The Woman’s Condom is a new option for barrier contraceptive protection. Developed by PATH, an international global health nonprofit organization, the Woman’s Condom is designed to offer women and their partners safe and effective protection from pregnancy and sexually transmitted infections (STIs). The Woman’s Condom is manufactured by the Dahua Medical Apparatus Company (Dahua) of Shanghai, China.

**Users as Designers**

With input from women and couples in several countries, PATH and its research partners designed the Woman’s Condom to be acceptable to use for both partners. Its unique design features enable easy insertion, secure fit during use, good sensation, and easy removal.

**Clinically Proven**

Years of clinical work with the first-generation female condom product show that the device is safe, effective, and well accepted by women in many countries. A comprehensive Cochrane review of clinical studies comparing the female condom to the male condom found that female condoms offer effective protection from unwanted pregnancy and STIs and are as effective as male condoms.¹ Researchers estimate through mathematical modeling that consistent female condom use could reduce the risk of HIV infection by up to 90 percent compared to unprotected sex.² Since 2004, the Woman’s Condom has been evaluated for acceptability, performance, and safety in clinical studies across five countries. 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. Three additional clinical studies are under way that will further support this evidence. These include a contraceptive effectiveness study, funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); a slippage and breakage study comparing the Woman’s Condom and FC2 using prostate-specific antigen (PSA) as a biomarker of semen exposure; and a multisite study comparing performance, safety, and acceptability of four female condom products.

**Our Supporters**

PATH received support from many donors to develop and validate the Woman’s Condom. We gratefully acknowledge support from the US Agency for International Development and our research and regulatory partners at CONRAD. In addition, we have received funding from the Netherlands Ministry of Foreign Affairs, the Universal Access to Female Condoms (UAFC) Joint Programme, and the Bill & Melinda Gates Foundation.
### Completed Clinical Studies

#### Design verification study of the Woman’s Condom: Mexico, South Africa, and Thailand (2006)

<table>
<thead>
<tr>
<th>Principal investigator</th>
<th>Description</th>
<th>Sample</th>
<th>Product uses</th>
<th>Endpoint</th>
<th>Key findings</th>
</tr>
</thead>
</table>
| P. Coffey, PATH        | Nonrandomized, multisite posttest evaluation to determine user acceptability of the PATH-fabricated Woman’s Condom. | 60 couples, consisting of new and experienced users. Most women from Mexico and Thailand were married. | 180 | Safety, function, and acceptability | Female and male participants reported:  
  - High levels of condom stability during sex.  
  - Acceptable condom comfort during insertion and use.  
  - Positive sensation when using the condom during sex.  
  - Relative ease of use. |

#### Phase 1 comparative performance, failure mode, and safety study: United States (2008)

<table>
<thead>
<tr>
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</thead>
</table>
| J. Schwartz, CONRAD    | Open-label, multi-center, randomized crossover study to compare the functional performance, safety, and acceptability of the PATH-fabricated Woman’s Condom and the FC1 female condom. | 75 couples, the majority of whom lived together. Women and men both had a mean age of about 30. | 274 | Functional performance, safety, and acceptability | • Both female condoms were safe and acceptable in short-term use, but the Woman’s Condom led to less failure, was associated with fewer adverse events, and was more acceptable than the FC1 female condom.  
  - Woman’s Condom was preferred by 57% of women and 43% of men while the FC1 was preferred by 22% of both women and men. |

#### Woman’s Condom performance, failure mode, and acceptability study: China (2012)

<table>
<thead>
<tr>
<th>Principal investigator</th>
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<th>Sample</th>
<th>Product uses</th>
<th>Endpoint</th>
<th>Key findings</th>
</tr>
</thead>
</table>
| H. Zirong, Fudan University  
W. Junqing, SIPPR  
P. Coffey, PATH  | Performance and failure mode study to ascertain functionality, acceptability, and safety of the Dahua-fabricated Woman’s Condom. | 59 couples, almost all of Han ethnicity and married. Mean age of women just under 40. | 234 | Functional performance, safety, and acceptability | • Woman’s Condom performed well in terms of clinical failure with a total clinical failure rate of 4.3% (types of failures that could result in pregnancy or STIs).  
  - 15 mild and no serious adverse events were reported.  
  - Further analysis on acceptability is under way. |
### Comparative performance and acceptability study: South Africa (2011)

