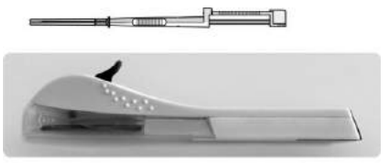
SUBDERMAL IMPLANTS

WHAT ARE SUBDERMAL IMPLANTS?

Subdermal implants are progestin-only implants that are inserted under the skin of the inner upper arm of women through a preloaded applicator under local anesthesia. These implants release progestin at a controlled rate and thus provide very small doses to achieve the desired contraceptive effect.

Two preparations of subdermal implants are available:



Source: MSD Drug Sheet, 2012

- The single-rod system (Implanon) releases etonogestrel and has a life span of three years. This implant is 40 mm long with a 2 mm diameter and contains 68 mg of etonogestrel.

- The two-rod system (Jadelle) containing 75 mg of levonorgestrel is effective for up to five years. This implant is 43 mm long, with each rod consisting of a drug-releasing core.

HOW EFFECTIVE ARE SUBDERMAL IMPLANTS?

Subdermal implants are 99.9% effective with perfect use and 99.5% effective with typical use.

WHAT ARE THE ADVANTAGES OF USING SUBDERMAL IMPLANTS?

- Reversible, as fertility returns almost immediately after the rods are removed
- Does not require daily intake
- Does not interfere with intercourse
- Effective within 24 hours after insertion
- No estrogen-related side effects, such as nausea and dizziness
- Has beneficial non-contraceptive effects:
  - Helps prevent iron-deficiency anemia
  - Makes sickle cell crises less frequent and less painful
  - Helps reduce risk of endometrial cancer
  - Reduces risk of ectopic pregnancies

WHAT ARE THE DISADVANTAGES OF USING THE SUBDERMAL IMPLANT?

- Clients cannot start or stop use on their own. Rods must be inserted and removed by a specially trained healthcare provider.
- Minor surgical procedure with local anesthesia is required to insert and to remove rods.
- Discomfort at the insertion site is common up to several days after insertion.
- Rods must be removed after a certain period.
- Initial cost is high.
- In very rare instances when pregnancy occurs, as many as one in every six pregnancies is ectopic.
- No protection is provided against STIs such as HIV/AIDS.

- Implants are more difficult to remove than to insert.

HOW DO SUBDERMAL IMPLANTS WORK?

- Suppresses ovulation through the action of the progestin
- Thickens cervical mucus, thus hindering sperms from passing through the cervical cana

WHO CAN USE SUBDERMAL IMPLANTS?

The Medical Eligibility Criteria (MEC) screening checklist for subdermal implants (Appendix E) should be used to determine the eligibility/suitability of the method to the client. Clients with the following characteristics and conditions can use the method:

Table 11. MEC Categories for subdermal implants

Category 1: Use the method without restriction.

- Women of reproductive age
- Women who may or may not have given birth
- Breastfeeding women, more than six weeks after childbirth
- Any time for non-breastfeeding postpartum women
- Any time post-abortion
- Past ectopic pregnancy
- History of pelvic surgery
- Women who smoke at any age
- Body mass index of more than or equal to 30 kg/m^2
- Any thyroid disorder
- Non-migrainous headache
- History of high blood pressure during pregnancy
- Family history of DVT/PE
- Surgery WITHOUT immobilization
- Superficial venous thrombosis
- Diagnosed with benign ovarian tumor, endometriosis, severe dysmenorrhea
- Have increased blood pressure (systolic of 140 mm Hg to 159 mm Hg or diastolic of 90 mm Hg to 99 mm Hg)
- Depressive disorders
- Any type of valvular heart disease
- Current or history of PID or STIs such as HIV/ AIDS
- Benign breast disease, or family history of cancer
- Cervical ectropion
- Tuberculosis
- Epilepsy
- Schistosomiasis
- Among women with uterine anatomical abnormalities (e.g., fibroids)
- Malaria
- History of gestational diabetes
- Adequately controlled hypertension, in which blood pressure CAN be evaluated
- History of pregnancy-related cholestasis
- Any classification of viral hepatitis
- Mild liver cirrhosis
- Anemias such as thalassemia, sickle cell disease, or iron-deficiency anemia
- Women with gestational trophoblastic disease, endometrial cancer, or ovarian cancer

- Current use of nucleoside reverse transcriptase inhibitors, lamotrigine, broad-spectrum antibiotics, antifungal, or antiparasitics

Category 2: Generally use the method but with more than the usual follow-up.

