

# Feasibility of SILCS Introduction in South Africa



## Background

PATH designed the SILCS diaphragm to expand women's options for nonhormonal contraception. Its single-size design makes it easy to use and provide, thus reducing barriers that have limited use of traditional diaphragms, which require a fitting by a health care provider. Like other diaphragms, however, SILCS is intended to be used with a contraceptive gel. Since diaphragms have not been available in developing countries in recent decades, PATH and its partners conducted health systems assessments and market research between 2010 and 2013 in three countries—India, South Africa, and Uganda—to explore the feasibility of and opportunities for SILCS diaphragm introduction in low-resource settings, and to identify likely target audiences and strategies for introduction.

This brief summarizes the results of the health systems assessment in South Africa in 2013 that examined the potential for SILCS introduction in the country as both a contraceptive and a potential multipurpose prevention technology (MPT) when combined with a microbicide gel. It explored the perceived need for this method, how it could be integrated into the family planning (FP) system, and challenges that would need to be addressed prior to introduction. Information from this assessment is intended to inform strategies for future introduction. The full report can be accessed [here](#). Separate reports and briefs on the research conducted in India and Uganda are also available at [www.path.org](http://www.path.org).

The SILCS diaphragm has been evaluated in 14 clinical studies in five countries to build evidence of its safety, acceptability, ease of use, and effectiveness. In 2010, PATH licensed the SILCS technology to Kessel medintim GmbH for manufacturing and marketing. In 2013, Kessel launched the Caya® contoured diaphragm after gaining European regulatory approval. Since then the Caya diaphragm has been approved in Australia, Canada, and the United States. As of 2016, the Caya diaphragm is available in more than 25 developed and middle-income countries and is poised for introduction in developing countries. Kessel also markets Caya® Gel/Contragel®, a contraceptive gel that contains lactic acid that is used with the Caya diaphragm.

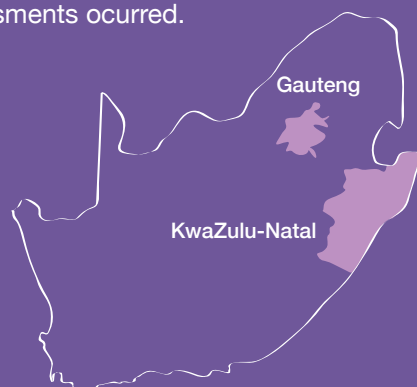


## Family planning in South Africa

While use of modern contraceptive methods is high in South Africa, at 65 percent, so are unplanned pregnancy rates, especially among young women (34 percent for women younger than 20 years).<sup>\*</sup> In recent years, high rates of sexually transmitted infections (STIs), including HIV, have overshadowed the country's focus on FP services. According to the 2003 Demographic and Health Survey report, 7.7 percent of women who had ever had sex reported an STI, vaginal discharge, or genital ulcer in the previous 12 months.<sup>\*</sup> And South Africa has one of the highest rates of HIV infection in the world, with an overall population prevalence of 12.3 percent in 2012, and peaking among women aged 30 to 34 years at 36.8 percent.<sup>\*\*</sup>

Contraceptive use in South Africa is skewed heavily toward injectable hormonal methods; other methods are less available. Diaphragms are currently unavailable in the public health sector and not widely available in the private sector. The need for better integration of family planning with HIV/STI services, including dual protection methods, is widely recognized in South Africa.

**Figure 1.** Provinces where assessment interviews, FGDs and facility assessments occurred.



<sup>\*</sup> Department of Health, Medical Research Council, ORC Macro. *South Africa Demographic and Health Survey 2003*. Pretoria, South Africa; 2007.

<sup>\*\*</sup> Human Sciences Research Council (HSRC). 2012 *South African National HIV Prevalence, Incidence and Behaviour Survey*. Pretoria, South Africa: HSRC; 2014.

## Methodology

This health systems assessment was implemented by Maternal, Adolescent and Child Health (MatCH) Research in Durban.<sup>†</sup> The assessment commenced with a desk review of national policies relevant to SILCS introduction, followed by one-on-one interviews with more than 30 stakeholders (Table 1), seven facility assessments of potential service delivery sites (Table 2), and three focus group discussions (FDGs) with potential users (Table 3). In November 2013, MatCH convened a stakeholder meeting to summarize key findings from this assessment and obtain stakeholder feedback and recommendations for next steps.

