

NORPLANT[®] SYSTEM

(levonorgestrel implants)

This product is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases (STDs) such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

PATIENT LABELING

WHAT YOU SHOULD KNOW ABOUT NORPLANT BEFORE YOU DECIDE TO USE IT

You need to read and understand this leaflet *before* you decide to use the NORPLANT SYSTEM. The leaflet contains information vital to your health. It tells you about the benefits and risks of NORPLANT. Discuss it with your health-care professional. Ask them to explain anything you do not understand.

There is a more technical leaflet about NORPLANT that was written for health-care professionals. If you would like to read that leaflet too, ask your health-care professional for a copy. You may need their help to understand some of the information.

There is also a videotape that provides more information about the NORPLANT SYSTEM. If you would like to watch it, ask your health-care professional.

Before you decide to use NORPLANT or any other birth control method, compare it to other birth control methods. If you want to learn more about other methods, ask your health-care professional. One of these other methods may be better for you than NORPLANT.

NORPLANT is different from other methods of birth control. The capsules are made of Silastic[®], a silicone rubber tubing. It must be inserted in your arm during a minor surgical procedure. The procedure can be performed by a health-care professional in the office. It is important that health-care professionals who insert NORPLANT be instructed in both insertion and removal procedures. You should know that some health-care professionals have more experience than others in inserting and removing NORPLANT. Be sure to discuss with your health-care professional whether he/she has received instruction in how to insert NORPLANT and remove it and his/her level of confidence in insertion and removal procedures.

You can decide to have NORPLANT removed at any time. Removals can also be performed by a health-care professional in the office. You should know that removing NORPLANT may be more difficult than inserting it. It may take longer and involve more pain. It may leave scars. This risk does not exist with most other birth control methods.

Some women should not use NORPLANT. To find out whether you are one of those women, talk to your health-care professional and read below the sections entitled “**WHO SHOULD NOT USE THE NORPLANT SYSTEM**” and “**OTHER CONSIDERATIONS BEFORE CHOOSING THE NORPLANT SYSTEM.**”

Some women who use NORPLANT will experience side effects. You should know the danger signs. To learn about them, talk to your health-care professional and read below the sections entitled “**RISKS OF USING THE NORPLANT SYSTEM,**” “**WARNING SIGNALS,**” “**PRECAUTIONS,**” and “**SIDE EFFECTS OF THE NORPLANT SYSTEM.**”

INTRODUCTION

Each woman who considers using the NORPLANT SYSTEM should understand the benefits and risks of this form of family planning as compared with other contraceptive methods. This leaflet will give you much of the information you will need to make this decision, but it is not a replacement for a careful discussion with your health-care professional. You should discuss the information provided in this leaflet with him or her, both when choosing whether to use the NORPLANT SYSTEM and during revisits. You should also follow your health-care professional’s advice with regard to regular checkups while using the NORPLANT SYSTEM.

The NORPLANT SYSTEM consists of six thin, flexible capsules, made of silicone rubber tubing (Silastic[®]), that are inserted just under the skin on the inside of your upper arm in a minor, outpatient surgical procedure. The capsules contain a synthetic hormone, levonorgestrel (a progestin), that is also used as one of the active ingredients in many oral contraceptives. Immediately after insertion of the NORPLANT SYSTEM, a low continuous dose of the hormone is released into your body. Pregnancy is prevented through a combination of mechanisms. The most important ways are by inhibiting ovulation, so eggs will not be produced regularly, and thickening the cervical mucus, making it more difficult for the sperm to reach the egg. There may also be other mechanisms that contribute to these contraceptive effects. When the NORPLANT SYSTEM capsules are removed, the drug is cleared from the body within 5 to 14 days and a woman can become pregnant at a rate similar to women who have not used the method.

