



## Female condom

### Description

The female condom is a condom made of a soft, thin material that is worn loosely by the woman inside her vagina. Like the male condom, the female condom is a barrier method, keeping the penis from contact with the cervix and vagina. But unlike the male condom, it also covers parts of the external female genitalia. The sperm remain in the condom, preventing their contact with the vagina and cervix. 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 or sponge at the closed end of the condom, enabling insertion of the device and helping to keep the condom in place during sex. A ring/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. 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 (FC<sup>®</sup>)<sup>†</sup> was made from polyurethane—a thin, odorless material that is hypoallergenic, stronger than natural rubber latex, and conducts heat. FC<sup>®</sup> may be used with any type of lubricant, including oil-, silicone-, or water-based products (however, oil-based lubricants are destructive condoms made of latex). FC<sup>®</sup> has been on the market since 1992.

Since 2006, different types of female condoms have become available. The new models are made from latex and nitrile—a synthetic form of latex. The latex female condom (the “VA w.o.w.<sup>®</sup>” or Reddy female condom) comes lubricated with silicone, but can also be used with water-based lubricants. The nitrile female condom (FC2<sup>®</sup>) also comes with a silicone-based lubricant. With special precautions, the polyurethane female condom (FC<sup>®</sup>) could be reused.<sup>1</sup> The latex (VA w.o.w.<sup>®</sup>) and nitrile (FC2<sup>®</sup>) female condoms cannot be reused.

Other female condom models are currently under development; this document will be amended and updated as needed.

### Efficacy

Data from the 2007 World Health Organization family planning handbook indicate that about 21 pregnancies occur per 100 women using female condoms over the first year. When used correctly with every act of sex, about five pregnancies occur per 100 women over the first year.<sup>2</sup>

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

<sup>†</sup> See table below for additional information on currently available brands of female condoms.

Although female condoms work along the same principles as male latex condoms, there is far more variety among female condoms, both in terms of design and materials. The FC<sup>®</sup> is currently the product with the most rigorous effectiveness studies, and while one cannot extrapolate these data to all female condoms, they do provide basis for discussion. Estimates of its contraceptive efficacy 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.<sup>3</sup> FC<sup>®</sup> maintains lower failure rates than the cervical cap and diaphragm.

In vitro studies of the FC<sup>®</sup> also 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.<sup>4</sup>

Research conducted on the FC<sup>®</sup> in Brazil, India, Thailand, the United States, and Zambia indicates an increase of protected sexual acts and decrease in STI prevalence when FC<sup>®</sup> is available alongside male condoms.<sup>5,6,7,8,9</sup> 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.<sup>10</sup>

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.<sup>11</sup>

### **Current program/sector use**

Since 1993, 165 million FC<sup>®</sup> female condoms have been distributed in 142 countries, and public-sector programs are underway in over 90 countries. Availability of FC<sup>®</sup>, particularly in developing countries, has increased from 14 million units in 2005 to 25.9 million in 2007.<sup>12</sup> The FC<sup>®</sup> 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 (FHC), manufacturer of the FC<sup>®</sup>, 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. Approximately five million VA w.o.w.<sup>®</sup> female condoms were sold commercially between 2003 and 2007.<sup>13</sup> Currently, female condoms only account for approximately 0.24 percent of global condom use.<sup>14</sup>

### **Manufacturer**

FHC manufactures, markets, and sells the FC Female Condom<sup>®</sup> and FC2 Female Condom<sup>®</sup>. Medtech Products Ltd. of India manufactures, markets, and sells the VA w.o.w.<sup>®</sup> female condom, and National Sensation of Colombia is the manufacturer of the National Sensation Panty Condom<sup>®</sup>.

### **Registration status**

Both the FC<sup>®</sup> and FC2<sup>®</sup> have completed the evaluation process of the World Health Organization's (WHO) Technical Review Committee on female condoms. The FC<sup>®</sup> received approval by the US Food and Drug Administration (USFDA) in 1993; more recently, in March

2009, the USFDA granted approval to the FC2<sup>®</sup>. To date, FC2<sup>®</sup> has been registered or distributed in 77 countries.<sup>15</sup> Both products also have European Union approval and the CE mark.

As of January 2009, the VA w.o.w.<sup>®</sup> female condom has not yet completed the WHO process, but carries the CE mark. The VA w.o.w.<sup>®</sup> female condom has received approval from the India Drug Control Authority and the Ministry of Health in Brazil.

The Natural Sensation Panty Condom<sup>®</sup> has received the European Commission's CE mark and in early 2009, the manufacturer was in discussions with the USFDA about seeking US regulatory approval.

### **Public-sector price agreements**

FC2<sup>®</sup> is designed to replace the FC<sup>®</sup> 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<sup>®</sup> to drop as global distribution increases.

Public-sector pricing information on the VA w.o.w.<sup>®</sup> 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. The Natural Sensation Panty Condom<sup>®</sup> does not have negotiated a public-sector price at this time.

