Design history

During the past decade, there has been growing recognition that additional female-controlled barrier methods should be developed and encouraged as a contraceptive option for women. Female-controlled barrier methods that are acceptable and easy to use can enhance a woman's ability to prevent pregnancy. Until now, most barrier method devices have been designed for ease of manufacture or have been developed from the inspiration of a single developer. Both approaches have lacked wide-scale user input during the early stages of development to ensure that the device meets users' needs.

In 1994, PATH obtained funding from USAID-supported CONRAD to develop a new female-controlled barrier device. This project has resulted in the development of a new, single-size contraceptive diaphragm. The project began with a needs assessment study whereby users and clinicians identified improvements they would like to see over traditional diaphragm designs. Women participants have been integral codesigners in the formative stages of research and throughout the iterative design and development process.

The SILCS diaphragm was designed to address necessary improvements identified in the needs assessment stage. Functional design improvements included: easier insertion and removal, easier fit (one size fits most), increased comfort, elimination of latex-related odors and allergic reactions, and greater durability than latex diaphragms. It is anticipated that this diaphragm will provide, at minimum, equivalent contraception to currently available diaphragms.

The SILCS diaphragm was developed through iterative rounds of user evaluation. After each evaluation, the design features were modified to incorporate changes recommended by our evaluators, resulting in a device that is comfortable to use and fits a broad range of women. By 1998, almost 60 women at two sites in the United States had provided input into refining the device design and feature set, culminating in Prototype V of the SILCS diaphragm. In clinical fittings, women representing a wide range of diaphragm sizes, parity, and body size reported the SILCS device was easy to insert and remove, comfortable

SILCS Clinical evaluations and user acceptability studies

The studies outlined below describe the additional SILCS clinical evaluations starting with the first study where couples evaluated SILCS acceptability during use, and moving on to the Phase 1 studies of barrier effectiveness. Design refinements were made after the first two clinical studies to allow for a better fit and improve comfort for couples with a broader set of anatomical characteristics. CONRAD repeated the Phase 1 barrier study with the updated Prototype VI design. During the same period, couples in three international sites also evaluated the SILCS Prototype VI for fit, comfort, and acceptability during couples' use. Results of these studies confirmed that the SILCS diaphragm is easy to use, fits a range of women, is comfortable and acceptable to partners, and is ready for evaluation in a contraceptive effectiveness study.

- In 1998, a preliminary assessment of fit and acceptability of the SILCS diaphragm (Prototype V) during intercourse was conducted at the CONRAD Clinical Research Center, Eastern Virginia Medical School (EVMS). Eighteen couples used the device during a total of 76 coital acts. Results from this evaluation suggested that the SILCS diaphragm was easy, safe, and comfortable to insert, use, and remove.
- In 1999, a Phase 1 open label, multicenter, crossover postcoital test (PCT) clinical study of the SILCS diaphragm (Prototype V) and the Ortho All-Flex® diaphragm was conducted at EVMS and the University of Pittsburgh Medical Center. Both diaphragms were used with spermicide (2% nonoxynol-9 [N-9]), in 42 healthy, sexually active women not at risk for pregnancy due to previous bilateral tubal ligation or salpingectomy. A total of 56 cycles were completed as follows: baseline (21), Ortho All-Flex® diaphragm (17), and SILCS diaphragm (18). Each subject underwent three PCTs, one in each of three consecutive menstrual cycles. The first PCT was a baseline, done without the use of any device, in order to demonstrate the couples' ability to meet the protocol requirements. The participants were randomized to the sequence of device use in two PCTs, which were carried out during the second and third menstrual cycle, using either the SILCS diaphragm or the Ortho All-Flex® diaphragm.

  Both the SILCS and the Ortho All-Flex® diaphragms performed well in this study, reducing the average number of progressively motile sperm per high powered field (HPF) to 0 in the case of the Ortho All-Flex® diaphragm and to 0.1 for the SILCS diaphragm. The SILCS diaphragm remained in place during most uses.