- Multiple risk factors for arterial cardiovascular disease such as old age, smoking, diabetes, and hypertension
- History of hypertension, in which blood pressure CANNOT be evaluated
- Have high blood pressure (systolic of more than or equal to 160 mm Hg or diastolic of more than or equal to 100 mm Hg)
- Hypertension with vascular disease
- History or currently diagnosed with DVT/PE on anticoagulant therapy
- Major surgery with prolonged immobilization
- Known thrombogenic mutations
- Initiation of method in women with current or history of ischemic heart disease or stroke
- Known hyperlipidemia
- Systemic lupus erythematosus with negative antiphospholipid antibodies
- Migraine with or without aura
- Women with irregular vaginal bleeding patterns
- Diagnosed with cervical intraepithelial neoplasia or cervical cancer prior to treatment
- Undiagnosed breast mass
- Diabetes with non-vascular or vascular disease
- Any gallbladder disease
- History of COC-related cholestasis
- Benign liver tumors such as focal nodular hyperplasia
- Current use of non-nucleoside reverse transcriptase inhibitors and ritonavir-boosted protease inhibitors, certain anticonvulsants, rifampicin or rifabutin therapy

WHO CANNOT USE THE METHOD?

Subdermal implants should not be used by women with the following conditions:

Category 3: Do not use the method unless no other appropriate method is available with close supervision.

- Breastfeeding women, less than 6 weeks after childbirth
- Acute DVT/PE
- Continued use in women with current or history of ischemic heart disease or stroke
- Systemic lupus erythematosus with positive antiphospholipid antibodies
- Unexplained vaginal bleeding prior to evaluation
- History of breast cancer with no evidence of disease in the last 5 years
- Severe liver cirrhosis
- Liver tumors such as hepatocellular adenoma or malignant hepatoma

Category 4: DO NOT use the method.

- Diagnosed with breast cancer

HOW IS THE SUBDERMAL IMPLANT USED?

The illustrations below demonstrate the insertion of subdermal implants. Note that these illustrations* should in no manner replace formal training in inserting the implants.

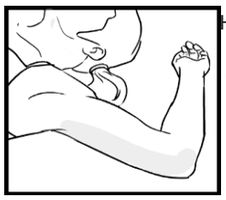
Implant insertion

Inserting implants usually takes a few minutes or longer depending on the skill of the provider. The insertion of Implanon does not require an incision because it is specially made with an

applicator similar to a syringe. Aseptic technique must be practiced.

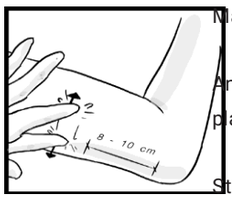
*INFO Project. Insertion and Removal of the New Implants. 2007. Johns Hopkins Bloomberg School of Public Health Merck, Sharpe and Dohme. 2013. Implanon: Reference Guide. MSD

Step 1



Have the woman lie on her back on the examination table with her non- dominant arm flexed at the elbow and externally rotated so that her wrist is parallel to her ear or her hand is positioned next to her head.

Step 2

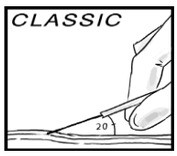


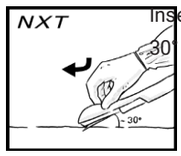
Mark the insertion site (8 cm to 10 cm from the medial epicondyle).

Anesthetize the insertion area (by injecting 2 mL of 1% lidocaine) just under the skin along the planned insertion tunnel.

Stretch the skin around the insertion site with the thumb and index finger.

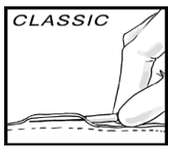
Step 3

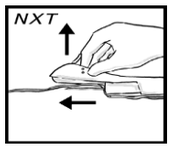




Insert only the tip of the cannula (needle) at 20° for the Classic Implanon and at about 30° for the new Implanon NXT.

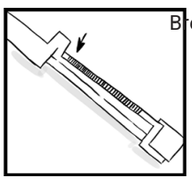
Step 4





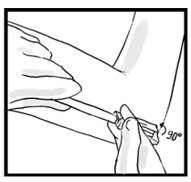
Lower the applicator to a horizontal position. While lifting the skin with the tip of the needle, slide the needle to its full length. Slight resistance is possible, but caution must be exerted in preventing use of excessive force. If the needle is not inserted to its full length, the implant will not be inserted properly.

Step 5 (for the Classic Implanon)



Break the seal of the applicator.

Turn the obturator (the rounded end of the applicator) at a 90° angle.

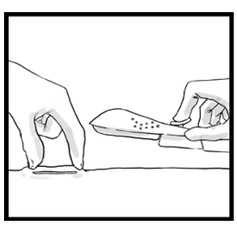


Fix the obturator with one hand against the arm. With the other hand, slowly draw the cannula (needle) out of the arm.

Step 5 (for Implanon NXT)

While keeping the applicator in the same position and with the needle inserted to its full length, unlock the purple slider by pushing it slightly down. Move the slider fully back until it stops, leaving the implant now in its final subdermal position and locking the needle inside the body of the applicator. If the slider is not completely moved to the back, the needle will not be fully retracted, and the implant will not be inserted properly. The applicator can now be removed.

