



Female condom

Description

The female condom (FC) 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. Unlike the male condom, however, 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 containing foam shapes 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.**

A number of female condom products are currently available to consumers while others are still in development. The first generation female condom (FC1[®]), manufactured by the Female Health Company (FHC), was a silicone-lubricated, polyurethane sheath, which came on the market in 1992. It has now been replaced by a second-generation product, the FC2[®], identical in design and appearance to FC1[®] but made of nitrile, synthetic latex, which has lower manufacturing costs. In addition to the FC2[®], there are other female condom models on the market, such as Cupid[™], the Woman's Condom, and Phoenurse[®]. The Cupid[™] female condom is made of natural rubber latex and comes lubricated with silicone, but can also be used with water-based lubricants. Oil-based lubricants cannot be used with natural rubber latex condoms. The Phoenurse[®] female condom is made of polyurethane and comes pre-lubricated with a

silicone-based lubricant. The Woman's Condom is made of thin polyurethane film and is packaged un-lubricated. Each Woman's Condom is supplied with a separate sachet of water-based lubricant to be applied at point of use.

In 2012, the United Nations (UN) Commission on Life-Saving Commodities for Women and Children endorsed female condoms as one of its 13 Life-Saving Commodities, catalyzing inter-organizational efforts to overcome several commodity-specific barriers currently inhibiting women in the developing world from benefiting from this product.

Safety, efficacy, and acceptability

Data from the 2007 World Health Organization (WHO) 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 Although earlier effectiveness studies of female condoms were undertaken with FC1[®] female condom (no longer on the market), the WHO and the US Food and Drug Administration (USFDA) have determined that the FC2[®] is equivalent to the FC1[®], based on pre-clinical and clinical studies.² Currently, FC2[®] female condom is used as a control in studies to assess performance and acceptability of newer female condom models. For example, a randomized crossover study published in 2012 assessed the functional performance, safety, and acceptability of three new FCs: the Woman's Condom, Cupid[™], and VA w.o.w[®] (not currently on the market). The study was conducted in China and South Africa and concluded that the three condoms are non-inferior and function as well as the FC2[®].³

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.^{4,5}

* The amount of time prior to sexual intercourse varies per female condom model; please check manufacturer specifications.

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

Current program/sector use

Since 1993, female condoms have been distributed in 130 countries, and public-sector programs are underway in several of these countries.

The FC2® is purchased for public-sector programs by organizations such as the US Agency for International Development (USAID), the United Nations Population Fund (UNFPA), and governmental health ministries. The Female Health Company reported sales of 60 million units of FC2® in 2012.⁶

The Cupid™ female condom has recently been WHO prequalified and approved for bulk procurement by UN agencies. Until now, the Cupid™ was distributed through limited channels in Brazil, India, Indonesia, Kyrgyz Republic, Mozambique, the Netherlands, and South Africa. Between 2010 and 2013, Cupid Ltd. reported that over 2.5 million units of the female condom were sold.

The Woman's Condom and Phoenurse® are newer products with limited distribution in China. The Woman's Condom, branded O'lavie™ for the Chinese market, has been available in China in limited channels since late 2011. It is expected to become available in South Africa in 2013.

According to the Reproductive Health Interchange, female condoms worth US\$28.2 million were procured and distributed globally in 2012, by major procurement agencies.⁷

Manufacturers and distribution

Included below is key information on the manufacture and registration status of the five female condom products that are currently on the market.

PRODUCT	MANUFACTURER	REGULATORY STATUS	DISTRIBUTION	PRICE ESTIMATES***
FC2® female condom (also known under the brand name Femidon, Protectiv, Care, and many other names) Made of nitrile (synthetic latex), pre-lubricated	Female Health Company	CE marking;*** WHO prequalified 2007, 2012; USFDA approved 2009	Available in 130 countries	\$0.55/unit
Cupid™ female condom Made of rubber latex, pre-lubricated	Cupid Ltd., India	CE marking; WHO prequalified 2012; USFDA registration process initiated in 2012	Brazil, India, Indonesia, Kyrgyz Republic, Mozambique, the Netherlands, and South Africa	\$0.45/unit at 5 million units
Woman's Condom (also known as O'lavie™ for the China market) Pouch, ring, and foam shapes made of polyurethane; dissolving insertion capsule made of polyvinyl alcohol; Non-lubricated, packaged with water-based lubricant	Shanghai Dahua Medical Apparatus Company, China	CE marking; Under WHO review for prequalification; Undergoing contraceptive effectiveness study needed for USFDA approval	Limited private-sector distribution in China	\$0.87/unit at 5 million units, volume discounts may apply
Phoenurse® female condom Made of polyurethane, pre-lubricated with silicone-based lubricant	Tianjin Condbao Medical Polyurethane Tech. Co. Ltd, Tianjin, China	CE marking	Brazil, China, Kenya, Mexico, and Sri Lanka	0.59/unit; volume discounts may apply

*** Pricing information in this table is based on the most accurate information and/or estimates provided by the manufacturer. Prices may fluctuate depending on various procurement conditions, including volume and contractual stipulation.

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

Registration status

The FC2[®], Cupid[™], Phoenurse[®], and Woman's Condom all have a CE marking, which certifies that the product has met European Union consumer safety, health, and environmental requirements.

In addition to being WHO prequalified and USFDA approved, the FC2[®] is registered in 30 countries and is currently pending registration in four countries. After receiving WHO prequalification in 2012, Cupid Ltd. has initiated the female condom registration process with USFDA. Cupid[™] female condom is currently registered with the Brazilian Regulatory Agency (ANVISA), Indian Drug Control Authority, and South African Bureau of Standards. The Woman's Condom is registered in China and registration in South Africa is underway. Phoenurse[®] is currently registered in Brazil and China.

Public-sector price agreements

At the 2012 Family Planning Summit in London, the Female Health Company pledged to increase access to FC2[®] female condom for the world's poorest countries and announced a prospective pricing arrangement based on aggregate purchases and 5 percent free goods based on the prior year's purchases, together with a multiyear agreement to provide \$14 million in training and education by FHC over the next six years.

The Cupid[™] female condoms have been sold in Kyrgyz Republic through UNFPA for their public distribution system. The Woman's Condom has been sold to the public sector in China. Phoenurse[®] female condoms have not been sold to public-sector purchasers as of the date of this publication.

Globally, it is acknowledged that further price reductions are necessary to achieve universal access to female condoms. Based on market analysis it is expected that sustainable price reductions are feasible.

References

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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 Supplies 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.