WomanCare GLOBAL | A COMPANY OF dkt INTERNATIONAL

LEVOPLANT

Levonorgestrel Contraceptive Implant

Providers Guide

The prequalified WHO[1] global brand Levoplant™ is also known as Sino-implant (II).

01 The implant is a set of two flexible, cylindrical, sealed, white or off-white rods. Each implant is 44 mm in length and 2.4 mm in diameter and contains 75mg of levonorgestrel, the active ingredient, a total of 150mg.

02 Levoplant™ works by a combination of factors. The most important of these are prevention of ovulation and thickening of the cervical mucus, making it more difficult for sperm to reach the egg.

03 Safety and efficacy of Levoplant™ have been demonstrated for 3 years of use. Once the implants are inserted they may be removed at the request of the user at any time.

04 Levoplant™ is among the most effective reversible contraceptive methods. The average annual pregnancy rate for Levoplant™ over a 3-year period is less than 1%.

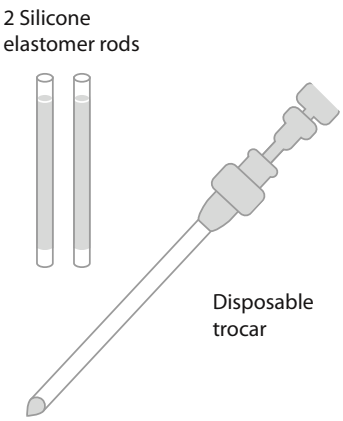
05 Levoplant™ implants affect bleeding patterns in many women. Irregular, prolonged and intermenstrual bleeding, spotting and amenorrhea have been reported. In general, such irregularities decrease with continuing use. Patients should be reassured that such changes are not harmful and do not affect fertility.

Patient counseling

Counseling is key to increase method uptake and continuation.

- Levoplant™ is a long-acting method demonstrated for 3 years of use. Until removal is desired, no action from the user or routine clinical follow-up is required after initial insertion. Implants do not provide protection from STIs.
- After removal of the rods, there is no delay in a woman's return to fertility. Women who discontinue use of Levoplant™ can expect pregnancy rates that are comparable to women who are not using a contraceptive method.
- Levoplant™ is appropriate for women of any age including adolescents and women over 40 who wish to space or limit births.
- Changes in bleeding pattern may occur with Levoplant™; appropriate counseling may make these changes more acceptable.
- Thoroughly review risks, benefits and possible side effects, allowing patient adequate time to ask questions.

[1] https://extranet.who.int/pqweb/medicine/3997



Side effects

- Headache.
- Nausea.
- Irregular Menstruation.
- Weight Gain.
- Please refer to the Prescribing Information for a complete list of adverse events.

Contraindications

Use of Levoplant™ is contraindicated in patients with:

- Hypersensitivity to levonorgestrel or any other component of Levoplant™.
- Current (history of) breast cancer.
- Other diagnosed or suspected sex hormone-dependent neoplasia.
- Severe liver disease, infection, or tumor.
- Thromboembolic disease.
- Unexplained vaginal bleeding.
- Systemic lupus erythematous with positive or unknown antiphospholipid antibodies.

Interactions

The Prescribing Information of concomitant medications should be used by the provider to identify potential drug interactions.

Pregnancy

The implants should be removed if pregnancy occurs during the use of Levoplant™, but there is good evidence that contraceptive implants do not cause birth defects or harm the fetus.

Implants are safe for all women who have just given birth or after abortion at any gestation and can be inserted immediately (if they are medically eligible). She may require a back up method of contraception for 7 days if there is a delay in insertion or if her monthly bleeding has returned, please consult prescribing guidance.

Breast Milk

Levels of levonorgestrel obtained with implants do not affect the quality or quantity of breast milk. Women who are fully or nearly fully breast-feeding and whose monthly bleeding has not returned can have implants inserted any time between giving birth and 6 months postpartum without needing a back-up method.

Key facts about insertion of Levoplant™

Levoplant™ can be inserted at any time of the menstrual cycle if it is reasonably certain that the woman is not pregnant[2] and she is medically eligible for the method. Check guidance to confirm if a back up method of contraception is required for 7 days.