  No product-related adverse events or gross irritation were reported or observed in this study. Minor new colposcopic findings were seen after about half of the uses of both devices. No findings involved deep disruption of the epithelium or combined disruption of the epithelium and blood vessels.

  Couples reported that both devices were quite acceptable, but the SILCS diaphragm was somewhat preferred by the women. Among women who had used a diaphragm before, the SILCS diaphragm was described as being much better in terms of insertion and comfort than other diaphragms by about half the respondents, compared with the Ortho All-Flex® diaphragm which was felt by most to be about the same as other diaphragms.

  The study concluded that the SILCS diaphragm with N-9 was safe and acceptable to both men and women following a single use. It performed well in postcoital testing and was likely to give acceptable results in a contraceptive effectiveness trial. It was likely that, like the Ortho All-Flex® diaphragm and other mechanical barrier devices, the SILCS diaphragm would need to be used in conjunction with a chemical barrier to be most effective.

  Although the results of the first PCT study showed that the SILCS diaphragm performed well, a number of women and clinicians reported difficulty in some instances either fitting the device or inserting it, or both, during the screening visit. A

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follow-up investigation with those women who experienced fitting difficulties led to modifications designed to accommodate fit in larger-sized women: 1) cervical cup enlarged, 2) finger dome deepened, 3) spring tension increased, and 4) slight ridges near the removal dome added.

- In 2003–2004, CONRAD conducted a second Phase 1 PCT clinical study. The study design was similar to the previous PCT, except that the devices compared were the SILCS diaphragm (Prototype VI-metal spring) used with spermicide (2% N-9) and the SILCS diaphragm (Prototype VI-metal spring) used with lubricant (K-Y Jelly). Preliminary results indicate that both the SILCS diaphragm with N-9 and the SILCS diaphragm with K-Y performed well in this study, reducing the average number of progressively motile sperm per HPF to 0 in the case of the SILCS with N-9 and to 0.5 for the SILCS with K-Y jelly. A subset of women at both sites completed PCT evaluations of the Prototype VI (polymer spring) with N-9. The polymer-spring device performed as well as the Prototype VI (metal spring) with N-9 as it also reduced the average number of progressively motile sperm per HPF to 0. The advantage of the polymer spring over the metal spring is that it is less expensive and easier to assemble.
- Couples in South Africa and Thailand completed a nonrandomized, nonblinded acceptability and safety study of the SILCS diaphragm (Prototype VI-metal spring) in 2004. A total of 41 women and their partners (21 from South Africa and 20 from Thailand) participated in the study by providing feedback on the ease of handling, comfort, fit, stability, and acceptability of the SILCS diaphragm during use. Data were collected for a total of 164 device uses. Women represented Ortho All-Flex® diaphragm sizes of 65–80 mm, parity 0–4, and BMI ranging from normal to obese. No adverse events were reported during the course of the study. A subset of couples (n=7) from South Africa subsequently evaluated the SILCS polymer-spring diaphragm during 28 coital acts. Women reported the SILCS polymer-spring diaphragm was easy to insert and remove, with better comfort and fit than the SILCS metal spring.
- A second user acceptability study was conducted by Profamilia in the Dominican Republic from 2004–2005. This study compared the ease of handling, comfort, fit, stability, and acceptability of the SILCS polymer-spring diaphragm to the Ortho All-Flex® diaphragm. Twenty couples evaluated each device during four acts of intercourse. Data were collected for a total of 80 uses per device. Women in this study represented Ortho All-Flex® diaphragm sizes 70–85 mm, parity 0–7, and BMI ranging from normal to obese. The SILCS diaphragm performed significantly better than the Ortho device in two important use parameters: difficulties with device insertion and positive experience of device removal. Both female and male study participants reported that they would like to change the SILCS device significantly less often than the Ortho device. At the end of the study, 19 of 20 couples stated that they preferred to use the SILCS device compared to the Ortho All-Flex® diaphragm.

