

# Levoplant

## Levonorgestrel Subdermal Contraceptive Implant



# What is Levoplant?

- Two small, flexible rods
  - each about the size of a matchstick
- Highly effective contraception for 3 years
- can be inserted anytime as long as the woman is not pregnant
- World Health Organization prequalified contraceptive implant



# Implants

	<b>Nexplanon</b>	<b>Jadelle</b>	<b>Levoplant</b>
<b>Rods</b>	1	2	2
<b>Progestin</b>	Etonogestrel 68 mg	Levonorgestrel 75 mg/rod	Levonorgestrel 75 mg/rod
<b>Length</b>	4 cm	4 cm	4 cm
<b>Diameter</b>	2 mm	2.4 mm	2.4 mm
<b>Plastic</b>	ethylene vinyl acetate	Silastic*	Silastic*
<b>Approved duration of use</b>	3 years	5 years	3 years

# Effectiveness

- Levoplant is one of the most effective contraceptive methods available
- Sustained release of very low dose of levonorgestrel into the bloodstream
- Fewer than 1 pregnancy per 100 women (< 1%) occurs in the first year
- For heavier women (>80 kg), effectiveness of Levoplant may decrease near the end of the duration of use.
  - Consider replacing their Levoplant implants sooner than 3 years

# Mode of Action

## Primary mode of action:

- Production of thick cervical mucus which prevents sperm penetration
- Inhibition of ovulation – in about 50% of menstrual cycles

## Other secondary actions:

- Decrease natural progesterone production by the ovary during the postovulatory (luteal) phase even in those cycles in which ovulation occurs
- Suppression of endometrial growth (hypoplasia)

# Efficacy

Year	Cumulative Pregnancy Rate
1	0.0-0.1%
2	0.2-0.3%
3	0.0-0.3%
4	0.9-1.1%
5	0.7-2.1%

# Benefits of Levoplant

- Long-lasting, safe and effective
- Effective within 24 hours of insertion
- Does not require any further action after insertion
- Almost immediate return to fertility once removed
- Limited side effects
- Convenient – does not interfere with normal activities, sexual desire, or intercourse
- No routine return visit is required until time of removal
- No estrogen

# Disadvantages

- Need a trained service provider for insertion and removal
- Changes in monthly bleeding patterns
- Implants may be visible under skin
- Does not prevent sexually transmitted infections (STIs)



# Who can use Levoplant?

- Levoplant is safe for nearly all women:
  - Any age – teens to over 40 years
  - With or without children
  - Married or unmarried
  - Recent abortion, miscarriage, or ectopic pregnancy
  - Smokers, regardless of age or number of cigarettes smoked
  - Breastfeeding (can use Levoplant at 6 weeks after childbirth)
  - HIV positive (whether on antiretroviral therapy or not)

# Who cannot use Levoplant?

- Levoplant is NOT suitable for women who:
  - May be pregnant
  - Have unexplained vaginal bleeding
  - Have a severe liver infection or tumor
  - Are on special medication
  - Have a history of breast cancer
  - Allergy to levonorgestrel or other component of Levoplant

# Precaution: Drug Interactions

Some drugs decrease the effectiveness of implants:

