

# H6-1 FDA Birth Control Guide

The FDA has approved a number of birth control methods. The choice of birth control depends on factors such as a person's health, frequency of sexual activity, number of sexual partners, and desire to have children in the future. Failure rates, based on statistical estimates, are another key factor. The most effective way to avoid both pregnancy and sexually transmitted disease is to practice total abstinence (refrain from sexual contact).

**Failure rates** in this handout are based on information from clinical trials submitted to the FDA during product reviews. This number represents the percentage of women who become pregnant during the first year of use of a birth control method. For methods that the FDA does not review, such as periodic abstinence, numbers are estimated from published literature. *For comparison, about 85 out of 100 sexually active women who wish to become pregnant would be expected to become pregnant in a year.*

Serious medical risks from contraceptives, such as stroke related to oral contraceptives, are relatively rare. This chart is a summary of important information, including risks, about drugs and devices approved by the FDA for contraception and sterilization. It is not intended to be used alone, and a health professional should be consulted regarding any contraceptive choice. Review product labeling carefully for more information on use of these products.

## Male Condom, Latex/Polyurethane

**FDA Approval Date:** Latex: Use started before premarket approval was required. Polyurethane: cleared in 1989; available starting 1995.

**Description:** A sheath placed over the erect penis blocking the passage of sperm.

**Failure Rate** (number of pregnancies expected per 100 women per year): 11 (a, b)

**Some Risks:** Irritation and allergic reactions (less likely with polyurethane)

**Protection from STDs:** Except for abstinence, latex condoms are the best protection against STDs, including HIV

**Convenience:** Applied immediately before intercourse; used only once and discarded. Polyurethane condoms are available for those with latex sensitivity.

**Availability:** Nonprescription

## Female Condom

**FDA Approval Date:** 1993

**Description:** A lubricated polyurethane sheath shaped similarly to the male condom. The closed end has a flexible ring that is inserted into the vagina.

**Failure Rate** (number of pregnancies expected per 100 women per year): 21

**Some Risks:** Irritation and allergic reactions

**Protection from STDs:** May give some STD protection; not as effective as latex condom

**Convenience:** Applied immediately before intercourse; used only once and discarded.

**Availability:** Nonprescription

## Diaphragm with Spermicide

**FDA Approval Date:** Use started before premarket approval was required.

**Description:** A dome-shaped rubber disk with a flexible rim that covers the cervix so that sperm cannot reach the uterus. A spermicide is applied to the diaphragm before insertion.

**Failure Rate** (number of pregnancies expected per 100 women per year): 17 (b, d, e)

**Some Risks:** Irritation and allergic reactions, urinary tract infection. (c) Risk of toxic shock syndrome, a rare but serious infection, when kept in place longer than recommended.

**Protection from STDs:** None

**Convenience:** Inserted before intercourse and left in place at least six hours after; can be left in place for 24 hours, with additional spermicide for repeated intercourse.

**Availability:** Prescription

## Lea's Shield

**FDA Approval Date:** 2002

**Description:** A dome-shaped rubber disk with a valve and a loop that is held in place by the vaginal wall. Covers the upper vagina and cervix so that sperm cannot reach the uterus. Spermicide is applied before insertion.

**Failure Rate** (number of pregnancies expected per 100 women per year): 15

**Some Risks:** Skin irritation, spotting, discomfort (female and male partners), urinary tract infection. Theoretical risk of toxic shock syndrome.

**Protection from STDs:** None

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**Convenience:** Inserted before intercourse and left in place at least 8 hours after; can be left in place for up to 48 hours, with additional spermicide for repeated intercourse.

**Availability:** Prescription

### Cervical Cap with Spermicide

**FDA Approval Date:** Prentiff Cap—1988; FemCap—2003

**Description:** A soft rubber cup with a round rim, which fits snugly around the cervix.

**Failure Rate** (number of pregnancies expected per 100 women per year): Prentiff Cap—17; FemCap—23 (b, d, e)

**Some Risks:** Irritation and allergic reactions, abnormal Pap test. (c) Risk of toxic shock syndrome, a rare but serious infection, when kept in place longer than recommended.

**Protection from STDs:** None

**Convenience:** May be difficult to insert; can remain in place for 48 hours without reapplying spermicide for repeated intercourse.

**Availability:** Prescription

### Sponge with Spermicide

**FDA Approval Date:** 1983

**Description:** A disk-shaped polyurethane device containing the spermicide nonoxynol-9.

**Failure Rate** (number of pregnancies expected per 100 women per year): 14–28 (d, e)

**Some Risks:** Irritation and allergic reactions, difficulty in removal. (c) Risk of toxic shock syndrome, a rare but serious infection, when kept in place longer than recommended.

**Protection from STDs:** None

**Convenience:** Inserted before intercourse and protects for repeated acts of intercourse for 24 hours without additional spermicide; must be left in place for at least six hours after intercourse; must be removed within 30 hours of insertion. Is discarded after use.

**Availability:** Nonprescription

### Spermicide Alone

**FDA Approval Date:** Use started before premarket approval was required. Since November 2002, only one active ingredient has been allowed.

