

Patient Guide for use of the  
**ORTHO® ALL-FLEX®**  
**Diaphragm**

**WHAT IS A DIAPHRAGM?**

A diaphragm is a contraceptive device. It is a shallow, silicone (latex-free) cup with a flexible rim. It fits over the cervix (the entrance to the womb) and the pelvic muscles hold it in place. As a barrier form of contraception the diaphragm is designed to serve two purposes: it stops sperm from entering your cervical canal, and it holds a jelly or cream which kills sperm that may manage to swim around the rim of the diaphragm. The diaphragm should be used in combination with a spermicidal jelly or cream.

**HOW EFFECTIVE IS A DIAPHRAGM?**

A properly fitted and inserted diaphragm used with a contraceptive jelly or cream is an effective method of birth control. But it is only effective if used every time you have intercourse. It cannot be forgotten – not even once.

The ORTHO ALL-FLEX Diaphragm is moulded, buff-coloured vaginal diaphragm made from silicone. It contains a distortion-free, dual spring-within-a-spring (arcing spring) that provides a unique arcing action no matter where the rim is compressed.

Diaphragms should always be fitted by the Doctor or Family Planning Clinician to ensure correct sizing and instructions. Your doctor or family planning clinician has chosen the size that best fits you and which will be the most comfortable for you to use.

Before using this diaphragm, 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 family planning clinician 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>Sterilisation:</b>		
Male sterilisation	0.15%	0.1%
Female sterilisation	0.5%	0.5%
<b>Hormonal Methods:</b>		
Implant ( <i>Implanon™</i> )	0.05%	0.05%
Hormone Shot ( <i>Depo-Provera®</i> )	3%	0.3%
Combined Pill ( <i>Estrogen/Progestin</i> )	8%	0.3%
Minipill ( <i>Progestin only</i> )	8%	0.3%
Patch ( <i>EVRA®</i> )	8%	0.3%
Vaginal Ring ( <i>NuvaRing®</i> )	8%	0.3%
<b>Intrauterine Devices:</b>		
Copper T	0.8%	0.6%
Progesterone T	2%	0.2%
<b>Barrier Methods:</b>		
Male Latex Condom <sup>1</sup>	15%	2%
Diaphragm <sup>2</sup>	16%	6%
Vaginal Sponge ( <i>no previous births</i> ) <sup>3</sup>	16%	9%
<b>Vaginal Sponge</b> ( <i>previous births</i> ) <sup>3</sup>	32%	20%
Cervical Cap ( <i>no previous births</i> ) <sup>2</sup>	20%	9%

Female Condom	21%	5%
<b>Spermicide:</b> ( <i>gel, foam, suppository, film</i> )	29%	18%
<b>Natural Methods:</b>		
Withdrawal	27%	4%
Natural Family Planning ( <i>calendar, temperature, cervical mucus</i> )	25%	3-5%
<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, Nelson AL, Cates W, Stewart FH, Kowal D., Contraceptive Technology: Nineteenth Revised Edition. New York, NY: Ardent media, 2007

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**CARE OF THE DIAPHRAGM**

Clean your diaphragm after use with mild soap unperfumed and water, rinse thoroughly in clean water and dry carefully.

Except for mild, unperfumed soap, do not use any product on your diaphragm that is not made especially for use with ORTHO diaphragm. 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; store at room temperature and keep out of direct sunlight.

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 2 years.

Examine the diaphragm carefully before each use by holding it up to a bright light. Make sure that it has no cracks or tiny holes. **DO NOT USE** if any small holes are detected or if it is misshapen; replace immediately.

**WHAT ARE SPERMICIDES?**

Spermicides are used with a diaphragm to kill sperm that may manage to swim around the rim of the diaphragm. Should there be even the slightest gap between the rim of the diaphragm and the walls

of the vagina, sperm could enter the cervix (opening of the womb). Thus the spermicidal jelly or cream serves as extra protection because it kills sperm on contact.

Spermicides may cause local irritation. If irritation develops, use of the product should cease. Consult your doctor if necessary.

### **WARNINGS AND PRECAUTIONS FOR USE**

The diaphragm is **not** to be used if you have a prior history of Toxic Shock Syndrome or if you are sensitive to silicone.

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 (TSS)**

An association has been reported between diaphragm use and TSS, a serious condition that can be fatal.

For contraceptive effectiveness, the diaphragm should remain in place for 6-8 hours after intercourse (depending on which brand of spermicide you use). Continuous wearing of a diaphragm for more than 24 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 or more), vomiting, diarrhoea, 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 immediately. Women with 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 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.

### **Silicone or Spermicide Sensitivity**

Very rarely some people are sensitive to silicone. Some people are also 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.

### **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 2 years or sooner if there is visible deterioration or damage. You should record the date the diaphragm is first used on the compact supplied with the diaphragm.

