



# Diaphragm

## Description

The diaphragm is a barrier device that covers the cervix and part of the vaginal wall, preventing pregnancy by blocking sperm from entering the uterus. Traditionally, diaphragms were made of latex, but now most are made of silicone. Diaphragms are made in different sizes (generally four to seven sizes depending on the brand), and a woman must be fitted for the correct size by a clinician. Diaphragms are durable and reusable, making them a low-cost contraceptive method.

The diaphragm is held in place by a flexible rim. To use it, a woman inserts the diaphragm with contraceptive gel before intercourse and leaves it in place for six hours afterwards. The diaphragm can be inserted any time before sex, but should not be kept in place for more than 24 hours without removing it to wash. Continuous use of the diaphragm (removing it once a day for cleaning) has been evaluated and found to be safe and acceptable to women in clinical studies.<sup>1,2</sup> Clinical guidelines recommend using diaphragms with contraceptive gel (spermicide) to increase effectiveness, and adding additional gel before further acts of intercourse. However, there is little evidence on the added value of contraceptive gel (see Efficacy section). Women who use a diaphragm must have access to water to wash it after use.<sup>3</sup> The device comes in a case for storage.

Since it is worn internally, diaphragms offer more discreet protection than other barrier methods such as female or male condoms. As a female-initiated method, the diaphragm provides contraceptive protection without requiring male partner involvement. Although some men report not being aware of the diaphragm during sex, many women prefer to discuss method use with their partner, though this depends on the communication and expectations in the relationship. Diaphragms are appropriate for women who cannot or choose not to use hormonal or other long-term contraceptive methods, and for women who want protection only around the time they have sex. Diaphragms are also an appropriate back-up method in case a woman has missed taking oral contraceptive pills or her other method is out of stock at the family planning clinic.

Diaphragms can also be used in conjunction with fertility awareness methods such as Cycle Beads® to provide protection during the fertile period. There are no age or parity restrictions on use, and a woman can use a diaphragm throughout her reproductive life (although size requirements may change over time). Diaphragms are best suited for women who find using a method near or at the time of intercourse acceptable, can learn the insertion technique, and feel they have sufficient privacy for insertion and removal.

## Efficacy

Contraceptive effectiveness depends on correct and consistent use. A diaphragm used with contraceptive gel is 84 to 94 percent effective in preventing pregnancy during the first year of use.<sup>4</sup> Due to concern about its effect on the vaginal epithelium, contraceptive gel containing Nonoxynol-9 (N-9) is not recommended for women at high risk of HIV infection or women who participate in multiple sex acts on a daily basis.<sup>5</sup> Research is underway to evaluate alternative contraceptive gels that do not rely on N-9. Several prospective studies in developed countries have evaluated the efficacy of cervical barriers without contraceptive gel.<sup>6,7,8</sup> Additional studies from developing countries also evaluated diaphragm use without contraceptive gel and their results suggest that this is a strategy that should be considered in the future.<sup>1,9</sup> These prospective studies show that a cervical barrier without spermicides is safe and acceptable and contraceptive efficacy is not dramatically different than that of cervical barriers plus spermicides. However, definitive information on contraceptive efficacy without spermicides is not available.

## Current program/sector use

### Challenges

There are a number of obstacles to expanded use of traditional-sized diaphragms. One is the requirement for a fitting by a clinician; another is the complexity of supplying product in multiple sizes. A reanalysis of fitting data from previous barrier-method clinical trials suggests that many women could be correctly

fitted with a one-size diaphragm.<sup>10</sup> There are currently two single-sized products under evaluation; at least one is expected to be available in some markets in 2013.

Effective use also is dependent upon a continued supply of contraceptive gel. Given concern about increased risk of HIV, many family planning programs in regions with HIV prevalence have stopped supplying products containing N-9. Efforts are underway to identify contraceptive gel alternatives that do not use N-9. Even when an alternative gel is identified and validated, supply and cost issues will remain, which is why reproductive health researchers are interested in evaluating the efficacy and acceptability of the diaphragm without contraceptive gel.

### Opportunities

When women receive information from providers and support from their partners, they find diaphragms very acceptable and successful as a method of family planning. Over the past decade, clinical studies in 13 countries have found diaphragms can be used successfully by women in low-resource settings. One report from India emphasized that women can use diaphragms successfully even when they do not have access to private bathrooms or running water in the house.<sup>11</sup> Other studies in Kenya, Madagascar, and Zimbabwe—as well as Dominican Republic, South Africa, Thailand, and the United States—have found that diaphragms are well accepted, even among women who have no previous experience with the method.<sup>12,13,14,15</sup>

A June 2008 online discussion about diaphragm programs worldwide can be accessed by joining the “Cervical Barrier Methods” community at the Knowledge Gateway for Reproductive Health at <http://my.ibpinitiative.org>. The Cervical Barrier Advancement Society (CBAS) serves as a portal for diaphragm research and information ([www.cervicalbarriers.org](http://www.cervicalbarriers.org)) and posts an updated bibliography of abstracts.

## Manufacturers/suppliers

### ORTHO ALL-FLEX® Diaphragm

The ALL-FLEX® is a diaphragm with a shallow dome and a flexible rim with an arcing spring. The ALL-FLEX® diaphragm is now made from silicone and is available in four sizes (65 mm to 80 mm).<sup>16</sup> It is manufactured by Ortho-McNeil-Janssen Pharmaceuticals, Inc., the world market leader in diaphragm sales and distribution. ALL-FLEX® is available globally, though as of 2008 it has been discontinued in Canada.

### Milex™ Wide-Seal Diaphragm

Milex Wide-Seal® Arcing and Omniflex diaphragms are manufactured by Cooper Surgical and are distributed in Asia, Europe, the Middle East, Canada, and the United States. Both styles are available in eight sizes (60 mm to 95 mm) and are made of silicone.<sup>17</sup>

### Semina Diaphragm

The Semina diaphragm is a clear, silicone diaphragm with a visible coil spring. It comes in six sizes (60 mm to 85 mm) and is manufactured by Semina Industries and Commerce Ltd. The product is marketed in Brazil.<sup>18</sup>

### Reflexions Flat Spring® Diaphragm

The Reflexions Flat Spring® is a rubber diaphragm with a rim that is similar to the coil spring but thinner and more delicate. It is available in nine sizes (from 55 mm to 95 mm). Reflexions is manufactured and marketed in Britain.

## Public-sector price agreements

None.

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