



## ADVERSE REACTIONS

The following adverse reactions have been associated with the NORPLANT SYSTEM during the first year of use. They include:

Many bleeding days or prolonged bleeding	27.6%
Spotting	17.1%
Amenorrhea	9.4%
Irregular (onsets of) bleeding	7.6%
Frequent bleeding onsets	7.0%
Scanty bleeding	5.2%
Pain or itching near implant site (usually transient)	3.7%
Infection at implant site	0.7%

In addition, removal difficulties affecting subjects (including multiple incisions, capsule fragments remaining, pain, multiple visits, deep placement, lengthy removal procedure, or other) have been reported with a frequency of 6.2%, which is based on 849 removals occurring through 5 years of use. See "WARNINGS" and "PRECAUTIONS."

Clinical studies comparing NORPLANT SYSTEM users with other contraceptive method users suggest that the following adverse reactions occurring during the first year are probably associated with NORPLANT SYSTEM use. These adverse reactions have also been reported post-marketing:

Headache	Acne
Nervousness/Anxiety	Change of appetite
Nausea/Vomiting	Mastalgia
Dizziness	Weight gain
Adnexal enlargement	Hirsutism, hypertrichosis, and scalp-hair loss
Dermatitis/Rash	

In addition, the following adverse reactions have been reported with a frequency of 5% or greater during the first year and are possibly related to NORPLANT SYSTEM use:

Breast discharge	Abdominal discomfort
Cervicitis	Leukorrhea
Musculoskeletal pain	Vaginitis

The following adverse reactions have been reported post-marketing with an incidence of less than 1% and are possibly related to NORPLANT SYSTEM use:

Emotional lability	Dysmenorrhea
Idiopathic intracranial hypertension (IIH)	Migraine
pseudotumor cerebri, benign intracranial hypertension)	Arm pain
Induration	Depression
Bruising	Excessive scarring
Abscess, cellulitis	Hyperpigmentation
	Nerve injury

The following adverse reactions have been reported post-marketing with an incidence of less than 1%. These events occurred under circumstances where a causal relationship to the NORPLANT SYSTEM is unknown. These reactions are listed as information for physicians:

Breast cancer	Thrombotic thrombocytopenic purpura (TTP)
Congenital anomalies	Stroke
Pulmonary embolism	Pruritus
Superficial venous thrombosis	Urticaria
Deep-vein thrombosis	Asthenia (fatigue/weakness)
Myocardial infarction	Phlebitis
Blistering, ulcerations, and sloughing	

## OVERDOSAGE

Overdosage can result if more than six capsules of the NORPLANT SYSTEM are in situ. All implanted NORPLANT SYSTEM capsules should be removed before inserting a new set of NORPLANT SYSTEM capsules. Overdosage may cause fluid retention with its associated effects and uterine bleeding irregularities.

## DOSAGE AND ADMINISTRATION

The NORPLANT SYSTEM consists of six Silastic® capsules, each containing 36 mg of the progestin, levonorgestrel. The total administered (implanted) dose is 216 mg. Implantation of all six capsules should be performed during the first 7 days of the onset of menses by a health-care professional instructed in the NORPLANT SYSTEM insertion technique. Insertion is subdermal in the midportion of the upper arm about 8 to 10 cm above the elbow crease. Distribution should be in a fanlike pattern, about 15 degrees apart, for a total of 75 degrees. Proper insertion will facilitate later removal. (See section on Insertion/Removal.)

## HOW SUPPLIED

The NORPLANT SYSTEM Kit includes the following items:

1 NORPLANT SYSTEM (levonorgestrel implants), a set of six implants (capsules)	1 Package of skin closures
1 NORPLANT SYSTEM trocar	3 Packages of gauze sponges
1 Scalpel	1 Stretch bandage
1 Forceps	1 Surgical drape (fenestrated)
1 Syringe	2 Surgical drapes
2 Syringe needles	

Store at room temperature away from excess heat and moisture.

NDC 0008-2564-01

References available upon request.

## INSTRUCTIONS FOR INSERTION AND REMOVAL

The NORPLANT SYSTEM consists of six levonorgestrel-releasing capsules that are inserted subdermally in the medial aspect of the upper arm.

The NORPLANT SYSTEM provides up to 5 years of effective contraceptive protection.

