



# ORTHO<sup>®</sup>

## DIAPHRAGM FITTING SET

This set contains one of the following:

**ORTHO<sup>®</sup> COIL SPRING FITTING DIAPHRAGM SET**  
NDC 0062-3643-00

**ORTHO<sup>®</sup> ALL-FLEX FITTING DIAPHRAGM SET**  
NDC 0062-3641-03

**This product contains dry natural rubber.**

### HOW TO FIT ORTHO DIAPHRAGMS

#### 1. To measure for diaphragm size:

Hold index and middle fingers together and insert into vagina up to the posterior fornix. Raise hand to bring surface of index finger into contact with pubic arch. Use tip of thumb to mark the point directly beneath the inferior margin of the pubic bone and withdraw finger in this position.

#### 2. To determine diaphragm size:

Place one end of rim of fitting diaphragm or ring on tip of middle finger. The opposite end should lie just in front of the thumb tip. This is the approximate diameter of the diaphragm needed. Insert a fitting diaphragm or ring of the appropriate size into the vagina. Try both a larger and smaller size before making a decision.

3. The proper size will fit snugly in the posterior fornix and behind the pubic arch without undue pressure.

### CLEANING OPTIONS

#### FOR ORTHO DIAPHRAGM FITTING DEVICES

Fitting diaphragms and diaphragm fitting rings, being devices that come in contact with intact mucous membranes, are semicritical devices that require processing with a high level disinfectant according to OSHA guidelines. The following cleaning methods have been found to be compatible with Ortho Diaphragm Fitting Devices.

*The first and critically important step in preparation for any of the methods listed below is to clean the device thoroughly by scrubbing with liquid detergent and water, then rinsing well with water. This step serves to remove the majority of the bioburden in question.*

#### AUTOClave METHOD

1. Autoclave at 121 degrees C/15 psi for between 20 and 30 minutes. The time variation is dependent on whether the articles are wrapped or unwrapped (Results of 100 autoclave cycles show the material to meet ASTM standards for tensile strength.)

2. Allow to air dry and then place in container until ready for use.

#### CLOROX<sup>®</sup> METHOD

1. Soak in a 1:10 dilution of Clorox for 30 minutes at room temperature.

2. Rinse thoroughly with tap water.

3. Soak in 70% ethyl or isopropyl alcohol for 15 minutes.

4. Allow to air dry and then place in container until ready for use.

Clorox is a registered trademark of the Clorox Company.

#### CIDEX<sup>®</sup> GLUTARALDEHYDE METHOD

Note: This method requires adequate ventilation and running water.

1. Immerse in 2% CIDEX solution for 20 minutes at room temperature.

2. Rinse and place in boiling water for 30 minutes.

3. Allow to air dry and then place in container until ready for use.

For further information please call Medical Information at 1-800-682-6532.

CIDEX is a registered trademark of Johnson & Johnson.

#### ORTHO<sup>®</sup> DIAPHRAGM KITS

ORTHO Diaphragm Kits include two different types in a variety of sizes.

1. The ALL-FLEX<sup>®</sup> 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. It is appropriate not only where ordinary diaphragms are indicated, but also in patients with mild cystocele, rectocele or retroversion.

2. The ORTHO<sup>®</sup> Coil Spring Diaphragm is a molded dry natural rubber vaginal diaphragm. The rim encases a tension-adjusted spring which allows for compressibility in one plane only, thus allowing insertion with the ORTHO UNIVERSAL INTRODUCER.

#### ACTION

These Diaphragms when properly fitted serve two purposes:

a. To stop the sperm from entering the cervical canal;

b. To hold the spermicide.

#### INDICATIONS

ORTHO Diaphragms, in conjunction with an appropriate spermicide, are indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception.

#### CONTRAINDICATIONS

Known hypersensitivity to dry natural rubber and/or prior history of Toxic Shock Syndrome (TSS).

#### WARNINGS

An association has been reported between diaphragm use and toxic shock syndrome (TSS), a serious condition which can be fatal.

