Discover Implantable Contraception

Information for Patients About Contraception With

IMPLANON™
[etonogestrel implant] 88 mg
You’re looking for a method of contraception. Perhaps it’s the first method you’ll use, or maybe you’re looking for something that does not require daily, weekly, or monthly dosing. Or maybe you’re done having children but are concerned that sterilization is just too final.

IMPLANON™ is a flexible plastic rod the size of a matchstick that is put under the skin of your arm in an in-office procedure.

Effective Birth Control

IMPLANON™ is more than 99% effective: the chance of getting pregnant is less than 1 pregnancy per 100 women who use IMPLANON™ for 1 year when IMPLANON™ is inserted correctly. IMPLANON™ prevents pregnancy in several ways. The most important way is by stopping release of an egg from your ovary. IMPLANON™ also thickens the cervical mucus, which acts as a barrier to prevent sperm from fertilizing an egg.

Established Worldwide

Since 1998, there have been more than 4.5 million IMPLANON™ units sold worldwide. It is a progestin-only method of birth control and does not contain estrogen. IMPLANON™ does not contain latex or silicone and will not dissolve.

IMPORTANT INFORMATION

IMPLANON™ must be removed by the end of the third year and may be replaced with a new IMPLANON™. It is not known if IMPLANON™ is as effective in very overweight women because clinical studies did not include many overweight women. Tell your healthcare provider about any medicines you are taking, or intend to take, including over-the-counter medicines, herbal medicines, and prescription medicines. Certain medicines may make IMPLANON™ less effective, and you may also need to use a barrier method of contraception as backup.
Discreet

Most women can’t see IMPLANON™ after insertion. Only you and your Healthcare Provider will know you’re using it. For this reason, you should tell all of your Healthcare Providers if you are using IMPLANON™.

You should be able to feel where IMPLANON™ is by gently pressing on your skin in the area where it was inserted. However, to reduce the risk of infection, you should not touch the insertion site until it has healed.

Ask About IMPLANON™

Want to know more? The following pages provide answers to common questions about IMPLANON™. You should also refer to the enclosed Patient Labeling and Consent Form.

Please see enclosed detailed product information and consent form.
Q: How is IMPLANON™ inserted?
IMPLANON™ insertion should be a minor procedure that can be performed in a Healthcare Provider’s office. The entire procedure is done using a local anesthetic and generally takes a few minutes.

Q: What are the possible complications of the insertion procedure?
Rarely, IMPLANON™ is not inserted at all due to a failed insertion or the implant has fallen out of the needle. If this happens, you may become pregnant. After insertion, and with direction from your Healthcare Provider, you should be able to feel IMPLANON™ under your skin. If you can’t feel IMPLANON™, tell your Healthcare Provider.

Some other problems related to insertion are:
- Pain, irritation, swelling, or bruising
- Scarring, including a thick scar called a keloid
- Infection
- IMPLANON™ breaks, making it difficult to remove
- Expulsion of the implant (occurs rarely)

Q: Is it okay to leave IMPLANON™ in my arm for up to 3 years?
IMPLANON™ is made of a medical material that can be left in your body for up to 3 years. However, IMPLANON™ must be removed by the end of the third year and can be replaced by a new IMPLANON™ if continued contraceptive protection is desired.

Please see enclosed detailed product information and consent form.
Q: Will I feel IMPLANON™ being inserted?
Some women may feel a pinch, similar to a shot or injection, when IMPLANON™ is inserted. A local anesthetic is used to minimize discomfort.

After the insertion, a woman might feel some mild soreness or tenderness at the insertion site. It shouldn’t last more than a day or two and shouldn’t interfere with your usual activities. During clinical studies that included 942 women, only about 1% (nine women) had complications at insertion. Complications expected of a minor surgical procedure, such as pain, numbness/tingling, bleeding, bruising, scarring, or infection have been reported. If your symptoms do not resolve in a day or two, you should contact your Healthcare Provider.

Q: When should I have IMPLANON™ inserted?
Your Healthcare Provider will help you determine when to have IMPLANON™ inserted. The timing will depend upon whether you are currently using birth control and which method you are using. **You should not be pregnant when you start using IMPLANON™.**

Q: Will I need to use a backup method?
If IMPLANON™ is inserted as recommended in the product labeling, backup contraception is not necessary. Talk to your Healthcare Provider about the timing of IMPLANON™ insertion. In some situations, you may need a backup method of contraception for 7 days after insertion.

Q: What if I am taking another medication? Should I use backup protection?
It is important to tell your Healthcare Provider about any medications you are taking or intend to take, including prescription medicines, over-the-counter medicines, and herbal remedies or supplements, such as St. John’s Wort. There may be interactions with some of these medications that could decrease the effectiveness of IMPLANON™, and you may need to use a backup nonhormonal birth control method. Please see the Patient Labeling and talk with your Healthcare Provider about this.