Care should be taken to insert Levoplant™ correctly in the subdermal layer. Incorrect positioning deep into muscle can be painful and the implant may not be palpable at time of removal.

Insertions and removals should only be performed by providers who have been trained to competency.

[2] World Health Organization Department of Sexual and Reproductive Health and Research (WHO/SRH) and Johns Hopkins Bloomberg School of Public Health/ Center for Communication Programs (CCP), Knowledge SUCCESS. Family Planning: A Global Handbook for Providers (2022 update).

How to Insert Levoplant™

Scan this QR code to view our video tutorial on how to insert Levoplant™

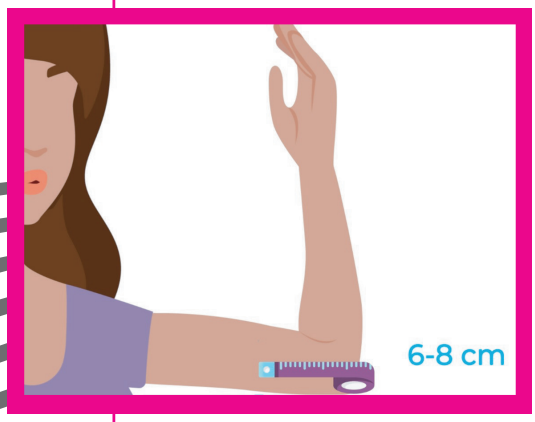
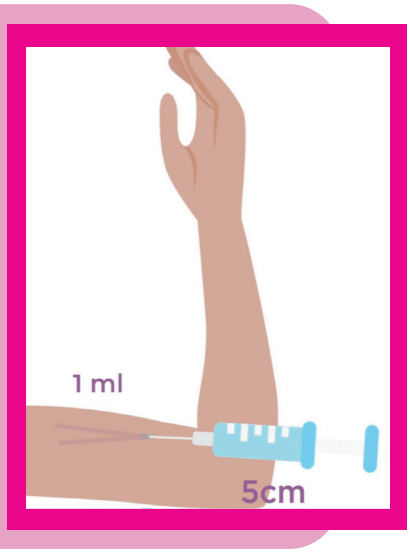


Figure 1

- Explain the procedure to the client and encourage questions.
- Determine that required sterile or high-level disinfected instruments and implants are present.
- Wash hands and thoroughly dry them.
- Check to be sure that the client has thoroughly washed and rinsed her entire arm.
- Position the woman's arm and place a clean, dry cloth under her arm.
- Mark position on arm for insertion of rods 6 cm to 8 cm above the elbow folder (this should form a "V" pattern).
- Put on a sterile pair of hand gloves.

Figure 2

- Set up sterile field and place implant rods and trocar on it.
- Prep insertion site with antiseptic solution.
- Place sterile or high-level disinfected drape over arm.
- Inject 2 mL of local anesthetic applied just under the skin, raising a wheal at the insertion point and advancing up to 5 cm along the first insertion track, injecting 1 ML of local anesthetic along the track as you withdraw. Without completely removing the needle, reorient to the second insertion track, advance up to 5 cm, and again inject 1 ml of local anesthetic along track as needle is withdrawn. Let the arm rest for approximately 5 minutes and check for anesthetic effect before making skin incision.



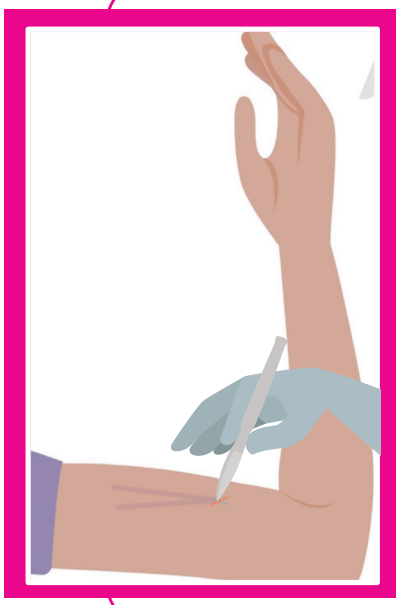


Figure 3

- Make a small incision with a scalpel in the skin on the inside of the upper arm. Alternatively, use the trocar to puncture the skin.
- Insert the tip of the trocar beneath the skin at a shallow angle. Gently advance the trocar superficially under the skin with the bevel facing up while tenting the skin. Tenting of the skin enables the implant to be placed under the skin and not deeper into the arm.
- The rod should be placed parallel to the skin. Take great care not to insert trocar into the arm muscle.

