

SILCS launches in early markets

THE HEALTH NEED

Worldwide, women experience significant health consequences of unintended pregnancy. More than 200 million women—mostly in developing countries—have an unmet need for contraception.¹ While some women lack access to safe and effective methods, many women with an unmet need cite issues related to methods (such as concern about side effects), infrequent sex, being postpartum, or breastfeeding as reasons for their nonuse. Expanding access to nonhormonal barrier contraception—like the SILCS diaphragm—could help address the needs for many of these women.

WOMEN AS CO-DESIGNERS

The SILCS diaphragm is a single-size contraceptive barrier designed to fit a broad range of women. PATH led a user-centered design process involving input from women, their partners, and providers. This feedback resulted in an innovative design that is easy and comfortable to use. PATH developed SILCS to expand women's options for nonhormonal protection. This is especially important in low-resource settings where women have a limited range of methods, and access to health care providers is limited. SILCS may also be relevant for women in developed countries who are interested in a nonhormonal, user-initiated method with no side effects.

CLINICALLY PROVEN SAFETY, ACCEPTABILITY, AND COMFORT

In multiple studies, SILCS has achieved high marks for safety, acceptability, ease of use, and comfort among women and men, even women with no previous diaphragm experience.²⁻⁵ CONRAD, the clinical and regulatory partner for this design, implemented a multisite contraceptive effectiveness study in the United States from 2008-2010. Data from this study confirm that SILCS provides protection similar to a traditional diaphragm when both are used with a contraceptive gel.⁶ Data from this study supported a 510(k) regulatory application to the United States Food and Drug Administration (USFDA).

EASY TO PROVIDE

The SILCS diaphragm was designed to be easy for women to use as well as for health care personnel, clinics, and suppliers to provide. The single-size design reduces the complexity of ordering and stocking multiple sizes. Where approved by regulatory authorities, SILCS can be provided over-the-counter since a fit exam to determine what size diaphragm a woman can wear is no longer needed. In low-resource settings where there is inconsistent access to contraceptive methods, SILCS could be a valuable choice; it can be used for up to two years, which means that women would be less reliant on the health care system to meet their contraceptive needs.

USER-FRIENDLY FEATURES

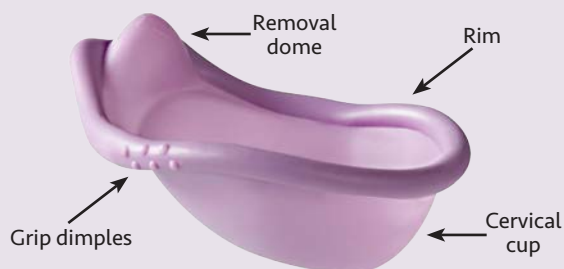


Photo: Kessel Marketing, CAYA® contoured diaphragm

Grip dimples	Orient the woman's fingers and provide a tactile cue for where to hold and squeeze the rim.
Removal dome	Allows for easy removal; a woman can hook her finger under or over the dome to remove the device.
Cervical cup	Accommodates a range of sizes of cervixes, yet is pliable enough to collapse when there is unused space.
Rim	Provides stability and helps guide the SILCS diaphragm deep into the vagina as the woman pushes on the anterior edge.



PRODUCT INQUIRES

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MARKET INTRODUCTION

PATH licensed the SILCS design to Kessel medintim GmbH (Kessel) of Germany in late 2010 for commercialization. This company has manufactured and distributed contraceptive and sexual health products for over 24 years. The SILCS diaphragm achieved regulatory approval and has since been launched in more than 20 countries under the brand name Caya® contoured diaphragm. The USFDA granted market clearance to the Caya® contoured diaphragm in late 2014 and in June 2015, Kessel launched the Caya® diaphragm in the U.S. Meanwhile, PATH is working with partners in developing countries to evaluate opportunities and challenges for future introduction in developing countries.

ACKNOWLEDGMENTS

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EVALUATING ALTERNATIVE CONTRACEPTIVE GELS

Diaphragms are used with a contraceptive gel to increase effectiveness. The most commonly available contraceptive gels contain nonoxynol-9, which is no longer recommended for use by women who are at risk of acquiring HIV. PATH is evaluating contraceptive gels in development or on the market that could be used with the SILCS device. PATH and CONRAD are also looking at SILCS as a delivery method for microbicide gel—a topical vaginal product that could protect women from HIV and other sexually transmitted infections (STIs).

References

- 1 Singh S, Darroch JE. *Adding It Up: Costs and Benefits of Contraceptive Services—Estimates for 2012*. New York: Guttmacher Institute and United Nations Population Fund; 2012.
- 2 Schwartz J, Ballagh S, Creinin M, et al. SILCS diaphragm: postcoital testing of a new single-size contraceptive device. *Contraception*. 2008;78:237–244.
- 3 Coffey P, Kilbourne-Brook M, Beksinska M, et al. Short-term acceptability of a single-size diaphragm among couples in South Africa and Thailand. *Journal of Family Planning and Reproductive Health Care*. 2008;34(4):233–236.
- 4 Coffey P, Kilbourne-Brook M, Brache V. Comparative acceptability of the SILCS and Ortho ALL-FLEX® diaphragms among couples in the Dominican Republic. *Contraception*. 2008;78:418–423.
- 5 van der Straten A, Sahin-Hodoglugil N, Clouse K, et al. Feasibility and potential acceptability of three cervical barriers among vulnerable young women in Zimbabwe. *Journal of Family Planning and Reproductive Health Care*. 2010;36(1):13–19.
- 6 Schwartz J, Weiner D, Lai J, Frezieres R, Creinin M, et al. Contraceptive efficacy, safety, fit, and acceptability of a single-size diaphragm developed with end-user input. *Obstetrics and Gynecology*. 2015;125(4):895–903.



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