**Description:** A foam, cream, jelly, film, suppository, or tablet that contains nonoxynol-9, a sperm-killing chemical

**Failure Rate** (number of pregnancies expected per 100 women per year): 20–50 (studies have shown varying effectiveness rates)

**Some Risks:** Irritation and allergic reactions, urinary tract infections (c)

**Protection from STDs:** None

**Convenience:** Instructions vary; check labeling. Inserted between 5 and 90 minutes before intercourse and usually left in place at least six to eight hours after.

**Availability:** Nonprescription

### Oral Contraceptives—combined pill

**FDA Approval Date:** First in 1960; most recent in 2003

**Description:** A pill that suppresses ovulation by the combined actions of the hormones estrogen and progestin. A chewable form was approved in November 2003.

**Failure Rate** (number of pregnancies expected per 100 women per year): 1–2

**Some Risks:** Dizziness; nausea; changes in menstruation, mood, and weight; rarely, cardiovascular disease, including high blood pressure, blood clots, heart attack, and strokes

**Protection from STDs:** None

**Convenience:** Must be taken on daily schedule, regardless of frequency of intercourse. Women using the chewable tablet must drink 8 oz. of liquid immediately after taking.

**Availability:** Prescription

## **H6-1 (continued)**

### **Oral Contraceptives—progestin-only minipill**

**FDA Approval Date:** 1973

**Description:** A pill containing only the hormone progestin that reduces and thickens cervical mucus to prevent the sperm from reaching the egg.

**Failure Rate** (number of pregnancies expected per 100 women per year): 2

**Some Risks:** Irregular bleeding, weight gain, breast tenderness, less protection against ectopic pregnancy

**Protection from STDs:** None

**Convenience:** Must be taken on daily schedule, regardless of frequency of intercourse.

**Availability:** Prescription

### **Oral Contraceptives—91-day regimen (Seasonale)**

**FDA Approval Date:** 2003

**Description:** A pill containing estrogen and progestin, taken in 3-month cycles of 12 weeks of active pills followed by one week of inactive pills. Menstrual periods occur during the 13th week of the cycle.

**Failure Rate** (number of pregnancies expected per 100 women per year): 1–2

**Some Risks:** Similar to oral contraceptives—combined pill

**Protection from STDs:** None

**Convenience:** Must be taken on daily schedule, regardless of frequency of intercourse. Since users will have fewer periods, they should consider the possibility that they might be pregnant if they miss scheduled periods. May have more unplanned bleeding and spotting between periods than with 28-day oral contraceptives.

**Availability:** Prescription

### **Patch (Ortho Evra)**

**FDA Approval Date:** 2001

**Description:** Skin patch worn on the lower abdomen, buttocks, or upper body that releases the hormones progestin and estrogen into the bloodstream.

**Failure Rate** (number of pregnancies expected per 100 women per year): 1–2 (Appears to be less effective in women weighing more than 198 pounds.)

**Some Risks:** Similar to oral contraceptives—combined pill

**Protection from STDs:** None

**Convenience:** New patch is applied once a week for three weeks. Patch is not worn during the fourth week, and woman has a menstrual period.

**Availability:** Prescription

### **Vaginal Contraceptive Ring (NuvaRing)**

**FDA Approval Date:** 2001

**Description:** A flexible ring about 2 inches in diameter that is inserted into the vagina and releases the hormones progestin and estrogen.

**Failure Rate** (number of pregnancies expected per 100 women per year): 1–2

**Some Risks:** Vaginal discharge, vaginitis, irritation. Similar to oral contraceptives—combined pill

**Protection from STDs:** None

**Convenience:** Inserted by the woman; remains in the vagina for 3 weeks, then is removed for 1 week. If ring is expelled and remains out for more than 3 hours, another birth control method must be used until ring has been used continuously for 7 days.

**Availability:** Prescription

### **Post-Coital Contraceptives (Preven and Plan B)**

**FDA Approval Date:** 1998-1999

**Description:** Pills containing either progestin alone or progestin plus estrogen

**Failure Rate** (number of pregnancies expected per 100 women per year): Almost 80% reduction in risk of pregnancy for a single act of unprotected sex

**Some Risks:** Nausea, vomiting, abdominal pain, fatigue, headache

**Protection from STDs:** None

**Convenience:** Must be taken within 72 hours of having unprotected intercourse.

**Availability:** Prescription

## **H6-1 (continued)**

### **Injection (Depo-Provera)**

**FDA Approval Date:** 1992

**Description:** An injectable progestin that inhibits ovulation, prevents sperm from reaching the egg, and prevents the fertilized egg from implanting in the uterus.

**Failure Rate** (number of pregnancies expected per 100 women per year): less than 1

**Some Risks** (serious medical risks from contraceptives are rare): Irregular bleeding, weight gain, breast tenderness, headaches

**Protection from STDs:** None

**Convenience:** One injection every three months.

**Availability:** Prescription

### **Injection (Lunelle)**

**FDA Approval Date:** 2000

**Description:** An injectable form of progestin and estrogen

**Failure Rate** (number of pregnancies expected per 100 women per year): less than 1

**Some Risks:** Changes in menstrual cycle, weight gain. Similar to oral contraceptives—combined.

**Protection from STDs:** None

**Convenience:** Injection given once a month.

**Availability:** Prescription

### **Implant (Norplant)**

**FDA Approval Date:** 1990

**Description:** Six matchstick-sized rubber rods that are surgically implanted under the skin of the upper arm, where they steadily release the contraceptive steroid levonorgestrel.