- **Anti-epilepsy drugs**

- Barbiturates  
(phenobarbital)
- Phenytoin
- Carbamazepine
- NOT valproic acid

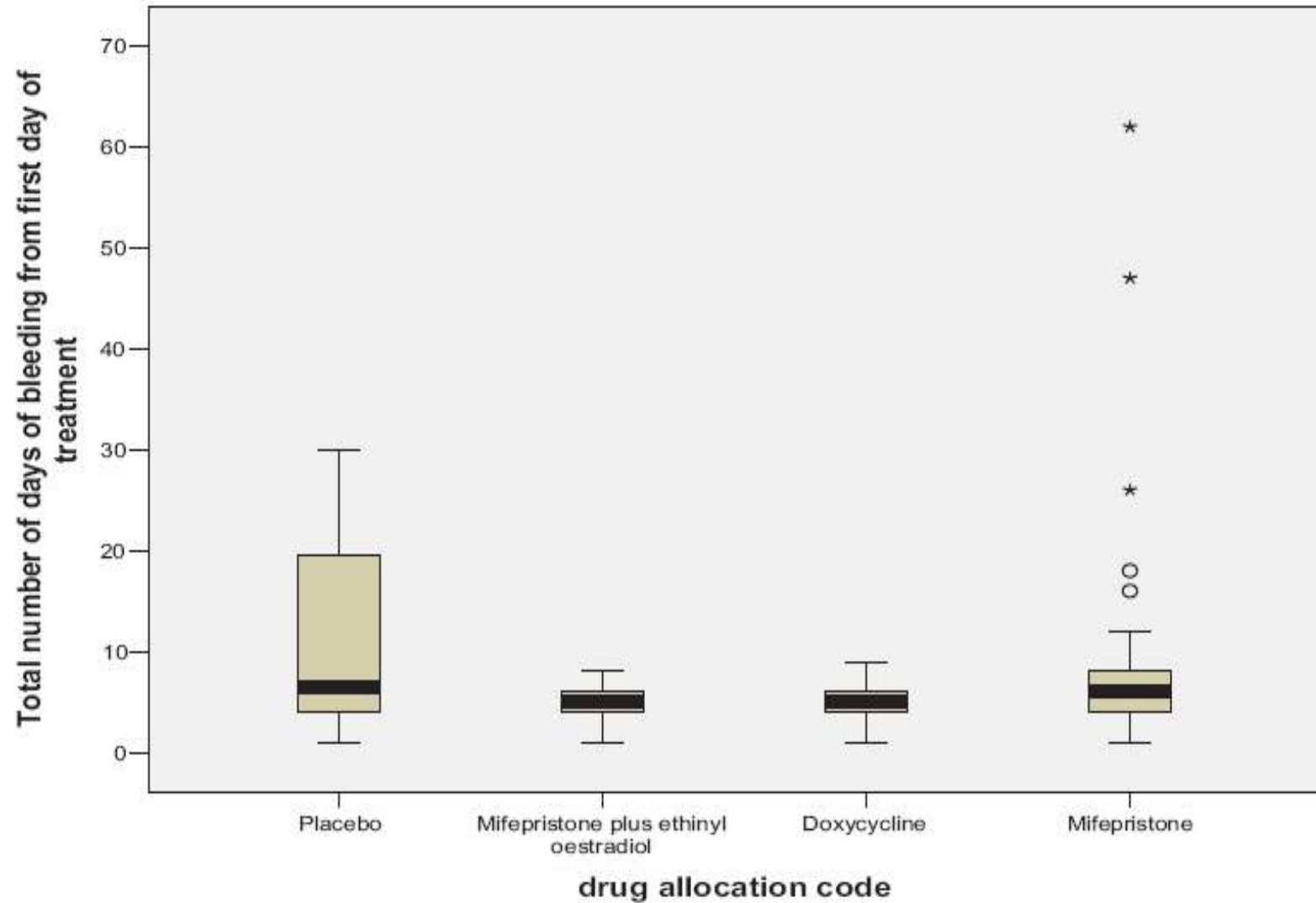
- **Antibiotics:**

- Rifampin
- Griseofulvin

# Side effects: irregular bleeding pattern

- 800 mg ibuprofen 3 times daily after meals for 5 days.
- Give client combined oral contraceptives with ethinyl estradiol and levonorgestrel.
  - One pill daily for 21 days.
  - Or 50 µg ethinyl estradiol daily for 21 days

# Treatment of Bleeding Episodes



# Side effects and their management (1)

SIDE EFFECTS	MANAGEMENT
Changes in menstrual bleeding pattern	800 mg ibuprofen 3 times daily after meals for 5 days. Give client combined oral contraceptives with the progestin levonorgestrel. Ask her to take one pill daily for 21 days. Or 50 µg ethinyl estradiol daily for 21 days
Nausea	Try local remedies
Headaches	For regular, not migraine, headaches, suggest: <ul style="list-style-type: none"><li>• aspirin (325–650 mg)</li><li>• ibuprofen (200–400 mg)</li><li>• paracetamol (325–1000 mg)</li></ul> Or other pain reliever.
Dizziness	Suggest iron tablets, multivitamins

# Side effects and their management (2)

SIDE EFFECTS	MANAGEMENT
Abdominal pain	Mild abdominal pain, you can suggest: <ul style="list-style-type: none"><li>• aspirin (325–650 mg)</li><li>• ibuprofen (200–400 mg)</li><li>• paracetamol (325–1000 mg), or other pain reliever.</li></ul> For severe abdominal pain: <ul style="list-style-type: none"><li>• Investigate for ectopic pregnancy</li><li>• Refer at once for immediate diagnosis and care.</li></ul>
Weight change	Review diet and exercise practices and changes and counsel accordingly
Breast tenderness	Wearing a supportive bra (day and night). Suggest: aspirin (325-650 mg), ibuprofen (200-400 mg), paracetamol (325-1000 mg), or other pain reliever
Mood change	If ectopic pregnancy or other serious health condition is suspected, <i>refer at once for immediate diagnosis and care.</i>

# Levoplant vs Jadelle (1)

	Levoplant	Jadelle
Active ingredient	Levonorgestrel	Levonorgestrel
Number of rods	2	2
Duration of use	WHO qualified for 3 years of use	WHO qualified for 5 years of use
Insertion	Sub-dermal insertion in V shape with trocar	Sub-dermal insertion in V shape with trocar
Removal	Suggested to use Crile/Kelly forceps for both stabilization and removal; however use of Mosquito forceps is also acceptable	Suggested to use Mosquito forceps to stabilize and Crile/Kelly forceps to remove the rods
How it works	<ol style="list-style-type: none"><li>1. Prevents ovulation, so no egg can be fertilized</li><li>2. Thickens cervical mucus (blocks sperm)</li></ol>	<ol style="list-style-type: none"><li>1. Prevents ovulation, so no egg can be fertilized</li><li>2. Thickens cervical mucus (blocks sperm)</li></ol>



# Levoplant vs Jadelle (2)

	Levoplant	Jadelle
How well it works	Very effective. < 1 pregnancy per 100 users over time used	Very effective. < 1 pregnancy per 100 users over time used
Side effects	Bleeding irregularities: none at all, regular, infrequent, heavy or prolonged or irregular lasting 8 days or more especially in first year  <i>Other:</i> Headaches, abdominal pain, breast tenderness	Bleeding irregularities: none at all, regular, infrequent, heavy or prolonged or irregular lasting 8 days or more especially in first year  <i>Other:</i> Headaches, abdominal pain, breast tenderness
Use in women >80kg	Yes, though replacement before maximum time may assure continued effectiveness	Yes, though replacement before maximum time may assure continued effectiveness
Use during breastfeeding	Yes	Yes

# Questions?

# Levoplant Medical Eligibility

Client Screening and Time of Insertion

# Objectives of the session

By the end of the session, participants will be able to:

- Describe medical eligibility of clients intended to use Levoplant
- Screen clients using checklist
- Use clinical judgment in special cases
- Advise when appropriate to insert Levoplant

# Medical Eligibility in Client Screening

Ask the client the following questions:

1. Are you breastfeeding a baby less than 6 weeks old?
2. Do you have cirrhosis of the liver, a liver infection, or liver tumor?
3. Do you have a problem now with a blood clot in your legs or lungs?
4. Do you have vaginal bleeding that is unusual for you?
5. Do you have or have you ever had breast cancer?

