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 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.

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 The FC1* was launched on the market in 1992, but is no longer manufactured and has been replaced by a second-generation product, the FC2*.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*, there are four other female condom models on the market: the VA w.o.w*, Cupid*, Phoenurse*, and the Woman’s Condom. The VA w.o.w* and the Cupid** female condoms are both made of natural rubber latex and come pre-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; comes pre-lubricated with a silicone-based lubricant; and is packaged with an insertion tool, sanitary towel, and disposable bag. 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.

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. The effectiveness studies these data are based upon 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 determined that the FC2* is equivalent to the FC1*. Estimates on the contraceptive efficacy of the FC1* are within the range of other barrier protective methods (e.g., male condoms). 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.

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

* 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.
Prevalence when FC1® is available alongside male condoms. 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.

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.

### Current program/sector use

Since 1993, approximately 300 million female condoms have been distributed in 120 countries, and public-sector programs are underway in more than 90 countries. Availability of female condoms, particularly in developing countries, has increased from 14 million units in 2005 to 50 million in 2010. However, based on data in the Reproductive Health Interchange, female

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**Included below are the five female condom products that are on the market:**

<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory status/availability</th>
<th>General price estimates</th>
<th>Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FC2® female condom</strong></td>
<td>CE marking. WHO prequalified, 2007. USFDA approved, 2009.</td>
<td>US $0.57/unit; volume discounts may apply. Retail: US$ 2.00.</td>
<td>Registered and/or distributed in 120 countries.</td>
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<tr>
<td>(also known under brand names</td>
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<tr>
<td>such as Femidon, Protectiv,</td>
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<tr>
<td>Care, and many others).</td>
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<tr>
<td>Nitrile (synthetic latex),</td>
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<tr>
<td>pre-lubricated.</td>
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<tr>
<td>Manufactured by the Female</td>
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<tr>
<td>Health Company.</td>
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<tr>
<td><strong>VA w.o.w.® female condom</strong></td>
<td>CE marking. India Drug Control Authority approval. Registered with Brazilian regulatory agency (ANVISA). USFDA Phase 1 clinical trials completed. Under WHO review for prequalification.</td>
<td>US $0.23/unit at 35 million units. Retail: US$1.00.</td>
<td>Argentina, Brazil, Germany, India, Indonesia, Portugal, South Africa, Swaziland, and the United Kingdom.</td>
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<td>(also known as: Reddy, V’Amour,</td>
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<tr>
<td>L’amour).</td>
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<tr>
<td>Polyurethane sponge and natural rubber latex, pre-lubricated.</td>
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<td>Manufactured by Medtech Products Ltd.</td>
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<tr>
<td><strong>Cupid™ Condom</strong></td>
<td>CE marking. Registered within Brazilian regulatory agency (ANVISA). Under WHO review for prequalification.</td>
<td>US $0.35/unit at 1 million units. Retail: US $0.65.</td>
<td>India, plus small-scale distribution in Brazil, Indonesia, the Netherlands, South Africa, and Mozambique. Will be distributed at a large scale in Mozambique from 2012 onwards.</td>
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<tr>
<td>Natural rubber latex, pre-lubricated.</td>
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<tr>
<td>Manufactured by Cupid.</td>
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<tr>
<td><strong>Phoenurse® female condom</strong></td>
<td>Tianjin Food and Drug Administration approval. Registered within Brazilian regulatory agency (ANVISA). Under WHO review for prequalification.</td>
<td>US$0.59/unit at 1 million units. Retail: approximately US$1.80-2.80.</td>
<td>Limited distribution in China. Currently seeking opportunities in South Africa and Brazil.</td>
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<tr>
<td>Polyurethane, pre-lubricated.</td>
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<tr>
<td>Manufactured by Tianjin Condombao Medical Polyurethane Tech. Co. Ltd, Tianjin, China.</td>
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<td><strong>Woman’s Condom</strong></td>
<td>CE marking. Shanghai Food and Drug Administration approval. Under WHO review for prequalification. Undergoing contraceptive effectiveness study needed for USFDA approval.</td>
<td>US$0.87/unit, volume discounts may apply. Retail in China: approximately US$2.35.</td>
<td>Limited private-sector distribution in China.</td>
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<td>(also known as O’lavie™ for the China market). Pouch, ring, and foam shapes made of polyurethane; dissolving insertion capsule made of polyvinyl alcohol. Condom is un-lubricated and packaged with water-based lubricant.</td>
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<tr>
<td>Manufactured by Shanghai Dahua Medical Apparatus Company, China.</td>
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*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.
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 (UNFPA), 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, the Netherlands, South Africa and
Mozambique.

The Phoenurse® and the Woman’s Condom are newer
products. Phoenurse® entered the Chinese market in
2009. Phoenurse® has limited distribution in China
and manufacturers are currently working on entering
the Brazilian and South African markets. The Woman’s
Condom, branded O’lavie™ for the China market, has
been available since September 2011 in limited private-sector distribution channels.

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. Cupid Ltd., also of India, manufactures,
markets and sells the Cupid™ condom. Tianjin
Condombao Medical Polyurethane Tech. Co. Ltd. of
Tianjin, China, manufactures, markets, and sells the
Phoenurse® female condom, while Dahua Medical
Apparatus Company of Shanghai, China, manufactures,
markets, and sells the Woman’s Condom.

Registration status

The FC2* completed the evaluation process of the
World Health Organization’s (WHO) Technical Review
Committee on female condoms in 2006, making it eligible for procurement by United Nations agencies.
In March 2009, FC2* received approval by the US Food
and Drug Administration (USFDA).13 The FC2* female
condom also has CE marking, which certifies that a
product has met European Union consumer safety,
health, and environmental requirements.3

The VA w.o.w.* female condom, Cupid™ condom,
and Woman’s Condom all carry CE marking. In
addition, the VA w.o.w.* and the Cupid™ condoms have

approval from the India Drug Control Authority and
the Brazilian regulatory agency (ANVISA), while the
Woman’s Condom has approval from the Shanghai Food
and Drug Administration in China. The Phoenurse®
female condom does not have CE marking, but it has
received approval from the Tianjin Food and Drug
Administration in China and from ANVISA.4 These
latter four female condoms, along with six other
female condom designs, are currently under review by
the WHO/UNFPA Technical Review Committee to
determine their suitability for public-sector purchase.

Public-sector price agreements

FC2* was designed to replace the FC1* female condom
and lower the cost of female condoms for UN agencies,
bilateral donors, governments, and nongovernmental
organizations. 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. The Cupid™,
Phoenurse®, and Woman’s Condom female condoms
have not been sold to public-sector purchasers as of the
date of this publication.

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of the female condom among couples at high risk of human
immunodeficiency virus infection in Zambia. Sexually
in sexually transmitted infection prevalence and condom use
following introduction of the female sex workers. International

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.

The FC2* also has approval of the Brazilian regulatory agency (ANVISA)
and regulatory agencies in many other countries. See table above.