<table>
<thead>
<tr>
<th>Principal investigator</th>
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</tr>
</thead>
<tbody>
<tr>
<td>C. Joanis, Family Health International</td>
<td>Acceptability, function, and product preference three-part study of three female condom types: Woman’s Condom (PATH-fabricated), FC2, and Reddy 6. Part 1: Random sequence crossover study Part 2: Simulated market with choice among 3 types Part 3: Qualitative study of product preference</td>
<td>Part 1: 165 women, majority of whom were African and unmarried. Ages ranged from 18–48 years old (mean=28.0). Part 2: 148 women (subset of Part 1)</td>
<td>Part 1: 798 Part 2: 1,898</td>
<td>Part 1: Functional performance, safety, and acceptability Part 2: Preference and acceptability</td>
<td>• Total clinical failures were low (&lt;4%) regardless of condom type. • In Part 1, participants preferred the Woman’s Condom and FC2 over the Reddy 6 (p &lt; .0001) and the Woman’s Condom over FC2 (p=.0007). • In Part 2, women took home more Woman’s Condoms than FC2 or Reddy 6, though this preference was not significant.</td>
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### Performance and safety of FC2 compared to the Woman’s Condom, VA WOW and Cupid Condoms: a randomized controlled non-inferiority crossover trial (2013)

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>ME Beksinska and JA Smit MatCH Wu Junqing SIPPR C Joanis Joanis Consulting</td>
<td>Randomized, controlled, non-inferiority, four-period crossover trial to evaluate device function, safety, and acceptability of four condoms. Implemented at three sites in Shanghai, China and one site in Durban, South Africa.</td>
<td>300 from Shanghai and 300 from Durban (600 total) were randomly assigned to condom-type order. Women were 18-45 years, literate, monogamous, and not sex workers. 572 (95%) women completed follow-up, with at least one condom of each type and were included in the analysis.</td>
<td>Women asked to use 5 of each condom type.</td>
<td>Primary non-inferiority endpoints were total clinical failure and total female condom failure, with a non-inferiority margin of 3%. Component failure events (clinical breakage; non-clinical breakage; slippage, misdirection, and invagination) also were assessed. Data on safety and acceptability also collected.</td>
<td>• Non-inferiority was shown for all condom failure events for the three new devices versus the FC2 within the predefined margin. • Total condom failure was 3.43% for FC2; 3.85% for Woman’s Condom; 3/02% for VA wow; and 4.52% for Cupid. • Total clinical failure was 2.88% for FC2; 3.05% for Woman’s Condom; 2.9% VA wow; and 3.87% for Cupid. • Adverse events and medical problems were low (fewer than 1%) for each condom type. • The low rates of clinical failure, total failure, and component failure are consistent with other studies.</td>
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</table>
**CLINICAL STUDIES IN PROCESS**

<table>
<thead>
<tr>
<th>Study type, timeline, and sponsor</th>
<th>Description</th>
<th>Sample *</th>
<th>Product uses*</th>
<th>Endpoint</th>
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</thead>
<tbody>
<tr>
<td>Study of vaginal semen exposure and clinical failure in the Woman’s Condom and FC2; 2010-2011; (CONRAD).</td>
<td>The Woman’s Condom will be compared with the FC2 by reported clinical failure and presence of PSA in the vagina. This is a comparative, open-label, two-period crossover study taking place in the United States.</td>
<td>422 women</td>
<td>1,650</td>
<td>Functional performance, safety, and acceptability of Woman’s Condom compared to FC2 using PSA as a marker of semen exposure.</td>
</tr>
<tr>
<td>Woman’s Condom safety and contraceptive efficacy study; 2011-2012; (NICHD).</td>
<td>This is a multicenter, open-label, noncomparative study testing the safety and efficacy of the Woman’s Condom taking place in the United States. A subset of women will assess detection of vaginal PSA by selfcollected swabs before and after intercourse.</td>
<td>500 women</td>
<td>Use Woman’s Condom for 6 months as primary contraceptive.</td>
<td>Contraceptive effectiveness, safety, and acceptability.</td>
</tr>
</tbody>
</table>

* Sample sizes and product uses are estimates because these studies are not complete.

**PRODUCT INQUIRIES**

For more information on the Woman’s Condom project, contact:

Patricia Coffey  
Woman’s Condom team leader  
PATH  
PO Box 900922, Seattle, WA 98109, USA  
womanscondom@path.org  
sites.path.org/rhtech/womans-condom

For commercial inquiries, contact:

Hua Chen  
President  
Shanghai Dahua Medical Apparatus Co., Ltd.  
A-B Flr. 20, Bld 5, Lane 413, Lujiabang Rd, Shanghai, China  
shdahua1@msn.cn

**REFERENCES**


PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.