

Drug Facts

Active ingredient (in each sponge)

Nonoxynol 9 (1000 mg)..... Purpose
Vaginal contraceptive

Use prevents pregnancy

Warnings

For vaginal use only

Toxic Shock Syndrome: Some cases of Toxic Shock Syndrome (TSS) have been reported in women using barrier contraceptives, including the sponge. TSS is a rare, but serious disease that may cause death. Warning signs of TSS include fever, nausea, vomiting, diarrhea, muscle pain, dizziness, faintness, or a sunburn-like rash on face or body. If you have any of these signs, remove the sponge and get medical help right away.

Allergy alert:

- this product contains sodium metabisulfite which may cause severe allergic reactions in some people. Do not use if you are allergic to sulfites.
- do not use if you have ever had an allergic reaction to nonoxynol 9 or to this product

Do not use

- within the first six weeks after giving birth
- during your menstrual period
- if you have had Toxic Shock Syndrome

Ask a doctor before use if you have

- recently had a miscarriage or an abortion
- been told that you should not become pregnant
- a vaginal or uterine condition, such as a vaginal septum or uterine prolapse, which may keep the product from working

Stop use and ask a doctor if

- you or your partner have a rash, burning, itching, or other irritation of the vagina or penis
- you or your partner have difficult or painful urination
- you get abdominal pain, fever, chills, or foul-smelling vaginal discharge
- you become pregnant

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- before using, read enclosed consumer information leaflet for complete directions and information
- wash hands before use
- remove the sponge from the pouch
- wet the sponge thoroughly with clean water, squeeze gently several times until sponge is very sudsy
- with the dimple side of sponge facing up, fold sponge upward and insert deep into vagina as shown in diagram in consumer information leaflet. The string loop must be on the bottom for easy removal.
- protection begins right away and lasts for 24 hours even with repeated acts of intercourse
- wait at least 6 hours after the last intercourse before removing sponge. **Do not leave sponge in vagina for longer than 30 hours.**
- if you have trouble removing the sponge from your vagina or you remove only a part of the sponge, call the *Today's Women Care* at 1-888-343-4499 or contact a health professional right away
- do not douche while sponge is in vagina

Other information

- no birth control product can prevent pregnancy all the time. See table of Pregnancy Rates for Birth Control Methods in the consumer information leaflet.
- correct use of a latex condom by your partner with every sexual act will help to reduce the risk of transmission of HIV infection (AIDS) and many sexually transmitted diseases (STDs)
- store at 20 - 25° C (68 - 77°F)

Inactive ingredients benzoic acid, citric acid, sodium dihydrogen citrate, sodium metabisulfite, sorbic acid, water in a polyurethane foam sponge

Questions or comments? call toll-free 1-888-343-4499 (*Today's Women Care*) [include hours available]

Sponsor's font type size used in the consumer information leaflet is adequate. The comments in red are the Agency's revisions to leaflet and refer to content only. Comments in blue italics type are only notations to sponsor)

Today ***sponge*** **Vaginal Contraceptive Sponge**

This 24-hour Vaginal Contraceptive Sponge is intended for the prevention of pregnancy.

Consumer Information Leaflet **Your Personal Guide**

Please read the Drug Facts label on the carton and this leaflet completely and carefully before using *Today* Vaginal Contraceptive Sponge.

If used ~~properly~~ correctly, according to the label and diagram instructions on back of leaflet, *Today* Sponge ~~can~~ may be a safe, effective and ~~exceptionally~~ convenient birth control method. *[Sponsor needs to delete the background shading in this section]*

IMPORTANT INFORMATION FOR USERS

Delete the clinical efficacy table and efficacy statements from this section. They are not consumer friendly. See revisions under Product Overview, Question B]

If you have no previous experience with vaginal birth control products you ~~may want to visit~~ should contact a ~~your~~ physician doctor, health professional or family planning clinic for advice on how to use this product ~~properly~~ correctly.

