

FDA-Approved Patient Labeling
IMPLANON® (etonogestrel implant)
Subdermal Use

IMPLANON® does not protect against HIV infection (the virus that causes AIDS) or other sexually transmitted diseases. Read this Patient Information leaflet carefully before you decide if IMPLANON is right for you. This information does not take the place of talking with your healthcare provider. If you have any questions about IMPLANON, ask your healthcare provider.

What is IMPLANON?

IMPLANON is a hormone-releasing birth control implant for use by women to prevent pregnancy for up to 3 years. The implant is a flexible plastic rod about the size of a matchstick that contains a progestin hormone called etonogestrel. Your healthcare provider will insert the implant just under the skin of the inner side of your upper arm. You can use a single IMPLANON implant for up to 3 years. IMPLANON does not contain estrogen.



What if I need birth control for more than 3 years?

The IMPLANON implant must be removed after 3 years. Your healthcare provider can insert a new implant under your skin after taking out the old one if you choose to continue using IMPLANON for birth control.

What if I change my mind about birth control and want to stop using IMPLANON before 3 years?

Your healthcare provider can remove the implant at any time. You may become pregnant as early as the first week after removal of the implant. If you do not want to get pregnant after your healthcare provider removes the IMPLANON implant, you should start another birth control method right away.

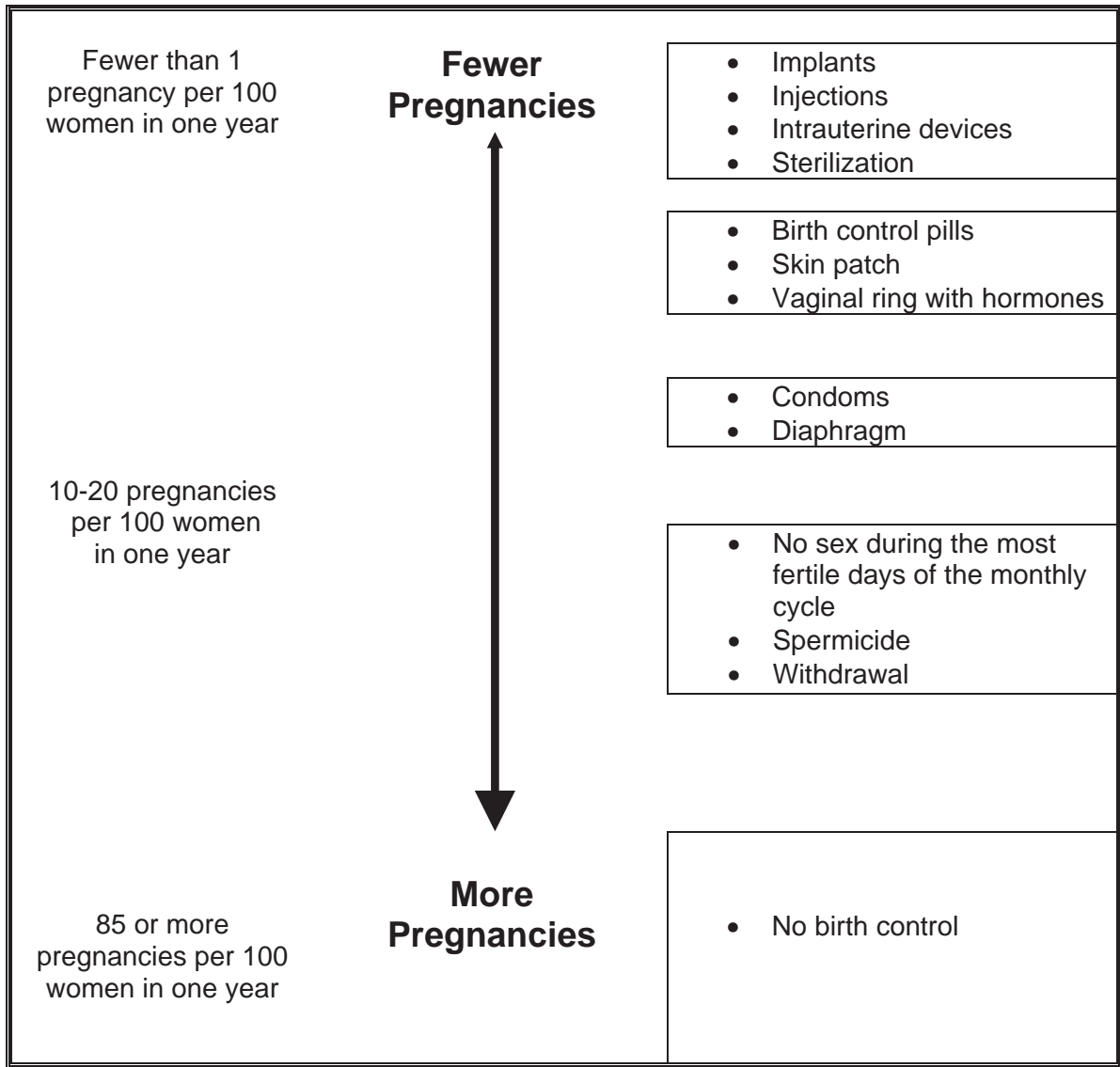
How does IMPLANON work?

