

# After your doctor or health care provider

## prescribes your ORTHO® Diaphragm

This product contains dry natural rubber.

### INTRODUCTION

This booklet is to allow you to become familiar with the ORTHO® ALL-FLEX® Diaphragm and its usage. Your doctor or health care provider will prescribe the appropriate size diaphragm which has been determined through the fitting process. The instructions in this booklet are suitable for most women; however, you should also pay attention to any specific instructions and techniques that are recommended by your doctor or health care provider based on his/her expertise with the diaphragm method of contraception.

### CONTRACEPTION WITH A DIAPHRAGM

The ORTHO® ALL-FLEX® Diaphragm, in conjunction with an appropriate spermicide, is used for the prevention of pregnancy.

The ORTHO® ALL-FLEX® Diaphragm is a shallow, dry natural rubber cup with a flexible metal rim. When it is properly fitted and inserted, it covers the cervix and is held securely in place behind the pubic bone and the rear wall of your vagina.

As a barrier contraceptive, the diaphragm is designed to serve two purposes: to stop sperm from entering your cervical canal and to hold a jelly (or cream) which kills sperm that may manage to swim around the rim of the diaphragm. The diaphragm should always be used in combination with a spermicidal jelly (or cream).

The ORTHO® ALL-FLEX® Arcing Spring Diaphragm is a molded, buff-colored, dry natural rubber vaginal diaphragm containing a distortion-free, dual spring-within-a-spring which provides unique arcing action no matter where the rim is compressed.

Your doctor or health care provider has chosen the size which best fits you and which will be the most comfortable for you to use.

Before using your diaphragm and spermicide, read this entire booklet, even if you are sure you know how to use a diaphragm. If there is anything you do not understand, or if you have further questions, talk to your doctor or health care provider before using your diaphragm for contraception.

Comparative pregnancy rates for various forms of contraception are found in the following table:

**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
<b>Sterilization:</b>		
Male Sterilization	0.15%	0.1%
Female Sterilization	0.5%	0.5%
<b>Hormonal Methods:</b>		
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%
<b>Intrauterine Devices (IUDs):</b>		
Copper T	0.8%	0.6%
Progesterone T	2%	1.5%
<b>Barrier Methods:</b>		
Male Latex Condom <sup>1</sup>	14%	3%
Diaphragm <sup>2</sup>	20%	6%
Vaginal Sponge ( <i>no previous births</i> ) <sup>3</sup>	20%	9%
Vaginal Sponge ( <i>previous births</i> ) <sup>3</sup>	40%	20%
Cervical Cap ( <i>no previous births</i> ) <sup>3</sup>	20%	9%
Cervical Cap ( <i>previous births</i> ) <sup>3</sup>	40%	26%
Female Condom	21%	5%
<b>Spermicide: (gel, foam, suppository, film)</b>		
	26%	6%
<b>Natural Methods:</b>		
Withdrawal	19%	4%
Natural Family Planning (calendar, temperature, cervical mucus)	25%	1-9%
<b>No Method:</b>	85%	85%

<sup>1</sup> Used Without Spermicide

<sup>2</sup> Used With Spermicide

<sup>3</sup> 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, 1996.

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

### WARNINGS AND PRECAUTIONS FOR USE

The diaphragm is not to be used if you (or your partner) have known hypersensitivity to latex or dry natural rubber products. The diaphragm is not to be used if you have a prior history of Toxic Shock Syndrome.

In the following situations you should consult your doctor or health care provider:

- If you are not sure about the insertion and placement of the diaphragm
- If you or your partner feel, or are made uncomfortable by the presence of the diaphragm
- If you experience any discomfort or pain while the diaphragm is in place. This may be due to incorrect diaphragm insertion, an abnormal pelvic condition, constipation, or incorrect diaphragm size
- If the diaphragm slips out of place when you walk, cough, sneeze or strain
- If the diaphragm no longer fits snugly above the pubic bone
- If, at times other than during menstruation, there is blood on the diaphragm when you remove it
- If you notice any holes, tears or other deterioration of your diaphragm
- If you are unable to remove the diaphragm

### Toxic Shock Syndrome

An association has been reported between diaphragm use and Toxic Shock Syndrome (TSS), a serious condition that can be fatal.

For contraceptive effectiveness, the diaphragm should remain in place for six (to eight) hours after intercourse (depending on which brand of spermicide you use) and should be removed as soon as possible thereafter.

Removal of the diaphragm before six (to eight) hours may increase the risk of becoming pregnant. Continuous wearing of a contraceptive diaphragm for more than twenty-four hours is not recommended. Wearing the diaphragm for any period of time may encourage the growth of certain bacteria in the vaginal tract. It has been suggested that under certain as yet unestablished conditions, overgrowth of these bacteria may lead to symptoms of TSS.