Step 6



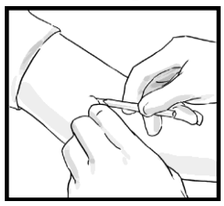
Always verify the presence of the implant in the woman's arm immediately after insertion by palpation. The presence of the 4 cm rod can be confirmed by palpating both ends of the implant.

Step 7

Apply a small adhesive bandage over the insertion site. Request that the client palpate the implant. Apply sterile gauze with a pressure bandage to minimize bruising. The client may remove the pressure bandage in 24 hours and the small bandage over the insertion site after three to five days.

Jadelle insertion

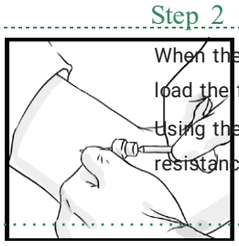
Step 1



Anesthetize the insertion area (by injecting 2 mL of 1% lidocaine). Make a small incision with a scalpel or trocar 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 (not shown).

Note that the trocar has three marks on it. The mark closest to the hub indicates how far the trocar should be introduced under the skin to place the Jadelle implants. The middle mark is not used. The mark closest to the tip indicates how much of the trocar should remain under the skin following placement of the first implant.

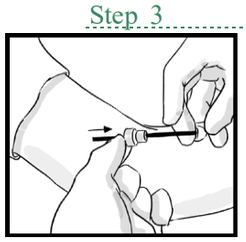
Step 2



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 the thumb and forefinger.

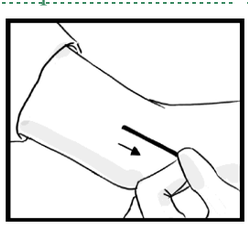
Using the obturator to push, gently advance the implant toward the tip of the trocar until resistance is felt. Never force the obturator.

Step 3



While 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. The obturator must be kept stationary, and avoid pushing the implant into the tissue. Do not completely remove the trocar until both implants have been placed.

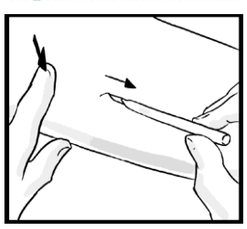
Step 4



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 and 4. The rods are placed in the shape of a “V” opening toward the shoulder. Leave a distance of approximately 5 mm between the incision and the tips of the implants. Remove the trocar.

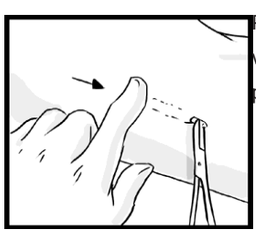
Implant removal

Step 1



Anesthetize the insertion area (by injecting 2 mL of 1% lidocaine). Using the scalpel, make an incision (4 mm for Jadelle and 2 mm for Implanon) close to the proximal ends of the implants (below the bottom of the V for Jadelle and below the single rod for Implanon). Do not make a large incision.

Step 2



Push each implant gently toward the incision with the finger. When the tip of the rod is visible, grasp it with the forceps, and gently pull out the rod with the forceps. Repeat procedure for the second implant (Jadelle).

WHEN SHOULD USE OF SUBDERMAL IMPLANTS BEGIN?

For interval clients

- Any time that the client is reasonably certain that she is not pregnant.
- Within the first seven days of the menstrual cycle, no backup method is needed.
- After the first seven days of the menstrual cycle, condoms should be used, or abstinence should be exercised for the next seven days.

Postpartum, breastfeeding

- As early as six weeks after delivery.
- If only partially breastfeeding, implant should be started at six weeks after childbirth.
- If menses have resumed, the client can start with the implant any time as long as she is reasonably certain that she is not pregnant.

Postpartum, NOT breastfeeding

- Immediately or at any time in the first six weeks after delivery. No need to wait for the client's menstrual period to return.
- After six weeks, implants may be used at any time as long as the client is reasonably certain that she is not pregnant. Otherwise, the client should avoid sex or use condoms until her first menstrual period.

Post-abortion clients

- Immediately or within seven days after an abortion.
- If more than seven days have passed since the abortion, the client may avail of the implants at any time as long as she is reasonably certain that she is not pregnant. She should avoid sex or use condoms for the next seven days.

The table below summarizes the periods when clients can have implants inserted with respect to their previous method.

Table 12. Recommended timing of insertion for women shifting to implants

Previous Method	Timing of Insertion
None or non-hormonal contraceptives	Days 1–5 of cycle
Combined oral contraceptives (COCs)	During hormone-free week
Progestin-only pill (POP)	Any time during treatment
Implanon/Intrauterine System (IUS)	Same day as removal
Progestin-only injectable	When the injection is due
After childbirth, not breastfeeding	Immediately
After childbirth, breastfeeding	Six weeks after childbirth

WHEN SHOULD FOLLOW-UP BE ADVISED?

