

6/7/00

Sandra Titus, Ph.D.
Advisors and Consultants Staff
FDA/CDER/ORM/HFD-21
5630 Fishers Lane
Rockville, MD 20857

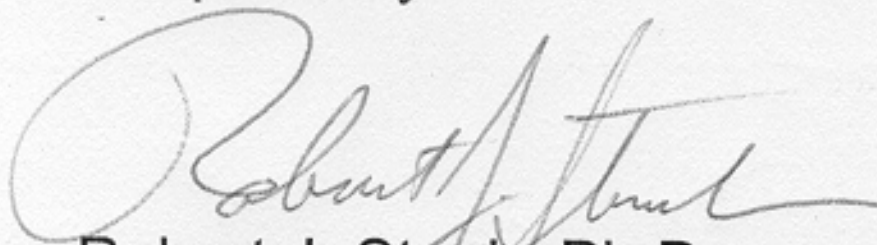
AVAILABLE FOR PUBLIC DISCLOSURE

Dear Dr, Titus:

Enclosed are 35 copies of background documentation for the Nonprescription Drugs Advisory Committee; as well, there is a CD with the same information.

Please let me know if you have any questions.

Respectfully.



Robert J. Staab, Ph.D.
Chief Scientific Officer

6/7/00

Nonprescription Drugs Advisory Committee
C/o
Sandra Titus, Ph.D.
Advisors and Consultants Staff
FDA/CDER/ORM/HFD-21
5630 Fishers Lane
Rockville, MD 20857

Dear Advisory Committee:

Allendale Pharmaceuticals is a small start-up company who intends to reintroduce the Today® Sponge (the Sponge) to the US and worldwide market. Following submission of the current (1995) label (attached) for the Sponge to the Division of OTC Products on April 29, 1999, several questions arose concerning the labeling of the product in the ensuing 13 months.

We were informed that the Division has requested that we provide background information to the Advisory Committee for consideration of labeling issues. So that we could comply with that request we have engaged several prominent experts in professional fields who are capable of addressing these label issues. We have asked Professor Andrew Onderdonk of Harvard Medical School to offer an overview of the bacterial disease, Toxic Shock Syndrome (TSS) and to assess the adequacy of labeling for the potential risk of Toxic Shock Syndrome. His background document is attached.

We have requested that Dr. Michael Burnhill, Vice President for Medical Affairs of the Planned Parenthood Federation of America to examine the safety history based upon their 12 years of experience with the Sponge. We also asked that he review the adequacy of the current label. His assessment is enclosed in the background information. Besides serving for years as a Professor of Obstetrics and Gynecology at RW Johnson, Medical School, leadership in nationally recognized professional medical organizations, Dr. Burnhill is internationally recognized as having extensive practical experience in the choice and use of over-the-counter contraceptives.

We have also asked Dr. Elizabeth Connell, Professor Emeritus Department of Gynecology & Obstetrics, Emory University School of Medicine to comment on the adequacy of the label. Dr. Connell's c.v. is attached. She brings a particularly appropriate background since she has been appointed as a consultant to FDA CDER, has chaired the OB GYN Devices Panel and has chaired the OTC Panel for Contraceptive and Other Vaginal Drug Products. Her practical experience in the use of local contraception and Nonoxynol 9 would serve those wishing to assess the adequacy of the labeling of the Sponge well.

We asked that the content of the label be considered with respect to the issues surrounding the warnings for TSS. Dr. Onderdonk has reviewed the current (1995) label for the Sponge concerning warnings for TSS and has judged that warning as adequate. He has pointed out that the incidence of the disease reported to the Centers for Disease Control has decreased dramatically during the time that the Sponge was marketed.

Dr. Burnhill has reviewed the efficacy stated on the current (1995) label and believes that the statements are adequate to inform the consumer. He has stated that warnings for irritation, insertion, removal and TSS are acceptable on the current label. He has dismissed the assertion that the minimal irritation observed in consumer use by a small percentage of users offers and demonstrated increased risk in disease transmission. He has cautioned against accepting specialized studies using prostitutes as appropriate for evaluating risks for the typical consumer.

