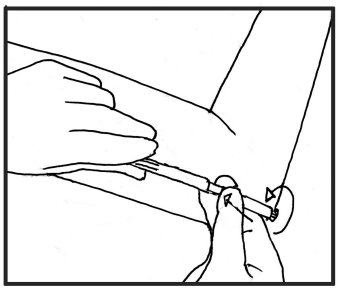


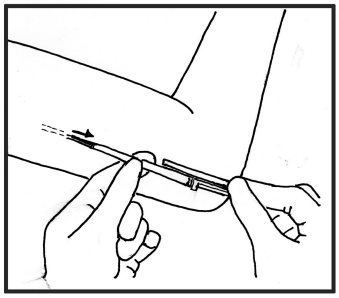
- Remove the plastic cover and introduce the needle in an upward direction (bevel up) under the skin as superficially as possible while lifting the skin with the tip of the needle. Insert the needle to its full length.



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

- Rotate the obturator 90 degrees in relation to the canula and fix it firmly against the arm with your right hand.
- With your left hand, slowly pull the canula out of the arm with the obturator immobilized in its place. By doing this, the implant will be left in the upper arm under the skin. This procedure is the opposite of giving an injection where you push the plunger while the syringe is fixed. Palpate the skin to check that the implant has been properly inserted.





- Lastly press on the incision with a gauzed finger for one minute or more to stop any bleeding, clean the skin around the incision and bring the edges of the incision together with a band–aid. Sutures are not necessary. Cover the insertion area with a pressure dressing and wrap gauze around the arm using slight pressure to minimize bruising.
- Before taking off the gloves, decontaminate the instruments, dispose of contaminated objects, then take off the gloves and wash your hands with soap and water.
- Observe the woman for at least 5 minutes for bleeding from the incision or any adverse effect and provide her with post–insertion care instructions before sending her home.

Care of the Wound

- Keep the area dry and clean for at least 48 hours
- Tenderness, bruising and swelling at the insertion site is usual for a few days
- The woman can return to work immediately but must avoid bumping the area
- The pressure bandage and gauze is to be removed after 48 hours and the band-aid after 3-5 days, after which she can wash.
- She should return to the clinic if she experiences fever, persistent pain or redness at the insertion site, or expulsion of a capsule. Other reasons to return to the clinic include problems with the method, if she wants to remove the capsules, or if she thinks she might be pregnant.
- The client should be instructed to report to the clinic immediately if she experiences symptoms such as:
  - Severe lower abdominal pain

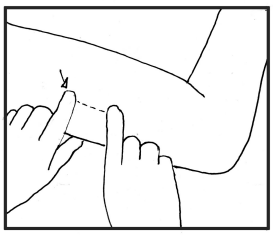
- Heavy vaginal bleeding
- Migraine or blurred vision
- Delayed menstruation after a long interval of regular menses

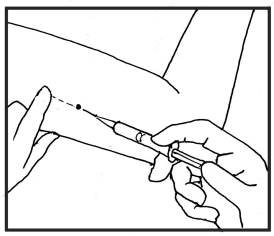
Removal of Implanon®

Removal should not be attempted unless the physician is trained and certified for the procedure. Strict infection prevention measures should be adhered to in performing removals.

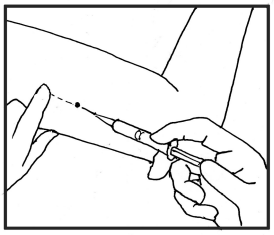
- Check that all instruments and other items are available and properly sterilized or HLD. The instruments needed for removal include:
  - Arm support
  - Antiseptic e.g. Betadine
  - Sterile gloves
  - 1% lidocaine solution or a surface spray anesthetic
  - 2 mosquito forceps
  - Scalpel
  - Butterfly bandage
  - Ordinary band-aid
  - Sterile gauze and compresses
- Ask the woman to lie on the table, her arm straight or slightly bent and supported on the armrest. Put a clean dry cloth under her arm.
- Wash your hands and wear sterilized or HLD gloves
- Clean the area with an antiseptic e.g. Betadine
- Cover the arm with sterile towels leaving clear the skin area on the capsules

- Locate the implant and anesthetize the proposed site of the incision (just below the distal end of the implant) with 0.5 - 1 ml of 1% lidocaine. Apply the anesthetic under the implant so the skin will not swell causing difficulty in locating the implant.