### **PREPARING FOR INSERTION**

To avoid pregnancy you must use the diaphragm every time you have intercourse. Proper placement of the diaphragm

1. For your personal comfort and correct fitting, empty your bladder and bowel and wash hands before inserting your diaphragm.
2. When a spermicide jelly is used, place a teaspoonful of contraceptive jelly or cream into the dome of the diaphragm. (Refer to package directions). Spread the spermicide around the inner and outer surface of the dome and also a small amount around the rim (A). The spermicide on the rim makes the diaphragm easier to insert and helps seal the diaphragm in place. Too much jelly or cream makes the diaphragm too slippery to handle during insertion. If spermicide foam or film is used, insert the diaphragm first (a water-based lubricant may be used to facilitate insertion), and then insert the foam or film high in the vagina.
3. You can insert the diaphragm while you are standing with one leg up, squatting or lying down (B). The position of the cervix (the opening of the womb) 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**

1. Hold the diaphragm with the dome down (spermicide up) and gently press the opposite sides of the rim together between your thumb and third finger (C). The diaphragm can be held from above or below.
2. Spread the lips of your vagina with your free hand. Hold the compressed diaphragm dome down (spermicide up) and push gently along the rear wall of the vagina as far as it can go. Your index finger, kept on the outer rim of the diaphragm, helps you guide the diaphragm into place (D).
3. With your index finger push the front rim of the diaphragm up until it is locked in place just above the pubic bone (E).

## HOW TO USE YOUR ORTHO DIAPHRAGM

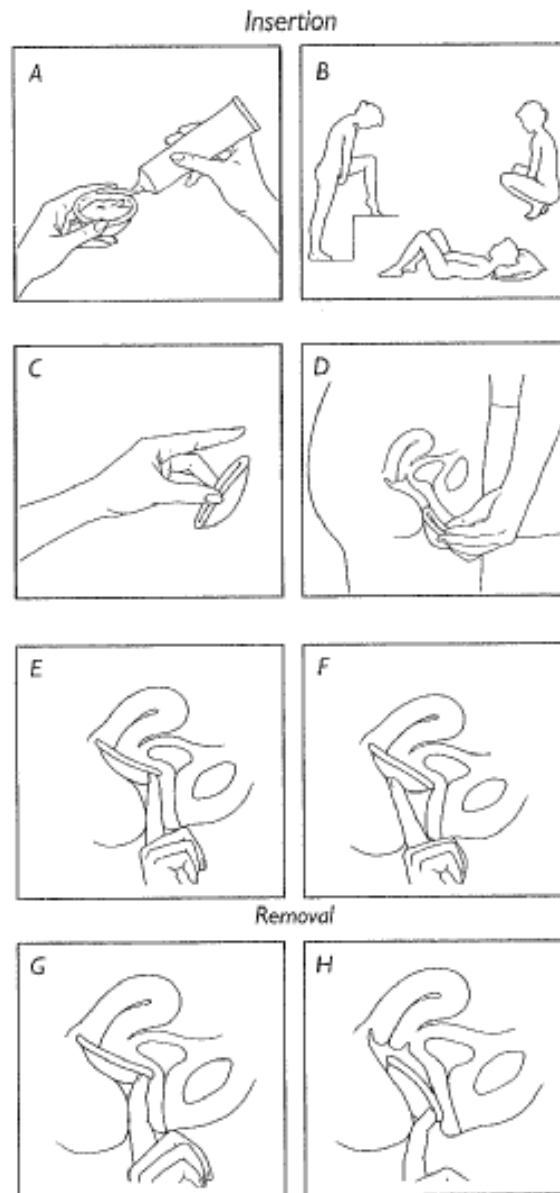
1. Check with your index finger to be sure the diaphragm is in place and is holding the contraceptive jelly or cream over the cervix. It is important that the cervix be covered by the diaphragm and spermicide and that the diaphragm be locked in place between the upper edge of the pubic bone and the rear wall of the vagina.

You should be able to feel your cervix through the rubber shield. You can feel the front rim of the diaphragm above the pubic bone, but may not be able to follow the rim all the way around since your fingers may not be long enough (F).

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

2. If, after some practice, you still find insertion awkward or difficult, vary your body and hand positions slightly until you can insert the diaphragm comfortably.

3. Some doctors recommend that the diaphragm be inserted every night to minimise unprotected intercourse.



## REMOVING THE DIAPHRAGM

1. To reduce the risk of TSS, the diaphragm should be removed six to eight hours after intercourse. 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 may increase your risk of becoming pregnant.

2. To remove the diaphragm, put your index finger behind the front rim (G) and pull the diaphragm down and out (H). Once the diaphragm is removed, remember to carefully wash it.

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.

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