EFFECTIVENESS OF NORPLANT SYSTEM

(levonorgestrel implants)

The NORPLANT SYSTEM is one of the most effective reversible contraceptive methods. No contraceptive is 100-percent effective. The average annual pregnancy rate over a 5-year period for the NORPLANT SYSTEM (levonorgestrel implants) is less than 1%. It is less than one pregnancy for every 100 women during the first year of use. In comparison, pregnancy rates that have been experienced with other methods of family planning during the first year of use are as follows:

Average Failure Rates (%)
During the First Year of Use of a Contraceptive Method

Methods	Average
NORPLANT SYSTEM	0.05
Male sterilization	0.15
Female sterilization	0.5
Depo-Provera [®] (injectable progestogen)	0.3
Oral contraceptives	5
IUD	
Progesterone	2.0
Copper T 380A	0.8
Condom (male) without spermicide	14
(female) without spermicide	21
Cervical cap	
Never given birth	20
Given birth	40
Diaphragm with spermicidal cream or jelly	20
Spermicides alone (foam, creams, jellies, and vaginal suppositories)	26
Periodic abstinence (all methods)	25
Withdrawal	19
No contraception (planned pregnancy)	85

Except for the NORPLANT SYSTEM, sterilization, and the IUD, the efficacy of these methods depends in part on how reliably they are used.

The NORPLANT SYSTEM may be less effective in preventing pregnancy in heavier women. Discuss this with your health-care professional.

The NORPLANT SYSTEM provides five years of protection against pregnancy but can be removed at any time. At the end of the fifth year, the capsules will be less effective and must be removed; a new set may be inserted at the time of removal for continued protection.

WHO SHOULD NOT USE THE NORPLANT SYSTEM

Some women should not use the NORPLANT SYSTEM. You should not have the capsules inserted if you are pregnant or think you may be pregnant. You should not use the NORPLANT SYSTEM if you have:

- Acute liver disease; noncancerous or cancerous liver tumors;
- Unexplained vaginal bleeding (until a diagnosis is reached by your health-care professional);
- Known or suspected breast cancer;

- Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), or eyes. Women who have had previous blood clots should consult with their health-care professional whether to use the NORPLANT SYSTEM;
- History of idiopathic intracranial hypertension (pseudotumor cerebri, benign intracranial hypertension);
- Hypersensitivity to levonorgestrel or any of the other components of the NORPLANT SYSTEM.

OTHER CONSIDERATIONS BEFORE CHOOSING THE NORPLANT SYSTEM

Tell your health-care professional if you or any family member has ever had:

- Breast nodules, fibrocystic disease of the breast, an abnormal breast X-ray or mammogram;
- Diabetes;
- Elevated cholesterol or triglycerides;
- High blood pressure;
- Headaches;
- Gallbladder, heart, or kidney disease;
- History of scanty or irregular menstrual periods;
- History of blood clots, heart attack or stroke;
- Depression;
- Migraine;
- Ectopic pregnancy.

Women with these conditions may need to be checked more often by their health-care professional if they choose the NORPLANT SYSTEM.

Be sure to inform your health-care professional if you smoke or are on any medications.

RISKS OF USING THE NORPLANT SYSTEM

A. Risks Based on Experience with the NORPLANT SYSTEM

1. Insertion and Removal Complications

A surgical incision is required to insert NORPLANT SYSTEM capsules. Complications related to insertion such as pain, swelling, and bruising may occur. There have also been reports of infection, blistering, ulcerations, sloughing, excessive scarring, phlebitis (inflammation of a vein), and discoloration of the skin at the insertion site. There have been reports of arm pain, numbness, and tingling following the insertion and removal procedures. There also have been

reports of nerve injury, most commonly associated with deep placement and removal. Expulsion of capsules (i.e., when a capsule unintentionally comes out of the insertion site/skin) has been reported more frequently when they were placed too close to the skin or too close to the incision or when infection was present.

After NORPLANT SYSTEM (levonorgestrel implants) capsules are inserted, they sometimes move from the original position, which may make them more difficult to remove. Infrequently, movement of a few to several inches has been reported. Some NORPLANT SYSTEM users have reported movement accompanied by pain and discomfort. Contact your health-care professional in the event that capsule movement accompanied by pain and/or discomfort occurs.

