

IMPLANON™ CONTRACEPTIVE IMPLANT

Implanon™ is a progestin-only (etonogestrel) single rod contraceptive system, inserted under the skin between biceps and triceps, that is effective for up to three years.

KEY POINTS

- **Attributes of Implanon™ include extremely high efficacy, rapid reversibility, steady hormone release, and a discreet placement site.**
- **Implanon™ use will cause changes in menstrual bleeding patterns such that predictable monthly periods will cease and all bleeding will be unscheduled. Potential Implanon™ users must be counseled regarding characteristic bleeding patterns and be willing to accept these changes before Implanon™ insertion is performed.**
- **Implanon™ must be inserted and removed only by clinicians who have completed a company-sponsored training program.**
- **All Implanon™ devices purchased for use in Family PACT clients must be obtained from the single source supplier and labeled for use in the United States (U.S.). Providers must maintain invoices for Implanon™ units billed to Family PACT for at least three years in accordance with Title 22, California Code of Regulations (CCR), Code 51476(a).**

QUESTIONS AND ANSWERS

How effective is Implanon™?

Implanon™ is one of the most effective contraceptives available. International studies showed no pregnancies in over 73,000 cycles of use. In later studies performed in the U.S., the failure rate was 0.4 failures per 100 couples per year. No ectopic pregnancies were reported in either study. There are no clinical studies of Implanon™ efficacy in women whose weight is more than 130 percent of ideal body weight. However, in one study, etonogestrel levels were sufficient to prevent ovulation even in women weighing 90 kg or more.

What is the mechanism of action of Implanon™?

The major mechanism of action of Implanon™ is by inhibiting ovulation. A large clinical trial showed that no women ovulated in the first 30 months of use and six percent ovulated in the last six months of use, although no pregnancies resulted. In addition, the progestin in Implanon™ causes thickening of cervical mucus, which contributes to contraceptive efficacy.

Are there any contraindications to Implanon™ insertion?

As a progestin-only method, Implanon™ has few contraindications. According to the 2004 World Health Organization (WHO) Medical Eligibility Criteria, current breast cancer is the only WHO-4 condition (an unacceptable health risk if the contraceptive is used). WHO-3 conditions (risks usually outweigh advantages of using the method) include past breast cancer (>five years ago and no recurrence), current deep vein thrombosis, active liver disease or history of liver tumors, and being less than three weeks post-partum.

What should the client expect in regard to menstrual patterns?

The menstrual bleeding pattern of women who use Implanon™ is unpredictable and all bleeding is unscheduled. Studies show that there are no predictable trends in bleeding patterns over time. Counsel the client that she will have fewer bleeding episodes and the same or fewer bleeding days, but that her bleeding days and episodes will be unpredictable and she may have more spotting days than before.

How should this bleeding pattern be managed?

Pre-insertion counseling regarding the nature of the expected bleeding pattern is an important step in improving method acceptability. When unpredictable bleeding occurs after insertion, reassure the client that this is an expected consequence of the method.

In addition, based on experience with treating irregular bleeding in women who use other progestin-only methods, the following interventions have been effective:

- Estradiol 1-2mg orally once a day for 10-14 days; or
- Oral contraceptives, given for two or three cycles; or
- Ibuprofen 800mg three times a day for seven days.

Since continuous progestin *prevents* endometrial hyperplasia; endometrial biopsy is rarely necessary.

Is this a good method for adolescents?

While Implanon™ is as safe and efficacious in adolescents as in older women, some will not be able to tolerate the unpredictable bleeding pattern induced by the method. Clear and direct post-insertion counseling that is easily accessible to the client will improve continuation rates.

What can clinicians do to be trained in Implanon™ insertion?

Only providers that have completed the company-sponsored three-hour training course will be permitted to purchase Implanon™. See Resources below for Organon's Web site to request training. Physicians and non-physician medical practitioners (nurse practitioners, CNMs, and physician assistants) can perform Implanon™ insertions and removals.

How will my practice be reimbursed for Implanon™?

Family PACT will reimburse providers for both the insertion kit (purchased from CuraScript Specialty Pharmacy, the single-source supplier) and for the insertion (and removal) procedures. Limited to one per client, any provider, per 34 months. While the duration of action of Implanon™ is 36 months, the 34-month limit will permit early removal and insertion of a new implant if necessary for scheduling purposes.

QUESTIONS AND ANSWERS (CONTINUED)

Can Implanon™ be used in women using rifampin (for tuberculosis or methicillin-resistant *Staphylococcus aureus* [MRSA] infections) or enzyme-inducing anti-seizure drugs?