**Table 1.** Key informant/stakeholder interview participant profile.

Types of participants	n
Policymakers	5
Service providers (private sector, public sector, nongovernmental)	13
Program managers	4
Advocacy groups	2
Logistics managers	1
Training sites	2
HIV prevention clinical trial sites	1
Regulatory authorities	5
<b>Total</b>	<b>33</b>

**Table 2.** Facility assessment profile.

Types of Facilities	n
Nongovernmental organizations	3
Primary health care clinics	2
Health care education institutions	1
District hospitals	1
<b>Total</b>	<b>7</b>

**Table 3.** Profile of focus group discussion participants.

Sex and age	n
Females aged 18–24 years	9
Females aged 25–49 years	8
Males aged 18 and older	7
<b>Total</b>	<b>24</b>

<sup>†</sup> MatCH Research is a division of the Wits Health Consortium (Pty) Ltd. of the Department of Obstetrics and Gynaecology, Faculty of Health Sciences, at the University of the Witwatersrand. In September 2016, MatCH was granted "Unit" status, and is now known as MatCH Research Unit.

# Key findings

## Is SILCS introduction feasible from a policy, regulatory, and program perspective?

Yes. The government of South Africa recognized the country's limited choice of contraceptives and the need to expand the contraceptive method mix and in 2012, the National Contraceptive and Fertility Planning Policy was updated with a focus on expanding access to a wider array of FP options. While policies or guidelines that deal specifically with diaphragms do not yet exist, all policymakers interviewed agreed that the SILCS diaphragm could be included in the FP policy by including diaphragm-specific guidelines in an update or addendum.

“We just have the new updated [contraceptive] policy, and the diaphragm is not one of the method[s] that has been considered there. So it... would need to have an addendum”

– Policymaker

In addition to its use as a contraceptive, both stakeholders and potential users were keenly interested in SILCS as a reusable delivery device for microbicide gels when they become available, which would allow SILCS plus gel to offer multipurpose protection.

“I think it could be a nice kind of way of introducing the microbicide,...I mean there are talks now in...the Department of Health in terms of progressing in... HIV prevention, we talk a lot about dual protection, so if we introduce something that will be an example of what a dual protection is, because we will be preventing HIV and unwanted pregnancy within the same device.”

– Policymaker



MatCH Research Unit has implemented assessments of the SILCS acceptability and explored health system readiness for SILCS introduction.  
Photo: MatCH Research Unit.

“[The diaphragm will keep] you safe from two things. You will not become pregnant and you will not get [STIs and HIV].”

– Female FGD participant, 25–49 years

The regulatory process for SILCS approval is straightforward and not considered problematic since diaphragms are known as an inert medical device, with a long record of safety and use globally. However, the regulatory strategy for approval of a contraceptive gel to use with the diaphragm needs further exploration, since currently there are no contraceptive gel products available in South Africa. During interviews, regulatory experts were unable to comment on the prospect of a contraceptive gel that would be approved for use only with the SILCS diaphragm, not as a standalone product.

Stakeholders suggested that registering SILCS with the South African Bureau of Standards and engaging early with government stakeholders would help to create a supportive environment for government procurement and public-sector introduction of SILCS.

“But my advice on that is to engage with the appropriate people in government and say this is something that we are working on. The most important thing that they would require from you is to have it cleared by the South African Bureau of Standards.”

– Policymaker

Once introduced, stakeholders agreed that systems for recordkeeping and monitoring would need to be adapted to measure distribution and uptake to refine future introduction strategies. Also, if SILCS is used as a microbicide delivery system, systems should be established to monitor microbicide distribution and use for product adherence. Data collection could also ensure that providers and clients actively and positively engage with each other, and that provider training and counseling messages meet user needs.

“We [will] need data, we need to evaluate...So that we can learn...about complications, or adverse events...so we can know our patients.”

– Service provider (physician)

## Who is the proposed target audience?

Stakeholders did not define one user group, but rather felt that SILCS would be relevant for multiple segments, especially women looking for a nonhormonal birth control method. Some stakeholders noted that the method could be particularly useful for women with HIV.

