

Users as co-designers: developing new female barrier contraceptives

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New protection options for women



**SILCS—a single-size
contoured diaphragm**

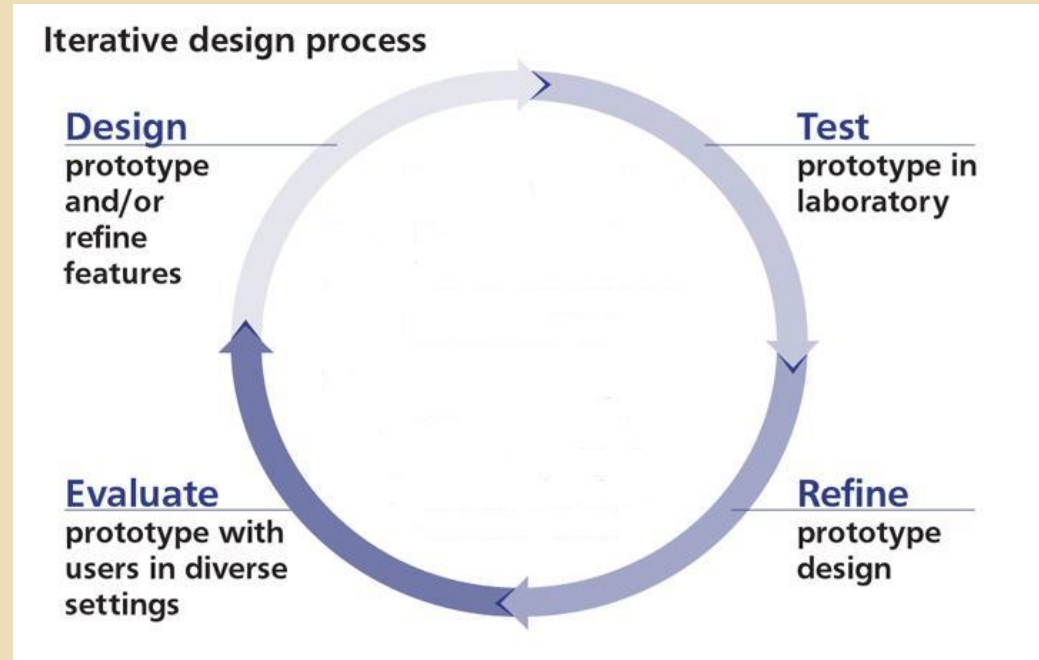


Woman's Condom

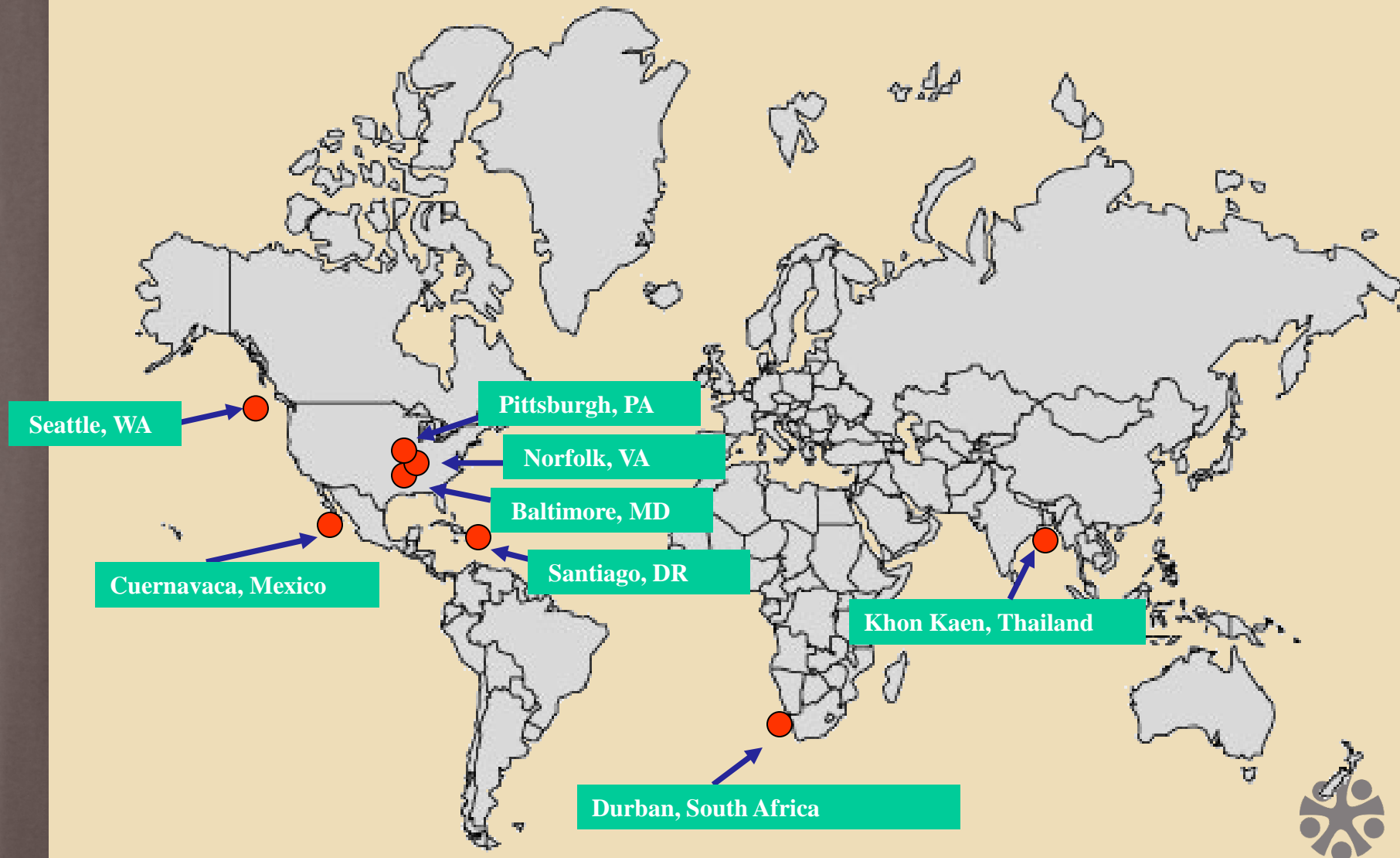


User-centered development

- Identify stakeholder priority issues.
- Develop performance objectives.
- Bench test prototypes.
- Assess clinical and couples' use evaluations.
- Refine prototypes.
- Use iterative process to evaluate and refine prototypes to meet user needs.



User evaluation sites: input from diverse regions



Woman's Condom: designed for ease of use

- Easy to handle and insert
- Easy to use (especially for new users)
- Stable fit during use
- Comfortable for both partners
- Easy to remove



**Pre-
insertion**



**Post-
insertion**



User feedback refines design



Refinements

From double ring to soft cling...



When the internal ring opens inside me, I might feel that, and it might hurt. I would prefer it didn't have that inner ring.

I felt scratching on the sides of my penis and felt tip of penis hitting the foam.

Triangles are much better than foam band, not so impeding... This was much better experience than before.



User feedback informed design refinements

Design recommendations

- Make device “softer,” more friendly.
- Refine internal stability feature for secure fit—needs to “get out of the way.”
