

ORTHO® ALL-FLEX® DIAPHRAGM FITTING SET

NDC 0062-3644-03

HOW TO FIT THE ORTHO® ALL-FLEX® DIAPHRAGM

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 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 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 THE ORTHO® ALL-FLEX® DIAPHRAGM FITTING SET

Fitting diaphragms, being devices that come in contact with intact mucous membranes, are semicritical devices that require processing with a high level disinfectant according to current guidelines. The following cleaning methods have been found to be compatible with the ORTHO® ALL-FLEX® Diaphragm Fitting Set.

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 and 15 psi for between 20 and 30 minutes. The time variation is dependent on whether the articles are wrapped or unwrapped.

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

CHLORINATION METHOD

1. Soak in a 1:10 dilution of 5 % sodium hypochlorite (bleach) 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 the fitting set in a container until ready for use.

GLUTARALDEHYDE METHOD

Note: This method requires adequate ventilation and sterile water.

1. Immerse in 2.5% glutaraldehyde solution for 20 minutes at room temperature.

2. Rinse thoroughly with sterile water.

3. Allow to air dry and then place the fitting set in a container until ready for use.

Alternatively to the above: Follow the disinfectant solution manufacturer's instructions.

CONTRAINDICATIONS

A history of Toxic Shock Syndrome or hypersensitivity to silicone

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

This device is not intended for contraception.

Duration of Use:

This device is intended for the sole purpose of properly fitting a diaphragm. It is intended to be inserted only for the time necessary for the diaphragm to be sized.

Diaphragm Fitting:

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.

THE FOLLOWING IS FOUND IN THE LABELING FOR THE ORTHO® ALL-FLEX® DIAPHRAGM:

The ORTHO® ALL-FLEX® Diaphragm is a molded, buff-colored, 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.

ACTIONS

A diaphragm, when properly fitted, serves two purposes: To stop sperm from entering the cervical canal and to hold spermicide.

INDICATIONS

The ORTHO® ALL-FLEX® Diaphragm, in conjunction with an appropriate spermicide, is indicated for the prevention of pregnancy in women who elect to use diaphragms as a method of contraception.

CONTRAINDICATIONS

Known hypersensitivity to silicone or a prior history of Toxic Shock Syndrome (TSS)

WARNINGS

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

To reduce the risk of TSS, but also to maintain contraceptive effectiveness, the diaphragm should be removed six to eight hours (depending on which brand of spermicide you use) after intercourse. 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 [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 diaphragms.

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, sneezing 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 to eight hours (depending on the brand of spermicide used) after intercourse and *it should be removed thereafter*. Continuous wearing of a contraceptive diaphragm for more than twenty-four hours is not recommended. Removal of the diaphragm before six to eight hours may increase the risk of becoming pregnant.

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 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. 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. 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 silicone or spermicides used with the diaphragm should discontinue use of the spermicide/diaphragm method of contraception.

HOW SUPPLIED

ORTHO® ALL-FLEX® Diaphragm Fitting Kits are available individually.

MANUFACTURER

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