In clinical studies with *Today* Sponge,

- about 1 out of 10 women (9 - 11%) became pregnant when using this product correctly all the time.
- the possibility of getting pregnant increased to about 1 out of 7 women (13 - 16%) when this product was not used correctly.

If you have any questions on the best birth control method for you, contact a doctor, health professional, or family health clinic, especially if:

- you were told that you should not become pregnant
- you have given birth before.

No birth control product can prevent pregnancy all the time. See Table of Pregnancy Rates for Birth Control Methods below for a comparison of pregnancy rates.

[insert Table here or if sponsor has a separate attachment for the Agency's table of Pregnancy Rates for Birth Control Methods, a statement must be included re referencing where it is, e.g., see attached table.]

1. Product Overview

A. What is *Today* Vaginal Contraceptive Sponge and how does it work?

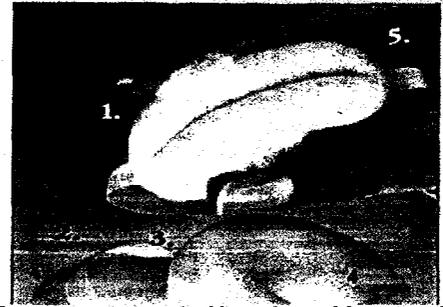
This birth control product is a soft, disposable polyurethane foam sponge containing 1000 mg of nonoxynol 9, which kills sperm on contact. It is inserted into the vagina and while in place provides protection against pregnancy for 24 hours. (See Question 3C for use during the menstrual period.) As long as the sponge is in place in the vagina, there is no need to add additional spermicidal creams or jellies, even if intercourse is repeated. ~~while wearing the sponge. There is enough nonoxynol 9 available to last a full 24 hours.~~

This makes it possible to insert the sponge in advance and enjoy uninterrupted lovemaking and multiple acts of intercourse without the need for additional contraception.

It is not necessary to use each sponge for a full 24 hours, as long as it is left in place at least 6 hours after the last act of intercourse.

~~For maximum protection always insert the sponge in advance whenever there is a possibility you may have intercourse within 24 hours. No birth control method can provide reliable protection if it is not used consistently. For maximum protection, always insert the sponge in advance whenever there is a possibility you may have intercourse within 24 hours. No birth control method can provide reliable protection if it is not used consistently.~~

Used as directed, *Today* Vaginal Contraceptive Sponge prevents pregnancy in three ways: 1) the nonoxynol 9 contained in *Today* Sponge kills sperm before they can reach the egg; 2) *Today* Sponge blocks the cervix opening to the uterus) so the sperm cannot enter; 3) *Today* Sponge traps and absorbs the sperm.



To save space, sponsor should consider simplifying picture]

1. Gentle Nonoxynol 9 contained within the sponge is released gradually over a 24-hour period.
2. Soft polyurethane foam sponge is formulated to feel like normal vaginal tissue.
3. Specially designed ribbon loop is attached to an interior web for maximum strength for removing sponge.
4. Anatomically contoured indentation covers cervix to help position sponge properly.
5. Sponge exterior is carefully shaped for easy insertion.
6. Store *Today* Sponge at 20 - 25° C (68 - 77°F).

B. How can I improve the effectiveness of the *Today* Vaginal Contraceptive Sponge?

No birth control method can provide reliable protection if it is not used correctly and consistently.

For greater birth control protection, you may want to use another method of birth control in addition to using the sponge, especially during the first few months while you become familiar with how to use it. Correct use of a latex condom by your partner together with your correct use of the *Today* Sponge may provide additional protection against getting pregnant.

C. How easy is it to use *Today* Vaginal Contraceptive Sponge?

This product is designed to be convenient and to avoid interruption of lovemaking because it can be inserted up to 24 hours before starting intercourse. Protection begins right away and lasts for 24 hours even with repeated acts of intercourse. However, the sponge should remain in place for at least 6 hours after the last act of intercourse, but should not be left in vagina longer than 30 hours.

