

Presentation to The Global Consultation on the Female Condom

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It is a privilege to be here at this conference with my colleagues from both the public and private sector to discuss the future of female condoms. I want to take a few minutes to talk about some of our shared challenges and opportunities in the evolving class of female condoms before I tell you about the PATH product. I've heard many times in the past few days "It's not the product—it's the program." I hope, after this session, we will see a greater role for products in achieving higher rates of protected sex.

Eighteen years ago, about the same time Mary Ann Leeper was starting work on the female condom, I was working with Bob Wheeler of Family Health International to develop what is now the EZ-On urethane male condom. Bob and I frequently discussed the potential of radically improved barriers using new materials and processes. At that time, most of the products I worked on went from invention to store shelves in less than two years, and widespread competition drove rapid evolution of the class. I expected to see many new barriers available long before now. Today, we all know barriers are not on such a "fast track."

We have all invested so much in making better barriers available, yet our challenges today are still enormous.

- There is a lack of money and other key resources.
- Female condoms face an arduous Class III regulatory process.
- Clinical trials take a lot of time and money.
- There are complex international distribution, social marketing, and programmatic challenges.
- And most of you here can name another dozen other, seemingly intractable obstacles to your success in making improved barriers widely available.

I am that convinced female condoms are a vital solution to increasing the rates of protected sex—partly because they have already demonstrated levels of effectiveness that far exceed those we are seeing for microbicides or cervical barriers. But I believe this mostly because women and their partners from all over the world have told us that female condoms work for them.

I was privileged to sit in on many exit interviews with couples who used male condoms, the Reality female condom, and our prototypes. They were thoughtful, frank, and emphatic about their needs as couples and as sexual beings. They made it clear. If we make a satisfactory product available, they will use it.

We can see this satisfactory product today. In fact, in this room is the ideal female condom that will dramatically increase the rates of protected sex! Not the *perfect* female condom—but a realistic combination of feasible design features that meet most all user and stakeholder needs and narrows the gap between perfect and typical use effectiveness.

The IDEAL Female Condom

- Highly protective
- Stable and secure - inside and out
- Less than 10 cents
- Extremely easy to use
- Provides great sensation
- Disposal is safe for the environment

Of course, this ideal condom is highly protective, inside the vagina and out. It stays put and maintains a continuous barrier against pathogens and sperm.

- Of course it is really inexpensive—it can't cost less than a male condom because it is bigger, more complex, and has increased functional demands—but it can be priced at under 10 cents US.
- This ideal condom is made of a gossamer thin material that allows full sensation and doesn't intrude on sex.
- This condom is so easy to use. It can be used successfully by first timers after looking at a few simple pictures.
- This condom feels good!
- This condom virtually disappears after use, leaving no waste that can mess up the environment.

So can I show you this ideal female condom?

Well, not in any single product in this room, but we can see it in the synthesis of all the best in this room, leavened with further commitment, competition, collaboration and hard work from all of us, and evolved over time.

The ideal female condom is made possible by the pioneering work of the Female Health Company who has single-handedly defined female condoms for over a decade. Mary Ann Leeper, Mike Pope, and literally thousands of others have invested an enormous level of effort in over 100 countries to make the female condom widely available. FHC is still going strong with a next-generation product that will substantially reduce the price, thus answering the number one priority need for female condom procurement.

We can see aspects of the ideal condom in the extreme innovations of Dr. Reddy and Max Abadi of Natural Sensations, both driving costs down even further with materials and process innovations while at the same time striving to provide sexual pleasure with their products.

We can also see elements of the ideal condom in the Belgium Condom and the Silk Parasol because a woman's perspective is absolutely necessary for this product to be successful.

The PATH Woman's Condom

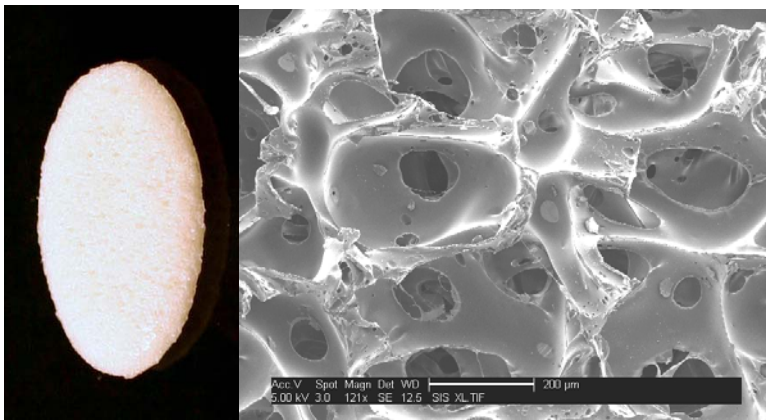


I believe we can see essential aspects of the ideal condom in the PATH Woman's Condom. Over the past seven years of product development, we have pursued a female condom that, first of all, works well—and is very easy and very satisfactory to use.



The PATH design is the first to feature an insertion capsule. This dissolving capsule is made of Polyvinyl Alcohol which is very similar to that used in contraceptive film. It allows easy proper placement of the condom so the outer ring sits snugly against the body, and the condom lines the vagina without twists, bunches, or movement.

The capsule ensures that four small foam pads gently, yet firmly, keep the condom in place. This provides dependable protection, good sensation, and fewer problems with noise, bunching, misrouting, or invagination.