Removal is also a surgical procedure and may take longer, be more difficult, and/or cause more pain than insertion and may be associated with difficulty locating capsules. These complications may lead to the need for additional incisions and/or office visits. See also “**PRECAUTIONS**” and “**SIDE EFFECTS OF THE NORPLANT SYSTEM.**”

2. Irregular Menstrual Bleeding (also see “SIDE EFFECTS OF THE NORPLANT SYSTEM**”)**

Most women experience some change in their usual monthly pattern. These menstrual irregularities vary from woman to woman and include:

- Prolonged bleeding (more days than you would usually experience), commonly during the first months of use;
- Untimely bleeding or spotting between periods;
- No bleeding at all for several months; or
- A combination of these patterns.

It cannot be predicted what kind of change you may experience. If increased frequency of bleeding occurs, the quantity of blood lost is rarely enough to cause anemia, but there have been a few cases that required treatment. In rare instances, patients experienced heavy bleeding that resulted in anemia. The irregularities frequently diminish gradually with continuing use.

3. Delayed Disappearance of Ovarian Follicles/Ovarian Cysts

If follicles (eggs and their surrounding cells) in the ovary develop while using the NORPLANT SYSTEM, disintegration or disappearance of the follicles is sometimes delayed, and the follicles may continue to grow beyond the size they would normally reach. These enlarged follicles, which are sometimes called ovarian cysts, may produce discomfort in some women, although most users would not be aware of them unless they were found incidentally on a physical exam. In the majority of women, enlarged follicles will disappear on their own and should not require surgery. Rarely, they may twist or rupture so that surgery is required. You should discuss this with your health-care professional.

4. Ectopic Pregnancies

Ectopic pregnancies (development of the fertilized egg outside of the uterus, sometimes called a tubal pregnancy) have occurred among NORPLANT SYSTEM users. Symptoms of an ectopic pregnancy include spotting and cramping pain, which usually begin shortly after the first missed period. Contact your health-care professional should you miss a period or experience abdominal pain.

5. Diseases of the Heart and Blood Vessels

As with oral contraceptives, there have been reports of blood clots and blockage of blood vessels in NORPLANT SYSTEM users. Blood clots and blockage of blood vessels can be serious. In particular, a clot in the veins of the legs can cause inflammation and risk of further clots, and a clot that travels to the lungs can cause a sudden blockage of the vessel carrying blood to the lungs, resulting in respiratory collapse and even death. Rarely, clots occur in the blood vessels of the eye and may cause double vision, impaired vision, or even blindness. There have also been reports of heart attacks and strokes while the NORPLANT SYSTEM (levonorgestrel implants) has been in place. Any of these conditions can cause serious disability or death.

Patients who develop blood clots in the legs, arms, lungs, or eyes should have the NORPLANT SYSTEM removed. In addition, patients restricted to bed rest or who have limited movement for a prolonged period due to surgery or other illness may be at increased risk of developing blood clots. The NORPLANT SYSTEM may need to be removed in such patients.

6. Idiopathic Intracranial Hypertension (*pseudotumor cerebri, benign intracranial hypertension*)

An increase in intracranial pressure has been reported in NORPLANT SYSTEM users. Symptoms may include headache (associated with a change in frequency, pattern, severity, or persistence; of particular importance are those headaches that do not stop) and visual disturbances. Contact your physician or health-care professional if you experience these symptoms, particularly if you are obese or have had recent weight gain. Your health-care professional may recommend that the NORPLANT SYSTEM be removed.

B. Risks Based on Experience with Combination Oral Contraceptives

Combination pills contain a progestin such as levonorgestrel and an estrogen, another type of hormone. Some rare but serious side effects have been associated with use of the combination pill. It is unknown whether the risks associated with combined oral-contraceptive use may also be risks with a progestin-only contraceptive like the NORPLANT SYSTEM.

Risks Associated with Combination Oral Contraceptives Include:

1. Risk of Heart Attacks and Strokes

The combination pill may increase the tendency to develop strokes (stoppage or rupture of blood vessels in the brain), angina pectoris, or heart attacks (blockage of blood vessels to the heart). Any of these conditions can cause death or serious disability. Smoking greatly increases the probability of suffering heart attacks and stroke.

