

## SILCS Diaphragm

### Health need

Despite the success of family planning programs since the 1960s, the unmet worldwide need for contraception remains high, with an estimated 120 million couples not having access to contraceptives. Each year, nearly 80 million women experience unintended pregnancies, about half of these end in abortion. Hundreds of millions of women annually suffer disability from pregnancy complications, and more than 500,000 die as a result of pregnancy, childbirth, or unsafe abortion. Almost all these deaths are preventable. Women also represent more than 50 percent of people living with AIDS, and sexually transmitted infections (STIs), excluding HIV/AIDS, are the second most important cause of loss of health in women, especially young women. Women want and need more female-initiated methods that can protect against pregnancy and STIs. Diaphragms could help meet this need, but some characteristics of traditional diaphragms limit their use and acceptability.

### Technology solution

PATH responded to the call for simple-to-use, female barrier protection by developing the SILCS Diaphragm, a single-size, reusable device with a contoured rim that allows the SILCS Diaphragm to fit most women with improved comfort. Design and development of the SILCS Diaphragm began in 1994, and user-centered evaluations of over 200 prototype designs refined performance and features. The single-size design will simplify the logistics of supply and provision. PATH used stakeholder assessments to ensure that comfort, ease of handling, and acceptability were built into the product. As a result, the SILCS Diaphragm directly addresses user and programmatic needs which will lead to improved access and acceptability. The SILCS Diaphragm performed well in postcoital testing. Acceptability studies among naïve users in South Africa and Thailand found that women were able to learn to use the device easily and that women and men found the SILCS Diaphragm acceptable during use. In a comparative crossover study of the SILCS Diaphragm with a traditional diaphragm in the Dominican Republic, 19 of 20 women reported preferring the SILCS Diaphragm device after short-term use. Eventually, the SILCS Diaphragm could be provided over the counter or outside the clinic-based system where regulatory authority and clinical practice allow.

### Current status and results

The SILCS design was patented by PATH in 1998; a second patent on a spring modification is expected in 2009. The Phase I safety and barrier effectiveness studies have been completed. The pivotal study, which will provide data necessary for approval of the SILCS Diaphragm device for marketing as a contraceptive, will be completed in late 2009. An application to USFDA for market approval as a contraceptive will be submitted in 2010. PATH also is evaluating the SILCS Diaphragm as a microbicide delivery system. PATH is actively seeking regional partners to manufacture, distribute, and introduce this new diaphragm.



**Intravaginal barrier contraceptive.**

**A better one-size-fits-most diaphragm will allow women to protect themselves from many STIs and unwanted pregnancy without high cost or risky negotiation with partners.**

### Availability

For more information regarding this project, contact Maggie Kilbourne-Brook at [mkilbou@path.org](mailto:mkilbou@path.org).

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