PATH WOMAN'S
CONDOM

PATH Woman's Condom Informational Updates

September 2005

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Overview

Using an innovative, user-driven design process, PATH has designed a product that could help couples around the world reduce their risk of HIV, other sexually transmitted infections, and unintended pregnancy.

The global health need

The HIV/AIDS pandemic is one of the world's most pressing health challenges. Over the next 20 years, AIDS is projected to result in the deaths of more than half of young adults in the most severely affected countries—an effect that will undermine many of the social, economic, and public health gains achieved over the last two decades.

Women are particularly vulnerable to HIV infection. Women represent nearly half of all people living with HIV, and in most developing countries, women now represent the fastest growing group of new infections.[1] Unfortunately, HIV and other sexually transmitted infections are not the only risks women face from unprotected sex. Globally, an estimated 50 million unintended pregnancies occur each year, and many end in unsafe abortion.[2] Many women in developing countries are simply unable to avoid these risks because they lack the power to negotiate sex or insist that their partners use male condoms.

The social and economic repercussions of these vulnerabilities are severe. Women with HIV suffer stigma, discrimination, and the threat of violence or rejection. Others must forgo jobs or school to care for HIV-positive family members—further undermining their potential to contribute to their families and communities.

A promising prevention option

To offer women another way to protect themselves, researchers are working to develop woman-controlled contraceptive methods that prevent pregnancy as well as HIV and other sexually transmitted infections. One such method—the female condom—has been shown to significantly reduce the risk of HIV infection. Experience with existing products approved by the US Food and Drug Administration—has also shown that women and men will use new barrier methods if the devices are acceptable and easy to use. Performance, acceptability, and cost issues with those devices have limited uptake in many countries, however.

PATH believes that researchers can overcome these challenges with a next-generation product that women and couples will embrace. Since we began developing a refined female condom in the 1990s, we have developed and tested more than 50 functional designs that reflect numerous solutions to cost and user-related concerns. The final design is an innovative product that is easy to handle and insert. Couples report it is comfortable for both partners, stays securely in place, and allows good sensation for women and men. Users in developed and developing countries find the device highly acceptable.

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Planning for impact

PATH is now planning to accelerate the scale-up, commercialization, and regulatory approval of the PATH Woman's Condom. Preliminary results from CONRAD's Phase 1 clinical trial on the PATH and FC products' safety, acceptability, slippage, and breakage are expected in late 2005, and a pivotal contraceptive effectiveness study is planned for 2006 and 2007. US Food and Drug Administration clearance for commercial distribution could begin as early as 2008.

Because PATH is not a product manufacturer, our next step is to establish partnerships with manufacturers that can produce the final product and commercialization partners that can commit to responding to public health goals. Equally important, we are pursuing donor support for these and other activities that will advance the PATH Woman's Condom and protect the health of women, couples, and families around the world.

About PATH

PATH is an international, nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act.

PATH currently works in more than 100 countries in the areas of reproductive health; vaccines and immunization; HIV, AIDS, and tuberculosis; and children's health and nutrition. Staff provide expertise in public health, epidemiology, technology design, technology development and transfer, technology introduction, immunodiagnostics and vaccine development, vaccine distribution systems, business development, education and training, communication, advocacy, and procurement. Headquartered in Seattle, Washington, since its inception in 1978, PATH currently operates 19 offices in 14 countries.

For more information about our work, visit our website at www.path.org.

For more information

To learn more about PATH's work on this product, contact Glenn Austin, the PATH Woman's Condom team leader, at womanscondom@path.org.

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Development timeline

The PATH Woman's Condom is the culmination of more than two decades of work on condom-related issues.

1980s: the early years

Throughout the 1980s, PATH developed and validated quality assurance testing methods for male condoms. We established a network of condom quality testing laboratories in developing countries to ensure that the condoms being distributed were of good quality.

1990s: brainstorming begins

PATH's product development and reproductive health staff soon began considering the need for a refined woman's condom and articulating initial concepts for desirable features. In 1998, we reviewed the available literature on female condom with a particular focus on user needs. With funding from USAID (through the CONRAD Program), we conducted focus group discussions in three countries and learned what women liked and disliked about the product. We then established a research site for evaluating female condom products in Seattle, where we asked women to provide feedback on the available product as well as those in the development pipeline.

Based on these initial evaluations, PATH recognized that the available or soon-to-be available products would not meet all user needs. We began developing prototypes of various feature sets that would be evaluated in clinical fittings.

2000s: rapid evolution of the final design

The next five years brought remarkable progress and momentum. By 2000, PATH had established three international research sites that allowed us to incorporate user needs from the outset.

In 2001, PATH's first design concept—the double-ring condom—was patented, and CONRAD began a three-site evaluation in the United States. The double-ring device was found to be very stable, but women had difficulty inserting it and felt the inner ring was too hard. Users at international sites also indicated that the prototype needed to be easier to insert, more comfortable to wear, and yet reliably stable.