Use of combination oral contraceptives together with cigarette smoking greatly increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and with the amount of smoking (15 or more cigarettes per day has been associated with a significantly increased risk) and is quite marked in women over 35 years of age who smoke. It is not known whether a similar interaction occurs with the NORPLANT SYSTEM. Therefore, women who use the NORPLANT SYSTEM should not smoke.

2. High Blood Pressure

An increase in blood pressure has been reported in combination oral-contraceptive users.

3. Gallbladder Disease

Combined-pill users probably have a greater risk than nonusers of gallbladder disease. Since this risk may be related to pills containing high doses of estrogens, it may not be a concern for NORPLANT SYSTEM users.

4. Liver Tumors

In rare cases, the combination oral contraceptive can cause noncancerous but dangerous liver tumors. These benign liver tumors can rupture and cause fatal internal bleeding. In addition, a possible but not definite association has been found with the pill and liver cancers. However, liver cancers are very rare.

5. Cancer of the Reproductive Organs

Breast cancer has been diagnosed slightly more often in women who use the pill than in women of the same age who do not use the pill. This very small increase in the number of breast cancer diagnoses gradually disappears during the 10 years after stopping use of the pill. It is not known whether the difference is caused by the pill. It may be that women taking the pill were examined more often, so that breast cancer was more likely to be detected. Some studies have found an increase in the incidence of cancer or precancerous lesions of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives.

WARNING SIGNALS

If any of these adverse effects occur following insertion of the NORPLANT[®] SYSTEM (levonorgestrel implants), call your health-care professional immediately:

- Sharp chest pain, coughing of blood, or sudden shortness of breath (indicating a possible clot in the lung);
- Pain in the calf or arm (indicating a possible clot in the leg or arm);
- Crushing chest pain or heaviness in the chest (indicating a possible heart attack);
- Sudden severe or persistent headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg (indicating a possible stroke or other neurologic problem);

- Persistent headaches, particularly if obese or recent weight gain (indicating possible idiopathic intracranial hypertension);
- Sudden partial or complete loss of vision (indicating a possible clot in the eye);
- Breast lumps (indicating possible breast cancer or fibrocystic disease of the breast; ask your health-care professional to show you how to examine your breasts);
- Severe pain or tenderness in the stomach area or lower abdominal area (indicating an ectopic pregnancy, a ruptured or twisted ovarian follicle, or possibly a ruptured liver tumor);
- Difficulty in sleeping, weakness, lack of energy, fatigue, or change in mood (possibly indicating severe depression);
- Jaundice or a yellowing of the skin or eyeballs, accompanied frequently by fever, fatigue, loss of appetite, dark-colored urine, or light-colored bowel movements (indicating possible liver problems);
- Heavy vaginal bleeding;
- Delayed menstrual cycles after a long interval of regular cycles;
- Arm pain;
- Pus or bleeding at implant site;
- Expulsion of a capsule.

PRECAUTIONS

General

This product is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases (STDs) such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

1. *Physical Examination and Follow-Up* – Prior to insertion of NORPLANT SYSTEM (levonorgestrel implants) capsules, your health-care professional will inquire about your medical history and perform a physical exam, including a gynecologic exam. Be sure to have periodic checkups as advised by your health-care professional while the capsules are in place.

2. *Insertion and Removal* – You should not have capsules inserted if you are pregnant. NORPLANT SYSTEM capsules should be inserted within 7 days after onset of menstrual bleeding or immediately following an abortion to provide effective contraception during the first cycle of use. If NORPLANT SYSTEM capsules are inserted at any other time during the cycle, pregnancy must be excluded, and a nonhormonal contraceptive method (such as condoms, spermicides, or diaphragms) must be used for at least 7 days following insertion.

The NORPLANT SYSTEM should be inserted and removed by a health-care professional who is familiar with the appropriate insertion and removal techniques. If infection occurs after insertion, contact your health-care professional for treatment. The NORPLANT SYSTEM may need to be removed in the event that infection continues.

If expulsion of a capsule occurs, your health-care professional should replace it with a new capsule that has not been previously used. If infection is present, it should be treated and cured before capsule(s) is (are) replaced. To avoid pregnancy, a back-up method of contraception should be used if less than six capsules are in place.