IMPLANON prevents pregnancy in several ways. The most important way is by stopping the release of an egg from your ovary. IMPLANON also thickens the mucus in your cervix and this change may keep sperm from reaching the egg. IMPLANON also changes the lining of your uterus.

How well does IMPLANON work?

When the IMPLANON implant is placed correctly, your chance of getting pregnant is very low (less than 1 pregnancy per 100 women who use IMPLANON for 1 year). It is not known if IMPLANON is as effective in very overweight women because studies did not include many overweight women.

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.



Who should not use IMPLANON?

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 (total or partial blindness), heart (heart attack), or brain (stroke)
- Have liver disease or a liver tumor
- Have unexplained vaginal bleeding
- Have breast cancer or any other cancer that is sensitive to progestin (a female hormone), now or in the past
- Are allergic to anything in IMPLANON

Tell your healthcare provider if you have or have had any of the conditions listed above. Your healthcare provider can suggest a different method of birth control.

In addition, talk to your healthcare provider about using IMPLANON if you:

- Have diabetes
- Have high cholesterol or triglycerides
- Have headaches
- Have gallbladder or kidney problems
- Have a history of depressed mood
- Have high blood pressure
- Have an allergy to numbing medicines (anesthetics) or medicines used to clean your skin (antiseptics). These medicines will be used when the implant is placed into or removed from your arm.

Interaction with Other Medicines

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Certain medicines may make IMPLANON less effective, including:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John's wort
- topiramate
- HIV medicines

Ask your healthcare provider if you are not sure if your medicine is one listed above.

If there are medicines that you have been taking for a long time, that make IMPLANON less effective, tell your healthcare provider. Your healthcare provider may remove the IMPLANON implant and recommend a birth control method that can be used effectively with these medicines.

When you are using IMPLANON, tell all of your healthcare providers that you have IMPLANON in place in your arm.

How is the IMPLANON implant placed and removed?

Your healthcare provider will place and remove the IMPLANON implant in a minor surgical procedure in his or her office. The implant is placed just under the skin on the inner side of your upper arm.

The timing of insertion is important. Your healthcare provider may:

- Perform a pregnancy test before inserting IMPLANON
- Schedule the insertion at a specific time of your menstrual cycle (for example, within the first days of your regular menstrual bleeding)

Immediately after the IMPLANON implant has been placed, you and your healthcare provider should check that the implant is in your arm by feeling for it.

If you and your healthcare provider cannot feel the IMPLANON implant, use a non-hormonal birth control method (such as condoms) until your healthcare provider confirms that the implant is in place. You may need special tests to check that the implant is in place or to help find the implant when it is time to take it out.

Your healthcare provider will cover the site where IMPLANON was placed with 2 bandages. Leave the top bandage on for 24 hours. Keep the smaller bandage clean, dry, and in place for 3 to 5 days.

You will be asked to review and sign a consent form prior to inserting the IMPLANON implant. You will also get a USER CARD to keep at home with your health records. Your healthcare provider will fill out the USER CARD with the date the implant was inserted and the date the implant is to be removed. Keep track of the date the implant is to be removed. Schedule an appointment with your healthcare provider to remove the implant on or before the removal date.

Be sure to have checkups as advised by your healthcare provider.

What are the most common side effects I can expect while using IMPLANON?

- **Changes in Menstrual Bleeding Patterns (menstrual periods)**

The most common side effect of IMPLANON is a change in your normal menstrual bleeding pattern. In studies, about one out of ten women stopped using the implant because of an unfavorable change in their bleeding pattern. You may experience longer or shorter bleeding during your periods or have no bleeding at all. The time between periods may vary, and in between periods you may also have spotting.

Talk with your healthcare provider right away if:

- You think you may be pregnant
- Your menstrual bleeding is heavy and prolonged

Besides changes in menstrual bleeding patterns, other frequent side effects that caused women to stop using the implant include:

- Mood swings
- Weight gain
- Headache
- Acne
- Depressed mood

Other common side effects include:

- Headache
- Vaginitis (inflammation of the vagina)
- Weight gain
- Acne
- Breast pain
- Viral infections such as sore throats or flu-like symptoms
- Stomach pain
- Painful periods
- Mood swings, nervousness, or depressed mood
- Back pain
- Nausea
- Dizziness
- Pain
- Pain at the site of insertion

This is not a complete list of possible side effects. For more information, ask your healthcare provider for advice about any side effects that concern you. You may report side effects to the FDA at 1-800-FDA-1088.

What are the possible risks of using IMPLANON?