Dr. Connell has very aptly described the history of the development of the Sponge, its introduction to the market and as well, its voluntary removal from the market by American Home Products for financial reasons. She agrees that the current warnings concerning TSS, irritation, insertion, removal, use instructions and advice as to when professional advice should be sought is adequate to communicate with the consumer.

She has reviewed reports on STD transmission with N9 use as well as diminution in lactobacillus and concurrent occasional increases in pathogenic bacteria and concluded that these reports are not of clinical significance for the Sponge.

She specifically addresses the issue of using data from small studies or beta analyses. She supports the use of the clinical study of 1847 women to assess efficacy as the appropriate study to use for assessing efficacy. This is the study used to assign the pregnancy rates to the current (1995) label.

Dr. Connell further warns against the use of multiple efficacy rates to communicate with consumers. If we publish the results of several clinical studies, we run the risk of confusing the consumer and the need to add explanations for the differences in the results. She specifically advises against the use of the Table¹ (attached) for this reason.

We at Allendale Pharmaceuticals believe that the current (1995) label that has been associated with the Sponge for over ¼ billion uses has adequately communicated the potential safety and efficacy issues.

The current label clearly states the efficacy rates for the Sponge. We also clearly state that the Sponge is not as effective as the pill or the IUD. The current label explains method effectiveness and use effectiveness and the rates to be expected very clearly. If the "Table" were included in the labeling, the label would then state:

The Sponge has a method effectiveness of	9.2-11.0%
The Sponge has a Lowest expected rate of pregnancy of	9%
The Sponge has a use effectiveness of	13.3-15.5%
The Sponge has a typical use rate of pregnancy of	20%
The Sponge has a lowest expected rate of pregnancy of	20%
	(previous births)
The Sponge has a typical use rate of pregnancy of	40%
	(previous births)

The "Table" states that spermicides have a lowest expected rate of pregnancy of 6%. The Sponge with spermicide, which has been tested in 1847 women, has a method effectiveness of 9.2-11%. This comparison becomes invalid when one considers a recent publication that reports an estimated 12-month typical spermicide failure rate of 39.8-44% for two spermicidal products covered by the Table². For reasons pointed out by Burnhill and Connell, these comparisons are very risky for professionals to judge at this point in time; for consumers they are entirely confusing and misleading.

We believe that the intent of the inclusion of the "Table" is worthy in that it attempts to allow a consumer to make an informed decision on the relative efficacy of various methods. However, in fact it confuses the consumer.

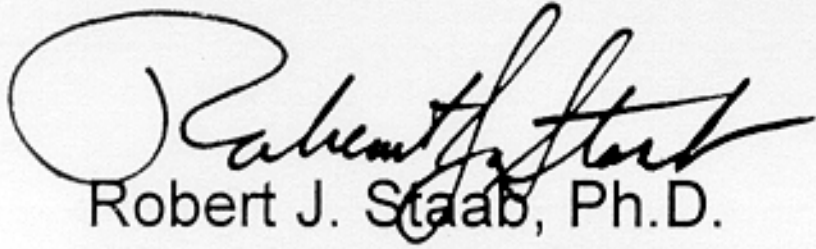
We believe that the small number of consumer complaints (22.3 complaints for any issue per million units sold) that have been received in the past are typical for products such as the Sponge. Our intention to continue the 800# form of communication will also offer an opportunity to explain any additional questions that consumers might have.

¹ "TABLE" Pregnancy Rates for Birth Control Methods (for one year of use)

² Raymond, E, et al, Obstetrics and Gynecology, Vol 93, No. 6, June, 1999

We believe that it is critical to communicate clearly and concisely with the consumer. We also believe that this current label as used when this product was voluntarily removed from market adequately addresses all of the current issues of safety and efficacy.

Respectfully.

