

March 1962



DIRECTIONS FOR USE



JANSSEN-000001

ALL-FLEX Diaphragm
ORTHO diaphragms are carefully constructed of high quality rubber to insure long life and dependable service. When your physician prescribes the use of the ORTHO® Diaphragm with ORTHO-GYNOL® Vaginal Jelly or ORTHO®-CREME Vaginal Cream you will find these companion products convenient, pleasing, economical and reliable.

ORTHO PHARMACEUTICAL CORPORATION

Raritan, New Jersey

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MARCH 1962

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**Care of the
ALL-FLEX Diaphragm**

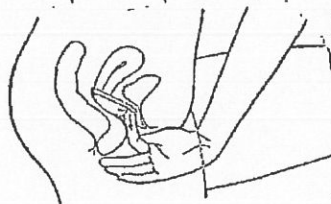
After removal, the diaphragm should be washed with mild soap in warm water, rinsed and patted dry with a towel. Do not dry on a hot surface or in sunlight. Dust diaphragm when dry with talcum powder and return it to the original container. Store at moderate temperature. Do not boil the diaphragm or use any antiseptic solution for cleaning it.

Inspection: Examine the diaphragm carefully before each use.

Check-up Visits

Visit your physician for a check-up to determine if you are using the method correctly. Consult your physician at least once a year, and following a pregnancy or pelvic operation, for you may need a different size diaphragm. Never use substitutes for the method or supplies recommended by your physician.

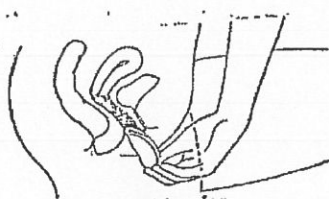
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To Remove the Diaphragm

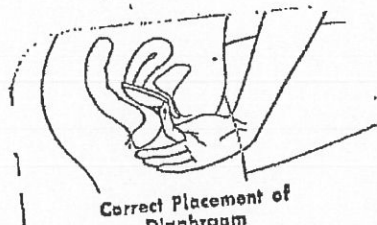
Hook the finger behind the rim, as shown in the illustration, and pull diaphragm down and out. If a douche is taken, one half of the douche may be used just before removal and the remainder after removal of the diaphragm. However, do not douche or remove diaphragm for six to eight hours after use.

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**Position for
Inserting Diaphragm**

One leg is raised and supported at right angles to the body. The diaphragm is then directed along the wall of the vagina as far back as it will go.



**Correct Placement of
Diaphragm**

The rim of the diaphragm is pushed upward behind the cervix in front, as illustrated. The diaphragm will automatically fit behind the cervix (mouth of the womb).

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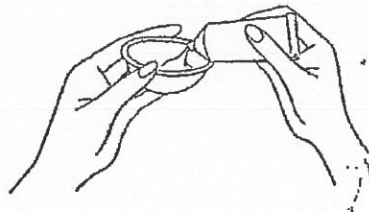
Method of Holding
ALL-FLEX Diaphragm
for Insertion

Grasp the diaphragm firmly between the thumb, index and third finger and squeeze the sides together. The diaphragm will form a perfect arc no matter where compressed.

The diaphragm must be inserted properly according to your physician's instructions. Insert diaphragm not more than one hour before need. It should remain in place for at least six to eight hours after use.

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Preparing the
ALL-FLEX Diaphragm
for Use



Hold the ALL-FLEX Diaphragm with the dome down. Squeeze one teaspoonful of ORTHO-GYNOL Vaginal Jelly or ORTHO-CREME Vaginal Cream into the dome of the diaphragm. With the tip of a finger, spread the jelly or cream inside the cup of the diaphragm and completely around the rim.

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Sept. 6, 1962

Personal
Instructions



JANSSEN-000008

Personal Instructions
ALL-FLEX Diaphragm Method

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JANSSEN-000009

Introduction Parenthood by choice rather than by chance is the right of every individual or couple. Today's scientific research has made this right of choice more of a certainty than ever before. Modern methods of contraception make possible well-spaced, healthy wanted babies, healthy mothers and better adjusted couples.