Primary symptoms of TSS are sudden high fever (usually 39°C [102°F] or more), and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like sunburn. There may also be other signs of TSS, such as aching of muscles and joints, redness of the eyes, sore throat, and weakness. If you have sudden high fever and one or more of the other symptoms, remove your diaphragm and consult your doctor or health care provider immediately. Women with a known or suspected history of TSS should not use the diaphragm.

### Genito-Urinary Tract Infections

Diaphragms may increase the risk of urinary tract infections, candidiasis or bacterial vaginosis, especially if not properly fitted. Consult your doctor or health care provider if you experience any of the signs or symptoms of these types of infection including pain on urination, blood in the urine, elevated temperature, frequent urination, a sensation of obstruction while urinating or vaginal itching, burning or discharge.

### Latex or Natural Rubber Sensitivity

The ORTHO® ALL-FLEX® Diaphragm contains dry natural rubber proteins. Persons sensitive to latex or natural rubber may have an allergic reaction to the diaphragm. If this occurs, discontinue use and consult your doctor or health care provider.

### Spermicide Sensitivity

Some people are sensitive to spermicides. If you or your partner notice any discomfort of the vagina or penis, discontinue use of the spermicide and diaphragm and consult your doctor or health care provider.

### Diaphragm Fittings

The size and shape of the vagina change and this may require a new size diaphragm. As a matter of routine, each time a pelvic examination is performed, refitting should be done.

### Replacing the Diaphragm

It is advisable to replace your diaphragm every 1-2 years.

### UNDESIRABLE EFFECTS

If you should have one of these or any other undesirable effect, contact your doctor or health care provider:

An association has been reported between diaphragm use and Toxic Shock Syndrome (TSS), a serious condition which can be fatal. (See WARNINGS AND PRECAUTIONS FOR USE.)

Primary symptoms of TSS are sudden high fever (usually 39°C [102°F] or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness or a rash that looks like sunburn. There may also be other signs of TSS, such as aching of muscles and joints, redness of the eyes, sore throat and weakness. If you have sudden high fever and one or more of the other symptoms, remove your diaphragm and consult your doctor or health care provider immediately.

An association between diaphragm use and urinary tract infections, candidiasis and bacterial vaginosis has been reported. Consult your doctor or health care provider if you experience any of the signs or symptoms of this type of infection including pain on urination, blood in the urine, elevated temperature, frequent urination, a sensation of obstruction while urinating or vaginal itching, burning or discharge.

Allergic reactions including serious hypersensitivity reactions such as anaphylaxis to the latex or natural rubber component of the diaphragm have been reported.

If the diaphragm is not placed correctly or if an incorrect size is used, discomfort or pain may occur while the diaphragm is in place.

### INSTRUCTIONS FOR PROPER USE

To avoid pregnancy you must use the diaphragm every time you have intercourse and the diaphragm must always be used in combination with a spermicidal jelly (or cream). Proper placement of the diaphragm is vital for effectiveness.

### When to insert the diaphragm and spermicide jelly (or cream)

The diaphragm can be put in any time before intercourse. However, remember that the diaphragm must stay in place for at least six (to eight) hours after intercourse (depending upon which brand of spermicide you use), and the diaphragm should not be worn for more than 24 continuous hours. (See WARNINGS AND PRECAUTIONS FOR USE.)

The anatomy of the vagina changes during sexual excitement. The vagina expands and the cervix is pulled back and up. If you insert the diaphragm at this stage the vaginal "landmarks" may feel a little different than usual, so be sure the diaphragm is positioned over the cervix. Because the spermicide becomes less effective in the presence of sperm, a fresh application of jelly (or cream) must be inserted before intercourse is repeated. Additional spermicide must also be applied if the diaphragm has been in place for more than six hours before intercourse. (There may be other times in which you will need to reapply spermicide depending upon what brand of spermicide you use; please refer to the manufacturer's instructions.) Do not remove the diaphragm to insert additional spermicide. Simply fill and insert a spermicidal applicator, making sure that the jelly (or cream) is inserted into the upper part of the vagina.

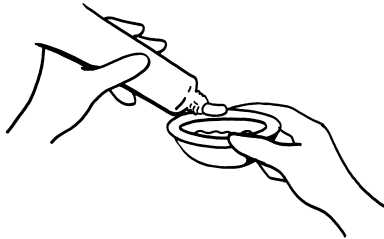
### Preparing for insertion

Cleanse the diaphragm before initial use by washing it with a mild, non-perfumed soap and warm water, rinsing and drying it carefully.

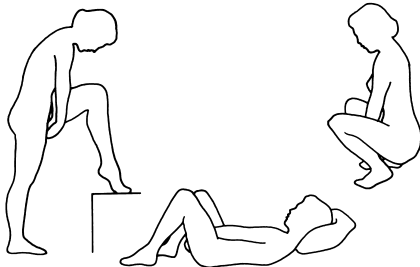
Empty your bladder (urinate) and wash your hands thoroughly before insertion.