For contraceptive effectiveness, the diaphragm should remain in place for six hours after intercourse and *should be removed as soon as possible thereafter.*

Continuous wearing of a contraceptive diaphragm for more than twenty-four hours is not recommended. Removal of the diaphragm before six hours may increase the risk of becoming pregnant. Retention of 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 toxic shock syndrome. Primary symptoms of TSS are sudden high fever (usually 102° 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. Patients should be instructed that if they experience sudden high fever and one or more of the other symptoms, they should remove the diaphragm and consult their physician or health care provider immediately.

The ORTHO 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.

#### PRECAUTIONS

Diaphragm users should be instructed to consult their physician or health care provider:

1. If they are not sure about the insertion and placement of the diaphragm

2. If they or their partner feel, or are made uncomfortable by the presence of the diaphragm

3. If they 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.

4. If the diaphragm slips out of place when walking, coughing, or straining

5. If the diaphragm no longer fits snugly above the pubic bone

6. If at times other than menstruation there is blood on the diaphragm when it is removed

7. If there are any holes, tears or other deterioration of the diaphragm

8. If unable to remove the diaphragm.

9. **IMPORTANT** - For contraceptive effectiveness, the diaphragm should remain in place for six hours after intercourse and *should be removed as soon as possible thereafter.* Continuous wearing of a contraceptive diaphragm for more than twenty-four hours is not recommended. Removal of the diaphragm before six hours may increase the risk of becoming pregnant. Retention of 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 toxic shock syndrome. Primary symptoms of TSS are sudden high fever (usually 102° or more), and vomiting, diarrhea, fainting or near fainting when standing up, dizziness or a rash that looks like a 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 the patient has a sudden high fever and one or more of the other symptoms, the diaphragm should be removed immediately and TSS should be considered.

10. Diaphragm users should have another diaphragm fitting if they have lost or gained more than ten pounds, have had the diaphragm for more than a year, or have had a baby or an abortion. As a matter of routine, each time a pelvic examination is performed, refitting should be done. The size and shape of the vagina changes and this may require a new size diaphragm. Even if the diaphragm size does not change, it is advisable to replace the diaphragm every two years or sooner.

11. Diaphragms may increase the risk of urinary tract infections especially if not properly fitted. Patients should be instructed to consult their physician if they experience any of the signs or symptoms of this type of infection, which include pain on urination, blood in the urine, elevated temperature, frequent urination, or a sensation of obstruction while urinating.

12. Persons sensitive to dry natural rubber may have an allergic reaction to diaphragm use.

13. Persons sensitive to spermicides used with the diaphragm should discontinue use.

14. Petroleum jelly, mineral oil, vegetable oil and cold cream lubricants should **NOT** be used concurrently with the diaphragm.

#### HOW SUPPLIED

All ORTHO Diaphragm Kits are available individually and contain a tube of ORTHO OPTIONS<sup>™</sup> GYNOL II Original Formula Contraceptive Jelly.

1. The ALL-FLEX Arcing Spring Diaphragm is available in sizes 55mm through 95mm in 5mm increments.

2. The ORTHO Coil Spring Diaphragm is available in sizes 55mm through 95mm in 5mm increments.



ORTHO-McNEIL PHARMACEUTICAL, INC.  
Raritan, New Jersey 08869

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For your information

# 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® Diaphragm and its usage. Your doctor or health care provider will prescribe the appropriate size which he/she has 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® Diaphragm, in conjunction with an appropriate spermicide, is used for the prevention of pregnancy.

The ORTHO® 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. (See illustration on the last page of this booklet.) 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) [e.g., ORTHO OPTIONS™ GYNOL II® Original Formula Contraceptive Jelly, ORTHO OPTIONS™ ORTHO-GYNOL Contraceptive Jelly.]

There are two types of ORTHO® Diaphragms: (1) ALL-FLEX® Arcing Spring Diaphragm and (2) ORTHO® Coil Spring Diaphragm.

The 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.

