

# Prevention Options for Women

## *Intravaginal Barrier Product Development*

Female barrier methods prevent conception and can protect women against sexually transmitted infections (STIs)—such as chlamydia and gonorrhea—that attack the cervix.<sup>1</sup> By reducing exposure to these infections and protecting the highly vulnerable tissue of the cervix, they may also offer some protection from HIV.<sup>2</sup>

Historically, use and acceptability of barrier methods have not been widespread in international family planning and reproductive health programs. Since the early 1990s, however, women's health advocates have called for greater attention to barrier methods, and recently some researchers have focused on the protective value of barriers that cover the cervix.<sup>2</sup>

### *Developing an Improved Design*

Realizing the benefits that an improved diaphragm would offer, PATH has devoted eight years to the development of this new intravaginal barrier product. The development process, now nearing the final stages, is built upon PATH's four-stage product-development approach:

**Stage I** (1994–1996): Discovery/Needs Assessment

**Stage II** (1995–1996): Proof of Concept and Preliminary Design Assessment

**Stage III** (1996–1998): Iterative Development

**Stage IV** (1999–2002): Pilot Production and Validation

During the initial stages, PATH conducted a qualitative needs assessment among current and former diaphragm users, clinicians, and policy makers to obtain information on factors that have prevented diaphragms from being more widely provided and promoted. Based on this input, we developed performance goals for an improved intravaginal barrier.

These goals became the roadmap that guided the development and evaluation of several generations of prototypes for the new intravaginal product, which is now called the SILCS diaphragm. User groups consisting of women representing a range of diaphragm sizes served as co-developers on the project. More than 40 women evaluated prototype designs and made recommendations for improving the form, fit, and function.

In the project's later phases, PATH and CONRAD performed additional research into use and acceptability. In 1998, the two groups conducted a preliminary acceptability trial of a fourth-generation prototype of the device. In 2000, they performed a Phase I study comparing post-coital testing and safety of the SILCS Diaphragm and the Ortho All-Flex diaphragm. The data obtained from this research have been supportive of the SILC device's

safety, comfort, and ease of use. The feedback also provided invaluable guidance about design modifications that have led to further improvements.

Throughout the development process, PATH worked with its manufacturing partner, SILCS, Inc., to design and document the manufacture of this improved device. SILCS brings extensive experience with injection-molded silicone and has established successful pilot production for this intravaginal barrier.

## Next Steps

Next steps for advancing this technology include:

- conducting Phase II clinical trials,
- developing an introduction strategy in consultation with public health agencies and organizations,
- identifying research partnerships in developing countries for preliminary acceptability studies and introductory activities,
- developing commercial partnerships to move the SILCS diaphragm to full-scale production.

Longer-range strategies to enhance acceptability of intravaginal barrier devices include:

- developing a “two-size” design and producing molds and trial parts, which may enhance the fit and function for a broader range of women’s body types;
- investigating the integration of a microbicide into the device material to increase its effectiveness as an STI-prevention device, and to reduce the cost and complexity of safe reuse.

PATH and its partners firmly believe that this improved intravaginal barrier will offer women a safe, effective, and easy-to-use option for protecting the cervix and preventing unwanted pregnancy.

*The SILCS intravaginal barrier project has received primary support from CONRAD, a cooperating agency of the United States Agency for International Development (USAID). Additional support has been provided by the Andrew W. Mellon Foundation, the William and Flora Hewlett Foundation, the Bill & Melinda Gates Foundation, and private donors.*

---

## References

1. Rosenberg MJ et al. Barrier contraceptives and sexually transmitted diseases in women: a comparison of female-dependent methods and condoms. *American Journal of Public Health*. 83(7):1053–1054 (1993).
2. Moench, TR et al. Preventing disease by protecting the cervix: the unexplored promise of internal vaginal barrier devices. *AIDS* 15:1595–1602 (2001).



### Performance Goals

- ▶ Easier and more convenient to use
- ▶ Easier to fit (one size fits most)
- ▶ More comfortable
- ▶ Easier to insert and remove
- ▶ Free of odors due to latex
- ▶ More effective as a barrier
- ▶ Less messy (retains spermicide better)