A handwritten signature in black ink, appearing to read "Robert J. Staab". The signature is written in a cursive style with a large, prominent initial "R".

Robert J. Staab, Ph.D.
Chief Scientific Officer

Today[®] Sponge

Vaginal Contraceptive Sponge

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

User Instruction Booklet Your Personal Guide

Please read this booklet completely and carefully before using *Today* Vaginal Contraceptive Sponge. If used properly according to these instructions, *Today* Sponge can be a safe, effective and exceptionally convenient birth control method.

IMPORTANT INFORMATION FOR THE NEW USER

If you have no previous experience with vaginal birth control products, you may want to visit your physician or family planning clinic for advice on how to use this product properly.

If you have difficulty removing *Today* Vaginal Contraceptive Sponge at first, don't panic. Learning to use *Today* Sponge (See Sections 5, 6, 7) is like learning to use contact lenses. Take your time. And relax. Bearing down (See Section 4D) will help push *Today* Sponge toward the vaginal opening, where it can be grasped easily.

If the sponge is discolored or has a foul smell when you remove it from your vagina, this may be an indication of a vaginal infection. Many women have vaginal infections and are not aware of them. If you notice these signs of infection, see your clinic or physician immediately.

1. Product Overview

A. What is *Today* Vaginal Contraceptive Sponge?

This birth control product is a soft, disposable polyurethane foam sponge containing a spermicide 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.)

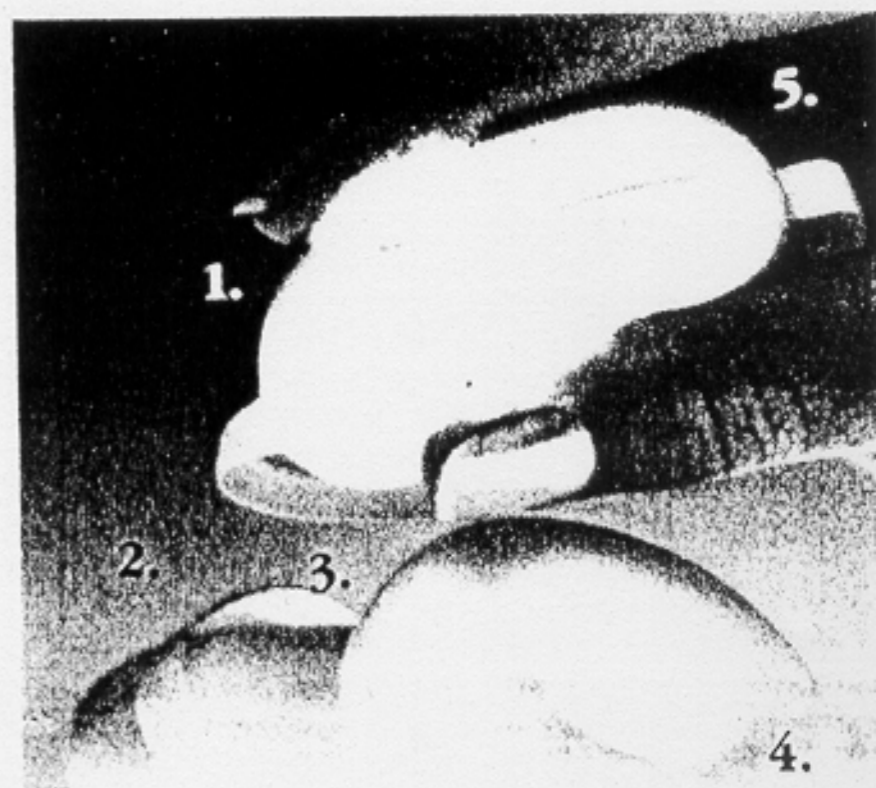
As long as the sponge is in place in the vagina, there is no need to add additional spermicidal creams or jellies, even if intercourse is repeated while wearing the sponge. There is enough spermicide available to last a full 24 hours.

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.



1. Gentle spermicide 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.
4. Anatomically contoured indentation covers cervix to help position sponge properly.
5. Sponge exterior is carefully shaped for easy insertion.