- **Problems with Insertion and Removal**

The implant may not be placed in your arm at all due to a failed insertion or if the implant has fallen out of the needle. If this happens, you may become pregnant. Immediately after insertion, and with help from your healthcare provider, you should be able to feel the implant under your skin. If you can't feel the implant, tell your healthcare provider.

Removal of the implant may be very difficult or impossible because the implant is not where it should be. Special procedures, including surgery in the hospital, may be needed to remove the implant. If the implant is not removed, then the effects of IMPLANON will continue for a longer period of time.

Other problems related to insertion and removal are:

- Pain, irritation, swelling, or bruising at the insertion site
 - Scarring, including a thick scar called a keloid around the insertion site
 - Infection
 - Scar tissue may form around the implant making it difficult to remove
 - The implant may come out by itself. You may become pregnant if the implant comes out by itself. Use a back up birth control method and call your healthcare provider right away if the implant comes out.
 - The need for surgery in the hospital to remove the implant
 - Injury to nerves or blood vessels in your arm
 - The implant breaks making removal difficult
-
- **Ectopic Pregnancy**

If you become pregnant while using IMPLANON, you have a slightly higher chance that the pregnancy will be ectopic (occurring outside the womb) than do women who do not use birth control. Unusual vaginal bleeding or lower stomach (abdominal) pain may be a sign of ectopic pregnancy. Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancies can cause serious internal bleeding, infertility, and even death. Call your healthcare provider right away if you think you are pregnant or have unexplained lower stomach (abdominal) pain.
-
- **Ovarian Cysts**

Cysts may develop on the ovaries and usually go away without treatment but sometimes surgery is needed to remove them.

- **Breast Cancer**

It is not known whether IMPLANON use changes a woman's risk for breast cancer. If you have breast cancer now, or have had it in the past, do not use IMPLANON because some breast cancers are sensitive to hormones.

- **Serious Blood Clots**

IMPLANON may increase your chance of serious blood clots, especially if you have other risk factors such as smoking. It is possible to die from a problem caused by a blood clot, such as a heart attack or a stroke.

Some examples of serious blood clots are blood clots in the:

- Legs (deep vein thrombosis)
- Lung (pulmonary embolism)
- Brain (stroke)
- Heart (heart attack)
- Eyes (total or partial blindness)

The risk of serious blood clots is increased in women who smoke. If you smoke and want to use IMPLANON, you should quit. Your healthcare provider may be able to help.

Tell your healthcare provider at least 4 weeks before if you are going to have surgery or will need to be on bed rest. You have an increased chance of getting blood clots during surgery or bed rest.

- **Other Risks**

A few women who use birth control that contains hormones may get:

- High blood pressure
- Gallbladder problems
- Rare cancerous or noncancerous liver tumors

When should I call my healthcare provider?

Call your healthcare provider right away if you have:

- Pain in your lower leg that does not go away

- Severe chest pain or heaviness in the chest
- Sudden shortness of breath, sharp chest pain, or coughing blood
- Symptoms of a severe allergic reaction, such as swollen face, tongue or pharynx; trouble swallowing; or hives and trouble breathing
- Sudden severe headache unlike your usual headaches
- Weakness or numbness in your arm, leg, or trouble speaking
- Sudden partial or complete blindness
- Yellowing of your skin or whites of your eyes, especially with fever, tiredness, loss of appetite, dark colored urine, or light colored bowel movements
- Severe pain, swelling, or tenderness in the lower stomach (abdomen)
- Lump in your breast
- Problems sleeping, lack of energy, tiredness, or you feel very sad
- Heavy menstrual bleeding

What if I become pregnant while using IMPLANON?

You should see your healthcare provider right away if you think that you may be pregnant. It is important to remove the implant and make sure that the pregnancy is not ectopic (occurring outside the womb). Based on experience with other hormonal contraceptives, IMPLANON is not likely to cause birth defects.


Can I use IMPLANON when I am breastfeeding?

If you are breastfeeding your child, you may use IMPLANON if 4 weeks have passed since you had your baby. A small amount of the hormone contained in IMPLANON passes into your breast milk. The health of breast-fed children whose mothers were using the implant has been studied up to 3 years of age in a small number of children. No effects on the growth and development of the children were seen. If you are breastfeeding and want to use IMPLANON, talk with your healthcare provider for more information.

Additional Information

This Patient Information leaflet contains important information about IMPLANON. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about IMPLANON that is written for healthcare professionals. You may also call 1-877-IMPLANON (1-877-467-5266) or visit www.IMPLANON-USA.com

Manufactured by: N.V. Organon, Oss,
The Netherlands, a subsidiary of

 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

Distributed by: Schering Corporation, a subsidiary of

 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

Copyright © 2012 N.V. Organon, a subsidiary of **Merck & Co., Inc.**
All rights reserved.

Revised: 03/2012

900415-IMP-IPT-PPI.6