Note: The trocar has two marks on it. The mark closest to the hub indicates how far the trocar should be introduced under the skin to place the implants. The mark closest to the tip indicates how much of the trocar should remain under the skin following placement of the first implant.

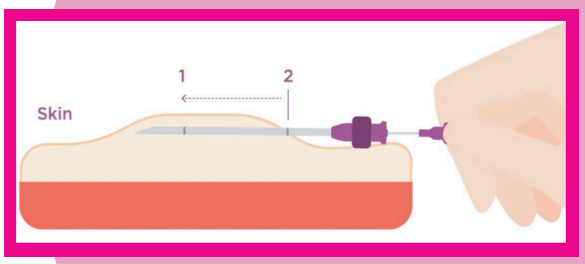
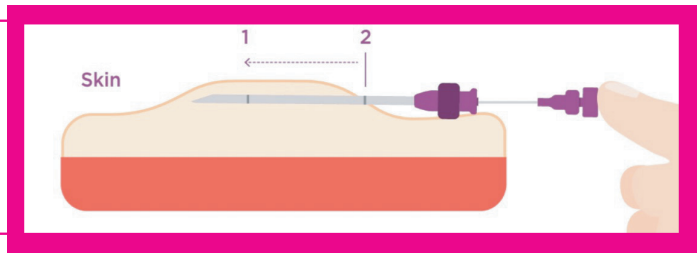


Figure 4

When the trocar has been inserted to the mark closest to the hub, remove the obturator and load the first implant into the trocar, using thumb and forefinger.

Figure 5

Using the obturator to push, gently advance the implant towards the tip of the trocar until you feel resistance. Never force the obturator.



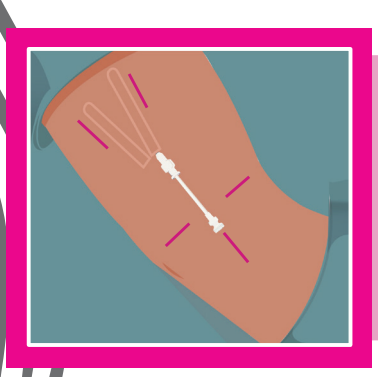
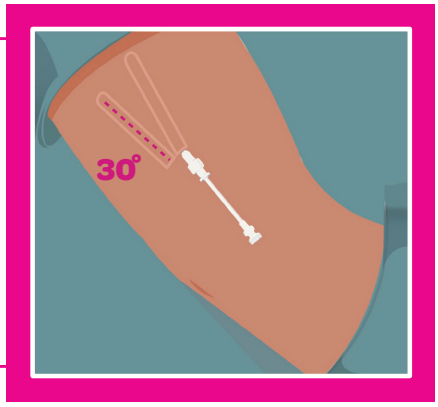


Figure 6

Holding the obturator stationary, withdraw the trocar to the mark closest to the trocar tip. The implant should be released under the skin at this point. It is important to keep the obturator stationary and to avoid pushing the implant into the tissue. Do not completely remove the trocar until both implants have been placed.

Figure 7

To place the second implant, align the trocar so that the second implant will be positioned at about a 30° angle relative to the first implant. Repeat steps 3-4. The rods are placed in the shape of a V opening toward the shoulder. Leave a distance of about 5 mm between the incision and the tips of the implants. Remove the trocar and immediately dispose of it in a sharps container.