Although there are no published studies on drug interactions with Implanon™, this method is not recommended for women who require chronic use of enzyme-inducing drugs, as contraceptive efficacy probably will be reduced. A backup method should be used by women using rifampin for a limited period of time.

When is the recommended time to insert Implanon™?

Implanon™ package labeling includes the following guidelines. If inserted as recommended, backup contraception is not necessary.

- Standard start-up: insert within five days of initiation of menses.
- Switching from combined hormonal methods: insert within seven days of last active dose.
- Switching from progestin-only method: insert any day when progestin only-pills are used or before due date of next DepoProvera injection.
- After first trimester abortion: insert within five days of procedure.
- After second trimester abortion or postpartum, but not exclusively breast feeding insert between 21 to 28 days after pregnancy has ended.
- If exclusively breast feeding, insert Implanon™ after the fourth postpartum week.

If an "off cycle" insertion is performed, pregnancy should be excluded and the client should use a non-hormonal method of birth control during the first seven days after the insertion. In addition, emergency contraception should be offered if there has been unprotected intercourse during the five days before the insertion.

APPLICATION OF FAMILY PACT STANDARDS

1. Informed Consent

- All clients shall be advised of the availability of Implanon™ and offered this option in a non-coercive manner.
- Consent shall be voluntary and the client may withdraw this consent at any time.
- Parental consent is not required for provision of an Implanon™ to a minor.
- The consent process shall be provided verbally in language understood by the client and supplemented with written materials.
- The client must sign a written consent for Implanon™ insertion and removal. The consent form provided by the Implanon™ manufacturer with the insertion kit is recommended but another with equivalent content may be used.

2. Confidentiality

- A confidential contact address should be obtained from the client so that she can be notified in the event of a product recall or other Implanon™-related safety considerations.

3. Access to Care

- Implanon™ insertion, follow-up visits, and removal shall be provided without cost to all Family PACT clients, either onsite or by referral.

4. Availability of Covered Services

- Implanon™ services may be provided onsite or by referral. The enrolled provider shall have an established referral arrangement with the other provider(s) when making referrals for these procedures.
- The management of certain Implanon™ complications is a benefit of Family PACT, as specified in the *Policies, Procedures, and Billing Instructions* (PPBI). These services must be requested and authorized by the use of a Treatment Authorization Request.
- To facilitate client contact in the case of a product recall, providers must keep a written log or electronic record of all Implanon™ inserted for at least three years from the insertion date. The log must include the client's name, record number, Health Access Program (HAP) identification number, date of insertion, and the lot number of the Implanon™ used.
- All Implanon™ inserted through the Family PACT program must be Food and Drug Administration-approved, labeled for use in the U.S., and obtained from the single source distributor. Providers must maintain invoices for insertion kits billed to Family PACT for at least three years from the date of insertion.

5. Scope of Clinical and Preventive Services

- Follow-up care for complications associated with a client's contraceptive method at no cost to the client.
- Medical record documentation shall support services claimed for reimbursement.

6. Education and Counseling Services

- All staff performing education and counseling services shall be knowledgeable about Implanon™ and the policies for use under the Family PACT Program.
- Specific instructions for the use of Implanon™ should be provided both verbally and in written form. Clients should be given the opportunity to ask questions and discuss personal concerns about Implanon™.

PROGRAM POLICY

This Alert provides an interpretation of the Family PACT Standards regarding care of adolescent clients: Providers should refer to the Family PACT PPBI for the complete text of the Family PACT Standards, official administrative practices, and billing information. For the purposes of this and other Family PACT Clinical Practice Alerts, the term "shall" indicates a program requirement; the term "should" is advisory and not required.

RESOURCES FOR INFORMATION ON IMPLANON™

- Implanon™ consumer Web site: <http://www.implanon-usa.com/>.
- Implanon™ provider Web site: <http://www.implanon-usa.com/hcp/?OrgDom=www.implanonusa.com>.
- World Health Organization Medical Eligibility Guidelines: <http://www.who.int/reproductive-health/publications/mec/>.
- Hohmann H, Creinin MD. The contraceptive implant. *Clin Obstet Gynecol*. 2007 Dec;50(4):907-17.
- Shulman LP, Gabriel H. Management and localization strategies for the nonpalpable Implanon™ rod. *Contraception*. 2006 73(4):325.
- Tolaymat LL, Kaunitz AM. Long-acting contraceptives in adolescents. *Curr Opin Obstet Gynecol*. 2007 Oct;19(5):453-60.