- Develop different insertion aid (not an inner ring).
- Refine packaging to be smaller to improve aesthetics and handling.
- Refine dissolving capsule to improve aesthetics.



Design verification study in three countries*

Couples' use performance, safety, and acceptability study (n=60 couples)

- Easy to handle/insert 88%
- Stable during use 97%
- Comfortable for both partners during use >95%
- Good sensation for both partners > 95%



*Coffey PS, Kilbourne-Brook M, Austin G, Seamans Y, Cohen, J. Short-term acceptability of the PATH Woman's Condom among couples at three sites. *Contraception*. 2006;73:588–593.



Additional studies confirm performance and acceptability

- Phase I clinical study in the US—Woman's Condom resulted in fewer failures and less slippage, and was preferred by men and women when compared to FC1 performance.*
- In South Africa, the Woman's Condom performed well and was preferred over two other female condom designs for ease of use.**
- In China, the Woman's Condom performed well in terms of safety, acceptability, and performance. Similar to performance results in other countries.†

* Schwartz J, Barnhart K, Creinin M, et al. Comparative crossover study of the PATH Woman's Condom and the FC Female Condom. *Contraception*. 2008;76:465–473.

** Joanis C, Beksinska M, Hart C, et al. Three new female condoms: which do South African women prefer? *Contraception*. 2011;83:248–254.

† Zirong H, et al. manuscript in press, 2011.