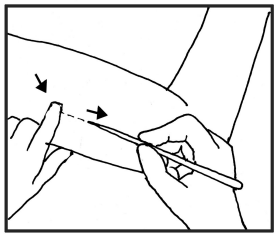




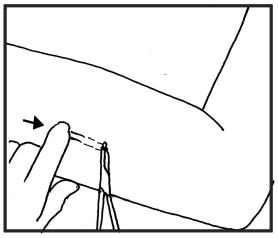
- Touch the proposed site for incision by the tip of the scalpel to ensure that the anaesthesia has worked.



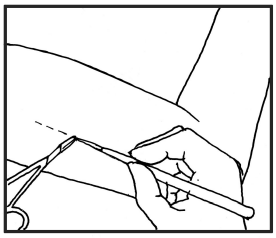
- Make a longitudinal incision 2 mm long at the distal end of the implant.

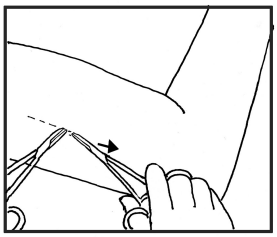


- Push the implant gently towards the incision until its tip becomes visible.
- Grasp the implant with a mosquito forceps and pull it out.



- If the Implanon® implant is encapsulated and its tip will not appear, incise the tissue on its tip with a scalpel and then grasp the tip of the implant and pull it. If the tip of the Implanon® implant is not visible, gently insert a forceps into the incision and grasp the implant. With a second forceps or a scalpel, dissect the tissues around the implant, grasp its tip and pull it.





- Clean the skin and apply pressure with a piece of gauze for 1-2 minutes to control any bleeding
- Bring the edges of the incision together with a band aid (sutures are not necessary)
- Cover the wound with a pressure dressing and wrap gauze snugly around the arm to ensure hemostasis and to minimize bruising

- Remove the gloves and wash your hands with soap and water.
- Watch the woman for at least 5 minutes and give her the following instructions:
  - If she feels intolerable pain after the effect of the anesthetic wears off, she can take a tablet of paracetamol or any other suitable analgesic
  - Keep the area clean and dry and remove the gauze pressure bandage after 48 hours. Some subcutaneous bruises are normal.
  - Instruct her to remove the band aid after 3-5 days and then she can wash
  - She should come to the clinic if she experience fever, persistent pain and/ or local redness
  - Upon removal the contraceptive effect is lost immediately and she must use another contraceptive if she does not want to become pregnant

Key Counseling Topics for Implanon® Users

- Safety and efficacy
- How Implanon® works
- Initiation and discontinuation involves minor surgical procedures
- Advantages and disadvantages
- Possible side effects with emphasis on menstrual irregularities
- Provider can discontinue Implanon® at the client's request by removing the implant at any time
- The implant is effective for 3 years after which it should be removed
- The method provides no protection against STIs including HIV

Basic Learning Guides for Implanon®

Basic Learning Guides do not include the steps involved in counseling clients.

BLGs are designed to be used primarily during the early phases of learning (i.e. skill acquisition) when trainees are practicing on models.

Before using the BLG, the clinical trainer will review the entire insertion/removal activity with the trainees using slides, videotapes, and arm models. The trainees can use the BLGs to follow the steps as the clinical trainer demonstrates the insertion/removal procedures.

Subsequently, BLGs serve as step-by-step guides for trainees as he/she performs the skill in arm model.

The clinical trainer circulates to each trainee to observe how his/her learning is progressing and checks to see that he/she is following the steps outlined in the BLG.