<b>Product Name</b>	<b>Regulatory Status/Availability</b>	<b>General price estimates*</b>	<b>Distribution</b>
<p><b>FC Female Condom<sup>®</sup></b></p> <p>-Polyurethane, two soft rings, prelubricated.</p>	<p>-USFDA approved, 1993.</p> <p>-Conformité Européenne (CE) Marking, 1997.</p> <p>-WHO approved.</p>	<p>US\$0.68 public-sector price (UNAIDS negotiated price is approximately US\$0.58).</p>	<p>-Sold commercially in 11 countries.</p> <p>-Available via public-sector agencies in more than 90 countries.</p> <p>-25.9 million units in 2007.</p>
<p><b>FC2 Female Condom<sup>®</sup></b></p> <p>-Nitrile (synthetic latex), prelubricated.</p>	<p>-CE Marking.</p> <p>-WHO approved, 2007.</p> <p>- USFDA approved, 2009.</p>	<p>US\$0.57</p> <p>Volume discounts may apply.</p> <p>Retail: approximately US\$1.96–2.80</p>	<p>-Registered or distributed in 77 countries.</p>
<p><b>VA w.o.w.<sup>®</sup> female condom</b> (also known as: Reddy/V'Amour/L'amour)</p> <p>-Polyurethane sponge and latex pouch in v-shaped frame, prelubricated.</p>	<p>-CE Marking.</p> <p>-India Drug Control Authority approval.</p> <p>-Brazil MOH approval.</p> <p>-USFDA Phase 1 clinical trials completed.</p> <p>-Under WHO review.</p> <p>-Expected approval in China, Russia, and South America.</p>	<p>-US\$0.23 at 35 million units.</p> <p>-Retail: US\$1.00.</p>	<p>Argentina, Brazil, Germany, India, Indonesia, Portugal, South Africa, Swaziland, and the United Kingdom</p>
<p><b>Natural Sensation Panty Condom<sup>®</sup></b></p> <p>-Polyurethane resin, non- and pre-lubricated, with cotton or nylon panty.</p>	<p>-CE Marking, 2003.</p> <p>-In discussions with USFDA about regulatory requirements.</p> <p>-Under review for approval to sell in Argentina, Australia, and Brazil.</p>	<p>-Retail: US\$2.90</p>	<p>Venezuela, Colombia, Panama, Costa Rica, Dominican Republic, United Kingdom, Spain.</p>

\* 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.

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<sup>1</sup> The World Health Organization (WHO). The Safety and Feasibility of Female Condom Reuse: Report of a WHO Consultation. Geneva: WHO; 2002. Available online at: [http://www.who.int/reproductive-health/stis/docs/report\\_reuse.pdf](http://www.who.int/reproductive-health/stis/docs/report_reuse.pdf).

<sup>2</sup> World Health Organization Department of Reproductive Health and Research and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), INFO Project. Family Planning: A Global Handbook for Providers. Baltimore and Geneva: CCP and WHO; 2007.

<sup>3</sup> Joint United Nations Programme on HIV/AIDS and the World Health Organization. The female condom—an information pack. Available at: <http://www.femalehealth.com/resources.html>. Accessed October 21, 2008.

<sup>4</sup> Trussell J, Sturgen K, Strickler J, Dominik R. Comparative contraceptive efficacy of the female condom and other barrier methods. *Family Planning Perspectives*. 1994;26:66–72.

<sup>5</sup> Barbose RM, Berqu E, Kalckmann S. *Acceptability of the female condom in different social contexts: Final research report*. Brazil: Ministry of Health, National STD/AIDS Coordinating Office; 2007.

<sup>6</sup> Hindustan Latex Family Planning Promotion Trust/The Female Health Company. *Female Condom: The Indian Experience: Final Research Report*. The Female Health Company; 2004.

<sup>7</sup> Fontanet AL, Saba J, Chandelying V, et al. Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: results from a randomized controlled trial. *AIDS*. 1998;12(14):1851–1859.

<sup>8</sup> Latka M, Gollub E, French P, et al. Male-condom and female-condom use among women after counseling in a risk-reduction hierarchy for STD prevention. *Sexually Transmitted Diseases*. 2000;27(8):431–437.

<sup>9</sup> Musaba E, Morrison CS, Sunkutu MR, et al. Long-term use of the female condom among couples at high risk of human immunodeficiency virus infection in Zambia. *Sexually Transmitted Diseases*. 1998;25(5):260–264.

<sup>10</sup> Hoke TH, Feldblum PJ, Van Damme K, et al. Temporal trends in sexually transmitted infection prevalence and condom use following introduction of the female sex workers. *International Journal of STD & AIDS*. 2007;18:461–466.

<sup>11</sup> Female condom acceptability page. Family Health International website. Available at: [www.fhi.org/en/RH/Pubs/Briefs/FemCondom/acceptability.htm](http://www.fhi.org/en/RH/Pubs/Briefs/FemCondom/acceptability.htm). Accessed September 3, 2008.

<sup>12</sup> Personal communications. Katy Pepper, Global Public-Sector Team. March 6, 2009.

<sup>13</sup> Personal communications. Rino Meyers, IDA Solutions. July 3, 2008.

<sup>14</sup> Oxfam International. Failing women, withholding protection: 15 lost years in making the female condom accessible. Presented at: The International AIDS Conference, August, 2008; Mexico City, Mexico. p. 14.

<sup>15</sup> Reuters. USFDA approves new, cheaper female condom. March 11, 2009. Available online at: <http://www.reuters.com/article/latestCrisis/idUSN10547381>

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 sectors. Responsibility for the selection and contents of the technical 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](mailto:secretariat@rhsupplies.org).