Any woman who can use a tampon ~~can use this birth control method.~~ *[sponsor should delete phrase because it is misleading]* should not have difficulty using the sponge. It does not require a special fitting or prescription.

[The background shading for the Warnings section needs to be lighter to increase readability or the font color for leaflet should be more contrasting.]

2. WARNINGS Warnings

For vaginal use only

Toxic Shock Syndrome: Some cases of Toxic Shock Syndrome (TSS) have been reported in women using barrier contraceptives, including the sponge. TSS is a rare, but serious disease that may cause death. Warning signs of TSS include fever, nausea, vomiting, diarrhea, muscle pain, dizziness, faintness, or a sunburn-like rash on face or body. If you have any of these signs, remove the sponge and get medical help right away. You can avoid the risk of getting sponge-associated TSS by not using the sponge.

Allergy alert:

- this product contains sodium metabisulfite which may cause severe allergic reactions in some people. Do not use if you are allergic to sulfites.
- do not use if you have ever had an allergic reaction to nonoxynol 9 or to this product

Do not use

- within the first six weeks after giving birth
- during your menstrual period
- if you have ever had Toxic Shock Syndrome

Ask a doctor before use if you have

- recently had a miscarriage or an abortion
- been told that you should not become pregnant
- a vaginal or uterine condition, such as a vaginal septum or uterine prolapse, which may keep the product from working
- signs of pregnancy such as a late menstrual period

Stop use and ask a doctor if

- you or your partner have a rash, burning, itching, or other irritation of the vagina or penis
- you or your partner have difficult or painful urination
- you get abdominal pain, fever, chills, or foul-smelling vaginal discharge
- you become pregnant

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

(For most people, ingestion of small quantities of the spermicide alone should not be harmful.)
[sponsor needs to add this new Directions section]

3. Directions

Before using, read the back of this leaflet for diagram instructions for inserting and removing sponge

- wash hands before use
- remove the sponge from the pouch
- wet the sponge thoroughly with clean water, squeeze gently several times until sponge is very sudsy
- with the dimple side of sponge facing up, fold sponge upward and insert deep into vagina as shown in diagram (see section 9). The ribbon loop must be on the bottom for easy removal.
- protection begins right away and lasts for 24 hours even with repeated acts of intercourse
- wait at least 6 hours after the last intercourse before removing the sponge. **Do not leave sponge in vagina for longer than 30 hours.**
- if you have trouble removing the sponge from your vagina or you remove only a part of the sponge, call the *Today's Women Care* at 1-888-343-4499 or contact a health professional right away
- do not douche while sponge is in vagina.

Douching is not necessary. If you want to douche wait at least 6 hours after last intercourse and remove the sponge before douching.

[sponsor should consider placing diagram instruction here in the following order for the numbered sections: sections 1, 2, 3, 8, 9, 10, 6, 4, 5, and 7.]

4. Inactive ingredients benzoic acid, citric acid, sodium dihydrogen citrate, sodium metabisulfite, sorbic acid, water in a polyurethane foam sponge

5. Questions or comments?

call toll-free 1-888-343-4499 (*Today's Women Care*) (include hours available and website)

6. Other questions you may have

A. How can I reduce the chances of a serious infection including sexually transmitted diseases (STDs)?

- read all Warnings before use.
- correct use of a latex condom by your partner with every sexual act (intercourse) will help to reduce the risk of transmission of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) and many sexually transmitted diseases (STDs).
- you may want to see a doctor or health professional for advice on how to reduce the risk of STDs, especially if you have a new sex partner or multiple sex partners
- do not leave the sponge in vagina longer than 30 hours.
- make sure that all of sponge is removed from vagina.
- wash hands before inserting and removing the sponge.

B. Can I use *Today Sponge* during my menstrual period?

Today Sponge should not be used during the menstrual period. Some cases of Toxic Shock Syndrome have been reported in women using the sponge during their menstrual period.