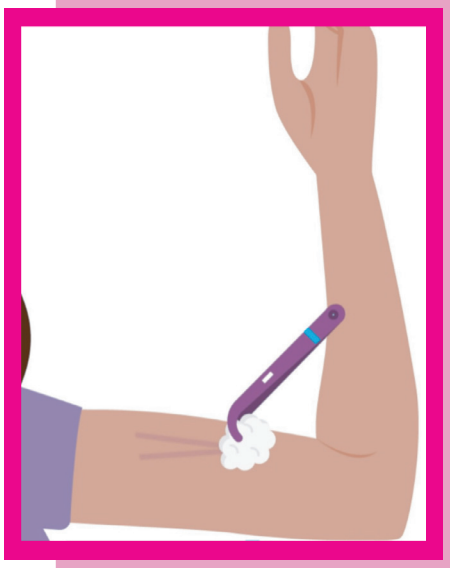


Figure 8

- Remove drape and wipe the client's skin with alcohol.
- Bring edges of incision together and close it using surgical tape, then cover it with tape on a sterile gauze (2x2) or an adhesive bandage.
- Apply firm pressure dressing.
- Instruct client regarding wound care.
- Keep the area around the insertion site dry and clean for at least 48 hours.
- Leave the gauze pressure bandage in place for 48 hours and the surgical tape or adhesive bandage in place until the incision heals (normally 3-5 days).
- Discuss with the client what to do if she experiences any problems following insertion or side effects from the implant. Advise client that she can have the rods removed at any time if she desires.
- Make return visit appointment, if necessary.
- Observe the client for at least 15-20 minutes before discharging.

How to Remove Levoplant™

Scan this QR code to view our video tutorial on how to remove Levoplant™

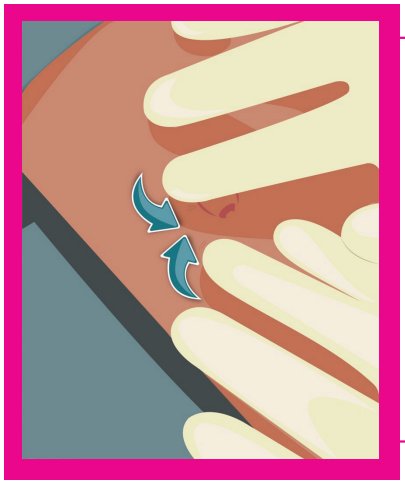
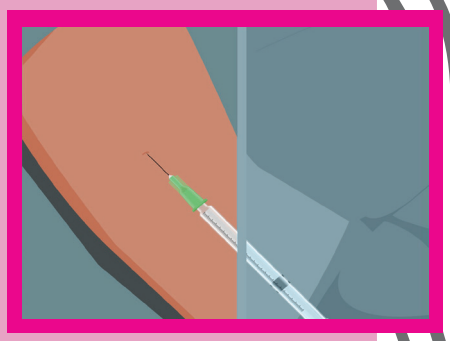


Figure 1

- Determine that required sterile or high-level disinfected instruments are present.
- Check that the client has thoroughly washed and rinsed her arm.
- Explain the procedure to the client and encourage questions.
- Position the woman's arm and place a clean, dry cloth under her arm.
- Palpate the rods to determine point of removal. Mark position on arm where the tip of the rods is palpated.

Figure 2

- Wash hands thoroughly and dry clean them.
- Put on sterile pair of hand gloves.
- Arrange instruments and supplies.
- Prep removal site with antiseptic solution twice.
- Place sterile or high-level disinfected drape over arm.
- Inject 1ml of local anesthetic applied at the incision site and under the end of the rods.
- Check for anesthetic effect before making skin incision.



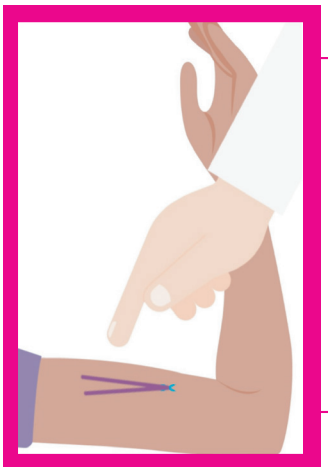


Figure 3

Before starting the removal, the implants must be located by palpation with ungloved fingers and the position of each rod marked. To help view the proximal tip near the insertion incision (bottom of the V), push down on the distal end of the implant. After cleaning the skin with an antiseptic, a small amount of local anesthetic is infiltrated under the implant ends. Anesthetic injected over the implants may obscure their position and make removal more difficult.