B. How does *Today* Vaginal Contraceptive Sponge work?

Used as directed, *Today* Vaginal Contraceptive Sponge prevents pregnancy in three ways: 1) the spermicide 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.

C. How effective is *Today* Vaginal Contraceptive Sponge in preventing pregnancy?

In clinical trials of *Today* Vaginal Contraceptive Sponge since 1979, over 1,800 women worldwide have completed over 12,000 cycles of use. The results of these clinical trials are as follows:

Study	Pregnancy Rates per 100 Women		
	Number of Women	Method-effectiveness* Pregnancy Rate	Use-effectiveness* Pregnancy Rate
United States	721	9.7-12.7	15.3-18.7
International	1126	8.2-10.6	11.4-14.0
Worldwide	1847	9.2-11.0	13.3-15.5

***Method-effectiveness**—The level of effectiveness expected by women who follow the printed instructions exactly, and who use the sponge every time they have intercourse.

***Use-effectiveness**—The level of effectiveness which can be expected by a large group of women some of whom either fail to use the sponge correctly or do not use it every time they have intercourse.

WOMEN CAN EXPECT AN EFFECTIVENESS RATE OF 89-91% IF THEY USE *TODAY* SPONGE CONSISTENTLY AND ACCORDING TO LABEL INSTRUCTIONS. IN CLINICAL TRIALS INCLUDING WOMEN WHO DID NOT USE *TODAY* SPONGE CONSISTENTLY AND PROPERLY, THE EFFECTIVENESS WAS 84-87%.

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

This product is designed to be convenient and easy to use, and to avoid interruption of lovemaking. Because it can be inserted up to 24 hours in advance, there is no need to stop and deal with contraception immediately before, during, or directly after intercourse. Insertion and removal of the sponge itself is fast and simple. For maximum spontaneity, it is best to insert *Today* Sponge well in advance of intercourse.

Difficulty in removing *Today* Sponge has been reported by a small number of women. After reading instructions

for removal (See Section 7), if you are having difficulty removing the sponge from your vagina or you remove only a portion of the sponge, contact the *Today* TalkLine or consult your physician or clinic immediately.

E. Who can use *Today* Vaginal Contraceptive Sponge?

Any woman who can use a tampon can use this birth control method. It does not require a special fitting or a prescription.

A small number of men and women may be sensitive to the spermicide in this product (nonoxynol-9) 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.

After childbirth, miscarriage or other termination of pregnancy, it is important that you consult your physician or clinic before using *Today* Sponge.

If you have ever had Toxic Shock Syndrome, do not use *Today* Sponge.

2. WARNINGS

- Some cases of Toxic Shock Syndrome (TSS) have been reported in women using barrier contraceptives including *Today* Sponge. Although the occurrence of TSS is uncommon, some studies indicate that there is an increased risk of non-menstrual TSS with the use of barrier contraceptives, including *Today* Sponge.

- *Today* Sponge should not be left in place for more than 30 hours after insertion.

- If you experience two or more of the warning signs of TSS including fever, vomiting, diarrhea, muscular pain, dizziness and rash similar to sunburn, consult your physician or clinic immediately.

- If you have difficulty removing the sponge from your vagina or you remove only a portion of the sponge, contact the *Today* TalkLine or consult your physician or clinic immediately.

- *Today* Sponge should not be used during the menstrual period.

- After childbirth, miscarriage or other termination of pregnancy, it is important to consult your physician or clinic before using this product.

- If you have ever had Toxic Shock Syndrome, do not use *Today* Sponge.

- For best protection against pregnancy, follow instructions exactly.

- If you or your partner think you have ever experienced an allergic reaction to the spermicide used in this product, it is best to consult a physician before using *Today* Vaginal Contraceptive Sponge.

- If either you or your partner develops burning or itching in the genital area, stop using this product and contact your physician.