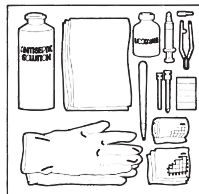
The basis for successful use and subsequent removal of NORPLANT SYSTEM capsules is a correct and carefully performed subdermal insertion of the six capsules. It is recommended that health-care professionals performing insertions or removals of NORPLANT SYSTEM capsules avail themselves of instruction and supervision in the proper technique prior to attempting these procedures. During insertion, special attention should be given to the following:

- asepsis.
- correct subdermal placement of the capsules.
- careful technique to minimize tissue trauma.

This will help to avoid infections and excessive scarring at the insertion area and will help keep the capsules from being inserted deeply in the tissue. If the capsules are placed deeply, they will be more difficult to remove than correctly placed subdermal capsules.

### Insertion Procedure

Insertion should be performed within seven days from the onset of menses. However, NORPLANT SYSTEM capsules may be inserted at any time during the cycle provided pregnancy has been excluded and a nonhormonal contraceptive method is used for at least 7 days following insertion. It is recommended that a complete history and physical examination, including a gynecologic examination, be performed before the insertion of NORPLANT SYSTEM capsules. Determine if the subject has any allergies to the antiseptic or anesthetic to be used or contraindications to progestin-only contraception. If none are found, the capsules are inserted using the procedure outlined below. One NORPLANT SYSTEM set consists of six capsules in a sterile pouch. The insertion is performed under aseptic conditions using a trocar to place the capsules under the skin.



**Figure 1:** The following equipment is recommended for the insertion:

- an examining table for the patient to lie on.
- sterile surgical drapes, sterile gloves (free of talc), antiseptic solution.
- local anesthetic, needles, and syringe.
- #11 scalpel, #10 trocar, forceps.
- skin closure, sterile gauze, and compresses.

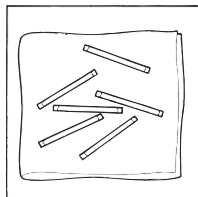
The plastic cover and tray are NOT STERILE.



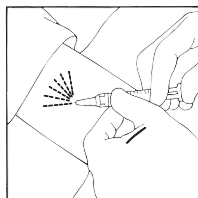
**Figure 2:** Have the patient lie on her back on the examination table with her left arm (if the patient is left-handed, the right arm) flexed at the elbow and externally rotated so that her hand is lying by her head. The capsules will be inserted subdermally through a small 2-mm incision and positioned in a fanlike manner with the fan opening towards the shoulder.



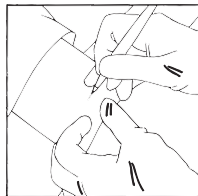
**Figure 3:** Prep the patient's upper arm with antiseptic solution; cover the arm above and below the insertion area with a sterile cloth. The optimal insertion area is in the inside of the upper arm about 8 to 10 cm above the elbow crease.



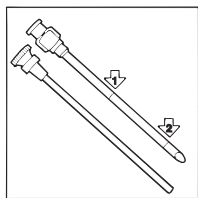
**Figure 4:** Open the sterile NORPLANT SYSTEM (levonorgestrel implants) package carefully by pulling apart the sheets of the pouch, allowing the capsules to fall onto a sterile drape. Count the six capsules.



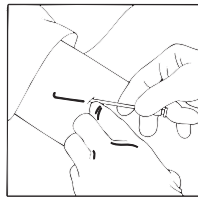
**Figure 5:** After determining the absence of known allergies to the anesthetic agent or related drugs, fill a 5-mL syringe with the local anesthetic. Since blood loss is minimal with this procedure, use of epinephrine-containing anesthetics is not considered necessary. Anesthetize the insertion area by first inserting the needle under the skin and injecting a small amount of anesthetic. Then anesthetize six areas about 4 to 4.5 cm long, to mimic the fanlike position of the implanted capsules.



**Figure 6:** Use the scalpel to make a small incision (about 2 mm) just through the dermis of the skin. Alternatively, the trocar may be inserted directly through the skin without making an incision with the scalpel. The bevel of the trocar should always face up during the insertion.



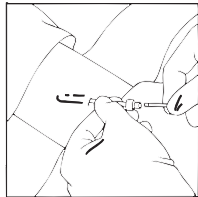
**Figure 7:** The trocar has two marks on it. The first mark is closer to the hub and indicates how far the trocar should be introduced under the skin before the loading of each capsule. The second mark is close to the tip and indicates how much of the trocar should remain under the skin following the insertion of each implant.