As the trainee progress through the course and gains experience, dependence on the detailed BLG decreases.

Basic Learning Guide for Implanon® Insertion Clinical Skills

Using the Checklist-To Be Used by Participants

Rate the performance of each step or task observed using the following rating scale:

A Needs Improvement: Step or task not performed correctly, is out of sequence or is omitted

B Competently Performed: Step or task performed correctly in proper sequence but participant does not progress from step to step efficiently

C Proficiently Performed: Step or task efficiently and precisely performed in the proper sequence

Participant Name _____Course Dates_____

TASK/ACTIVITY	CASES				
	1	2	3	4	5
Getting Ready					
1. Determine that client has been counseled for insertion procedure.					
2. Review "Client Assessment Checklist" and further evaluate client, if indicated.					
3. Ask client about allergies to anesthetic agents.					
4. Check to be sure client has thoroughly washed her entire arm and hand with soap and water and completely rinsed to remove all soap.					
5. Help client get on table, position her non-dominant arm.					
6. Select and position woman's arm and place clean, dry cloth under her arm.					
7. Determine that required sterile or HLD instruments are present.					
Pre-Insertion Tasks					
1. Wash hands thoroughly with soap and water, and dry with sterile cloth.					

2. Put sterile or HLD gloves on both hands; if gloves are powdered, wipe talc off glove fingers with gauze soaked in sterile or HLD water.					
3. Arrange instruments and supplies.					
4. Prepare insertion site by swabbing area with antiseptic solution, moving outward in a circular motion; allow to air dry.					
5. Place sterile or HLD surgical drape over arm					
Insertion of Implanon®					
1. Assure woman she will not feel pain					
2. Determine insertion site by measuring 6-8 cm above the elbow between bicep and tricep muscles on medial side of arm.					
3. Anesthetize the insertion site with anesthetic spray or by injecting 2 ml Lidocaine solution.					
4. Ask assistant to open the sealed envelop and remove the sterile disposable applicator.					
5. Hold applicator with needle up to prevent Implanon® capsule from falling..					
6. Never touch the needle or implant.					
7. Ensure that implant is inside the needle.					
8. Stretch the skin at insertion site before inserting the needle.					
9. Remove plastic cover, introduce needle bevel up to its full length, as superficial, as possible, under the skin.					
10. Break the seal of the applicator.					
11. Rotate the obturator 90 degrees.					
12. Fix the obturator and pull the canula out of the arm.					
13. Palpate the skin to ensure that the implant is in place.					
Post-insertion Tasks					
1. Press on incision with gauzed finger to stop bleeding.					
2. Bring edges of incision together and close it with band-aid.					

3. Apply pressure dressing to insertion area and wrap gauze bandage snugly around the arm.					
4. Instruct client regarding wound care, when to remove bandage, washing, and symptoms that necessitate immediate reporting to clinic.					
5. Fill needle and syringe with chlorine solution and soak for ten minutes.					
6. Dispose of contaminated waste materials according to guidelines.					
7. If using reusable gloves, briefly immerse gloved hands in chlorine solution, then remove gloves and soak them in chlorine solution for 10 minutes.					
8. Wash hands thoroughly with soap and water and dry with clean cloth.					
9. Observe client for at least 5 minutes before sending her home with post-insertion instructions.					

Basic Learning Guide for Implanon® Removal Clinical Skills

Using the Checklist - To Be Used by Participants

Rate the performance of each step or task observed using the following rating scale:

A Needs Improvement: Step or task not performed correctly, is out of sequence or is omitted

B Competently Performed: Step or task performed correctly in proper sequence but participant does not progress from step to step efficiently

C Proficiently Performed: Step or task efficiently and precisely performed in the proper sequence

Participant Name _____Course Dates_____

TASK/ACTIVITY	CASES				
	1	2	3	4	5
Getting Ready					
1. Ask client the reason for removal if less than three years after insertion.					
2. Ensure that client understands the removal procedure.					
3. Assure that she will feel little or no pain.					
4. Ask client about previous allergies to anesthetic agents.					
5. Check to be sure client has thoroughly washed her entire arm and hand with soap and water and completely rinsed it to remove all soap					
6. Help client get on the table, position arm and place clean, dry cloth under her arm.					
7. Palpate capsules to locate point for removal incision.					
8. Open sterile instrument pack.					
9. Determine that all required sterile or HLD instruments are present.					
Pre-Removal Tasks					
1. Wash hands thoroughly with soap and water, and dry with sterile cloth.					