The capsules must be removed at the end of five years when the method starts to become less effective. They can be removed at any time before then, however, if you want to stop using the method for any reason. If the capsules are placed deeply, they can be more difficult to remove. If some of the capsules are more difficult to remove, additional visits and incisions may be required.

See also “**RISKS OF USING THE NORPLANT SYSTEM,**” “**SIDE EFFECTS OF THE NORPLANT SYSTEM,**” and “**INSERTION AND REMOVAL OF THE NORPLANT SYSTEM CAPSULES.**”

3. *Carbohydrate and Lipid Metabolism* – Blood sugar levels may be increased by progestin-only contraceptives such as the NORPLANT SYSTEM (levonorgestrel implants). Diabetic patients should be observed carefully while using the NORPLANT SYSTEM.

Some progestins may increase lipid (e.g., cholesterol, triglycerides) levels. Patients being treated for increased lipid levels should be followed closely while using the NORPLANT SYSTEM.

4. *Liver Function* – The NORPLANT SYSTEM may need to be removed if yellowing of the skin or whites of the eyes occurs. Hormones may be poorly metabolized in patients with liver diseases.

5. *Fluid Retention* – Hormonal contraception may cause fluid retention with swelling of the fingers or ankles and may raise your blood pressure. If you experience fluid retention, contact your health-care professional.

6. *Emotional Disorders* – The NORPLANT SYSTEM may need to be removed if you become severely depressed.

7. *Contact Lenses* – If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your health-care professional.

8. *While Breast-feeding* – Women who are breast-feeding or intend to breast-feed should discuss this with their health-care professional when considering the use of the NORPLANT SYSTEM. Studies have shown no significant effects on the growth or health of infants whose mothers used the NORPLANT SYSTEM beginning five to seven weeks after childbirth. There is no experience to support the use of the NORPLANT SYSTEM in breast-feeding mothers earlier than this after childbirth.

Drug Interactions

Certain drugs may interact with the hormone delivered by the NORPLANT SYSTEM to make the capsules less effective in preventing pregnancy. Such drugs include drugs used for epilepsy, such as phenytoin (Dilantin[®] is one brand) and carbamazepine (Tegretol[®] is one brand). Certain other drugs may also make the NORPLANT SYSTEM less effective. You may need to use additional contraception when you take drugs that can make the NORPLANT SYSTEM less effective. Discuss this with your health-care professional.

Drug/Laboratory Tests Interactions

If you are scheduled for any laboratory tests tell your health-care professional that you are using the NORPLANT SYSTEM. Certain blood tests are affected by synthetic hormones.

SIDE EFFECTS OF THE NORPLANT SYSTEM

The most frequently reported side effects are menstrual cycle irregularities. Such changes vary from woman to woman and may include:

- Prolonged menstrual bleeding (more days than you would usually experience), commonly during the first months of use;
- Untimely bleeding or spotting between periods;
- Frequent onset of bleeding;
- Scanty bleeding;
- No bleeding at all for several months; or
- A combination of these patterns.

It cannot be predicted before insertion of the NORPLANT SYSTEM what kind of bleeding pattern you will have. Many women can expect an altered bleeding pattern to become more regular after 9 to 12 months. Despite the increased frequency of bleeding in some women, the monthly blood loss is usually less than normal menses. In fact, in some studies, patient blood counts have improved.

Contact your health-care professional if you experience heavy bleeding. If you have normal cyclic periods and then miss a period, a pregnancy test should be obtained. If you are pregnant, the NORPLANT SYSTEM must be removed.

There have been rare reports of birth defects in offspring of women who were using the NORPLANT SYSTEM unintentionally during early pregnancy. Though the association has been neither confirmed nor refuted, you should check with your health-care professional about the risks to your unborn child of any medication taken during pregnancy.

Women using the NORPLANT SYSTEM have complained about the following conditions, which are probably related to the NORPLANT SYSTEM:

- Headache;
- Nervousness/Anxiety;
- Nausea/Vomiting;
- Dizziness;
- Enlargement of the ovaries and/or fallopian tubes;
- Dermatitis (inflammation of the skin)/Rash;
- Acne;
- Change of appetite;
- Weight gain;
- Mastalgia (breast tenderness);
- Hirsutism (excessive growth of body or facial hair) or alopecia (hair loss);
- Discoloration of the skin over the site of implantation (usually reversible).