Please see enclosed detailed product information and consent form.
Q: Who should not use IMPLANON™?
IMPLANON™ is not for everyone. Do not use IMPLANON™ if you:
- Are pregnant or think you may be pregnant
- Have or have had serious blood clots, such as blood clots in your legs (deep venous thrombosis), lungs (pulmonary embolism), eyes (retinal thrombosis), heart (heart attack), or head (stroke)
- Have unexplained vaginal bleeding
- Have liver disease
- Have or have had breast cancer
- Are allergic to anything in IMPLANON™

Tell your Healthcare Provider if you have ever had any of these conditions. He or she can suggest another method of birth control.

In addition, talk to your Healthcare Provider about using IMPLANON™ if you have or have had diabetes, high cholesterol or triglycerides, headaches, seizures or epilepsy, gallbladder or kidney disease, depression, high blood pressure, or an allergic reaction to anesthetics or antiseptics.

Q: What if I want to become pregnant?
Once IMPLANON™ is successfully removed, your ability to get pregnant usually returns quickly. Some women have become pregnant within days after removal of IMPLANON™.

Q: What do I have to do when it is time to have IMPLANON™ removed?
You must schedule an appointment and have IMPLANON™ removed no later than 3 years after the date of insertion. Although IMPLANON™ is designed to last up to 3 years, your Healthcare Provider can remove it at any time. When IMPLANON™ is inserted, your Healthcare Provider will give you a User Card that lists the date of insertion and expected date of removal. Keep this card at home with your other important health records.

After removal, if you do not want to become pregnant, you should start another birth control method right away.

If you switch to a new Healthcare Provider before IMPLANON™ is removed, be sure to ask if he or she is trained to insert and remove IMPLANON™. If you need help finding a Healthcare Provider who has been trained at a program sponsored by Organon USA Inc. (a part of Schering-Plough) to perform these procedures, call 1-877-IMPLANON (1-877-467-5266).

Please see enclosed detailed product information and consent form.
Q: How is IMPLANON™ removed?
Your Healthcare Provider can remove IMPLANON™ at any time with a minor surgical procedure in the office. He or she will make a small incision in your arm and remove IMPLANON™. A local anesthetic is used for the procedure. Some minor bruising, redness, swelling, and/or pain may occur where IMPLANON™ was removed. Your Healthcare Provider should not attempt to remove IMPLANON™ unless its location has been firmly established (eg, by palpation [touching]).

Q: What are the possible risks of removal?
During clinical trials, only 15 out of 942 women (1.7%) had complications at implant removal. Complications expected of a minor surgical procedure, such as pain, bleeding, bruising, scarring, keloid (thick scar) formation, and infection have been reported. Rarely, removal of IMPLANON™ is difficult or even impossible because thick scar tissue has formed around IMPLANON™ or IMPLANON™ is not where it should be. If IMPLANON™ cannot be removed, then the effects of IMPLANON™ will continue for a longer period of time. There have been rare reports of IMPLANON™ breaking during removal, making it difficult to remove.

Deep insertions may result in the need for a surgical procedure in an operating room in order to remove IMPLANON™. Any of the possible complications of surgery may occur. Removals of deeply inserted implants can lead to scarring, nerve damage, or other complications.

Failure to remove IMPLANON™ may result in infertility, pregnancy outside of the womb (ectopic pregnancy), or inability to stop a drug-related adverse event.

Please see enclosed detailed product information and consent form.

Q: Will the insertion or removal of IMPLANON™ leave a permanent mark?
There is a slight risk that you will get a scar from insertion or removal of IMPLANON™. Women with a personal or family history of developing raised, thickened scars (keloids) should be sure to tell their Healthcare Providers. Women with this condition may be more likely to scar.

Q: What if I want to continue using IMPLANON™?
A new IMPLANON™ can be inserted in the same place where the old one was, or it can be inserted in the other arm. Your Healthcare Provider will decide the best place to insert IMPLANON™.
Questions About Side Effects

The answers to the following questions will provide you with helpful information about side effects patients may experience while using IMPLANON™.

Be sure to read the enclosed Patient Labeling and Consent Form and discuss any concerns or questions you have with your Healthcare Provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Q: How will my bleeding change?

Don’t be concerned if your menstrual periods vary while using IMPLANON™. Most of the time, you will experience infrequent bleeding or no bleeding at all. The number of bleeding/spotting days is similar to that experienced by a normal, menstruating woman who is not on contraception.

You should discuss any questions you may have about irregular bleeding with your Healthcare Provider. Be sure to let him or her know if you think you may be pregnant or if your bleeding is heavy and prolonged.

Q: What are the side effects that caused women to stop using IMPLANON™?

In clinical trials involving 942 women, one in 10 women stopped using IMPLANON™ because of bleeding changes. Besides irregular bleeding, the most frequent side effects that caused women to stop using IMPLANON™ in clinical trials were mood swings, weight gain, headache, acne, and depression. This is not a complete list of possible side effects.

Q: What are the most common side effects?