Examine the diaphragm closely before use by holding it in front of a light to make sure that it has no cracks or tiny holes. Take care not to stretch or puncture the diaphragm with sharp fingernails. Do not use if you observe any visible cracks or holes.

The diaphragm should always be inserted before intercourse. To prepare your diaphragm for insertion, you should put the spermicide into the cup of the diaphragm. This ensures that the spermicide is placed between the cervix and the diaphragm. Use the amount of spermicide recommended by the manufacturer of the spermicide you use. Using your fingertip, spread some of the spermicidal jelly (or cream) around the rim of the diaphragm that will be in contact with the cervix (entrance to the womb). If the amount applied to the rim is excessive, it will be difficult to control the diaphragm during insertion.

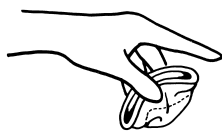


You may insert the diaphragm while you are standing with one leg up, squatting, or lying down. The position of the cervix and the walls of the vagina will be different depending on your position. If you are used to one position and then change to another, take extra care in positioning the diaphragm to be sure the cervix is covered.



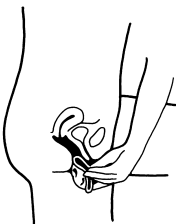
### Inserting the diaphragm

Hold the diaphragm with the dome down (spermicide up) and press the opposite sides of the rim together between your thumb and third finger. The diaphragm can be held from above or below.



ALL-FLEX® Diaphragm Compressed

Separate the lips of your vagina with your free hand. Hold the compressed diaphragm with the dome down (spermicide up) and push it gently inward, along the rear wall of the vaginal canal, directing it backwards as far as it will go. Your index finger, kept on the outer rim of the diaphragm, helps to guide the diaphragm into place.



ALL-FLEX® Diaphragm being introduced

Always insert the diaphragm as far back as it will go behind the mouth of the cervix. Then push the front rim of the diaphragm up until it is locked in place just behind the pubic bone.



It is important that the cervix be covered by the spermicide and that the diaphragm be locked in place between the upper edge of the pubic bone and the rear wall of the vagina. Test for correct position by running the index or middle finger over the diaphragm's dome to be sure it covers the cervix. You should be able to feel your cervix through the rubber. The cervix will feel like the end of your nose. It is normal to feel folds in the diaphragm when it is in place.



Bodily movements or changes in body position should not dislodge a correctly-inserted diaphragm. A properly-fitted diaphragm should stay in place during urination or bowel movement.

### Removing the Diaphragm

To reduce the risk of TSS, the diaphragm should be removed six (to eight) hours after intercourse (depending upon which brand of spermicide you use). Continuous wearing of a diaphragm for more than 24 hours is not recommended. (See WARNINGS AND PRECAUTIONS FOR USE.)

Removal of the diaphragm before six (to eight) hours after intercourse (depending on which brand of spermicide you use), may increase your risk of becoming pregnant.

Do not douche until the diaphragm is removed. To remove the diaphragm, put your index finger behind the front rim and pull the diaphragm down and out. Avoid puncturing the diaphragm with your fingernails.



To facilitate removal, straining down as with a bowel movement may help to push the rim down so that the index finger can reach the rim more easily. If suction is holding the diaphragm, the suction may be broken by placing a finger between the vaginal wall and the rim.

If your 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.

### CARE OF THE DIAPHRAGM

After removal of the diaphragm, it should be cleansed thoroughly with mild, non-perfumed soap and water, rinsed and dried carefully. Powders should not be used with the diaphragm. Never boil the diaphragm or use antiseptic solutions in cleaning it.

Store the diaphragm, unrolled, in its original container; the diaphragm should not be stored unprotected. Prolonged exposure to light or heat will deteriorate the rubber.

Never stretch or puncture the diaphragm with sharp fingernails. With regular use, and in the absence of evident deterioration, the diaphragm should be replaced every 1-2 years.

Some vaginal medications and lubricating agents may contain ingredients that can damage a contraceptive diaphragm. You should discuss the use of any such vaginal preparation with your doctor, health care provider, pharmacist or the manufacturer or distributor. Petroleum jelly, mineral oil, vegetable oil and cold cream lubricants should **NOT** be used concurrently with the diaphragm. Latex-based products may deteriorate over time when repeatedly exposed to oil-based products.

### Products that may be used with your diaphragm

These Ortho contraceptive jelly brands for use with diaphragms are available without a prescription at most pharmacies and some grocery stores.

ORTHO OPTIONS® GYNOL II® Original Formula large tube only – 3.8 oz.

ORTHO OPTIONS® GYNOL II® Extra Strength includes applicator w/small tube

If added vaginal lubrication is necessary, you may want to consider K-Y® BRAND Jelly Personal Lubricant which is available without a prescription in a 0.4 oz., 2 oz. and a 4 oz. Tube or K-Y® Liquid and K-Y® Long Lasting™ vaginal moisturizer. K-Y® BRAND Jelly Personal Lubricants are not contraceptives.

### Manufacturer



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