Preexisting conditions of acne or excessive growth of body or facial hair could also be worsened. Occasionally, an infection may occur at the implant site, or there may be a brief incidence of pain or itching. Removals may be more difficult than insertions in some cases.

An enlargement of ovarian follicles (sometimes called ovarian cysts) may occur in NORPLANT SYSTEM (levonorgestrel implants) users. These would be detectable during a physical examination. The enlarged follicles usually disappear on their own without surgical intervention, but in rare instances they may twist or rupture, so that surgery is required.

Women using the NORPLANT SYSTEM have complained about the following conditions, which are possibly related to the NORPLANT SYSTEM:

- Abdominal discomfort;
- Arm pain;
- Breast discharge;
- Cervicitis (inflammation of the cervix, detected by physician);
- Gallbladder disease;

- High blood pressure;
- Idiopathic intracranial hypertension (pseudotumor cerebri);
- Implantation site reactions including blistering; bruising; excessive scarring; hyperpigmentation (darkening of the skin); induration (hardening of tissue); infection; nerve injury; numbness; sloughing; swelling (edema); tingling; ulcerations;
- Leukorrhea (whitish discharge from the vagina and uterine cavity);
- Migraine headaches;
- Muscle and skeletal pain;
- Phlebitis (inflammation of a vein);
- Vaginitis (inflammation of the vagina).

There are a number of other complaints reported by NORPLANT SYSTEM users or discovered by health-care professionals, but an association with the NORPLANT SYSTEM has been neither confirmed nor refuted:

- Birth defects;
- Blood clots (for example in the arms, legs, or lungs);
- Breast cancer;
- Dysmenorrhea (pain during menstruation);
- Fatigue/Weakness;
- Heart attack;
- Mood swings, including depression, sometimes severe;
- Stroke;
- Thrombotic thrombocytopenic purpura (TTP);
- Urticaria (hives), pruritus (itching);
- Vaginal bleeding, heavy;
- Vision disturbances;
- Weight gain of more than 10 pounds.

INSERTION AND REMOVAL OF THE NORPLANT SYSTEM CAPSULES

A. Insertion

Insertion and removal of the NORPLANT SYSTEM should be performed by a health-care professional knowledgeable of the procedures.

Prior to insertion of NORPLANT SYSTEM capsules, your health-care professional will inquire about your medical history and perform a physical examination. To make sure you are not already pregnant, NORPLANT SYSTEM capsules should be inserted within 7 days after the onset of menstrual bleeding or immediately following an abortion. If NORPLANT SYSTEM capsules are inserted at any other time during the cycle, pregnancy must be excluded, and a nonhormonal contraceptive method (such as condoms, spermicides, or diaphragms) must be used for at least 7 days following insertion.

NORPLANT SYSTEM capsules are inserted under the skin on the inner surface of your upper arm during a minor, outpatient surgical procedure under sterile conditions. A local anesthetic is used to numb a small area in the upper arm, after which a small incision, less than 1/8 inch long, is made in the same area. The six capsules are placed one at a time with a special instrument just under the skin in a fan shape. The incision is covered with a small adhesive bandage and protective gauze.

Because a local anesthetic is used, there should be little or no discomfort during insertion. When the anesthetic wears off, there may be some tenderness in the area of the implants for a day or two. Some discoloration, bruising, and swelling may also be present for a few days after the procedure. This should not interfere with your usual activities. Other skin reactions that have been reported include blistering, sloughing, and ulceration.

Following insertion, you can resume work and other activities. Be careful, however, not to bump the site or get the incision wet for at least 3 days. Also avoid heavy lifting for 2 to 3 days. The protective gauze should remain in place for 24 hours and a small adhesive bandage for 3 days.

If the capsules are inserted during menses, you may resume sexual relations as soon as you wish. If the capsules are inserted more than 7 days after the onset of menses, then a nonhormonal contraceptive method must be used for at least 7 days following insertion.

Be sure to have periodic checkups as advised by your health-care professional while the capsules are in place.