- A higher degree of protection against pregnancy will be afforded by using another method of contraception in addition to a spermicidal contraceptive. This is especially true during the first few months, until you become familiar with the method. In our clinical studies, approximately one-half of all accidental pregnancies occurred during the first three months of use.

- Where avoidance of pregnancy is essential, the choice of contraceptive should be made in consultation with a doctor or a family planning clinic.

- Any delay in your menstrual period may be an early sign of pregnancy. If this happens, consult your physician or clinic as soon as possible.

- Keep this and all drugs out of the reach of children.

- In case of accidental ingestion of the sponge, call a Poison Control Center, emergency medical facility or doctor. (For most people, ingestion of small quantities of the spermicide alone should not be harmful.)

- As with any drug, if you are pregnant or nursing a baby, seek professional advice before using this product.

3. Answers to some other questions you may have:

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

Today Vaginal Contraceptive 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.

B. Can I leave *Today* Vaginal Contraceptive Sponge in place when I swim or bathe?

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

C. Can I use *Today* Vaginal Contraceptive Sponge during my menstrual period?

Today Sponge should not be used during the menstrual period.

D. 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. There may be minor separation, or "splitting," of sponge material at stress points surrounding the string loop or in the center of the indentation. But these minor separations do not affect the contraceptive capabilities of *Today* Sponge in any way.

After reading instructions for removal (See Section 7), if you are having difficulty removing the sponge from your vagina or you remove only a portion of the sponge, contact the *Today* TalkLine or consult your physician or clinic immediately.

E. 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. If the odor persists, however, see your physician or family planning clinic. It may be an indication of vaginal infection.

F. Can I use *Today* Sponge after intercourse?

No. *Today* Vaginal Contraceptive Sponge must be inserted *before* intercourse begins. Once the penis enters the vagina, there may be leakage of sperm without ejaculation. Once ejaculation occurs, sperm reaches the fallopian tubes quickly.

G. Is *Today* Vaginal Contraceptive Sponge as effective as the pill or IUD?

No. *Today* Sponge is not as effective as the pill or IUD.

For more information...

If you have any questions after reading this insert, see your physician or local family planning clinic. If you wish, you may also contact us directly.

Whitehall Laboratories Inc., New York, N.Y. 10017 or call the Toll Free *Today* TalkLine, 1-800-223-2329.

Para instrucciones en español, escriba a Whitehall Laboratories Inc., New York, N.Y. 10017

Active Ingredient: Nonoxynol-9, One Gram
Inactive Ingredients: Benzoic Acid, Citric Acid, Sodium Dihydrogen Citrate, Sodium Metabisulfite, Sorbic Acid, Water in a Polyurethane Foam Sponge.



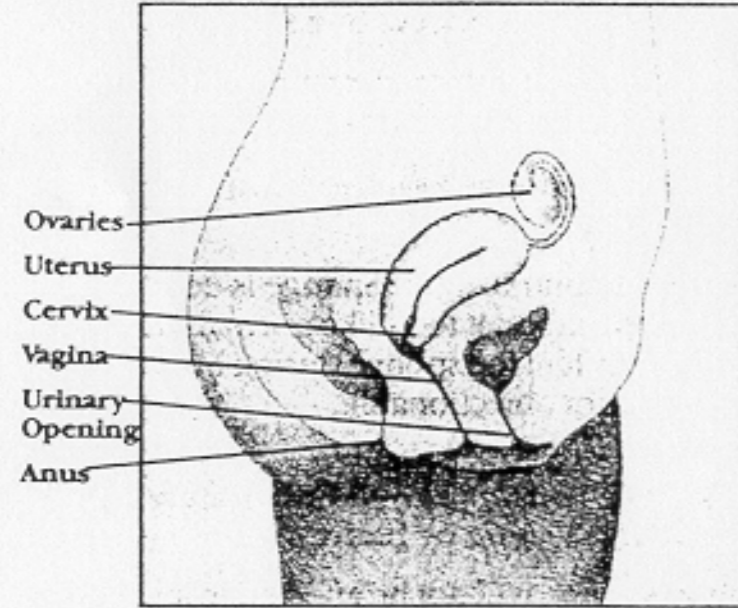
WHITEHALL LABORATORIES INC.
NEW YORK, N.Y., 10017