Each design concept went through many cycles in which the team designed or refined a prototype and then evaluated it among users in diverse settings.

By 2002, PATH received a provisional patent on the "soft-cling" device, which incorporates polyurethane foam that is welded to the outside of the condom pouch. The foam gently clings to the vagina to provide internal stability during use. The soft-cling concept helped PATH meet the first main performance objective: stability during use.

In 2002 and 2003, PATH focused on optimizing the correct amount and placement of the foam to provide good stability as well as features that would improve ease of handing, correct insertion, comfort, and aesthetics. By mid-2003, user evaluations from all four research sites indicated that the materials and features of the soft-cling prototype came closest to meeting the user-identified performance goals. We refined our production processes to prepare for a final acceptability evaluation.

This final round of design development—called a preliminary verification of the design—was the first time that users in all sites evaluated the same design from the same build of materials at the same time. All couples—both new and repeat users—reported on functionality, comfort, and acceptability after the first, second, and third product uses. They gave the design high marks on all performance objectives.

The present and future: clinical trials forge a path to introduction

Since the preverification study, PATH has been refining the materials and production processes to reduce cost of the prototype design and establish manufacturing processes that can be scaled up to produce large volumes.

In 2004 and 2005, CONRAD sponsored a Phase 1 clinical trial of the PATH Woman's Condom and FC Female Condom® to evaluate acceptability, safety, slippage, and breakage during use. Preliminary results from the study, which was conducted at three sites in the United States, are anticipated by late 2005.

We also plan to undertake a contraceptive effectiveness study in 2006 and 2007. The US Food and Drug Administration's approval of the PATH Woman's Condom as a contraceptive device could occur as early as 2008. Once manufacturing and commercial partnerships are established, production can proceed, and the PATH Woman's Condom will be introduced in countries around the world.

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PATH WOMAN'S CONDOM

Features and specifications

The PATH Woman's Condom is the outcome of a five-year development effort involving user evaluations on four continents. The product's final performance objectives, features, and design specifications reflect feedback obtained from women and couples at each step of the design and development process.

In all, PATH has developed and tested more than 50 designs reflecting various solutions to user-related concerns. The design was verified in a final user evaluation by couples in Mexico, South Africa, and Thailand in 2003 and 2004, when it received high marks for ease of use, comfort, stability, and sensation.

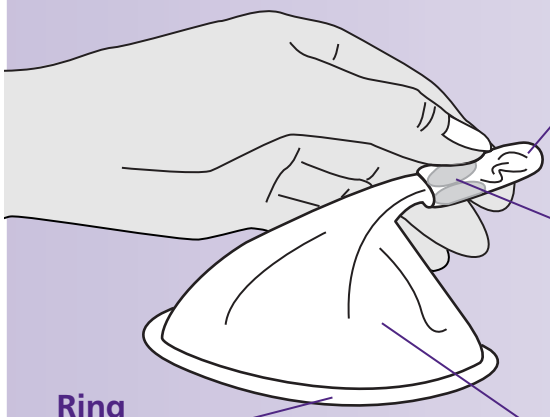
Performance objectives

Women's groups, health care providers, and donor agencies provided input on the performance objectives that would improve use and acceptability of a woman's condom. The ideal woman's condom would be:

- Easy to handle and insert.
- Easy to use (especially for new users).
- Stable during use.
- Comfortable for both partners.
- Easy to remove.
- Less expensive than currently available options.

Key features

The PATH Woman's Condom is a single-use, unlubricated device. (Women apply lubricant to the inside of the condom sheath before use.) A polyvinyl alcohol capsule contains the condom sheath until after insertion and then dissolves quickly. The capsule has a rounded tip for comfort.



Insertion capsule

- Dissolving capsule made of polyvinyl alcohol (PVA) used in C-film.
- Insertion similar to an applicator-free tampon.

Foam shapes

- Small, thin sections of hydrophilic urethane foam used in wound dressing applications.
- Sections cling lightly to vaginal walls, ensuring stability of the device.

Ring

- Low profile.
- Soft urethane material.
- Ring gently hugs the body, providing comfortable, flexible coverage of external genitals.

Sheath

- 1.2 mil urethane film.
- Sheath provides good sensation and comfort; stability of the condom ensures no movement.

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Product specifications

All materials have been tested individually for biocompatibility. Where available, United States Pharmacopeia (USP) Class VI materials—that is, materials commonly used in medical devices—have been selected. All assembly is accomplished by thermo-welding.