C. Can I have an allergic reaction or other side effects from the *Today Sponge*?

- If you have ever had a severe allergic reaction to sulfites, do not use this product because it contains sodium metabisulfite.
- A small number of men and women may be sensitive to the spermicide, nonoxynol 9, in this product and should not use this product if irritation occurs and persists. Of the women in the clinical trials, between 2 - 3% discontinued use of the sponge because of itching, irritation, or rash, and 1 - 3% discontinued because of allergic reactions.

D. What if *Today Sponge* develops an odor?

It is unlikely that you will notice an odor while *Today Sponge* is in place. If there is a noticeable odor when you remove the sponge, do not be concerned. Any material placed in the vagina will occasionally produce an odor when exposed to normal vaginal fluids and semen.

E. Can I insert *Today Sponge* after intercourse?

No, the sponge must be inserted before intercourse begins. Once the penis enters the vagina, there is a greater chance of getting pregnant because there may be the leakage of sperm without ejaculation and, with ejaculation, sperm reaches the fallopian tubes even more quickly. ~~there may be leakage of sperm without ejaculation. Once ejaculation occurs, sperm reaches the fallopian tubes quickly.~~

F. How does *Today Sponge* stay in place. Can the sponge get lost in my body?

The sponge is held in place by the muscles of the upper vagina. The cup-like indentation in the sponge helps to keep it in place directly over the cervix. The opening from the vagina to the uterus is far too small for *Today Sponge* to pass through. There is no other normal opening in the vagina that would provide access to any other part of your body.

G. Can *Today Sponge* tear while it is in place?

Today Sponge should not tear with normal muscular movement within the vagina or even during intercourse. Be careful not to push a fingernail through sponge when inserting or removing sponge. There may be minor separation, or "splitting," of sponge material at stress points surrounding around the ribbon loop or in the center of the indentation. But these minor separations do not affect the contraceptive capabilities of the *Today Sponge* in any way.

H. What if I have trouble removing *Today Sponge*?

If you have trouble removing the sponge or think that parts of the sponge are still in your vagina, carefully follow the removal instructions on the back of this leaflet. If you still have trouble removing the sponge, call the *Today's Women Care* at 1-888-343-4499 or contact a health professional right away.

I. Can my partner feel *Today Sponge* during intercourse?

Today Sponge is designed to be soft and comfortable. It feels like normal vaginal tissue. Some men may feel the sponge during intercourse, but this is usually not objectionable.

J. Can I leave *Today Sponge* in place when I swim or bathe?

Yes. *Today Sponge* will not be affected in any way.

K. Is *Today Sponge* as effective as the pill or IUD?

No. *Today Sponge* is not as effective as the pill or IUD. See table of Pregnancy Rates for Birth Control Methods.

Today's
women care

DIVISION OF ALLENDALE PHARMACEUTICALS INC.
ALLENDALE, NJ 07401

Component #934Tri001

Made in U.S.A.
U. S. Pat. 4393871
Pat. 4393871

8. Some basic information about your reproductive system

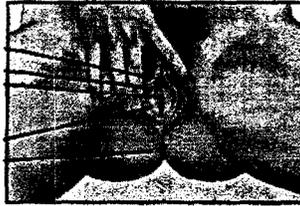
A. To use this method effectively, it is important for you to understand your anatomy.



Today vaginal contraceptive sponge is inserted through the vaginal opening and placed in the deepest part of the vagina, just below the cervix. The cervix is the bottom end of the uterus, and has a small opening through which sperm must travel to reach and fertilize the egg.

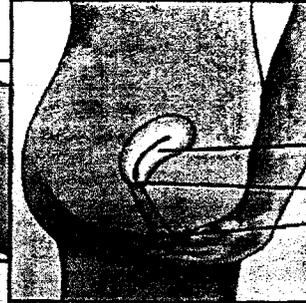
B. How do I find the vaginal opening?