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

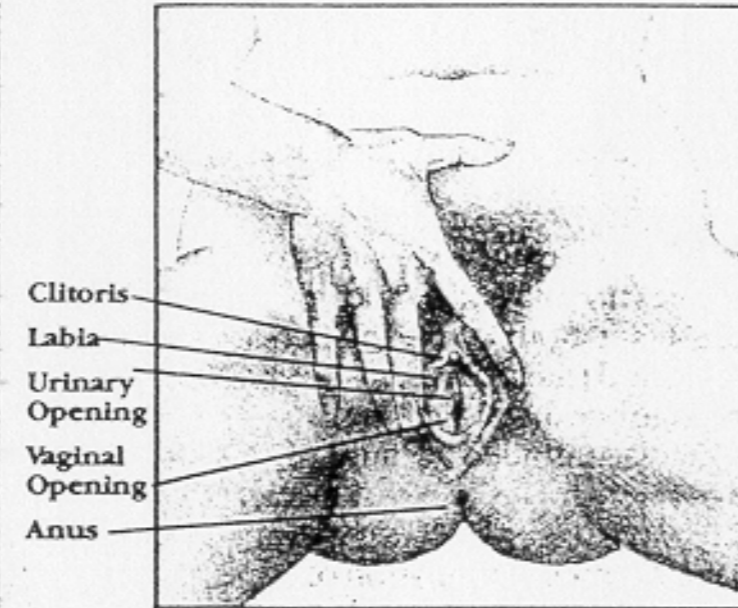
4. Some basic information about your reproductive system.

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



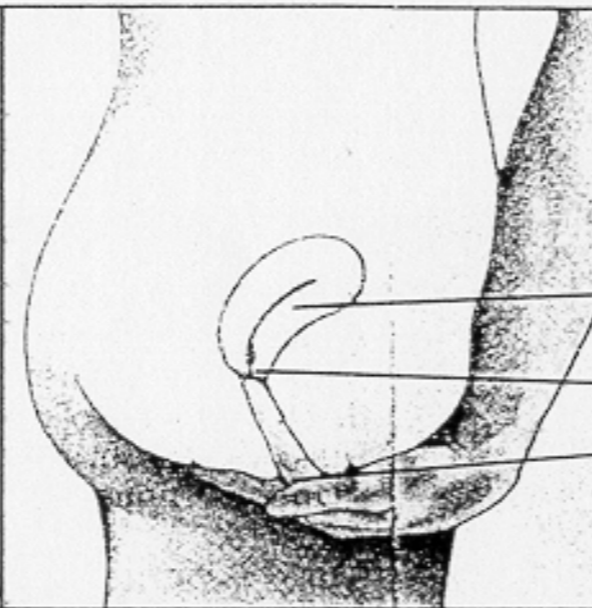
Today Vaginal Contraceptive Sponge is inserted through the vaginal opening and placed in the deepest part of the vagina, just below the cervix. The cervix is the bottom end of the uterus, and has a small opening through which sperm must travel to reach and fertilize the egg.