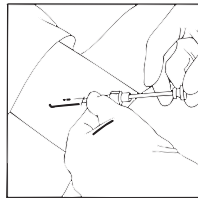
**Figure 8:** Insert the tip of the trocar through the incision beneath the skin at a shallow angle. Once the trocar is inserted, it should be oriented with the bevel up toward the skin to keep the capsules in a superficial plane. It is important to keep the trocar subdermal by tenting the skin with the trocar, as failure to do so may result in deep placement of the capsules and could make removal more difficult.

Advance the trocar gently under the skin to the first mark near the hub of the trocar. The tip of the trocar is now at a distance of about 4 to 4.5 cm from the incision.

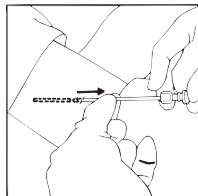
Do not force the trocar, and if resistance is felt, try another direction.



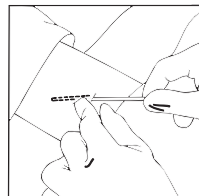
**Figure 9:** When the trocar has been inserted the appropriate distance, remove the obturator and load the first capsule into the trocar using the thumb and forefinger.



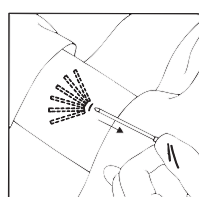
**Figure 10:** Gently advance the capsule with the obturator towards the tip of the trocar until you feel resistance. Never force the obturator.



**Figure 11:** Hold the obturator steady, and bring the trocar back until it touches the handle of the obturator.

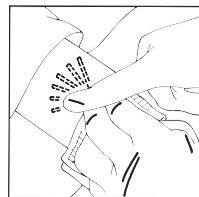


**Figure 12:** The capsule should have been released under the skin when the mark close to the tip of the trocar is visible in the incision. Release of the capsule can be checked by palpation. It is important to keep the obturator steady and not to push the capsule into the tissue.



**Figure 13:** Do not remove the trocar from the incision until all capsules have been inserted. The trocar is withdrawn only to the mark close to its tip. Each succeeding capsule is always inserted next to the previous one, to form a fanlike shape. Fix the position of the previous capsule with the forefinger and middle finger of the free hand, and advance the trocar along the tips of the fingers. This will ensure a suitable distance of about 15 degrees between capsules and keep the trocar from puncturing any of the previously inserted capsules.

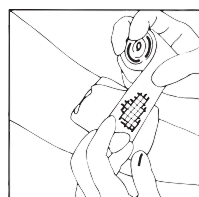
Leave a distance of about 5 mm between the incision and the tips of the capsules. This will help avoid spontaneous expulsions. The correct position of the capsules can be ensured by feeling them with the fingers after the insertion has been completed.



**Figure 14:** After placement of the sixth capsule, a sterile gauze may be used to apply pressure briefly to the insertion site to ensure hemostasis. Palpate the distal ends of the capsules to make sure that all six have been properly placed.



**Figure 15:** Press the edges of the incision together, and close the incision with a skin closure. Suturing the incision should not be necessary.



**Figure 16:** Cover the insertion area with a dry compress, and wrap gauze around the arm to ensure hemostasis. Observe the patient for a few minutes for signs of syncope or bleeding from the incision before she is discharged. Advise the patient to keep the insertion area dry and avoid heavy lifting for 2 to 3 days. The gauze may be removed after 1 day, and the butterfly bandage as soon as the incision has healed, i.e., normally in 3 days.

## Removal Procedure

Described below is a removal procedure which was developed and used during the clinical trials for the NORPLANT SYSTEM (levonorgestrel implants). As with many surgical procedures, variations of the technique have appeared and some have been published. No one particular procedure routinely appears to have any advantage over another.

It is recommended that removals be prescheduled so that preparations for carrying out the procedure can be facilitated.

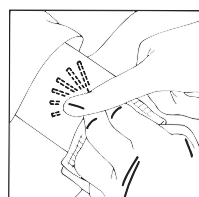
Removal of the capsules should be performed very gently and will usually take more time and may be more difficult and/or more painful than insertion. Capsules are sometimes nicked, cut, or broken during removal, or may be difficult to locate. The incidence of overall removal difficulties, including those that did not result in patient complaints (e.g., damage to the capsules), was 13.2%. Less than half of these removal difficulties have caused inconvenience to the patient. If the removal of some of the capsules proves difficult, have the patient return for another visit. The remaining capsule(s) will be easier to remove after the area is healed. It may be appropriate to seek consultation or provide referral for patients in whom initial attempts at capsule removal prove difficult. If contraception is still desired, a barrier method should be advised until all capsules are removed.