If the answer is **NO** to all of these, then proceed for further steps in screening.

# Clinical Judgment in Special Cases

Women with any of the conditions below should NOT use Levoplant:

1. Breastfeeding and less than 6 weeks since childbirth
2. Severe liver disease, infection, or tumor
3. Acute blood clot in deep veins of legs or lungs
4. Unexplained vaginal bleeding
5. Had breast cancer more than 5 years ago and it has not returned
6. Systemic Lupus Erythematosus with positive (or unknown) anti-phospholipid antibodies

# When to Insert Levoplant

## **IMPORTANT:**

A woman can start using Levoplant any time she wants if it is reasonably certain she is not pregnant.

Use the Pregnancy Rule-Out Checklist to be reasonably certain she is not pregnant.

Woman's situation	When to start
Having menstrual cycles or switching from a non-hormonal method	If she is starting within 7 days after the start of her monthly bleeding, no need for a backup method.
	If it is more than 7 days after the start of her monthly bleeding, she can have Levoplant inserted if reasonably certain she is not pregnant. She will need a backup method for the first 7 days after insertion.
	If switching from an IUD, she can have Levoplant inserted immediately.
Switching from a hormonal method	<b>Immediately, if she has been using the hormonal method consistently and correctly or if it is otherwise reasonably certain she is not pregnant.</b> No need to wait for her next monthly bleeding. No need for a backup method.
	If she is switching from injectables, she can have Levoplant inserted when the repeat injection would have been given. No need for a backup method.



Woman's situation	When to start
Fully or nearly fully breastfeeding <ul style="list-style-type: none"> <li>• <b>LESS</b> than 6 months after childbirth</li> </ul>	If she gave birth less than 6 weeks ago, delay insertion until at least 6 weeks after giving birth.
	If her monthly bleeding has <b>NOT</b> returned, Levoplant can be inserted any time between 6 weeks and 6 months. No need for a backup method.
	If her monthly bleeding has returned, she can have Levoplant inserted as advised for women having menstrual cycles (on previous page).
Fully or nearly fully breastfeeding <ul style="list-style-type: none"> <li>• <b>MORE</b> than 6 months after childbirth</li> </ul>	If her monthly bleeding has <b>NOT</b> returned, she can have Levoplant inserted any time it is reasonably certain she is not pregnant. She will need a backup method for the first 7 days after insertion
	If her monthly bleeding has returned, she can have Levoplant inserted as advised for women having menstrual cycles

# Pregnancy Rule-Out Checklist for Levoplant

NO	1. Did your last menstrual period start within the past 7 days?	YES
NO	2. Have you abstained from sexual intercourse since your last menstrual period or delivery?	YES
NO	3. Have you been using a reliable contraceptive method consistently and correctly since your last menstrual period or delivery?	YES
NO	4. Have you had a baby in the last 4 weeks?	YES
NO	5. Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then?	YES
NO	6. Have you had a miscarriage or abortion in the past 7 days?	YES

If the client answer **NO** to *all of the questions*, pregnancy cannot be ruled out using the checklist. Rule out pregnancy by other means.

If the client answered **YES** to *at least one of the questions* and she is free of signs or symptoms of pregnancy, you can be reasonably sure she is not pregnant.

Questions?

Thank you for your attention!

# Levoplant contraceptive implant

## Steps for Insertion and Removal



# Before You Begin

- Always use sterile gloves or forceps when handling the rods.
- If a Levoplant rod is contaminated (for example, falls on the floor), LEAVE IT for later disposal and OPEN A NEW PACKAGE and continue with the procedure.

# Required Equipment

- An examination table
- Sterile surgical cloth/drapes and gloves
- Antiseptic solution
- Local anesthetic, needles, and syringe
- Trocar, forceps
- Scalpel (optional)
- Skin closure, sterile gauze, and compresses

# Proper timing for Insertion

- Within 7 days from the onset of menstrual bleeding
- Immediately or within 7 days post-abortion
- Immediately or within 3 weeks postpartum if the woman is not breastfeeding
- From 6 weeks postpartum if the woman is breastfeeding



# Levoplant with Disposable Trocar & Cannula

- Levoplant is provided with a disposable trocar
  - sharp enough to penetrate the skin directly
- Disposable trocar can be used to puncture the skin and insert the rods
  - No need for incision