B. How do I find the vaginal opening?



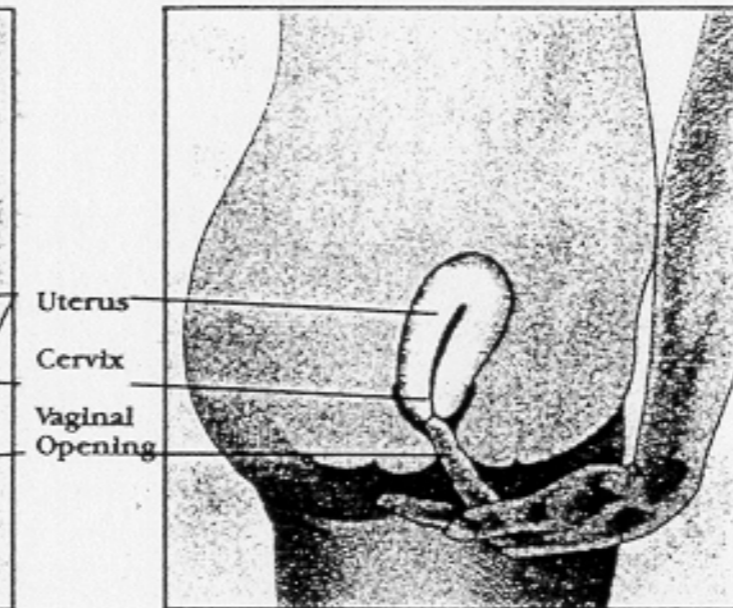
Sit on the edge of a chair with knees apart. Place a good source of light about arm's length in front of you and use a hand mirror to examine the region between the outer "lips," or labia. The vaginal opening is between the labia, just below the small urinary opening and one or two inches below the clitoris.

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.

6. Important Points to Remember

- If you are unsure about how to use *Today Vaginal Contraceptive Sponge*, see your physician or family planning clinic for assistance.
- To avoid introducing germs into your vagina, always wash your hands before handling *Today Sponge* and before inserting your fingers into your vagina.
- You may insert *Today Vaginal Contraceptive Sponge* any time up to 24 hours before intercourse. After inserting the sponge, intercourse can occur immediately.
- *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.
- *Today Sponge* contains enough spermicide for repeated intercourse during a 24-hour period.
- 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 not be left in place for more than 30 hours.
- *You must wait six hours after your last act of intercourse before removing the sponge.*

5. How to insert *Today* Vaginal Contraceptive Sponge

A. Insertion Procedure

1. Remove the sponge from the airtight inner pack 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 soft. Be sure you do not squeeze the sponge dry. (The sponge should remain soft for insertion.)

4. Fold the sides of the sponge upward with a finger, doing each side to support it. The sponge should look long and narrow. Be sure the string 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 string 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. Slide 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.

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 finger nail 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 string loop.

B. Questions about insertion of *Today* Sponge.

If you follow the instructions in this booklet, *Today* Sponge should be positioned correctly in the upper vagina. To check its position, simply slide your finger around the edge of the sponge. If your cervix is not exposed, the sponge is in the proper position. You should be able to feel the string loop. If the sponge is out of position, simply slide it back in place.

It is unlikely that *Today* Sponge will fall out. During a bowel movement or other form of internal straining, it

may be pushed down to the opening of the vagina and perhaps fall out. If you suspect this happening, simply insert your finger into your vagina and push it back. If it should fall into the toilet, moisten a new sponge and insert it immediately. Do not flush the old sponge down the toilet. Discard it in a waste container.

Today Sponge is held in place by the muscles of the upper vagina. In addition, the cap-like indentation on the top of the sponge helps to keep it in position directly over the cervix.

7. 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.



2. Put your finger into your vagina and reach up and back to find the string loop. If you cannot find the loop immediately, bear down until you can feel the loop. (See "Bearing down," Section 4D.) 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 4D). Now remove the sponge as you continue to relax.



4. Dispose of the sponge in a waste container.

Do not flush it down the toilet.



B. Special removal situations.

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 7A(2)).

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.

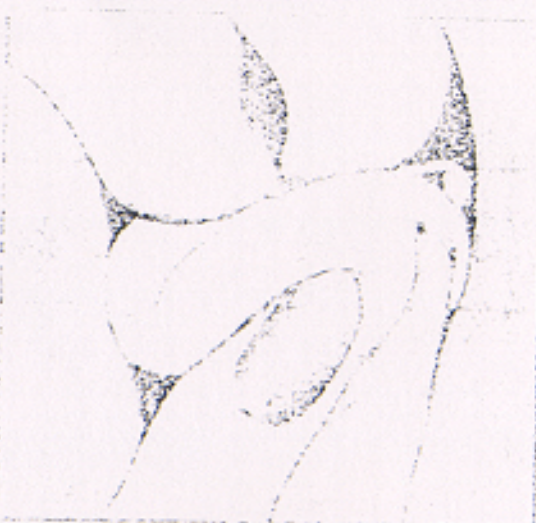
If none of the above suggestions seems to help, see your physician or family planning clinic. You may wish to take several unused *Today* Sponges along so your medical advisor can help you refine your insertion and removal technique.