The ORTHO Coil Spring Diaphragm is a molded, dry natural rubber vaginal diaphragm. The rim encases a tension-adjusted coil spring which provides for compressibility in one plane only.

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

Before using your diaphragm and spermicide, read the 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.

### 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 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 your diaphragm

### Toxic Shock Syndrome

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

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 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

Ask for another diaphragm fitting if you have lost or gained more than 4.5 kg [10 pounds], have had your diaphragm for more than a year or have had a baby, miscarriage or an abortion. As a matter of routine, ask for a fitting each time you have a pelvic examination, as the size or shape of your vagina may change.

### Replacing Your 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 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.)

### 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

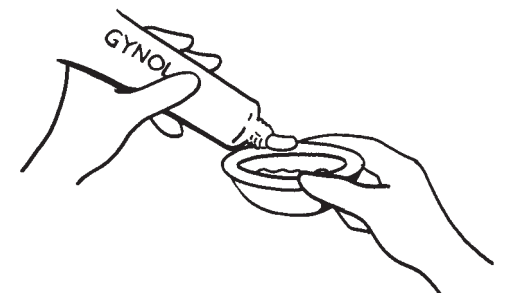
Cleanse the diaphragm before initial use by washing it with mild, non-perfumed soap and warm water, rinsing and drying it carefully.

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

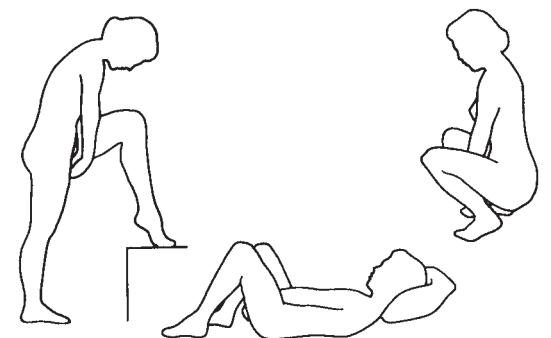
Examine the diaphragm carefully before use by holding it in front of a light to make sure that it has no cracks or tiny holes. Take care not to stretch or puncture the diaphragm with sharp fingernails. Do not use if you observe any visible cracks or holes.

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 finger tip, 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.

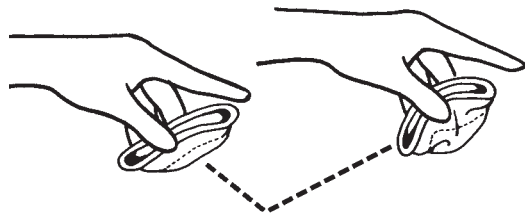


You can insert the diaphragm while you are standing with one leg up, squatting, or lying down. The position of the cervix and the walls of the vagina will be different depending on your position. If you are used to one position and then change to another, take extra care in positioning the diaphragm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



## Inserting the diaphragm

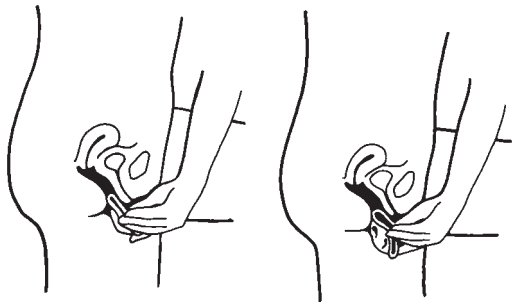
Hold the diaphragm with the dome down (spermicide up) and press the opposite sides of the rim together between your thumb and third finger. The diaphragm can be held from above or below



Coil Spring Diaphragm Compressed

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.



Coil Spring Diaphragm being introduced

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

## Preparation and insertion using an introducer

Another way to insert the diaphragm is with an [ORTHO Universal] introducer.

The ALL-FLEX Diaphragm cannot be used with an introducer. The [ORTHO Universal] introducer may be used with a Coil Spring Diaphragm.