# Steps of Insertion (1)



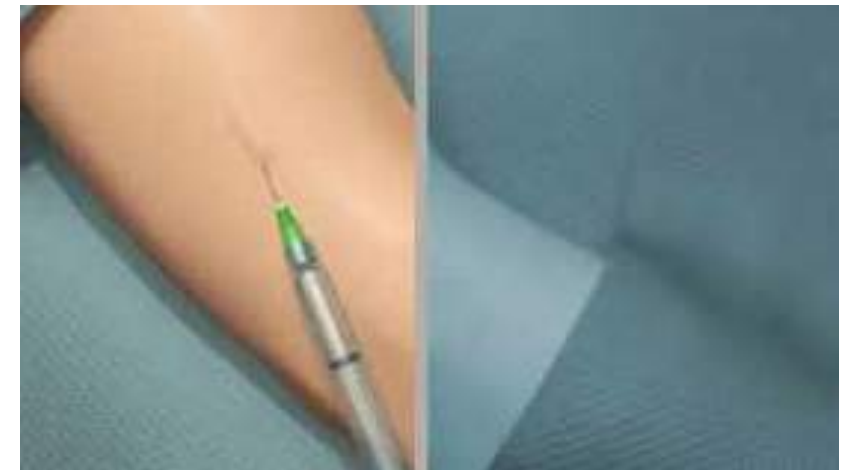
1. Wash the non-dominant arm
2. Allow the client to lie down on the procedure table with her non-dominant arm extended on a sterile or clean cloth on the other table, at a right angle to her body
3. The implants will be inserted subdermally using the disposable trocar, in the shape of a narrow V, opening towards the armpit

## Steps of Insertion (2)

4. Confirm the absence of known allergies to anesthetic agent or related drugs
5. Locate the site of Levoplant insertion at the inner side of the upper arm, 6-8 cm above the elbow
6. Use a sponge forceps to hold a cotton or gauze swab soaked with antiseptic (betadine or chlorhexidine)
  - Begin by wiping at the insertion site and move outward in a circular motion for 8 to 13 cm (3 to 5 in.).
  - If an iodophor (e.g., Betadine) is used, allow to air dry for about 2 minutes before proceeding (iodophors require up to 2 minutes to contact time to release free iodine).

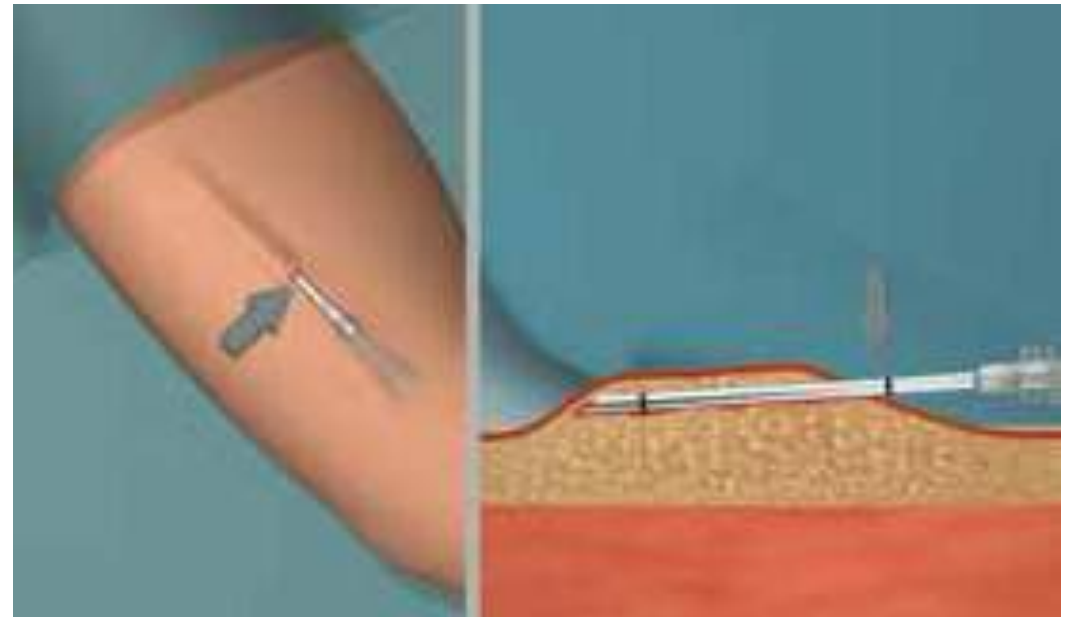
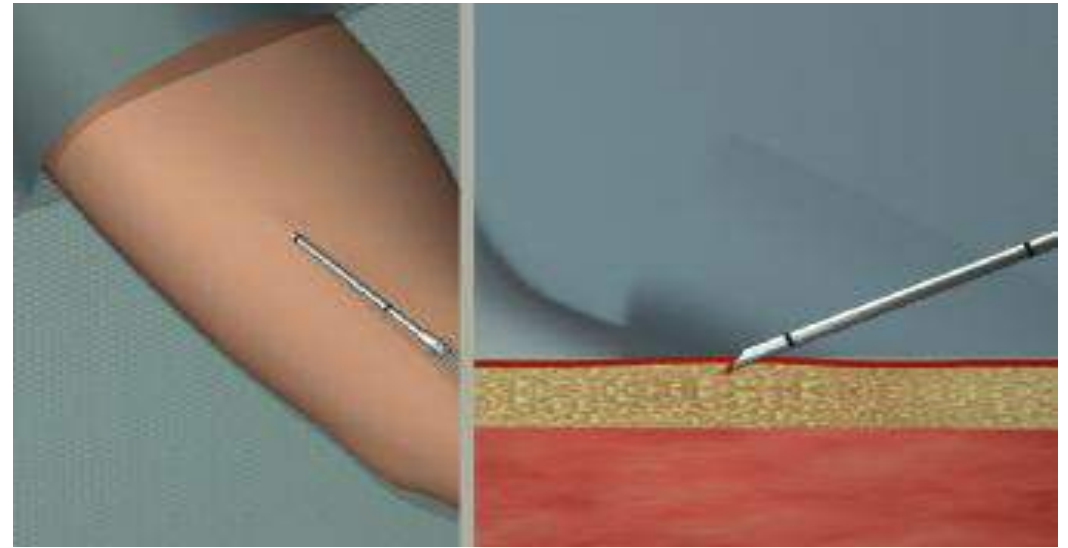
## Steps of Insertion (3)