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Table 1—Summary of clinical evaluations

Type	Description	N using SILCS	Coital acts using SILCS	Endpoint
Preliminary assessment (Prototype V)	User preference	18	76	Safety, function, and acceptability
Phase 1, PCT (Prototype V)	Randomized crossover, comparison of SILCS/N-9 with Ortho All-Flex®/N-9	18	18[3]	Barrier performance assessing motile sperm, safety, and acceptability
Phase 1, PCT (Prototype VI, metal and polymer spring [subset[1]])	Randomized crossover, comparison of SILCS with N-9 vs. K-Y jelly	14	33[3]	Barrier performance assessing motile sperm, safety, and acceptability
Consumer preference (Prototype VI, metal and polymer spring [subset[2]])	User preference in Thailand and South Africa	41	164	Safety, function, and acceptability
Consumer preference, (Prototype VI, polymer spring)	Crossover comparison to Ortho All-Flex® in Dominican Republic	20	80	Safety, function, and acceptability
Total		111	371	

1 Eight of the couples also used the polymer spring in a total of 8 coital acts.

2 Seven couples also used the polymer spring in a total of 28 coital acts.

3 Indicates coital acts during completed test cycles with SILCS diaphragm.

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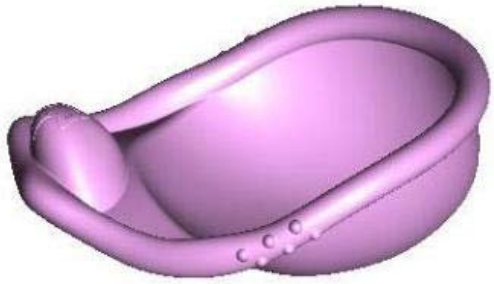
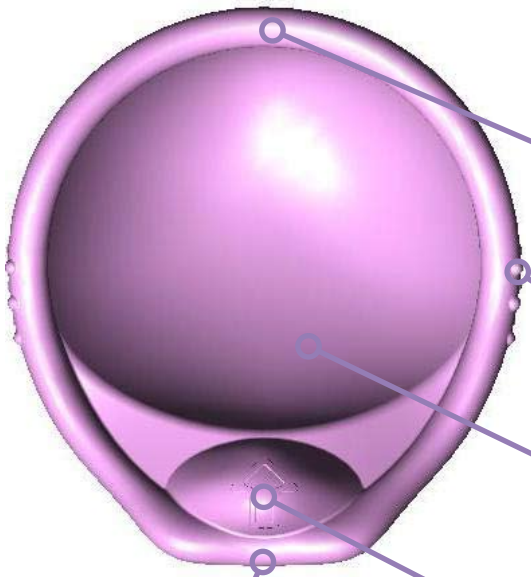
Product Benefits:

- Easier insertion and removal
- Easier fit (one size fits most)
- More comfortable
- Eliminates latex-related odors
- Less messy in retaining spermicide or microbicide





Relief Arch

- Provides finger rest during insertion
- Extra clearance for partner

Product Specifications:

Elastic body:	50-shore-A durometer medical-grade silicone
Core:	Contoured, one-piece polymer spring
Overall length:	75 mm
Overall width:	67 mm
Membrane:	0.010” nominal thickness

Product Features:

Dynamic contours

- Folds in optimal insertion shape
- Embeds gently in supportive tissue

Gentle folding dynamics

- Soft, easy folding during insertion and removal (1/2 the force of standard diaphragms)
- Slides gently out of the vagina

Firm insertion edge

- Folds compactly for easier insertion
- Stable shape when pushing into vagina
- Supports cervical cup in posterior fornix

Grip dimples (nubs)

- Enhanced grip when slippery
- Cue for bending locations

Cervical cup membrane

- Enhanced barrier properties (surrounds the cervix)
- Clings gently to soft tissue

Finger-tip removal dome

- Enables easier hooking for removal (from top or bottom)
- Cue for insertion orientation

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