Woman's Condom: what users say*

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

“I like the comfort, stability and the way it looks.”
(M-206, female)

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

*n = 130 product uses; Round II, III; 4 sites (PU56, P51, PU52)



Single-size diaphragm: designed to meet user needs

- Easy to insert
- Comfortable to wear
- Stable, confident fit
- Easy to remove
- Single-size device
 - no need for pelvic exam
 - simplifies supply logistics



SILCS Diaphragm design evolution



Design verification results from three countries*

	Women all sites (n=135 uses)		Men all sites (n=135 uses)	
	Good %	OK %	Good %	OK %
Ease of insertion	85	14	NA	NA
Ease of removal	84	16	NA	NA
Comfort during sex	89	11	74	25
Sensation during sex	87	13	74	24

* Coffey, PS, Kilbourne-Brook M, Beksinska M, Thongkrajai E. Short-term acceptability of a single-size diaphragm among couples in South Africa and Thailand. *The Journal of Family Planning and Reproductive Health Care*. 2008;34(4):233–236.

* Coffey PS, Kilbourne-Brook M, Brache V, Cochón L. Comparative acceptability of the SILCS and Ortho ALL-FLEX diaphragms among couples in the Dominican Republic. *Contraception*. 2008;78(5):418–423.



SILCS Diaphragm: what users say

- “You feel you are safe when using this device unlike male condoms” (SA-016, female)
- "...This is comfortable and feels good. I like that you don't have to change it and replace it like male condoms." (SA-007, male)
- “I like the cup, because it acts as a cushion when you thrust in and out. It feels good. It does not hurt.” (T-101, male)



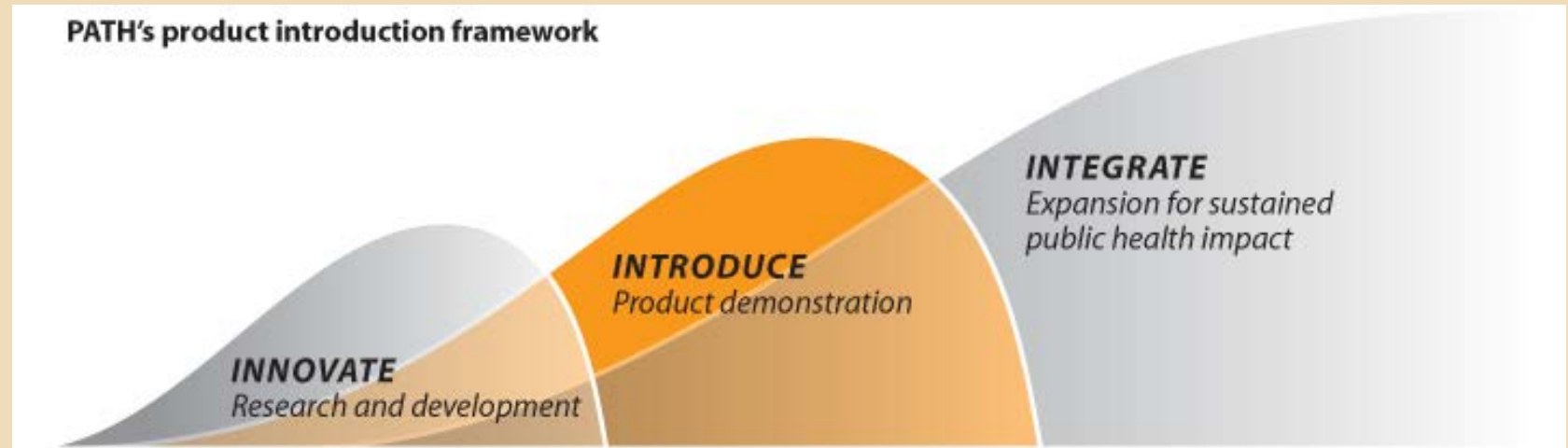
Additional study confirms safety, performance, and fit

CONRAD recently completed a contraceptive effectiveness study among 450 women in the United States who used the SILCS Diaphragm for six months.

- Single-size device is easy to insert and use.
- Most women can learn to insert and check fit from Instructions for Use.
- Single size contoured diaphragm provides contraceptive protection similar to a traditional sized diaphragm.



Market development: a backdrop to product introduction



- **Market development builds both product supply and demand.**
- **User-centered introduction: develop and test strategies to build sustainable markets to address the reproductive health needs of women.**



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Photo: Richard Lord