The position of the patient and the asepsis are the same as for insertion.

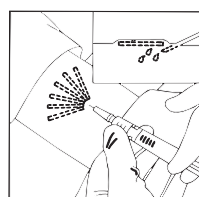


**Figure 17:** The following equipment is needed for the removal:

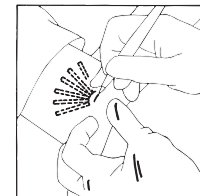
- an examining table for the patient to lie on.
- sterile surgical drapes, sterile gloves (free of talc), antiseptic solution.
- local anesthetic, needles, and syringe.
- #11 scalpel, forceps (straight and curved mosquito).
- skin closure, sterile gauze, and compresses.



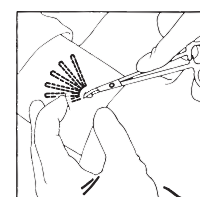
**Figure 18:** Palpate the capsules to make sure that all six capsules have been located, marking their position with a sterile marker. If all six capsules cannot be located by palpation, they may be localized by ultrasound (7 MHz), X-ray, or compression mammography.



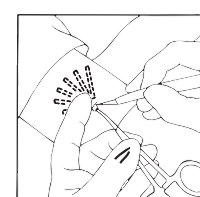
**Figure 19:** Once all six capsules are located, apply a small amount of local anesthetic under the capsule ends nearest the original incision site. This will serve to raise the ends of the capsules. Anesthetic injected over the capsules will obscure them and make removal more difficult. Additional small amounts of the anesthetic can be used for the removal of each of the capsules, if required.



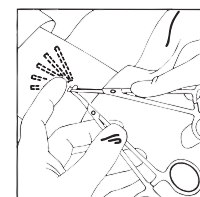
**Figure 20:** Make a 4-mm incision with the scalpel close to the ends of the capsules. Do not make a large incision.



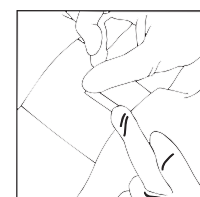
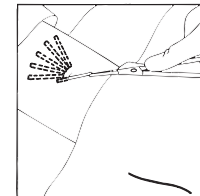
**Figure 21:** Push each capsule gently towards the incision with the fingers. When the tip is visible or near to the incision, grasp it with a mosquito forceps.



**Figure 22:** Use the scalpel, forceps, or gauze to very gently open the tissue sheath that has formed around the capsule.



**Figures 23 and 24:** Remove the capsule from the incision with the second forceps.



**Figures 25 and 26:** After the procedure is completed, the incision is closed and bandaged as with insertion. The upper arm should be kept dry for a few days.

Following removal, fertility rates return to levels comparable to those seen in the general population of women using no method of contraception, and a pregnancy may occur at any time. If the patient wishes to continue using the method, a new set of NORPLANT SYSTEM (levonorgestrel implants) capsules can be inserted through the same incision in the same or opposite direction.

## HINTS

### Insertion

- Counseling of the patient on the benefits and side effects of the method prior to insertion will greatly increase patient satisfaction.
- Correct subdermal placement of the capsules will facilitate removal.
- Before insertion, apply the anesthetic just beneath the skin so as to raise the dermis above the underlying tissue.
- Never force the trocar.
- To ensure subdermal placement, the trocar with bevel up should be supported by the index finger and should visibly raise the skin at all times during insertion.
- To avoid damaging the previous implanted capsule, stabilize the capsule with your forefinger and middle finger and advance the trocar alongside the finger tips at an angle of 15 degrees.
- After insertion, make a drawing for the patient's file showing the location of the 6 capsules and describe any variations in placement. This will greatly aid removal.

### REMOVAL

- Alternate removal techniques have been developed.
- The removal of the implants will usually take more time and may be more difficult and/or more painful than the insertion. Capsules are sometimes nicked, cut, or broken during removal, or may be difficult to locate.
- Before initiating removal, all capsules should be located by palpation. If all six capsules cannot be located by palpation, they may be localized by ultrasound (7 MHz), X-ray, or compression mammography.
- Before removal, apply the anesthetic under the capsule ends nearest the original incision site.
- If the removal of some of the capsules proves difficult, interrupt the procedure and have the patient return for another visit. The remaining capsule(s) will be easier to remove after the area is healed.
- It may be appropriate to seek consultation or provide referral for patients in whom initial attempts at capsule removal prove difficult.