Clitoris
Labia
Urinary
Opening
Vaginal
Opening
Anus



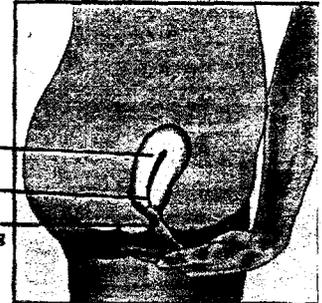
Sit on the edge of a chair with knees apart. Place a good source of light about arm's length in front of you and use a hand mirror to examine the region between the outer "lips," or labia. The vaginal opening is between the labia, just below the small urinary opening and one or two inches below the clitoris.

C. How do I find the cervix?



It is easier to find the cervix if you squat. Insert your finger gently into the vagina, reaching up on an angle toward the back until you find the firm, round surface of the cervix. It feels something like the tip of your nose. In some cases, it may be difficult to locate, so you may have to explore a bit before you find it.

D. Bearing down.



You can bring your cervix down closer to the vaginal opening, and thus make it easier to locate, by bearing down. Take a deep breath and bear down as if you were having a bowel movement. You should now be able to locate your cervix just above the vaginal opening. This technique is also very useful for removing the sponge.

[Make this section either as the first section (7.) on back of leaflet and move in front of section 8 above or as the last section as section 10. Note if last section you will need to renumber sections and references.]

7. Important Points to Remember

- If you are unsure about how to use *Today Vaginal Contraceptive Sponge*, ~~see~~ contact your physician - a doctor, health professional, or family planning clinic ~~or assistance~~ for help.
- To avoid introducing germs into your vagina, always wash your hands before handling *Today Sponge* and before inserting your fingers into your vagina.
- Wetting *Today Sponge* with clean water is important. This is what activates the spermicide. You will notice a light foam or "suds." Do not try to rinse this out.
- You may insert *Today Vaginal Contraceptive Sponge* any time up to 24 hours before beginning intercourse. After inserting the sponge, you may have intercourse ~~can~~ ~~immediately~~ right away.
- *Today Sponge* contains enough spermicide for repeated acts of intercourse during a 24-hour period.
- It is not necessary to use the sponge for a full 24 hours, as long as it is left in place 6 hours after the last act of intercourse.
- If you have intercourse when the sponge has been in place for 24 hours, leave it in place an additional 6 hours after intercourse before removing it. *Today Sponge* ~~should~~ must not be left in place for more than 30 hours.
- If you have trouble removing the sponge or if you remove only a part of the sponge call *Today's Women Care* at 1-888-343-4499 [include hours available] or contact a health professional right away.
- ~~You must wait six hours after your last act of intercourse before removing the sponge.~~

9. How to insert *Today* Vaginal Contraceptive Sponge

The sponge may be inserted any time up to 24 hours before beginning intercourse.

1. Wash hands before use. Remove the sponge from the airtight inner-pack individual pouch and hold it in one hand with the "dimple" side up. The loop should dangle under the sponge.



2. Wet the sponge thoroughly with clean tap water. The water activates the spermicide.



3. Squeeze the sponge gently several times until it becomes very sudsy. Be sure you do not squeeze the sponge dry.

(The sponge should remain sudsy for insertion.)

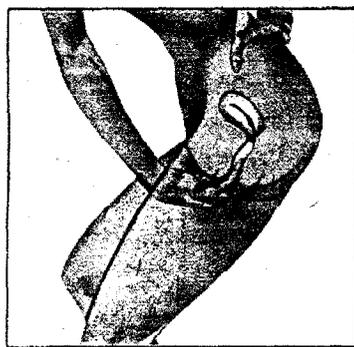


4. Hold the sponge in one hand with the "dimple" side up. Fold the sides of the sponge upward with a finger along each side to support it.