The most common side effect is irregular bleeding. Other common side effects reported in women using IMPLANON™ during clinical trials include: headache, vaginitis (inflammation of the vagina), weight gain, acne, breast pain, viral infections such as colds, sore throats, sinus infections, or flu-like symptoms, stomach pain, painful periods, mood swings, nervousness, or depression, back pain, nausea, dizziness, pain, and pain at the site of insertion.
IMPLANON™ (etonogestrel implant) is for the prevention of pregnancy in women.

IMPORTANT RISK INFORMATION

IMPLANON™ does not protect against HIV (AIDS) or other sexually transmitted diseases.

IMPLANON™ must be removed by the end of the third year and may be replaced by a new IMPLANON™ at the time of removal, if continued contraceptive protection is desired. Failure to remove IMPLANON™ may result in infertility, ectopic pregnancy, or inability to stop a drug-related adverse event.

If IMPLANON™ is not placed properly, it may not prevent pregnancy or it may be difficult or impossible to remove. After you receive IMPLANON™, check that it is in place by pressing your fingertips over the skin in your arm where IMPLANON™ was placed. You should be able to feel the IMPLANON™ rod.

Serious complications may be associated with the insertion and removal of IMPLANON™. This may result in the need for a surgical procedure in an operating room in order to remove IMPLANON™. Any of the possible complications of surgery may occur. In clinical trials, nine out of 942 (1.0%) patients had complications at implant insertion and 15 out of 942 (1.7%) had complications at implant removal.

You should not use IMPLANON™ if you: are pregnant or think you may be pregnant; have or have had blood clots; have unexplained vaginal bleeding; have liver disease; have or have had breast cancer; or if you are allergic to anything in IMPLANON™.

The use of IMPLANON™ and other progestin-only hormonal contraceptives have been associated with ectopic pregnancy, bleeding irregularities, and ovarian cysts. The use of hormonal contraceptives is associated with increased risks of several serious side effects including blood clots which may lead to stroke or heart attack. Blood clots are a side effect of birth control pills and pregnancy. It is unknown if the risk of blood clots with IMPLANON™ is different than with birth control pills. Some examples of blood clots are: deep vein thrombosis (legs), pulmonary embolism (lungs), retinal thrombosis (eyes), stroke (head) and heart attack (heart). There have been reports of blood clots, including pulmonary emboli and strokes, in patients using IMPLANON™. Tell your doctor at least 4 weeks before if you are going to have surgery or will need to be on bed rest because you have an increased chance of experiencing blood clots during surgery or bed rest.

Cigarette smoking increases the risk of serious cardiovascular side effects from the use of hormonal contraceptives. The risk increases with age (women > 35), and with heavy smoking. Women who use hormonal contraceptives are strongly advised not to smoke.

The most common side effect of IMPLANON™ is a change in your menstrual periods. In studies, about 1 in 10 women stopped using IMPLANON™ because of bleeding problems. Expect your menstrual periods to be irregular and unpredictable throughout the time you are using IMPLANON™. You may have more bleeding, less bleeding, or no bleeding. The time between periods may vary, and in between periods you may have spotting. Other common side effects reported in women using IMPLANON™ during clinical trials include: headache, vaginitis, weight gain, acne, breast pain, viral infections such as colds, sore throats, sinus infections, or flu-like symptoms, stomach pain, painful periods, mood swings, nervousness, or depression, back pain, nausea, dizziness, pain, and pain at the site of insertion.

Please see accompanying detailed product information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

IMPLANON™
(etongestrel implant) 68 mg
Insurance Coverage

Q: Will IMPLANON™ be covered by insurance?

IMPLANON™ may be covered by your insurance plan. To determine if you have coverage, you should call the customer service number on the back of your insurance card. Ask if IMPLANON™ is covered under your policy. You may need to explain that IMPLANON™ is an implantable contraceptive. You may also be asked to provide the billing code for IMPLANON™. Possible codes your insurance provider may use include:

NDC: 0052-0272-01 or 00052-0272-01
Billing code: J7307
Insertion procedure codes: 11981 or 11975

Schering-Plough makes no guarantee that the use of any particular code will result in coverage or reimbursement.

Please see enclosed detailed product information and consent form.

Getting Started

Q: How do I know if IMPLANON™ is right for me?

Your Healthcare Provider will help you determine if IMPLANON™ is right for you. He or she will review the Patient Labeling and Consent Form with you to be sure you understand all of the potential risks and benefits of using IMPLANON™. This brochure does not take the place of a thorough discussion with your Healthcare Provider.

If IMPLANON™ is covered, ask the customer service representative to send verification of coverage to your Healthcare Provider.
Fast Facts

FACT: Implants are one of the most effective birth control methods available.

FACT: More than 4.5 million IMPLANON™ have been sold worldwide.*

FACT: IMPLANON™ is soft and flexible and can be left in the body for up to 3 years.

FACT: IMPLANON™ is designed to be palpable but not visible, and should not interfere with daily activities.

FACT: IMPLANON™ is a progestin-only method that will change your bleeding patterns.

FACT: It is safe to insert a new IMPLANON™ at the time of removal.

*Based on cumulative unit sales of IMPLANON™ worldwide.

Please see enclosed detailed product information and consent form.