“[We have a] high HIV prevalence so you need a method that a woman [who] is already taking piles of medication, so if you are telling them here’s a method,... there would be no interaction with your medication, that would be a big benefit and big help for them.”

– Policymaker

SILCS also could provide a convenient, woman-controlled alternative to male condoms.

“I think many women will want to use it. I think many because there is nothing or there is very few that they can use except for the female condom there is nothing else that they can use; that they can control.”

– Advocacy representative

Stakeholders indicated that target groups could vary depending on whether SILCS is introduced as a contraceptive method or as an MPT. In either case, stakeholders agreed, SILCS diaphragm introduction would expand the method mix and provide a new option for women. As a contraceptive method, SILCS would likely appeal primarily to groups of women looking for nonhormonal birth control. However, in the future, if a microbicide gel becomes available and SILCS could be used as an MPT, the diaphragm would reach a broader group of women. Market research is needed to define the target user groups more clearly and to understand what motivates them to use a method like SILCS.

“If they talk about it and include the fact that it prevents HIV, women will be more interested in it than if it is considered a family planning method.”

– Female FGD participant, 25–49 years

## How and where should SILCS be introduced?

Many stakeholders felt that the SILCS diaphragm could be made available through multiple service delivery points. Possible avenues for introduction included the public health sector, mobile clinics, tertiary-level education institutions, shops, taverns, pharmacies, and nongovernmental organizations.



MatCH Research provided feedback about the Caya pelvic model during the health systems assessment in South Africa.

Photo: MatCH Research Unit

Stakeholders emphasized that SILCS should always be included as part of an integrated set of services. They also agreed that it should be introduced first as a FP method. Establishing SILCS as a contraceptive method that is available in health care facilities and pharmacies would make the transition to also using SILCS as a microbicide delivery device easier. Guidelines would need to be developed to ensure appropriate service delivery.

“ Whatever we are doing, we should be integrating it in all of the service delivery points. So if I came to get my [antiretroviral medications], or if I came for my [tuberculosis] treatment, or I came to you because I have a chronic ailment, I will be able to get whatever products I need as far family planning from any of those settings.”

– Policymaker

Most service providers and program managers agreed that all health care workers should be trained on insertion and use of the SILCS diaphragm.

“ The lay counsellors have to be part of that training, because they’re the ones that are speaking directly to the women.”

– Program manager

Staff focused on family planning, particularly nurses and counselors, would need comprehensive training, including evidence of efficacy, theory, practical information on insertion, safety, storage, cost, and how the product is made.

“ I would think staff from family planning because they are usually registered nurses, and then, and they have, umm, more insight about the reproductive system, etc.”

– Service provider

## What is needed to raise awareness and build confidence in this new method?

Stakeholders agreed that promotion and advocacy should highlight the benefits of the SILCS diaphragm for women and their partners. SILCS should be marketed primarily as a FP method since that is how it will be used first. But in the future, when a microbicide gel is approved and it is shown that SILCS can be used as a reusable delivery system, marketing and educational information should highlight SILCS plus microbicide gel as an HIV prevention tool as well.

“ The benefits of using the SILCS need to be clearly explained, both in terms of preventing pregnancies and [in future] possible prevention of HIV [when used with microbicide].”

– Program manager

Intensive education and counseling will be a key factor in the success of SILCS introduction. Stakeholders also advised that basic education about the female anatomy and reproductive system should be a priority, beginning with focusing on young women. However, men also wanted to receive information about this new method.

“ It is at the clinics [that men can feel comfortable about getting information about the diaphragm]. At the clinic many things are discussed concerning people’s lives...and you get full information.”

– Male FGD participant

Stakeholders recommended that SILCS be introduced via a media campaign, since the diaphragm is not currently known in South Africa and product awareness is the first step to considering a method.

“ It must be really a big thing, it must be flashing on the media, TV, where, everywhere, it must be in people’s faces.”

– Trainer

“It should be shown on TVs, talked about on radios, and publicized in newspapers. People should be encouraged to go to the clinic to learn more.”