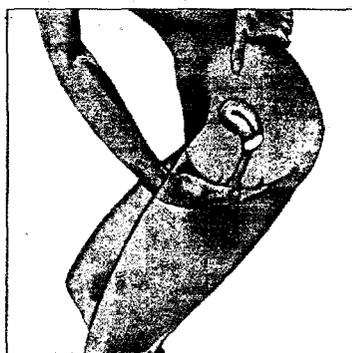


The sponge should look long and narrow. Be sure the ribbon loop dangles underneath the sponge from one end of the fold to the other, as shown.

5. Bend your wrist and point the end of the folded sponge toward your vagina. Be sure that you can see the fold when you look down at it and that the ribbon loop dangles below.



6. From a standing position, squat down slightly and spread your legs apart. Use your free hand to spread apart the lips of the vagina. You may also stand with one foot on a stool or chair, sit cross-legged or lie down. The semi-squatting position seems to work best for most women. Hold the sponge "dimple" side up between the thumb and finger. Insert the sponge into the opening of the vagina as far as your fingers will go. Let the sponge slide through your fingers, deeper into the vagina as far as your fingers will go. Let the sponge slide through your fingers, deeper into the vagina.



7. Now use one or two fingers to push the sponge gently up into your vagina as far as it will go. Be careful not to push a fingernail through the sponge. Check the position of the sponge by sliding your finger around the edge of the sponge to make sure your cervix is not exposed. You should be able to feel the ribbon loop. If you think the sponge is not in the correct position, simply insert your finger into your vagina and slide it back.

8. Sponge that falls out after inserting

It is unlikely that the *Today* Sponge will fall out if correctly inserted. However, during a bowel movement or other form of internal straining, the sponge may be pushed down to the opening of the vagina and perhaps fall out. If you think that the sponge has fallen down to the vagina opening, simply insert your finger into your vagina and push it back.

If the sponge falls out, do not reuse. Wash hands and moisten (wet thoroughly) new sponge and insert as directed. Do not flush old sponge down the toilet. Discard it in a waste container.

10. How to remove Today Vaginal Contraceptive Sponge

A. Removal Procedure

1. Always wait 6 hours after your last act of intercourse before removing the sponge. Do not leave the sponge in your vagina longer than 30 hours.



2. Put your finger into your vagina and reach up and back to find the ribbon loop. If you cannot find the loop immediately, bear down until you can feel the loop. (See "Bearing down," Section 8D) Hook your finger around the loop. (If you have not found the loop, grasp the sponge between your thumb and forefinger.)

3. Slowly and gently pull the sponge out. If the vaginal muscles seem to be holding it tightly, wait a few minutes and try again. If removal is still difficult, use the following exercise to relax your vaginal muscles: Tighten vaginal muscles as hard as you can and hold for 10 seconds, then relax and let go. Repeat. As you relax, breathe out slowly while bearing down (See Section 8D.). Now remove the sponge as you continue to relax.



Check to see if you removed all of the sponge. If only a part of sponge was removed and you are unable to get remaining parts out of vagina or if you have trouble removing the sponge, call the Today's Women Care at 1-888-343-4499 or contact a health professional right away.

4. Dispose of the sponge in a waste container. Do not flush it down the toilet.

Leave
Picture of toilet with
X through it here

B. Special-removal situations-Problems with Removal

1. Stuck Sponge.

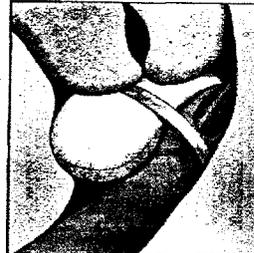
There are no structures in the vagina to interfere with removal of the sponge. With tension or unusually strong muscular pressure, the sponge may be held in the vagina more tightly than normal. Simple relaxation of the vaginal muscles and bearing down should make it possible to remove the sponge without difficulty (See Section 8D).

If you are still unable to remove the sponge, it may have adhered by suction to the cervix. To remove, it is necessary to break the suction. To do this, slip a finger between the sponge and the cervix on one side, tilting the sponge up and away from the cervix. Once free, the sponge may be removed normally.

