



Diaphragm

Description

The diaphragm is a barrier device that covers the cervix and part of the vaginal wall and prevents pregnancy by blocking sperm from entering the uterus (see below for a list of brand names). 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 before sex, but should not be kept in place for more than 24 hours without removing it to wash. Research evaluating the safety and acceptability of continuous use of the diaphragm (still removing once a day for cleaning) is ongoing.^{1,2} Clinical guidelines recommend adding additional contraceptive gel before further acts of intercourse. In addition, women who use the diaphragm must be able to wash and store the device.³

Since it is worn internally, diaphragms offer more discreet protection than 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, women may choose to discuss this method with their partner depending on the communication and expectations in their 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. There are no age or parity restrictions on use, and a woman can use a diaphragm throughout her reproductive life (although the size may need to be checked). Return to fertility is immediate after use. 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 that they have sufficient privacy for insertion and removal.

Efficacy

Contraceptive effectiveness depends on correct and consistent use. The diaphragm used with spermicide is 84–94 percent effective in preventing pregnancy during the first year of use.⁴

Use of a spermicide containing Nonoxynol-9 (N-9) is not recommended for women at high risk of HIV infection.⁵ Definitive information on the contraceptive efficacy of the diaphragm without spermicide is not available.

Current programme/sector use

Challenges

There are a number of obstacles to expanded use of traditional-sized diaphragms. One is the requirement for a clinician fitting; 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.⁶ There are currently two single-sized products under evaluation; at least one is expected to be available in late 2011.

Effective use also is dependent upon a continued supply of contraceptive gel. Given concern about increased risk of HIV, many family planning programmes in regions with HIV prevalence have stopped supplying products containing Nonoxynol-9 (N-9). Efforts are under way 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.

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.⁷ Other studies in Zimbabwe, Kenya, and Madagascar⁸, as well as Thailand, South Africa, Dominican Republic, and the United States have found

that diaphragms are well accepted even among women who have no previous experience.^{9,10,11}

A June 2008 online discussion about diaphragm programmes 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.cbas.org).

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).¹² The ALL-FLEX® diaphragm 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 Omnidex diaphragms are manufactured by Cooper Surgical and distributed in the United States, Canada, Europe, Asia, and the Middle East. Both styles are available in eight sizes (60 mm to 95 mm) and are made of silicone.¹³

Semina Diaphragm

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

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.¹⁴

Public-sector price agreements

None.

References

- 1 Behets F, Turner A, Van Damme K, et al. Acceptability and feasibility of continuous diaphragm use among sex workers in Madagascar. *Sexually Transmitted Infections*. 2005;81:472–476.
- 2 Penman-Aguilar A, Sweeney T, Turner AN, et al. Promoting continuous use as a strategy for achieving adherence in a trial of the diaphragm with candidate microbicide. *AIDS Education and Prevention*. 2009;21(6):512–525.
- 3 Female Barrier Methods page. Reproductive Health Outlook website. Available at: www.rho.org/html/cont-female_barriers.htm. Accessed August 1, 2008.
- 4 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. See www.contraceptivetechnology.com/table.html.
- 5 World Health Organization. WHO/CONRAD Technical Consultation on Nonoxynol-9: Summary Report. Geneva: World Health Organization; 2003. Available at: http://whqlibdoc.who.int/hq/2003/WHO_RHR_03.08.pdf.
- 6 Mauck C, Lai JJ, Schwartz J, Weiner DH. Diaphragms in clinical trials: Is clinician fitting necessary? *Contraception*. 2004;24(4):263–266. Available at: www.rho.org/html/cont-b-03.html#mauck04.
- 7 PATH. Re-examining the Role of Cervical Barrier Devices. *Outlook*. 2003;20(2). Available at: www.path.org/files/eol20_2.pdf.
- 8 Cervical Barrier Advancement Society website. Available at: www.cervicalbarriers.org/information/recentResearch.cfm. Accessed January 6, 2011.
- 9 Coffey PS, Kilbourne-Brook M, Brache V, Cochón L. Comparative acceptability of the SILCS and Ortho ALL-FLEX diaphragms among couples in the Dominican Republic. *Contraception*. 2008;78(5):418–423.
- 10 Coffey PS, Kilbourne-Brook M, Beksinska M, Thongkrajai E. Short-term acceptability of a single-size diaphragm among couples in South Africa and Thailand. *Journal of Family Planning and Reproductive Health Care*. 2008;34(4):233–236.
- 11 Schwartz et al. SILCS diaphragm: postcoital testing of a new single-size contraceptive device. *Contraception*. 2008;78(3):237–244.
- 12 Cervical Barriers Advancement Society website. Available at: <http://www.cervicalbarriers.org/information/diaphragms.cfm>. Accessed January 6, 2011.
- 13 Cooper Surgical. Milex™ Wide-Seal Diaphragms factsheet. Available at: <http://www.coopersurgical.com/Documents/Milex%20Wide%20Seal%20Diaphragms%20Literature.pdf>. Accessed January 6, 2011.
- 14 Williams Medical. Reflexions Flat Spring Diaphragm web page. Available at: http://www.wms.co.uk/Family_Planning/Contraceptive_Diaphragms/Reflexions_Flat_Spring_Diaphragm. Accessed January 6, 2011.

For more information on the Caucus on New and Underused RH Technologies, please visit our web page at <http://www.rhsupplies.org/working-groups/caucus-on-newunderused-rh-technologies.html>.

This publication forms part of a series of technical briefs, written by members of the Caucus on New and Underused Reproductive Health Technologies, a thematic group established under the auspices of the Reproductive Health Technologies Coalition. The Caucus’ aim is to broaden the discussion within the Coalition of reproductive health technologies that are not well integrated into the public or commercial health sectors. Responsibility for the selection and contents of the product briefs rests solely with the Caucus and does not imply endorsement by the Coalition or its wider membership. For additional information, please contact secretariat@rhsupplies.org.