– Female FGD participant, 18–24 years

Stakeholders also cited hospitals, mobile health services, community health workers, and community caregivers as appropriate sources for sharing information about SILCS. They felt that information, education, and communication materials, pelvic models, DVDs, and pamphlets would be useful tools for raising awareness and providing education and training. “Champions”—cultivated from within communities—and community health workers were identified as valuable, often untapped, educational resources.

“You need people who believe in what you’re doing. You need people who know research. Start from there. And you need people who are passionate about women’s problems. You need people who have been touched by the effect of HIV on communities. You need people who are out there who are bold, who are not afraid to be criticized. And you need people who are vocal.”

– Advocacy representative

“We must not underestimate the role of the community health workers. They are everywhere. They are known in the community. The community can easily go to their homes. If you give them enough information...think we can go places.”

– Advocacy representative

## Recommendations

Based on findings, the following recommendations emerged from the assessment and could pave the way toward introduction of the SILCS diaphragm in South Africa:

- Register SILCS with the South African Bureau of Standards and clarify policy and regulatory issues early, especially those concerning approval of the contraceptive gel, to facilitate introduction and prevent delays in introduction. Develop relationships with regulatory personnel.
- Introduce SILCS as part of a comprehensive sexual and reproductive health package, with integrated service delivery. Focus first on introducing SILCS as a FP method, then after a microbicide gel is approved, expand the messages and counseling to include SILCS as a microbicide delivery device that can protect from both unintended pregnancy and HIV/STIs.
- Consider a variety of distribution channels for SILCS, including public health facilities, private pharmacies, shops, tertiary education institutions, and nongovernmental organizations. It should also be part of youth-friendly services. The optimum strategy for introduction and distribution needs to be informed by market research to understand who will be “early adopters” of this new method.
- Expand the South African District Health Information System to include SILCS as a FP method, and in the future as an MPT. This will help to track distribution and uptake, and will inform further education and marketing efforts.
- Adapt existing provider and client materials to jumpstart development of counseling tools for health care workers for South Africa for the SILCS diaphragm. These should include ways to assist potential users with frequently asked questions, as well as negotiating diaphragm and condom use, and partner questions, such as impact during sexual encounters.
- Conduct market research to define user groups. This research will help to identify which segments are most interested in using SILCS as a contraceptive, which groups are more interested in using SILCS plus a microbicide gel, and the messages and strategies to reach each group.

- Use advocacy to raise awareness about SILCS and education, counseling, and promotion to highlight the benefits of SILCS as a nonhormonal, user-initiated contraceptive, and in the future as an MPT that can protect from both unintended pregnancy and HIV/STIs.
- Develop champions who can share the word about the SILCS diaphragm and broadcast early adopter experiences via existing community networks, including links with political leaders. This will facilitate buy-in by national and provincial stakeholders, and address women's questions about this new method.



Photo: iStock

## Conclusion

This assessment found that the single-size SILCS diaphragm could be introduced in South Africa to expand options for women who cannot or do not want to use existing contraceptive methods. While diaphragm-specific policies do not yet exist in South Africa, the country's overall policy, regulatory, and service delivery environment is supportive of SILCS introduction, and proposed changes in the regulatory system for medical devices may clarify the pathway for approval of a contraceptive gel such as Caya Gel/Contragel,<sup>†</sup> the lactic acid-based gel approved and used in Europe with the diaphragm. Multiple service delivery channels exist, and procedures, protocols, and data collection systems could be adapted to include SILCS introduction. Stakeholders recommended that SILCS introduction be closely integrated with other sexual and reproductive health services.

The assessment team also found significant support for and interest in use of SILCS as a microbicide delivery system. However, since a microbicide gel has not yet been approved, the regulatory, policy, and service delivery details for the microbicide gel that would enable SILCS to be used as an MPT were less clear and require further research and investigation. Another challenge for SILCS will be low levels of awareness among health care workers and potential users. However, this can be addressed by prioritizing education, training, promotion, and advocacy, as well as a phased approach to introduction.

Overall, SILCS is poised to provide many women in South Africa with a new, woman-controlled contraceptive option—and, eventually, perhaps a dual method for preventing pregnancy and HIV/STIs.

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<sup>†</sup> Additional information about Caya Gel/Contragel can be found at:  
[www.medintim.de/caya-diaphragm-gel/](http://www.medintim.de/caya-diaphragm-gel/)



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