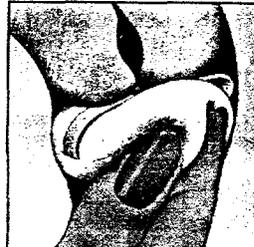
If none of the above suggestions seems to help, see your physician or family planning clinic. You may wish to take several unused Today Sponges along so your medical advisor can help you refine your insertion and removal technique. If you still have trouble removing the sponge, contact a doctor or health professional right away. If you need help in either inserting or removing the sponge, bring several unused Today Sponges to your doctor, health professional or family planning clinic so that they can help you learn how to insert and remove the sponge correctly.

2. Upside-down Sponge.

Occasionally, a sponge will turn upside down in the vagina, making the ribbon loop more difficult to find. To find the ribbon loop, run your finger around the edge on the back side of the sponge until you feel the ribbon loop where it's attached to the sponge.



If you cannot find the ribbon loop, simply grasp the edge of the sponge between your thumb and forefinger and pull it out slowly. Bearing down (Section 8D) will make it easier to reach the sponge.



3. Torn Sponge.

Today Sponge, like a soft contact lens, should be handled gently. Pulling too hard or too quickly on the removal ribbon loop may cause the sponge to tear. The procedure for removing a torn sponge is similar to that for an upside-down sponge. The important thing is to remove the sponge slowly. If you suspect that you have left small pieces of sponge inside the vagina, run a finger around the upper vault of your vagina with a sweeping movement and then toward the vaginal opening to find and remove any remaining sponge material. You may also want to douche with a mild solution.

To reduce the risk of infection, it is important that you get all parts of the sponge out of the vagina. If you have difficulty getting parts of sponge out of the vagina, call the Today's Women Care at 1-888-343-4499 (insert hours available and website) or contact a health professional right away.

not
electronic

Pregnancy Rates for Birth Control Methods

(For One Year of Use)

The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

"Typical Use" rates mean that the method either was *not always used correctly* or was *not used with every act of sexual intercourse* (e.g., sometimes forgot to take a birth control pill as directed and became pregnant), or was *used correctly but failed anyway*.

"Lowest Expected" rates mean that the method was *always used correctly with every act of sexual intercourse but failed anyway* (e.g., always took a birth control pill as directed but still became pregnant).

Method	Typical Use Rate of Pregnancy	Lowest Expected Rate of Pregnancy
Sterilization:		
Male Sterilization	0.15%	0.1%
Female Sterilization	0.5%	0.5%
Hormonal Methods:		
Implant (<i>Norplant™</i> and <i>Norplant™-2</i>)	0.05%	0.05%
Hormone Shot (<i>Depo-Provera™</i>)	0.3%	0.3%
Combined Pill (<i>Estrogen/Progestin</i>)	5%	0.1%
Minipill (<i>Progestin only</i>)	5%	0.5%
Intrauterine Devices (IUDs):		
Copper T	0.8%	0.6%
Progesterone T	2%	1.5%
Barrier Methods:		
Male Latex Condom ¹	14%	3%
Diaphragm ²	20%	6%
Vaginal Sponge (<i>no previous births</i>) ³	20%	9%
Vaginal Sponge (<i>previous births</i>) ³	40%	20%
Cervical Cap (<i>no previous births</i>) ²	20%	9%
Cervical Cap (<i>previous births</i>) ²	40%	26%
Female Condom	21%	5%
Spermicide: (gel, foam, suppository, film)	26%	6%
Natural Methods:		
Withdrawal	19%	4%
Natural Family Planning (<i>calendar, temperature, cervical mucus</i>)	25%	1-9%
No Method:	85%	85%

¹ Used Without Spermicide

² Used With Spermicide

³ Contains Spermicide

Data adapted from: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Stewart F, et al. Contraceptive Technology: Seventeenth Revised Edition. New York, NY: Ardent Media, 1998.

Table prepared by FDA: 5/13/97, revised 9/17/98