2. Put sterile or HLD gloves on both hands; if gloves are powdered, wipe talc off glove fingers with gauze soaked in sterile or HLD water.					
3. Arrange the instruments and supplies.					
4. Prepare removal site by swabbing area with antiseptic beginning at the incision site and moving outward in a circular manner, then allow to air dry.					
5. Place sterile or HLD surgical drape over arm.					
Removal of Implanon®					
1. Locate the Implanon® capsule and anesthetize the area below the distal tip by injecting 0.5 – 1 ml of anesthetic solution under the implant.					
2. Check for anesthetic effect before making the incision.					
3. Make a longitudinal incision 2 mm long at distal end of Implanon® implant.					
4. Gently push implant down until the tip becomes visible in the incision.					
5. Grasp the implant with a mosquito forceps and pull it out through the incision.					
6. If it does not come out, incise tissues with a scalpel and push the implant.					
Post-Removal Tasks					
1. Show the implant to the client.					
2. Clean the wound, bring edges of incision together and close it with a band-aid.					
3. Apply pressure dressing and wrap gauze bandage snugly around the arm					
4. Instruct client about wound care, when to remove the band-aid, washing, and symptoms that necessitate immediate reporting to clinic.					
5. Fill needle and syringe with chlorine solution and soak for 10 minutes					
6. Place all instruments in chlorine solution for 10 minutes.					
7. Dispose of contaminated waste materials and Implanon® capsules according to guidelines.					

8. If using reusable gloves, briefly immerse gloved hands in chlorine solution, then remove gloves and soak them in chlorine solution for 10 minutes.					
9. Wash hands thoroughly with soap and water.					
10. Observe client for at least 5 minutes before sending her home.					

Unit 5. Practical and Clinical Exercises

Using the Trainers' Evaluation Checklists

The trainer should evaluate each task based on the Basic Learning Guides.

A checklist should be completed for each participant at mid-course and at end of the course.

The mid-course evaluation should assist the trainer to identify areas in which the trainee needs further training. It should be used to provide feedback for the trainee on his/her performance and achievements, concentrating on positive achievements before providing suggestions for improvement.

The end of course evaluation is used for certification purposes. No trainee should be certified unless he/she proficiently performs all Norplant®/Implanon® insertion and removal tasks and activities.

Trainer's Evaluation Checklist for Norplant® Insertion

Using the Checklist-To Be Used by Trainers

Rate the performance of each step or task observed using the following rating scale:

A Needs Improvement: Step or task not performed correctly, is out of sequence or is omitted

B Competently Performed: Step or task performed correctly in proper sequence but participant does not progress from step to step efficiently

C Proficiently Performed: Step or task efficiently and precisely performed in the proper sequence

Participant Name _____Course Dates_____

TASK/SKILL	Mid-course	End of course
1. Getting ready		
2. Pre-insertion tasks		
3. Infection prevention measures		
4. Insertion of capsules		
5. Post insertion tasks		
a. Wound dressing		
b. Instructions to clients		
c. Observing women after insertion		
d. Disposing with instruments/equipment		
6. Talking to model in all steps as if it were an actual client		

Trainer's Evaluation Checklist for Norplant® Removal

Using the Checklist-To Be Used by Trainers

Rate the performance of each step or task observed using the following rating scale:

A Needs Improvement: Step or task not performed correctly, is out of sequence or is omitted

B Competently Performed: Step or task performed correctly in proper sequence but participant does not progress from step to step efficiently