You have had a pelvic examination and have received instructions on the ALL-FLEX Diaphragm method from your doctor. He has fitted you and described how this method of birth control will keep you from becoming pregnant until you wish to start your family.

To use this method successfully, it is important that you follow instructions carefully. Sexual relations, without a prescribed method of protection, may result in a pregnancy. Do not substitute other products for those recommended by your doctor. Cold creams or petro-

leum jelly will not prevent you from becoming pregnant. These substances are also harmful to your rubber diaphragm.

This method of birth control has been selected specifically for you by your doctor. It includes an ALL-FLEX Diaphragm used with ORTHO-GYNOL Vaginal Jelly or ORTHO-CREME Vaginal Cream—contraceptive (spermicidal) preparations which destroy male sperm.

Neither the diaphragm nor the contraceptive preparation will have any harmful effect on either you or your husband. Ample clinical evidence shows that the diaphragm will not injure your organs, cannot get lost inside your body and has no effect on future child bearing. When inserted correctly, you or your husband will not be aware of the diaphragm in the vagina, and there is no dulling of sensation.

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Your Anatomy Knowledge of your internal reproductive system (Figure 1) will help you understand how this birth control method keeps you from becoming pregnant. The vagina is an elastic muscular canal with its opening between those of the bladder and rectum. It can be seen when the protecting labia (lips) are separated. The uterus (womb) is similar in size and shape to a small pear with its small end pointing down into the vagina. The cervix (small end of uterus) has an opening (mouth of the womb) that leads into the cavity of the uterus.

During intercourse, your husband deposits a small amount of fluid containing millions of sperm (male cells) in the vagina. If these moving sperm enter the mouth of the uterus and unite with the ovum (female cell or egg), a pregnancy may result. When used properly, your diaphragm acts as a physical barrier by preventing sperm from entering the uterus. The contraceptive jelly or cream, used correctly with the diaphragm, destroys the sperm.



Figure 1. Female Reproductive Anatomy
 1—Labia (Lips), 2—Vaginal Opening, 3—Vagina, 4—Mouth of Uterus
 5—Cervix, 6—Cavity of Uterus, 7—Uterus, 8—Fallopian Tube(s),
 9—Ovary(s), 10—Bladder Opening, 11—Bladder, 12—Pubic Bone (Bone in
 front), 13—Rectum

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**HOW TO USE
YOUR ALL-FLEX DIAPHRAGM**

Preparing Diaphragm Always insert your diaphragm with ORTHO-GYNOL or ORTHO-CREME before intercourse. Do not depend upon the diaphragm alone for contraceptive protection. First, empty the bladder (urinate) and wash your hands thoroughly. Unless your doctor has given you special instructions, the jelly or cream then is applied to the diaphragm as shown in Figure 2.

Hold the ALL-FLEX Diaphragm with the dome down. Squeeze one teaspoonful of ORTHO-GYNOL or ORTHO-CREME into the dome of the diaphragm. Spread jelly or cream over this surface and on the rim of the diaphragm; this facilitates insertion and insures a more perfect seal over the cervix.

If desired, an additional amount may be spread on the opposite surface of the diaphragm to aid in lubrication.

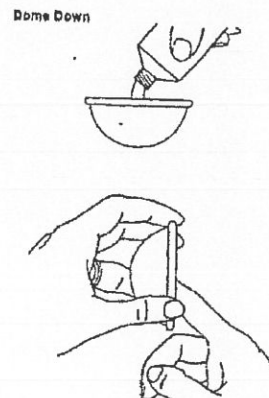


Figure 2. Applying ORTHO-GYNOL or ORTHO-CREME to the ALL-FLEX Diaphragm.

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Inserting Diaphragm Hold the diaphragm firmly between thumb, index and third fingers. Compress each side of rim at mid-points opposite each other, while keeping the index finger securely in place inside the compressed diaphragm (Figure 3). As pressure is exerted on the rim, your ALL-FLEX Diaphragm forms a perfect arc. This permits the diaphragm to pass along the floor of the vagina, beyond the cervix without difficulty.

Separate the labia (lips) and insert the diaphragm into the vaginal canal, directing it backwards as far as it will go (Figure 4). The diaphragm may be inserted while you are in a standing position, squatting position, or while lying in a reclining position (Figure 5).