Figure 4

A small skin incision of 2-4 mm is made close to the ends of the implants (below the bottom of the V). Do not make a large incision.

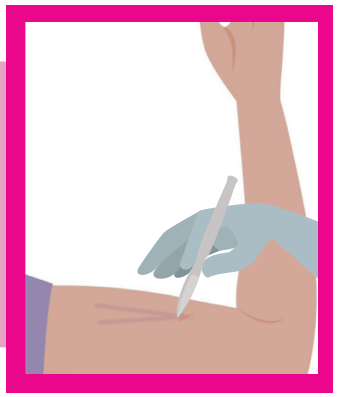
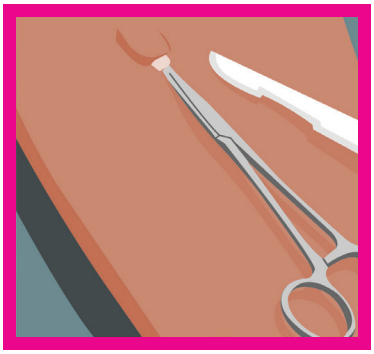
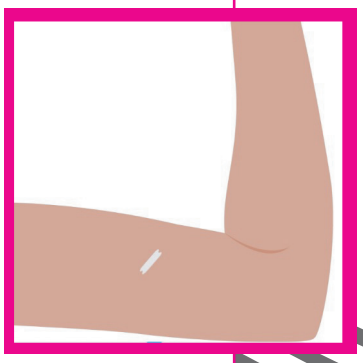


Figure 5A and 5B:

- Push each implant gently with your fingers towards the incision.
- When the tip is visible in the incision, grasp it with the straight Crile/Kelly forceps and gently pull out the rod without twisting or pulling on the rod, as this may lead to rod breakage.
- After the procedure is completed, close the incision, and bandage it as after insertion.
- The arm should be kept dry for 24-28 hours.





Considerations for implant removal

Levoplant™ should be removed after 3 years of use or at the request of the client at any time. Removal implants can be done at any time in the menstrual cycle.

When removing, if the tip of the implant does not become visible in the incision, gently insert the curved Crile/Kelly forceps into the incision, trying to grasp the implant. Flip the forceps over with your other hand and with the scalpel, carefully dissect the tissue around the implant to expose it and then grasp the implant with the straight Crile/Kelly forceps. The implant can then be removed, being careful to avoid a twisting or pulling motion.

If the implant is encapsulated, grasp and stabilize the exposed rod with the curved Crile/Kelly forceps. Use the scalpel to make a small incision very gently into the tissue sheath to expose the tip of the rod. Use the tip of the scalpel to gently separate the encapsulated tissue from the rod, moving distally, keeping light but steady traction on the rod until the rod is completely freed from the tissue.

Mosquito forceps can be used if Crile/Kelly forceps are not available; however, use of Crile/Kelly forceps has been shown to minimize damage to the implants during removal.

The implants should be removed very gently. This may take more time than the insertion. The implants may be nicked, cut or broken during removal. If removal proves difficult or both implants cannot be removed, the patient should be asked to return for a second visit after the removal area has healed. A non-hormonal method of contraception should be used until both implants have been completely removed. If the patient wishes to continue using the method, a new set of Levoplant™ may be inserted through the same incision, either in the same or in the opposite direction. Loss of contraceptive effect occurs practically immediately after removal, and another contraceptive method should be applied unless pregnancy is desired. Following removal, pregnancy may occur at any time.

DKT WomanCare Global
Email: contact@dktwomancare.org
www.dktwomancare.org

©WomanCare Global

A-PDV-LEV-501-EN, Rev:00

WomanCare GLOBAL | A COMPANY OF dkt INTERNATIONAL