**Failure Rate** (number of pregnancies expected per 100 women per year): less than 1

**Some Risks:** Irregular bleeding, weight gain, breast tenderness, headaches, difficulty in removal

**Protection from STDs:** None

**Convenience:** Implanted and removed by health-care provider in minor outpatient surgical procedure; effective for up to five years.

**Availability:** Prescription. In July 2002, Norplant's manufacturer announced that it will no longer distribute the Norplant system. Women using the system should contact their doctors about what their contraceptive options will be after the five-year expiration date of their Norplant systems.

### **IUD (Intrauterine Device)**

**FDA Approval Date:** 1976 (f)

**Description:** A T-shaped device inserted into the uterus by a health professional.

**Failure Rate** (number of pregnancies expected per 100 women per year): less than 1

**Some Risks:** Cramps, bleeding, pelvic inflammatory disease, infertility, perforation of uterus

**Protection from STDs:** None

**Convenience:** After insertion by physician, can remain in place for up to one or 10 years, depending on type.

**Availability:** Prescription

### **Periodic Abstinence**

**FDA Approval Date:** N/A

**Description:** To deliberately refrain from having sexual intercourse during times when pregnancy is more likely.

**Failure Rate** (number of pregnancies expected per 100 women per year): 20

**Some Risks:** None

**Protection from STDs:** None

**Convenience:** Requires frequent monitoring of body functions (for example, body temperature for one method).

**Availability:** Instructions from health-care provider

### **Trans-abdominal Surgical Sterilization—female (Falope Ring, Hulka Clip, Filshie Clip)**

**FDA Approval Date:** Early 1970s (g)

**Description:** The woman's fallopian tubes are blocked so the egg and sperm can't meet in the fallopian tube, preventing conception. (h)

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**Failure Rate** (number of pregnancies expected per 100 women per year): less than 1

**Some Risks:** Pain, bleeding, infection, other post-surgical complications, ectopic (tubal) pregnancy.

**Protection from Sexually Transmitted Diseases (STDs):** None

**Convenience:** One-time surgical procedure that requires an abdominal incision.

**Availability:** Surgery

### **Sterilization Implant—female (Essure System)**

**FDA Approval Date:** 2002

**Description:** Small metallic implant that is placed into the fallopian tubes. The device works by causing scar tissue to form, blocking the fallopian tubes and preventing conception. (h)

**Failure Rate** (number of pregnancies expected per 100 women per year): less than 1

**Some Risks:** Mild to moderate pain after insertion, ectopic (tubal) pregnancy.

**Protection from STDs:** None

**Convenience:** Minor surgical procedure, permanent sterilization. Device is inserted through the vagina using a catheter. Women must rely on another birth control method during the first three months, until placement is confirmed with an X-ray procedure.

**Availability:** Prescription

### **Surgical Sterilization—male**

**FDA Approval Date:** N/A

**Description:** Sealing, tying, or cutting a man's vas deferens so that the sperm can't travel from the testicles to the penis. (h)

**Failure Rate** (number of pregnancies expected per 100 women per year): less than 1

**Some Risks** (serious medical risks from contraceptives are rare): Pain, bleeding, infection, other minor postsurgical complications

**Protection from STDs:** None

**Convenience:** One-time surgical procedure.

**Availability:** Surgery

(a) Projected from six-month study and adjusted for use of emergency contraception.

(b) If spermicides are used with barrier methods, be sure that the spermicide is compatible with the condom or diaphragm (won't cause it to weaken or break). Oil-based lubricants (such as petroleum jelly or baby oil) will cause latex to weaken and should not be used with these methods.

(c) Spermicides used alone, with barrier devices, or with condoms can cause irritation to the skin lining the vagina, especially when the spermicide is used frequently. There is a possibility that spermicide might increase the risk of acquiring some sexually transmitted diseases because of disruption of the vaginal skin. Spermicide has not been proven to be effective against bacteria and viruses in people. Therefore, there is no reason to use spermicide during pregnancy.

(d) Medications for vaginal yeast infections may decrease effectiveness of spermicides.

(e) Less effective for women who have had a baby because the birth process stretches the vagina and cervix, making it more difficult to achieve a proper fit.

(f) First approval date of currently marketed IUDs. Some IUDs were sold before premarket approval was required. Those products are no longer on the market.

(g) Sold before premarket approval was required (1976).

(h) A contraceptive option for people who don't want children. Considered permanent because reversal is typically unsuccessful.

SOURCE: Food and Drug Administration. 2003. *FDA Consumer: Birth Control Guide* (Updated December 2003) (<http://www.fda.gov/fdac/features/19976/babytabl.html>; retrieved May 30, 2005).