



Woman condom's product information

All information is correct as of September 2013

Design

Shanghai Medical Apparatus Company, Ltd (Dahua) is the manufacturer of the Woman's Condom, branded as O'Lavie™ in China, a new female condom designed to offer protection from unintended pregnancy and sexually transmitted infections, including HIV. The product has unique features that make it easy to use and comfortable for both partners.

The Woman's Condom has a thin film polyurethane pouch that is partially enclosed in a soft capsule to aid insertion. The capsule dissolves after it is inserted into the vagina, allowing the pouch to expand. Four foam shapes on the outside of the pouch gently cling to the vaginal wall and hold the pouch stable during sex. The Woman's Condom is packaged unlubricated. Each condom comes with a small sachet of water-based lubricant to be applied at point of use allowing couples to use as much or as little lubricant as they desire.

Availability

Dahua and its partners are developing markets in China and sub-Saharan Africa, with the eventual goal of raising awareness and building demand about the Woman's Condom worldwide. In China, the Woman's Condom is available in limited distribution channels. The product will be available in South Africa soon through commercial channels.

The Woman's Condom is approved for sale in Europe, China and South Africa; it holds the CE Mark (2010), Shanghai Food and Drug Administration approval (2011), and SABS certification (2013).



In addition, the Woman's Condom is currently under review by a technical committee with members from the World Health Organization (WHO) and the United Nations Population Fund. The committee's approval would lead to WHO prequalification of the product.

Safety and effectiveness

Rigorous research has been conducted with the Woman's Condom in several countries to evaluate and validate the product's safety, performance, and acceptability. These studies have found that the Woman's Condom is safe, acceptable, and easy to use, and that it performs well when compared to other female condom products.

Additional clinical studies are in process, including a contraceptive effectiveness study taking place in the United States. For optimal effectiveness, the Woman's Condom must be used consistently and correctly each time a couple has sex.

*O'Lavie is a trademark of Shanghai Dahua Medical Apparatus Company.



How to purchase

Woman's Condom is approved for sale in Europe, China and South Africa.

.For product inquiries, please contact:

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About us

Dahua Medical Apparatus Company (Dahua) of Shanghai, China is the manufacturer of the Woman's Condom. Dahua is committed to improving reproductive health and expanding protection options for women and men globally.

Dahua has more than 25 years of experience in the medical device business and has specific capability in film production and welding, plastics molding, and assembly. Dahua is compliant with general medical device Good Manufacturing Practices, and we have [ISO 9000 series](#) and [ISO 13485 registration](#).

For more information about Dahua, please visit our company website: <http://www.dahuachina.com.cn>

Product specifications	
Brand name	O'lavie™ in China
Manufacturer	Shanghai Dahua Medical Apparatus Company, China
Regulatory Status	Received Shanghai Food and Drug Administration approval, CE marking, and SABS certification. Under WHO review for prequalification. Undergoing contraceptive effectiveness study needed for USFDA approval.
Distribution	Limited distribution in China. Available soon in South Africa.
Dimensions	Length: 227±10 mm, Width: 81mm (pouch), Thickness: 0.03mm
Pouch	Pouch is a 0.03 mm thin polyurethane flat film that is heat-welded into a pouch shape. Barrier to bacteriophage Phi X174 according to ISO 25841.
Outer ring	Outer ring molded from raw polyurethane.
Insertion Feature	Capsule made from polyvinyl alcohol dissolves in the vagina in less than 60 sec.
Retention Feature	Four small shapes cut from 3.2mm hydrophilic polyurethane foam.
Lubrication	Water based lubricant packaged in a 3mL sachet separate from condom. Main ingredients of the lubricant are water, glycerin, and propylene glycol.
Packaging	Condoms packed individually in aluminum laminate sachet. Packed 3 condoms, 3 lubricant sachet, and 1 instructional leaflet in 1 box; 360 boxes per carton.

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