Feature	Description
Sheath	Thin polyurethane film, welded
External retention feature	Polyurethane ring, welded to sheath
Internal retention feature	Four hydrophilic polyurethane foam shapes, welded to sheath
Insertion feature	Polyvinyl alcohol capsule
Lubricant	Water-based glycerin propylene glycol, applied at point of use
Packaging	Foil and low-density polyethylene

Next steps

To ensure broad acceptability, PATH is identifying materials and refining production processes that will reduce the cost of the prototype design and meet identified cost goals. We are also seeking a qualified commercial partner to help advance the product to pilot production and toward regulatory approval and introduction.

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Acceptability studies

The PATH Woman's Condom has evolved through more than 50 designs. The most promising design advanced to user evaluations through clinical fittings and couples use.

Early prototypes

From 1999 through 2003, PATH conducted iterative testing cycles in which design concepts were evaluated among users in diverse settings. These evaluations enabled us to respond to user concerns about ease of handling and insertion, comfort, and stability during use. Using interviews and questionnaires, PATH worked with couples from Africa, Asia, Latin America, and North America to ensure that the product design incorporated the needs of couples representing a range of cultural perspectives.

Final design

Once users indicated that the features and materials had a strong likelihood of meeting their needs, PATH froze design development. In 2003 and 2004, we organized a final round of evaluation among 60 couples in Mexico, South Africa, and Thailand to test the final design for functionality and acceptability. This was a nonrandomized, nonblinded, nonsignificant risk study among couples who were not at risk of pregnancy and at low risk of sexually transmitted infections.

Couples reported on their first, second, and third uses of the PATH Woman's Condom during a two-week period. Results were measured against predetermined product specification requirements. About half the couples had participated in previous evaluations of the PATH Woman's Condom during its development; half were new to the study and had never used any female condom device before. Reporting on 180 product uses, couples provided highly favorable feedback on all performance parameters:

- **Insertion:** Female users reported that the woman's condom was comfortable during insertion in 93% of product uses.
- **Comfort:** Female and male users reported that the product was comfortable during intercourse in 96% and 98% of uses, respectively.
- **Stability:** Users found the woman's condom pouch stable during intercourse in 97% of uses. The outer ring was stable in 98% of uses.
- **Acceptability of lubricant:** Couples used the supplied lubricant in 94% of product uses, and the amount of lubricant supplied to couples was sufficient in 100% of cases in which it was used. Couples found the lubricant easy to apply in 91% of product uses.
- **Overall sensation:** Female and male users found the sensation of the woman's condom during sex to be satisfactory in 98% and 99% of uses, respectively.

Giacomo Pirozzi

Key findings

This study also yielded important insights for the entire class of next-generation woman's condoms.

- **User "learning curve."** Lessons from previous studies point to the importance of first-time product use in people's decision to continue the method. Given the learning curve of three to four product uses with the FC Female Condom®, we hypothesized that users of the PATH product might also experience a learning curve. This was not the case, however. In general, participants in our study reported similarly positive experiences during the first, second, and third uses.
- **New versus repeat users.** We also hypothesized that experienced users would have relatively more positive experiences with the condom than new users. No significant differences were noted, however, suggesting that this product may meet the demands of both new and repeat users.
- **Men's perceptions.** Lack of male acceptability of the FC Female Condom® has been cited as an important reason for discontinuation of use of that product. The PATH Woman's Condom received exceptionally high overall acceptability ratings for male satisfaction with device sensation. Furthermore, there was little variation among male users across the three sites: men reported that the sensation of the device was satisfactory in 98% of the product uses in Mexico, 100% of product uses in South Africa, and 98% of product uses in Thailand.

Collectively, these results suggest that the PATH Woman's Condom is highly acceptable to both women and men from diverse populations. With an adequate reduction in price, the product has the potential to provide a highly acceptable method of both pregnancy and infection prevention that can be used by couples around the world.

Ongoing and future studies

In 2004 and 2005, the CONRAD Program conducted a Phase 1 study on the safety, acceptability, slippage, and breakage of the PATH Woman's Condom and the FC Female Condom®. Preliminary results are expected in late 2005.

In addition, PATH is planning a contraceptive efficacy study of the PATH Woman's Condom for 2006 and 2007. We anticipate that the application for the US Food and Drug Administration approval of the PATH Woman's Condom as a contraceptive barrier may occur as early as 2008.