7. Fill the syringe with 2-4 ml of 1% local anesthetic without adrenaline
8. Anaesthetize two areas about 4.5 cm long, to mimic the V shape of the insertion area
9. Gently touch the insertion site with forceps to make sure the anesthetic is working



## Steps of Insertion (4)

10. Introduce the trocar just beneath the skin at anesthetized area
11. Once the tip of the trocar is beneath the skin, advance the trocar along the skin horizontally to the mark closest to the handle of the trocar, pointing slightly upwards raising the skin (tenting) to keep the implant in the subdermal plane

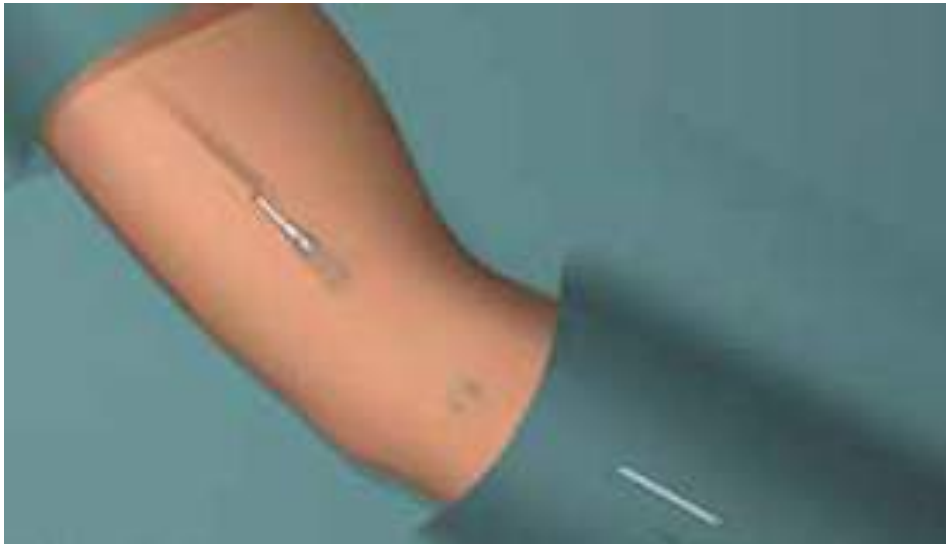


# Steps of Insertion (5)

## Note:

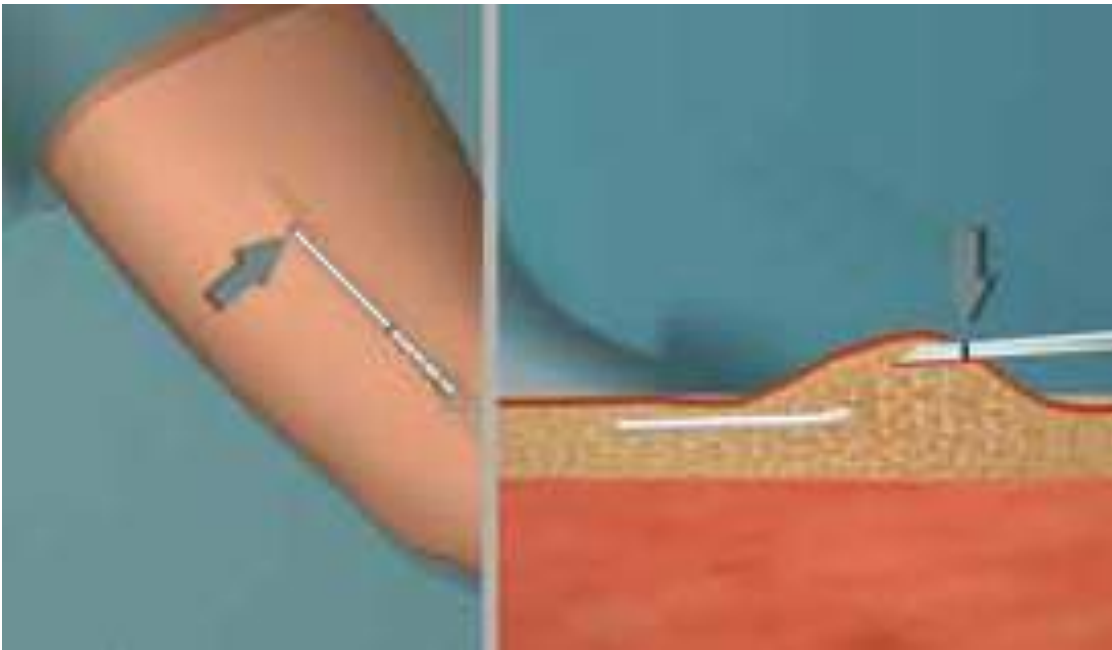
- Do not force the trocar, and if you feel any resistance, try another direction
- It is important to keep the trocar subdermal by tenting the skin with the trocar, as failure to do so may result in deep placement of the implants causing a more difficult removal
- Throughout the insertion procedure, the trocar should be oriented with the bevel up

## Steps of Insertion (6)



12. Remove the plunger when the trocar is advanced to the mark nearest the hub
13. Load the first implant into the trocar either with tweezers or gloved fingers
14. Push the implant gently with the plunger to the tip of the trocar until you feel resistance
15. Never force the plunger