B. Removal

The capsules must be removed at the end of five years when the method starts to become less effective. They can be removed at any time before then, however, if you want to stop using the method for any reason.

Just as for insertion, your health-care professional will apply a local anesthetic. Under sterile conditions, a small (1/8-inch) incision will be made through which all the capsules should be removed. The removal process usually takes more time and may be more difficult and/or more painful than the insertion procedure. Capsules are sometimes nicked, cut, or broken during removal, or may be difficult to locate. If the capsules are placed deeply, they can be more difficult to remove. If some of the capsules are more difficult to remove, additional visits and

incisions may be required. A nonhormonal method of contraception (such as condoms, spermicides, or diaphragms) should be used if less than six capsules are in place.

As after insertion, avoid bumping the incision site for a few days. The area should be kept clean, dry, and bandaged until healed (3 to 5 days) to avoid infection. Bruising may occur at the implant site following removal.

If you want to continue using the NORPLANT SYSTEM (levonorgestrel implants), you may receive a new set of capsules at the same time the old set is removed. The second set can be placed in the same arm, and frequently through the incision from which the earlier set was removed, or in the other arm. If you do not want to continue with the NORPLANT SYSTEM and do not want to become pregnant, make sure your health-care professional recommends another contraceptive method.

Once the capsules are removed, the contraceptive effects cease quickly and a woman can become pregnant at a rate similar to women who have not used the method.

Insertion and removal of the NORPLANT SYSTEM should be performed by a health-care professional knowledgeable of the procedures.

There have been reports of arm pain, numbness, tingling, and scarring following these procedures. There also have been reports of nerve injury, most commonly associated with deep placement and removal.

ADDITIONAL INFORMATION

If you would like more information about the NORPLANT SYSTEM, a copy of the Prescribing Information can be obtained from your health-care professional.

Distributed by



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A Wyeth-Ayerst Company
Philadelphia, PA 19101

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WHAT I KNOW ABOUT NORPLANT® (levonorgestrel implants)

I have read this leaflet and have discussed it with my health-care professional. They have answered all my questions. I understand that there are risks as well as benefits from using NORPLANT. I understand that there are other forms of contraception that do not have the risks of NORPLANT, but may have different risks. I also understand that this form is important. It demonstrates that I am making an informed and carefully considered decision to use NORPLANT. I have checked below those statements that I agree with:

_____ I have been told how NORPLANT works to keep women from getting pregnant.

_____ I have been told that the risk of getting pregnant while using NORPLANT is about 1 percent. (This means that about one woman out of every one hundred who use NORPLANT may get pregnant each year.)

_____ I understand that the NORPLANT capsules are made of Silastic®, a silicone rubber tubing.

_____ I have been told that the NORPLANT capsules are implanted under the skin of my arm during an in-office surgical procedure.

_____ I have been told that the NORPLANT capsules must be removed at the end of the five years. The removal procedure is also an in-office surgical procedure and may cause more pain and scarring than the insertion procedure. There have been infrequent reports of nerve injury, most commonly associated with deep placement and removal.

_____ I have been told that I can have NORPLANT taken out at any time and for any reason. I have also been told that, if I have trouble finding a health-care professional to remove it, I can call (800) 934-5556 for help.

_____ I have been told about the side effects of NORPLANT, including that most women have changes in their menstrual bleeding. I have been told that the side effects may vary in severity from one woman to another.

_____ I have been told about the NORPLANT warning signs and know that I should seek medical attention if any warning signs appear.

_____ I have been told that I need to receive a medical checkup yearly or any time I am having problems.

_____ I have been told that NORPLANT does not protect me from AIDS or any other sexually transmitted disease.

I have considered all the information in this leaflet and voluntarily choose to have the NORPLANT SYSTEM inserted by:

(Name of Health-Care Professional)

(Patient Signature)

(Date)

WITNESSED BY:

The patient above has signed this leaflet in my presence after I counseled her and answered her questions.

(Health-Care Professional Signature)

(Date)

I have provided an accurate translation of this information to the patient whose signature appears above. She has stated that she understands the information and has had an opportunity to have her questions answered.

(Signature of Translator)

(Date)