C Proficiently Performed: Step or task efficiently and precisely performed in the proper sequence

Participant Name _____Course Dates_____

TASK/SKILL	Mid-course	End of course
1. Getting ready		
2. Pre-removal tasks		
3. Infection prevention measures		
4. Removal of capsules		
a. Standard technique		
b. Pop-out technique		
c. U technique		
5. Post insertion tasks		
a. Wound dressing		
b. Instructions to clients		
c. Observing women after insertion		
d. Disposing of instruments/equipment		
6. Talking to model in all steps as if it were an actual client		

Trainer's Evaluation Checklist for Implanon® Insertion

Using the Checklist-To Be Used by Trainers

Rate the performance of each step or task observed using the following rating scale:

A Needs Improvement: Step or task not performed correctly, is out of sequence or is omitted

B Competently Performed: Step or task performed correctly in proper sequence but participant does not progress from step to step efficiently

C Proficiently Performed: Step or task efficiently and precisely performed in the proper sequence

Participant Name _____Course Dates_____

TASK/SKILL	Mid-course	End of course
1. Getting ready		
2. Pre-insertion tasks		
3. Infection prevention measures		
4. Insertion of capsules		
5. Post insertion tasks		
a. Wound dressing		
b. Instructions to clients		
c. Observing women after insertion		
d. Disposing with instruments/equipments		
6. Talking to model in all steps as if it were an actual client		

Trainer's Evaluation Checklist for Implanon® Removal

Using the Checklist - To Be Used by Trainers

Rate the performance of each step or task observed using the following rating scale:

A Needs Improvement: Step or task not performed correctly, is out of sequence or is omitted

B Competently Performed: Step or task performed correctly in proper sequence but participant does not progress from step to step efficiently

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Participant Name _____Course Dates_____

TASK/SKILL	Mid-course	End of course
1. Getting ready		
2. Pre-removal tasks		
3. Infection prevention measures		
4. Removal of capsules		
5. Post insertion tasks		
a. Wound dressing		
b. Instructions to clients		
c. Observing women after insertion		
d. Disposing of instruments/equipment		
6. Talking to model in all steps as if it were an actual client		

Unit 6. Evaluation

Course Evaluation Form

Participants should complete this course evaluation form. Indicate on a 1 - 5 scale your opinion of the following course components.

1	2	3	4	5
Strongly disagree	Disagree	No opinion	Agree	Strongly agree

Course Component	Rating
The pre-course questionnaire inspired me to learn more about Norplant®/Implanon®.	
The training slides, transparencies, videotapes, and data shows helped me to have a better understanding of Norplant®/Implanon® insertion and removal before practicing on arm models.	
The practice sessions on arm models helped me to acquire skills before performing Norplant®/Implanon® insertion and removal on women.	
There were enough clients to allow for training in Norplant® removal.	
There were enough clients to allow for training in Implanon® insertion.	
There were enough clients to allow for training in Implanon® removal.	
There was sufficient time scheduled to practice Norplant®/Implanon® insertion and removal on arm models.	
The Competency Based Training methodology helps to improve skills.	
The coaching session and the COACH Skill Inventory helped me to be a better trainer.	
The Basic Learning Guides were valuable tools to improve performance.	
I am now confident I can provide training in Norplant® removal.	
I am now confident I can provide training in Implanon® insertion.	
I am now confident I can provide training in Implanon® removal.	

Unit 7. Audio-Visual Materials List

Audio-Visual Materials List

Infection prevention	(Video)
Norplant® insertion and removal	(Video)
Norplant® removal	(Video)
Implanon® insertion and removal	(Video)
Implanon® insertion and removal	(CD)

PowerPoint Presentation List

PowerPoint Presentation One:	Competency Based Training and Coaching
PowerPoint Presentation Two:	Norplant® Clinical Profile Presentation, Insertion and Removal.
PowerPoint Presentation Three:	Implanon® Clinical Profile Presentation, Insertion and Removal.