Placing Diaphragm Always insert the diaphragm as far back as it will go behind the mouth of the cervix. Then push the near part of the rim up behind the pubic bone in front (Figure 6). Test for correct position by running the index finger over the diaphragm's dome to be sure

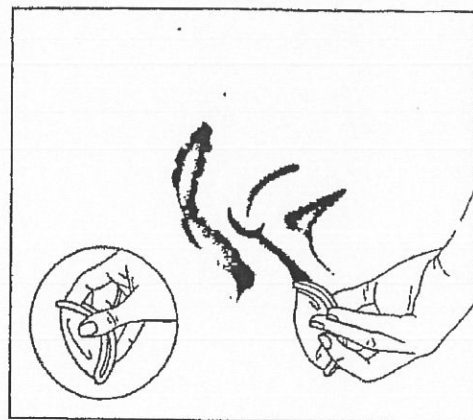


Figure 3. Holding the ALL-FLEX Diaphragm.
Figure 4. Inserting the ALL-FLEX Diaphragm.

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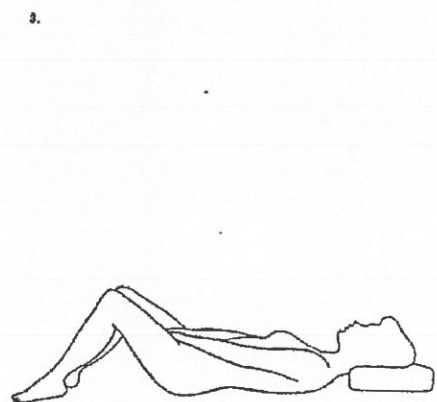
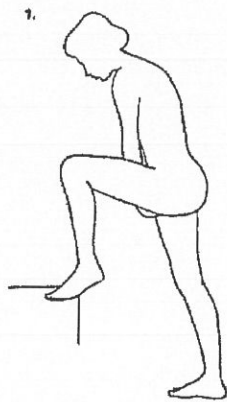


Figure 5. Positions for Inserting the ALL-FLEX Diaphragm:
1. In standing position: with left foot at chair height and left thigh at
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Figure 5 (continued)
right angles to the body. 2. Squatting position. 3. Reclining position.
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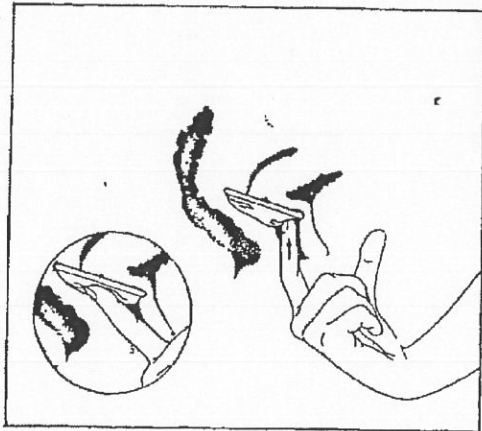


Figure 5. The front end of the ALL-FLEX Diaphragm is pushed upward behind the pubic bone in front. When correctly placed, it completely covers the cervix.

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It covers the cervix. The cervix will feel like the end of your nose (Figure 6). It also is normal to feel folds in the diaphragm when it is in place.

The diaphragm may be inserted into the vagina before retiring or just before intercourse. If intercourse is repeated, insert more jelly or cream with the ORTHO Applicator, outside the diaphragm, before the second time (Figure 7). Be careful not to dislodge the diaphragm when using the ORTHO Applicator.

Bodily movements or changes in position will not dislodge a correctly inserted diaphragm. Any discomfort or pain, while the diaphragm is in place, may be due to incorrect diaphragm insertion, an abnormal pelvic condition, constipation or incorrect diaphragm size. In such a case, be sure to consult your doctor.