These foam pads work three ways to provide stability for the condom. They are hydrophilic and they absorb a small amount of surface moisture from the mucosal tissue and thereby cling lightly. They are also sized and placed on the condom to nestle into the rugated tissue of the vagina. Finally, this foam has microscopic peaks and valleys that provide friction to reduce pull-out of the condom.

PATH Woman's Condom Performance Objectives

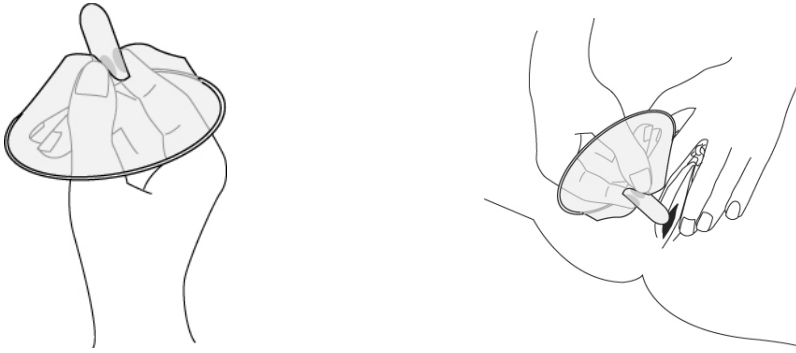
- Ease of Use
 - Ease and comfort during insertion and removal
- Stability
 - Of pouch and ring during use
- Comfort
 - For both partners, during insertion and sex
- Sensation
 - For both partners

There are many other features important to the performance of the PATH Woman's Condom including the comfortable conforming outer ring and the soft slinky sheath material. You can see and feel these features up close on the yellow board at our information table and in the handouts available there.

Here, briefly, is how the PATH Woman's Condom works



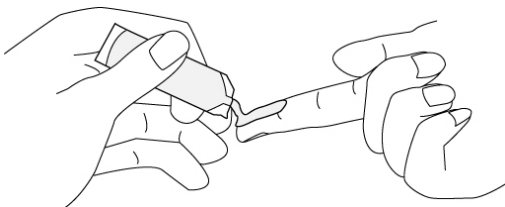
The woman opens the foil pouch



She removes the capsule and inserts it into her vagina



She pushes the capsule as far in as she can. Within 30 to 60 seconds the capsule dissolves and the man can penetrate, or she can open the condom inside with her finger.



If she wishes, she can lubricate the capsule before inserting it and we do recommend putting lubricant on the inside or penile side of the condom. We have found that couples have shown a wide ranging preference for lubricant volumes from none at all to about 3 ml.

We know our condom works. You just heard from Marianne Callahan how our hand-made prototypes fared in comparative testing with the Reality/FC1.

In our own preverification studies in South Africa, Thailand, and Mexico, women and their partners overwhelmingly said the condom performed satisfactorily.

Ease of Insertion and Removal				
Total Uses	Very Easy	Easy	OK	Difficult
Insertion (n=179)	40%	49%	9%	2%
	Cumulative 89%			
	Cumulative 98%			
Removal (n-178)	58%	39%	1%	1%
	Cumulative 97%			
	Cumulative 98%			

Stability of Condom During Sex		
Total uses (n-180)	Yes	No
Outer ring stable	98% (177/180)	2% (3/180)
Pouch stable	97% (175/180)	3% (5/180)

Comfort During Sex				
Total uses (n=180)	Very com- fortable	Comfortable	OK	Uncomfortable or very uncomfortable
Female	33%	55%	8%	4%
	Cumulative 88%			
	Cumulative 96%			
Male	30%	51%	17%	2%
	Cumulative 81%			
	Cumulative 98%			

"I like the comfort, stability and the way it looks." (Female, M-206)

Sensation with Condom in Place				
Total uses (n=180)	Very satisfactory	Satisfactory	OK	Unsatisfactory or very unsatisfactory
Female	34%	55%	9%	2%
	Cumulative 89%			
	Cumulative 98%			
Male	33%	54%	12%	1%
	Cumulative 87%			
	Cumulative 99%			

“I can recommend this condom to my friends as it does not change the taste of sex.”
(Male, SA-008)

“It felt the usual way we normally have sex. It was secure and never moved during sex.”
(Male, SA-004)

More details about this study are available at the information table and by request. The PATH Woman’s condom is now ready for the contraceptive effectiveness trials necessary for FDA approvals.

The PATH Woman’s Condom is far from the perfect answer as it stands. Our projected cost is between 30 and 40 cents. It needs to be made less expensive through scale-up and innovations in materials and processes.

After substantial investigation, we feel the cost can be brought down by more than half with the right investment. More important for today, we believe the PATH Woman’s Condom sets a new benchmark for the performance of female condoms, and that it will contribute to the overall advancement of the class.

I look forward to hearing from the other developers here and hope that in the future we can work together more effectively to advance female condoms rapidly. PATH would like to offer a consultation with any developer to discuss some of PATH’s R&D findings in the area of improved stability and ease of insertion.

How long will it be before we can offer the ideal female condom to women around the world? If we proceed as we have been, it could be another 18 years.

So I’d like to leave you with a question: What can we do differently that will bypass decades of competition-driven product evolution? How can we accelerate the process and take advantage of the innovations, strengths, and assets in this room?

We have an outstanding opportunity to discuss this over the next day or so.
Thank you