# Steps of Insertion (7)

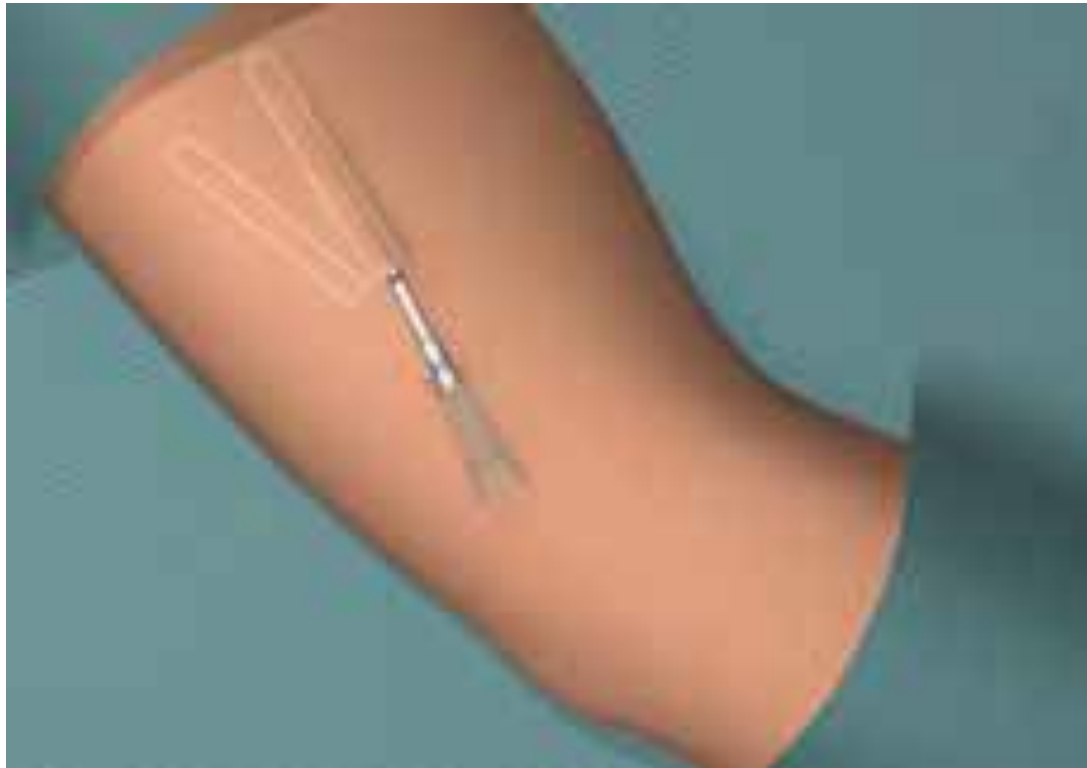


16. Hold the plunger steady and pull the trocar back to the mark near the tip

## NOTE:

- It is important to keep the plunger steady and not to push the implant into the tissue
- The trocar is withdrawn after insertion of the 1<sup>st</sup> rod only to the mark closest to its tip. DO NOT withdraw completely

## Steps of Insertion (8)



17. Fix the position of the first implant with the left fore-finger and advance the trocar to form a V shape along the side of the finger. The V should be about a 30-degree angle. Insert the second implant next to the first one

### NOTE:

- Leave 5mm between the puncture and the tip of the implants to avoid spontaneous expulsions.



## Steps of Insertion (9)



18. After the insertion, press the edges of the incision together and close the insertion point with a sterile butterfly adhesive
19. Cover the insertion area with a compress and wrap enough gauze around the arm to ensure hemostasis
20. Observe the patient at the clinic for 15 minutes for signs of syncope or bleeding from the incision before she is discharged after counseling

# Removal: Required Equipment

- An examination table
- Sterile surgical cloth/drapes and gloves
- Antiseptic solution
- Local anesthetic, needles, and syringe
- Sterile #11 scalpel, forceps (two Crile/Kelly forceps recommended, though one Crile/Kelly and one Mosquito acceptable)
- Skin closures, sterile gauze and compresses

# Removal (1)

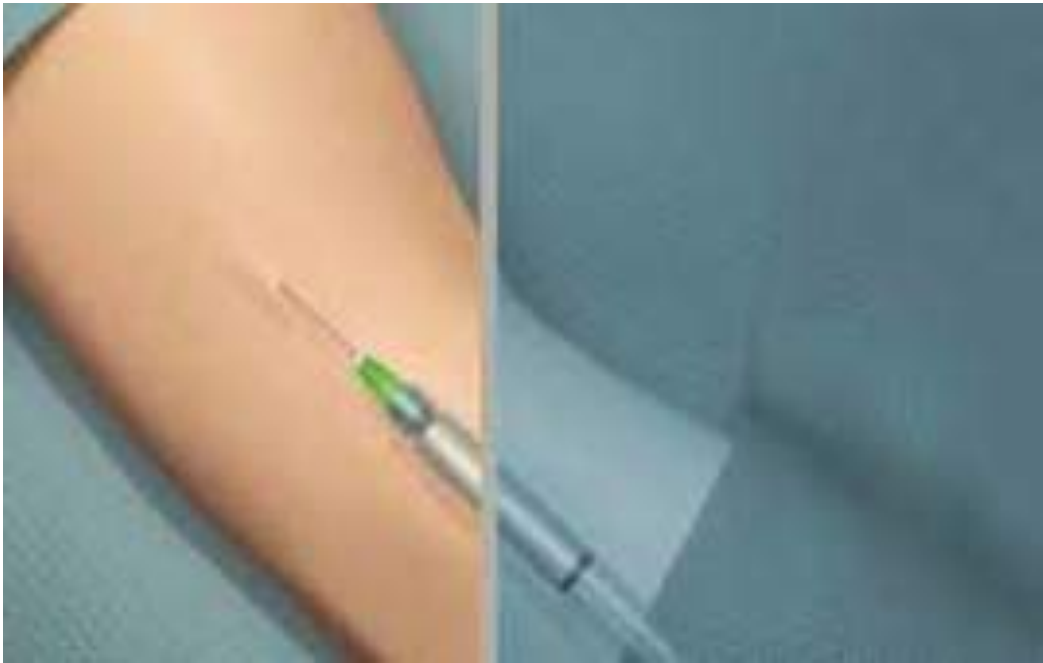
- For optimal readiness, implant removal should preferably be done on certain scheduled days
- The implants shall be removed very gently, and this will usually take more time than their insertion
- Implants may sometimes be nicked, cut or broken during removal. If removal proves difficult, close the incision and bandage the wound, and have the patient return for another attempt
- The remaining implant(s) will be easier to remove after the area is healed. A non-hormonal method of contraception should be used until both implant have been removed