Sites participating in PATH Woman's Condom evaluations

- National Institute of Public Health, Mexico
- Reproductive Health Research Unit, University of Witwatersrand, South Africa
- Department of Community Nursing, Khon Kaen University, Thailand
- Harborview Medical Center, University of Washington, United States

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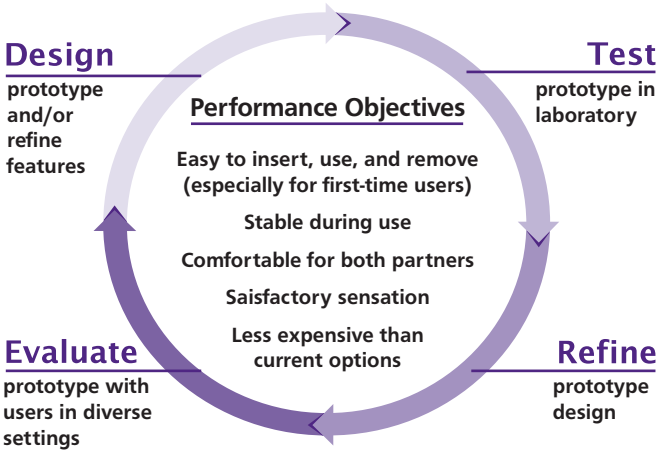
User-centered design

The difference between product success and failure is often rooted in the developer's ability to understand the perspectives of potential users. This is especially true for reproductive health technologies—such as a woman's condom—that must be used correctly and consistently in order to protect against sexually transmitted infections (including HIV) and unintended pregnancy.

User input drives the design process

PATH places user perspectives at the forefront of our design process. Since 1998, we have been working with representative users of a woman's condom to learn about their needs and obtain their input. Through a series of iterative testing and design cycles, our design process allowed us to:

- Identify concerns that affect acceptability.
- Systematically evaluate prototypes through clinical fittings and product use.
- Analyze prototype performance according to predetermined criteria.
- Inform subsequent designs through the successes and failures of product features.



Obtaining feedback

PATH evaluated prototype designs of the woman's condom among couples in monogamous relationships who were not at risk of pregnancy and at low risk of sexually transmitted infections. To ensure that a range of cultural perspectives were captured, we worked with couples in the United States, Mexico, South Africa, and Thailand.

Through clinical fittings and interviews with couples, we assessed the acceptability of more than 50 prototype designs and evaluated them against the performance objectives we defined in consultation with users. Each round of evaluations provided insights that helped us improve the acceptability of the device.

In 2003 and 2004, we obtained feedback from 60 couples who reported on 180 uses of the final design. Their experiences showed that the PATH Woman's Condom was easy to insert and remove, stable during use, comfortable for women and men, and effective at allowing good sensation. These results confirmed that the final design was ready to advance to clinical trials in preparation for licensure.

From evaluation to use

By enabling users to drive the design process, PATH has developed a final design that offers the greatest potential for broad acceptability and use. As we prepare for scale-up and introduction, our focus will now shift from representative users to actual users—the millions of couples around the world who face the risk of unintended pregnancy and sexually transmitted infections.

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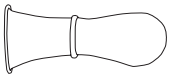
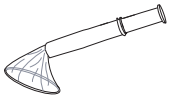
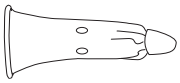
Development History

	2001	2002	2003	
	Round I Prototype A	**Round II Prototype B**	**Round III Prototype C**	**Round IV Prototype D**
				
Key features	▸ Polyurethane pouch ▸ Two fixed rings	▸ Inner ring replaced by foam band ▸ Tampon tube applicator	▸ Foam band reduced to foam dots ▸ Foam cap used for packaging, insertion aid, and device stability ▸ Different lubricants evaluated	▸ Foam cap replaced by dissolving band ▸ Different lubricants evaluated
Devices evaluated	40	19	130	98
Sample user feedback	"Device was easy and disappeared when inserted, but would prefer more flexible and elastic inner ring." (Mexico-101, July 2001) "Device is stable, but uncomfortable." (Mexico-205, February 2002)	"Felt pressure from ball of foam, disturbing." (Seattle-039, December 2001) "Applicator opening too wide, rough, jabbing." (Seattle-040, November 2001)	"Foam shapes much better than foam band—not so impeding, but enough grab to keep pouch from coming out." (Seattle-042, February 2002) "More comfortable than double-ring prototypes; external ring much better." (Mexico-205, May 2002)	"…the edge of the dissolving band needs to be softer." (Seattle-043, April 2003) "The material is the best feature because of its softness." (South Africa-001, June 2003)
Design recommendations	▸ Make device "softer," more friendly. ▸ Find different feature for internal stability—need "one-size device" to fit broad size range of women. ▸ Develop a different insertion aid—not the inner ring. ▸ Refine outer ring diameter, profile, and flexibility.	▸ Continue to refine internal stability feature to provide secure fit—but "get out of the way." ▸ Develop different insertion aid and packaging scheme to improve aesthetics and handling. ▸ Continue to investigate sizing—need one-size device.	▸ Handling/insertion still awkward. Refine package to be smaller, with more integrated features. ▸ Continue to refine foam dots (shape, number, placement, and material) for acceptability, aesthetics, and stability. ▸ Device still being evaluated in 2 sizes. Need to establish a one-size device that fits many.	▸ Dissolving band edge is too "sharp." ▸ Refine dissolving band to improve aesthetic appeal. ▸ Address safety of dissolving material in user instruction and counseling.

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