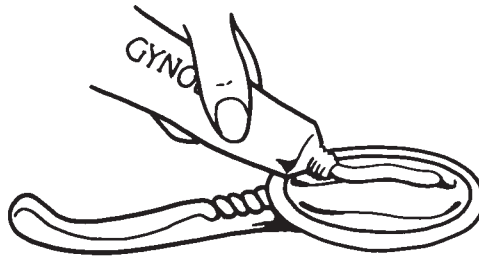
## Preparing the diaphragm when using an introducer

The introducer has been designed to insert diaphragms from size 60mm through 90mm. The introducer is slightly indented and used to hold one side of the diaphragm rim for insertion. The ORTHO Diaphragm has the size molded into the side of the rubber dome so that it is easy to read throughout the life of the diaphragm.

Hold the introducer in either hand with the notched-side down. Hold the diaphragm in your other hand with the dome

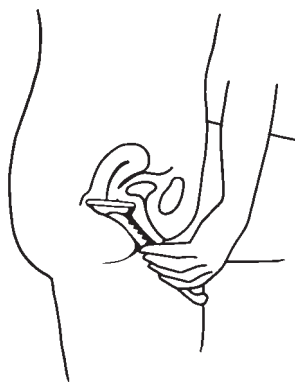
up. Squeeze the opposite sides of the diaphragm together and place one end of the diaphragm's rim into the notched end of the introducer, then fit the other end of the diaphragm over the notch corresponding to your diaphragm size (sizes are shown next to each notch on the introducer.)

Turn the introducer over and insert the amount of spermicidal jelly (or cream) recommended by the manufacturer of the spermicide you use into the folds formed on the top of the diaphragm (the cup side.) This ensures that the spermicide is placed between the cervix and the diaphragm. Using your fingertip, spread some of the spermicidal jelly (or cream) around the rim of the diaphragm to make insertion easier and to help seal the diaphragm in place.



## Inserting the diaphragm when using an introducer

With the spermicide up, insert the introducer into the vagina. Press gently inward along the rear wall of the vagina until the diaphragm has been inserted as far as possible.



Once the diaphragm is in place, twist the introducer slightly to the left or right to release the diaphragm. Then, gently withdraw the introducer. Using your index finger, check to ensure the rear rim of the diaphragm is pushed up behind the pubic bone.



Test for correct position by running the index or middle finger over the diaphragm's dome to be sure it covers the cervix. The cervix will feel like the end of your nose. It is normal to feel folds in the diaphragm when it is in place.



To cleanse the introducer, wash with soap and warm water, rinse and dry.

## 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.

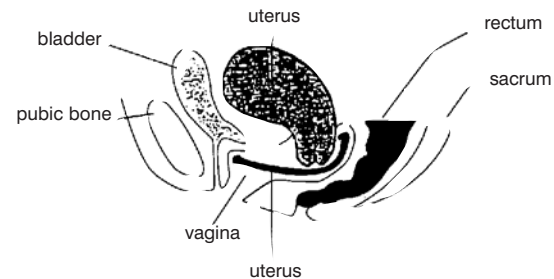
## CARE OF THE DIAPHRAGM

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. Do not allow the diaphragm to dry in the open. 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.



## Where to purchase Ortho Contraceptive Products

The ORTHO® Universal Introducer is available by prescription through pharmacies.

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

ORTHO OPTIONS™ ORTHO-GYNOL® large tube only — 3.8 oz.

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 .4 oz., 2 oz. and a 4 oz. tube. K-Y® Liquid and K-Y® Long Lasting™ vaginal moisturizer. K-Y® BRAND Jelly Personal Lubricant is not a contraceptive.

## APPLICATOR OFFER

For an applicator for use with ORTHO OPTIONS GYNOL, send your name and address to: ACP Applicator Offer, P.O. Box 4498, Maple Plain, MN 55592-4498. Please print clearly. You will receive one applicator by mail. Please allow 6-8 weeks for delivery. Good only in U.S.A. No group or organization requests will be honored. Offer void where restricted or prohibited by law. Offer good while supplies last.

## Manufacturer



ORTHO-McNEIL  
PHARMACEUTICAL, INC.  
Raritan, New Jersey 08869

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