## Removal (2)



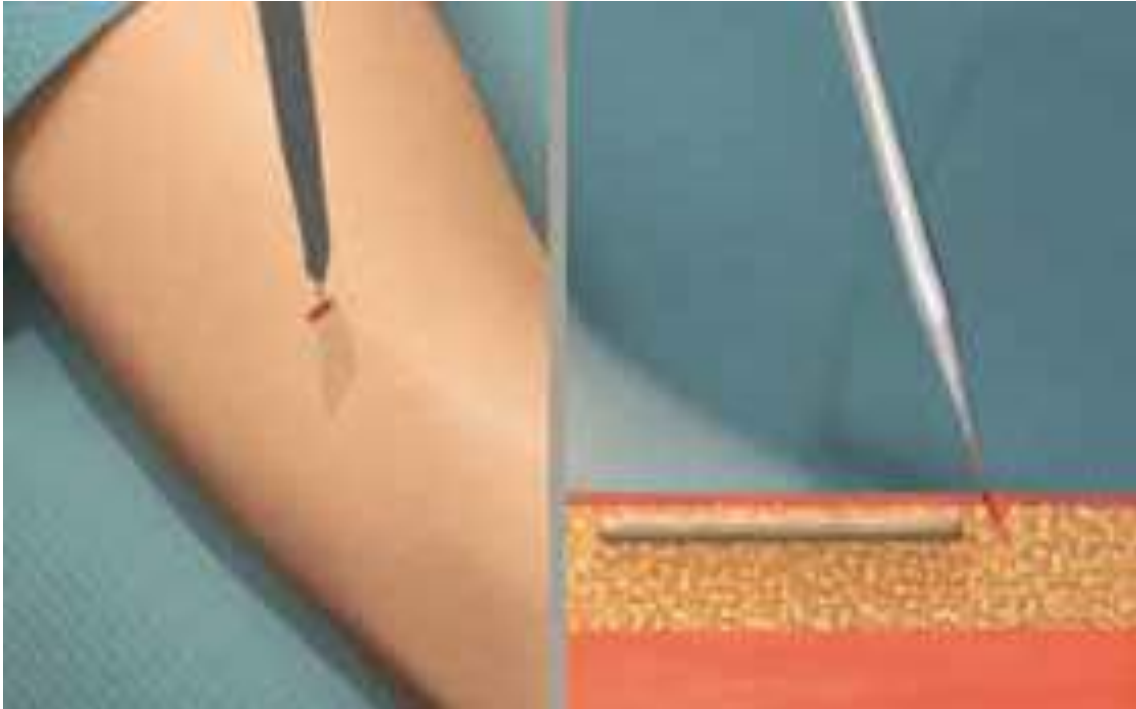
- The patient shall be in a similar position, and a similar aseptic technique shall be applied as for insertion
- Locate the implants by palpation, possibly marking their position with a marker pen
- If they cannot be palpated, they may be located by ultrasound or soft tissue X-ray

## Removal (3)



- Inject a small amount of local anesthetic under the ends of the implant that are closer to each other – this will raise the ends of the implants
- Anesthetic injected over the implants may obscure their position and make removal more difficult
- If necessary, more anesthetic can be given in small amounts at a time

## Removal (4)



- Make a 4-mm incision with the scalpel close to the ends of the implants (below the bottom of the V)
- Keep the incision small

## Removal (5)



- Push each implant with your fingers gently towards the incision
- When the tip is visible or near to the incision, grasp it with Crile/Kelly forceps. Mosquito forceps can also be used

## Removal (6)



- Stabilize the implant with the Crile/Kelly forceps. Mosquito forceps can also be used
- Use a scalpel and very gently open the tissue sheath around the implant



