Female condom

Description

The female condom is a condom made of a soft, thin material that fits inside a woman's vagina. Like the male condom, the female condom is a barrier method, keeping the penis and sperm from contact with the cervix and vagina. But unlike the male condom, it also covers parts of the external female genitalia. The female condom offers protection against both unintended pregnancy and sexually transmitted infections (STIs), including HIV.

Current models on the market have a flexible ring, sponge, or capsule at the closed end of the condom, enabling insertion of the device and helping to keep the condom in place during sex. A ring or frame at the open end of the condom stays outside the vagina, lying flat across the genital area and ensuring that the condom stays in place, as well as protecting from external STIs. The female condom can be inserted into the vagina prior to sexual intercourse, is not dependent on a male erection, and can remain in place after ejaculation. It has no known side effects or risks and can be used by women of all ages.*

The first-generation female condom (FC1®), manufactured by the Female Health Company (FHC), was made from polyurethane—a thin, odorless material that is hypoallergenic, stronger than natural rubber latex, and conducts heat. The FC1® was launched on the market in 1992 but is no longer manufactured and has been replaced by a second-generation product, the FC2®.† The FC2® is made of nitrile rubber—a synthetic type of latex—and can be used with any type of lubricant, including oil-, silicone-, or water-based products.

In addition to the FC2® female condom, there are other female condoms made of natural rubber latex. Currently, there are two models of natural rubber latex female condoms on the market: the "VA w.o.w.®" or "Reddy" female condom and the Cupid™ female condom. Both come lubricated with silicone, but can also be used with water-based lubricants. Oil-based lubricants cannot be used with natural rubber latex condoms.

Three other female condom models are currently under development; this document will be amended and updated as needed once the condoms are available for purchase.

Efficacy

Data from the 2007 World Health Organization family planning handbook indicates that about 21 pregnancies occur per 100 women using female condoms over the first year. When female condoms are used correctly with every act of sex, about five pregnancies occur per 100 women over the first year.[1]

The most rigorous effectiveness studies were undertaken with the FC1® female condom (no longer on the market), and while one cannot extrapolate this data to all female condoms, they do provide basis for discussion. The World Health Organization and the US Food and Drug Administration have indicated that the FC2® is deemed equivalent to the FC1® and it is thus safe to assume that the studies conducted on the FC1® would produce similar results for the FC2®. Estimates on the contraceptive efficacy of the FC1® are within the range of other barrier protective methods (e.g., male condoms); over the course of one year, the accidental pregnancy rate ranges from 15 to 25 percent for actual use to as low as 5 percent for correct use with every act of intercourse.[2] FC1® maintains lower failure rates than either the cervical cap or diaphragm.

In vitro studies of the FC1® confirm that the product provides an effective barrier against many common STIs, including HIV. Calculations based on correct and consistent use estimate a 97.1 percent reduction in the risk of HIV infection for each act of intercourse.[2]

Research conducted on the FC1® in Brazil, India, Thailand, the United States, and Zambia indicates an increase of protected sexual acts and decrease in STI prevalence when FC1® is available alongside male condoms.[3,4,5,6,7] In a pilot study from Thailand, protected sexual acts increased from 57 to 88 percent, and STI prevalence decreased from 52 to 40 percent when both male and female condoms were available.[8]

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* Women who are allergic to latex are recommended to not use latex female condoms.

† See table below for additional information on currently available brands of female condoms.

Product	Regulatory status/ availability	General price estimates[a]	Distribution
FC2® female condom Nitrile (synthetic latex), pre-lubricated Manufactured by the Female Health Company	CE marking WHO approved, 2007 USFDA approved, 2009	US$0.57/unit Volume discounts may apply Retail: approximately US$1.96–2.80	Registered or distributed in 114 countries
VA w.o.w.® female condom (also known as: Reddy/V'Amour/L'amour) Polyurethane sponge and natural rubber latex, prelubricated Manufactured by Medtech Products Ltd.	CE marking India Drug Control Authority approval Brazil MOH approval USFDA Phase 1 clinical trials completed Under WHO review	US$0.23 at 35 million units Retail: US$1.00	Argentina, Brazil, Germany, India, Indonesia, Portugal, South Africa, Swaziland, and the United Kingdom
Cupid™ Condom Natural rubber latex prelubricated Manufactured by Cupid Ltd.	CE marking Under WHO review	US$0.40 approximately	India plus small scale distribution in Brazil and Indonesia. Limited private market sales in Europe

[a] Pricing information in this table is based on the most accurate information and/or estimates available. Prices may fluctuate depending on various procurement conditions, including volume and contractual stipulations.

Female condoms are the only female-initiated methods of HIV prevention that are safe and effective. Studies from 40 countries show acceptability rates ranging from 37 to 93 percent.[9]

Current program/sector use

Since 1993, approximately 260 million female condoms have been distributed in 114 countries, and public-sector programs are underway in over 90 countries. Availability of female condoms, particularly in developing countries, has increased from 14 million units in 2005 to 50 million in 2010.[10] However, based on data in the Reproductive Health Interchange, female condoms only account for approximately 0.19 percent of global condom procurement.[11]

The FC2® is purchased for public-sector programs by organizations such as the US Agency for International Development, the United Nations Population Fund, and governmental health ministries. The Female Health Company funds a global public-sector team consisting of professional program advisors that work with stakeholders on a pro-bono basis to build strong, comprehensive reproductive health, family planning, and HIV prevention programs. In addition, approximately five million VA w.o.w.® female condoms were sold commercially between 2003 and 2007.[12] The Cupid condom has limited distribution in India, Brazil, Indonesia, and some European countries.

Manufacturer

The Female Health Company manufactures, markets, and sells the FC2®. Medtech Products Ltd. of India manufactures, markets, and sells the VA w.o.w.® female condom, and Cupid Ltd. also of India manufacturers, markets and sells the Cupid™ condom.

Registration status

The FC2® has completed the evaluation process of the World Health Organization's (WHO) Technical Review Committee on female condoms, making it eligible for procurement by United Nations agencies. FC2® also received approval by the US Food and Drug Administration (USFDA) in March 2009.[13] In addition, the FC2® female condom has CE marking, which certifies that a product has met European Union consumer safety, health, and environmental requirements.‡

As of January 2010, the VA w.o.w.® female condom has not yet completed the WHO process, but carries the CE mark. The VA w.o.w.® female condom has received approval from the India Drug Control Authority and the Ministry of Health in Brazil.

‡ The manufacturer of a product affixes the CE marking to it, assuring the product meets European Economic Area regulations. However, the manufacturers does have to take certain obligatory steps before the product can bear CE marking: they must complete a conformity assessment, set up a technical file, and sign an European Community declaration of conformity. The documentation has to be made available to authorities on request.

The Cupid™ condom has received the CE mark and approval from the India Drug Control Authority, but has also not yet completed the WHO process.

Public-sector price agreements

FC2® is designed to replace the FC1® female condom and lowers the cost of female condoms for UN agencies, bilateral donors, governments, and nongovernmental organizations. Economies of scale allow for the cost of FC2® to drop as global distribution increases.

Public-sector pricing information on the VA w.o.w.® female condom is not currently available, although it has been supplied in small quantities to public-sector programs in Brazil, Finland, Portugal, Swaziland, South Africa, and Indonesia.

References

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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**.

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