No routine return visit is required (MEC Recommendation). However, request the client to visit the clinic for removal of the implants according to the manufacturer's recommendations and for any questions or problems that suggest pregnancy or any underlying medical condition. A follow-up visit is recommended for good medical practice. Ask clients to return one week after insertion and yearly thereafter to determine the status of the insertion and to address any complaints.

WHAT ARE THE IMMEDIATE AND LASTING EFFECTS OF USING SUBDERMAL IMPLANTS?

- Light spotting or bleeding between monthly periods is common. Reassure the client that this is normal and common among implant users, especially in the first three to six months. If these conditions are not tolerable, offer the following:
  - Any non-steroidal anti-inflammatory drug (NSAIDs; mefenamic acid or ibuprofen) except aspirin
  - One cycle of low-dose COCs if estrogen is not contraindicated for the client. A COC that has the same progestin in the implant, such as levonorgestrel, is preferable.
- Very heavy or prolonged bleeding may occur but is uncommon. Such bleeding often decreases after the first few months of use. Currently available therapies in stopping unscheduled bleeding in subdermal

contraceptive implant users are shown in Table 13.

- Amenorrhea may occur, but counsel the client that
  - This condition is normal among implant users and is not harmful.
  - She is not pregnant.
  - Her body is not producing menstrual blood and that blood is not building up inside her.
  - This condition can help prevent anemia.
  - If the client still finds this unacceptable, remove the implants or refer for removal. Help her choose another method.
- Weight gain is common but can be remedied by dietary management (low- calorie diet). Explain to the client that other women using contraceptive implants lose weight.
- The insertion site might become infected.
- Some women may complain about enlargement of ovaries, or ovarian cysts. If the cysts are less than 5 cm, the implant can remain in place, but the client should be evaluated by a gynecologist. Reassure the client that these cysts usually disappear on their own and do not require surgery. To check if the problem persists, see the client again after three weeks.
- If the cysts are more than 5 cm, immediately refer the client to a gynecologist. Reassure the client that headaches are not serious and that NSAIDs can be provided.

Table 13. Currently available therapies for stopping bleeding among users of subdermal contraceptive implant

Therapy regimen	Supporting evidence
COC taken daily for 21 days followed by a seven-day break. Use for up to three months.	Little published evidence Anecdotally, appears to help in practice
High-dosecyclical progestogen for up to three months (medroxyprogesterone acetate 10 mg twice daily or norethisterone 5 mg twice daily for 21 days with a seven-day break)	No published evidence Anecdotally, appears to Help in practice
POP, particularly a desogestrel POP, taken daily for up to three months	No published evidence Anecdotally, may wrok in Some cases
NSAIDs, especially COX-2 inhibitors, taken daily for 5 to 10 days	Some publshed evidence Anecdotally,may work in practice
Tranexamic acid, 1 g every six hours for five to seven days	POGS Clinical Practice Guidelines on Abnormal Uterine Bleeding

WHAT ARE THE FACTS ABOUT SUBDERMAL IMPLANTS?

Contrary to popular beliefs,

- implants do not cause cancer. Instead, implants help prevent endometrial cancer.
- in case pregnancy occurs, one in every six pregnancies is ectopic.
- if not removed beyond the recommended period of use, implants no longer provide protection from pregnancy and are relatively inert.

WHAT HAPPENS WHEN THE METHOD IS STOPPED?

Fertility returns without undue delay.

IS A REFERRAL NEEDED? HOW AND WHEN?

The following warning signs and symptoms warrant immediate attention:

- Severe lower abdominal pain. Check for ovarian cysts or tumors, PID, appendicitis, or ectopic pregnancy.
- Severe headaches with blurred vision. Remove the implant, or refer the client to a specialist. Help the client choose a non-hormonal contraceptive.
- Pain after insertion of the rod. Check for signs of infection at the insertion site (pain, heat, and redness) or abscess (presence of pus).

Infection but without abscess

- Do not remove the implant.
- Clean the area with soap and water or an antiseptic.
- Give oral antibiotic for seven days, and ask the client to return after a week. If the condition does not improve, remove the implant, or refer the client to an appropriate specialist.

Infection with abscess

- Prepare infected area with antiseptic, make an incision, and drain the pus.
- Remove the implant, or refer the client to a specialist.
- Treat the wound, and give oral antibiotics for seven days.

WHAT COUNSELING TIPS SHOULD BE OFFERED TO THE CLIENT?

Advise the client on the following:

- The physical characteristics of the implants and how they should feel under the skin
- The procedures of insertion and removal, as well as the cost
- When to remove the implant and the implication when the effective life span of the implant has expired
- Possible changes in menstrual patterns, which usually decrease with time
- Side effects and complications to watch out for