2. Upside-down Sponge.

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



If you cannot find the string loop, simply grasp the edge of the sponge between your thumb and forefinger and pull it out *slowly*. Bearing down (Section 4D) 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 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.

C. Questions about removal of *Today* Sponge.

1. Is it necessary to douche after removing *Today* Sponge?

No, it is not necessary. However, you may douche after using the sponge if you like. But do not douche while the sponge is inside the vagina. And always wait at least 6 hours after intercourse before removing the sponge.

2. Can *Today* Vaginal Contraceptive Sponge get lost in my body?

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.

DIRECTIONS: Remove a *Today* Sponge from airtight inner pack, wet thoroughly with clean water and squeeze gently several times until it becomes very sudsy. Fold the sides of the sponge upward and insert it deeply into the vagina. Protection begins immediately and continues for 24 hours. It is **not** necessary to add creams, jellies, foams, or any other additional spermicide as long as the sponge is in place, no matter how many acts of intercourse may occur during this 24-hour period. **Please read enclosed insert for complete instructions and warnings.**

Questions? Call the toll-free *Today* TalkLine, see below.

WARNINGS:

- Some cases of Toxic Shock Syndrome (TSS) have been reported in women using barrier contraceptives including *Today* Sponge. Although the occurrence of TSS is uncommon, some studies indicate that there is an increased risk of non-menstrual TSS with the use of barrier contraceptives, including *Today* Sponge.
- *Today* Sponge should not be left in place for more than 30 hours after insertion.
- If you experience two or more of the warning signs of TSS including fever, vomiting, diarrhea, muscular pain, dizziness and rash similar to sunburn, consult your physician or clinic immediately.
- If you have difficulty removing the sponge from your vagina or you remove only a portion of the sponge, contact the *Today* TalkLine 1-800-223-2329 or consult your physician or clinic immediately.
- *Today* Sponge should not be used during the menstrual period.
- After childbirth, miscarriage or other termination of pregnancy it is important to consult your physician or clinic before using this product.
- If you have ever had Toxic Shock Syndrome do not use *Today* Sponge.
- In case of accidental ingestion of the sponge, call a Poison Control Center, emergency medical facility, or a doctor. (Ingestion of small quantities of spermicide alone should not be harmful.) Keep this and all drugs out of the reach of children.

Today SPONGE

Today Vaginal Contraceptive Sponge is a soft polyurethane foam sponge containing nonoxynol-9, a spermicide used by millions of women for more than 20 years in other forms of intravaginal drug products.

Today Sponge has a unique 3-way action which provides safe and reliable protection without hormones and without serious risk of dangerous side effects: **1. *Today* Sponge** continuously releases an extremely effective spermicide which quickly kills sperm on contact.

2. *Today* Sponge blocks the path of the sperm.

3. *Today* Sponge absorbs sperm.

Active Ingredient: Nonoxynol-9, One Gram.

Inactive Ingredients: Benzoic Acid, Citric Acid, Sodium Dihydrogen Citrate, Sodium Metabisulfite, Sorbic Acid, Water in a Polyurethane Foam Sponge.

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).

<i>Method</i>	<i>Typical Use Rate of Pregnancy</i>	<i>Lowest Expected Rate of Pregnancy</i>
Sterilization:		
Male Sterilization	0.15%	0.1%
Female Sterilization	0.5%	0.5%
Hormonal Methods:		
Implant (<i>Norplant™ and 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: (<i>gel, foam, suppository, film</i>)	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