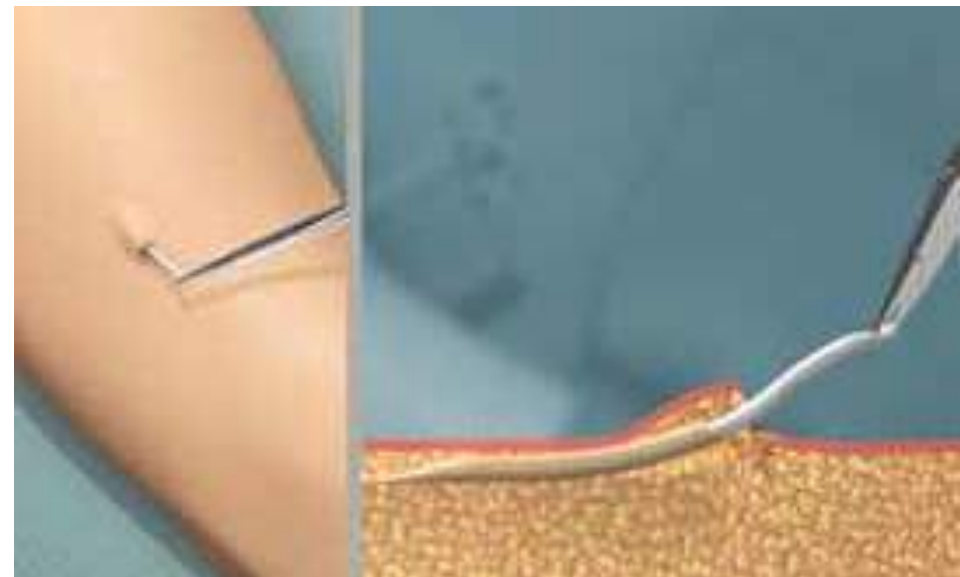
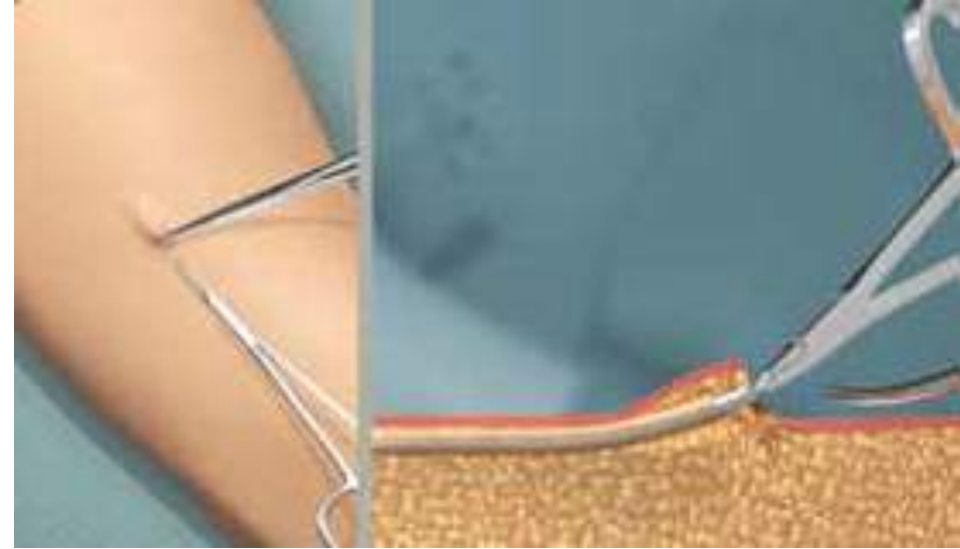
# Removal (7)



- Grasp the end of the implant with the second forceps (Crile/Kelly forceps)

# Removal (8)

- Release the stabilizing (first) forceps
- Use the second forceps holding the end of the implant to gently remove the implant



## Removal (9)



- Repeat the procedure for the second implant
- Measure the length of the removed implants to make sure the patient had two Levoplant implants and not other contraceptive implants
- The length should be 44 mm

# Removal (10)



- After the procedure is completed, close the incision and bandage it as after insertion. The arm should be kept dry for a few days

# Wish to continue Levoplant

- If the client wishes to continue using the method, a new set of Levoplant can be inserted through the same incision, in the same or the opposite direction
- If the client prefers, Levoplant can also be inserted in her other arm



Questions?

Thank you for your attention!

# Levoplant

## Pre & Post Insertion Care and Counseling: Client Follow-Up



# Before Insertion

- Counsel client on what to expect, both during and after insertion including common side effects
- Be clear and concise
- Reassure that common side effects are not harmful
- Project professionalism, clinical confidence, and receptivity to questions
- If possible, also provide printed materials



# Management after insertion

- Be open to patient question
- Practice active listening
- Rule out other causes of any complaints
- Give advice about managing the side effects
- Try medical management before removal first for side effects
- Honor the wishes of the woman
- If removal is chosen, contraceptive and/or pregnancy counseling

# Post-insertion care (1)

- Instruct client regarding wound care and make return visit appointment, if needed
  - She should keep the insertion area dry for 4 days. She can take off the elastic bandage or gauze after 2 days and the adhesive bandage after 5 days.
  - Seek a clinician if any irritation occurs at the site of insertion
  - After the anesthetic wears off, her arm may be sore for a few days. She may also have swelling and bruising at the insertion site. This is common and will go away without treatment.

## Post-insertion care (2)

- Observe client for at least 15 to 20 minutes and ask her how she feels before sending her home
- Discuss what to do if client experiences any problems following insertion or side effects
- Ask the client to repeat instructions
- Answer client's questions

# Follow-up

## *“Come back any time”*

- Assure every client she is welcome to come back any time – for example, when:
  - She has problems, questions, or wants another method
  - She has a major change in health status
  - She thinks she might be pregnant
- Remind her to bring the follow-up card during each visit to the clinic

# Warning signs or problems

The client should return to the clinic if she has any of the following problems (DISCUS):

- **D**elayed menstrual period after several months of regular cycles (may be a sign of pregnancy)
- **I**nfection – pus or bleeding at the insertion side
- **S**evere lower abdominal pain (may be a symptom of ectopic pregnancy)
- **C**apsule (expulsion of a rod)
- **U**nexplained heavy vaginal bleeding (either twice as long/heavy as normal)
- **S**evere headache – migraine (vascular) headaches, repeated very painful headaches or blurred vision

Questions?

Thank you for your attention!