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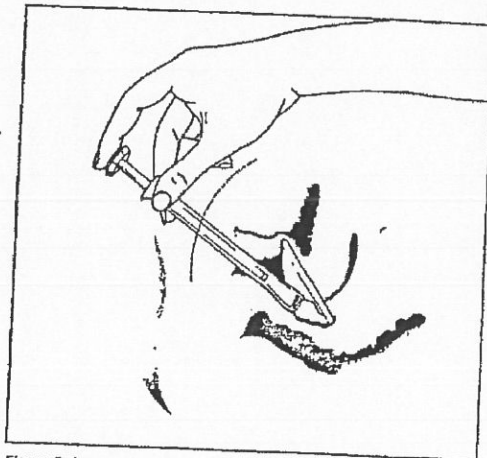


Figure 7. Inserting additional ORTHO-GYNOL or ORTHO-CREME with the ORTHO Applicator.

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Removing Diaphragm The diaphragm should remain in position for at least six to eight hours after intercourse. During this time you may pass urine or move the bowels if necessary, but the diaphragm must not be removed. Upon removal, if a douche is taken, half of the douche should be used before removal of the diaphragm and the remainder after removal.

To remove the diaphragm, place the forefinger behind the front portion of the rim and pull the diaphragm down and out (Figure 8). Straining down as with a bowel movement helps push the rim down so that the index finger can reach the rim more easily. If suction is holding the diaphragm firmly behind the bone in front, the suction may be broken by placing a finger between the vaginal wall and the rim.

If the menstrual period begins while the diaphragm is in place and blood is found in the cup of the diaphragm when it is removed, do not be concerned as this is not harmful.

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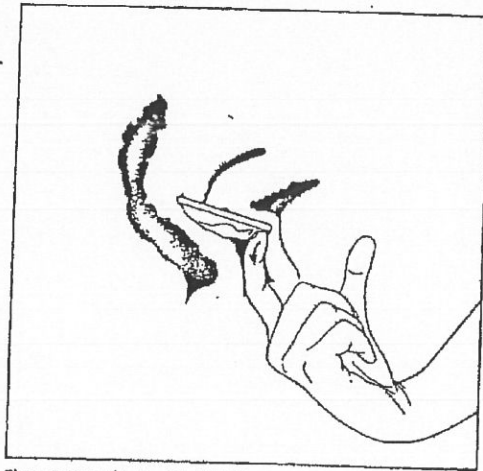


Figure 8. Removing the ALL-FLEX Diaphragm.

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CARE OF THE DIAPHRAGM After removal of the diaphragm, it should be cleansed thoroughly with mild soap and water, rinsed and dried carefully. Never boil the diaphragm or use antiseptic solutions in cleaning it.

Dust lightly with talcum powder or corn starch and immediately return it to the original container. Do not allow the diaphragm to dry in the open. Exposure to light or heat, and certain combinations of air and light, deteriorate rubber rapidly. The container provides the best storage protection. Examine the diaphragm carefully before each use by holding it in front of a light to make sure that no damage has occurred in handling. Never stretch or puncture the diaphragm with sharp fingernails.

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Care of the ALL-FLEX Diaphragm

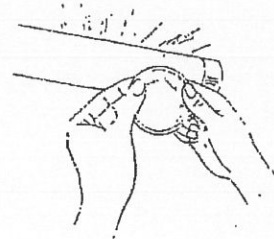


Cleaning

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Dusting



Examining

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SUMMARY After you have had occasion to use your diaphragm with jelly or cream at home, be sure to consult your doctor again if you do not thoroughly understand how to use it. Do not hesitate to ask questions.

At least one year from the time of your first fitting consult your doctor again, for you may need a different size diaphragm. This can be done at the time of your yearly pelvic checkup examination. Routinely, after having a baby or a pelvic operation, ask for another diaphragm fitting.

Best results are obtained when you cooperate with your doctor and follow his advice. Never substitute methods of your own or listen to suggestions of well-

meaning but often misinformed friends. Most important, be sure to keep scheduled appointments with your doctor.

Your ALL-FLEX Diaphragm has been produced under the most careful manufacturing and quality control procedures. In its manufacture, only the finest grade latex has been used. Before packaging, your diaphragm was rigidly inspected and its serviceability verified by thoroughly trained inspectors.

Ortho Pharmaceutical Corporation
Raritan, New Jersey

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ALL-FLEX ORTHO ORTHO-CREME ORTHO-GYNOL